ERRATA 3

Accreditation Requirements for Acute Care Hospitals, 2023 edition

Subsequent to CMS changes announced in the Federal Register on June 5, 2023, ACHC is retiring Standard 07.03.04. Effective June 5, 2023, acute care hospitals **will not be surveyed** against this requirement.

As always, contact us at customerservice@achc.org with questions or comments.

07 | Infection Prevention and Control/Antibiotic Stewardship	
07.03.04 ~~Employee health: COVID-19 Vaccination of Hospital Staff~~ **For Future Use**	
▪ Standard retired	STANDARD ~~*The hospital must develop and implement…*~~ REQUIRED ELEMENTS ~~All hospitals are required to achieve a 100% vaccination rate…~~ SCORING PROCEDURE ~~Verify:~~ ~~▪ Policies and procedures…~~

ERRATA 2

Accreditation Requirements for Acute Care Hospitals, 2023 edition

Below are additional post-publication edits to standard 03.01.09 the 2023 edition of ***Accreditation Requirements for Acute Care Hospitals.*** **Bolding** reflects content that is new in the 2023 edition. Additions for these corrections are underlined. Deletions are indicated with ~~strike-through~~.

As always, contact us at customerservice@achc.org with questions or comments.

03 | Medical Staff	
03.01.09 Exception for outpatient surgical procedures	
▪ Standard language revised to align with CMS CFR §482.22(c)(5)(iii-v) and §482.22(c)(5)(v)(A-C)	STANDARD ***An assessment of the patient (in lieu of the requirements of standards 03.01.07 and 03.01.08)*** **must** ***be completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at paragraph (c)(5)(v) of this section, specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.*** ***The assessment must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with State law and hospital policy.*** **The bylaws must include a requirement that** ***the medical staff develop and maintain a policy that identifies those patients for whom the assessment requirements*** **above** ***would apply. The provisions of*** **this standard** ***do not apply to a medical staff that chooses to maintain a policy that adheres to the requirements of*** **standards 03.01.07 and 03.01.08** ***for all patients.*** ***The medical staff, if it chooses to develop and maintain a policy for the identification of specific patients to whom the assessment requirements in*** **in this standard** ***would apply, must demonstrate evidence that the policy applies only to those patients receiving specific outpatient surgical or procedural services as well as evidence that the policy is based on:*** ***A.*** ***Patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and the level of anesthesia required for the surgery or procedure.*** ***B.*** ***Nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures.*** ***C.*** ***Applicable state and local health and safety laws.*** ***D.*** A history and physical completed no more than 30 days prior to the date of a procedure. The policy defines the required elements of the history and physical to be completed and documented in the medical record.

ERRATA

Accreditation Requirements for Acute Care Hospitals, 2023 edition

Below are post-publication edits to the 2023 edition of ***Accreditation Requirements for Acute Care Hospitals.*** **Bolding** reflects content that is new in the 2023 edition. Additions for these corrections are underlined. Deletions are indicated with ~~strike-through~~.

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07 | Infection Control and Antibiotic Stewardship	
07.03.03 Employee health vaccines for healthcare workers	
▪ Added reference to a related standard within the required elements ▪ Added clarification to the scoring procedure	REQUIRED ELEMENTS **Recommended vaccines for HCWs include:** ▪ **COVID-19 (see Standard 07.03.04)** SCORING PROCEDURE □ For vaccines required by state and federal law, employee vaccination status is maintained.
09 | Emergency Management	
09.01.03 Supplies	
▪ Added specificity to required elements	REQUIRED ELEMENTS **In advance of a communicable disease outbreak… …the hospital determines the quantities of supplies needed for a one-month period of time:** ▪ **PPE: Procedure masks, gowns, gloves, ventilator masks (such as N95 respirator)** ▪ **Hand sanitizer and hand soap** ▪ **Cleaning chemicals and supplies** ▪ **Paper products, such as toilet paper, paper towels** ▪ **Others** **The hospital has a process to update the Incident Command Center regarding available equipment and supplies, such as:** ▪ **Patient beds** ▪ **ICU patient beds** ▪ **Mechanical ventilators** ▪ **IV infusion pumps** ▪ **PPE: Procedure masks, gowns, gloves, ventilator masks (such as N95 respirator)** ▪ **Quantities of medications used to treat the communicable disease.**

13 | Life Safety	
13.00.01 Life Safety Code compliance	
▪ Standard revised	STANDARD ***In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary,*** **CMS** ***may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a hospital, but only if the waiver will not adversely affect the health and safety of the patients.*** ***§ 482.41(b)(2)***
15 | Patient Rights and Safety	
15.01.04 Participation in decision making	
▪ Typo correction	The second Note in the required elements references 10.01.15. That reference should be 10.01.16.
25 | Pharmacy Services/Medication Use	
25.01.03 Security of medications	
▪ Added specificity to required elements	REQUIRED ELEMENTS **…** mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing drugs or biologicals must be locked ~~in a~~ and secured ~~area~~ when not in use.
30 | Surgical Services	
30.00.11 Surgical informed consent	
▪ Typo correction	The reference to standard 15.01.09 in the required elements should be 15.01.04.

2023 EDITION

ACHC®

ACCREDITATION REQUIREMENTS FOR ACUTE CARE HOSPITALS

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Home Health[1,2]
Home Infusion Therapy[1]
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Palliative Care
PCAB (Compounding Pharmacy)[2]
Pharmacy[2]
Renal Dialysis[1,2]
Sleep[1]

Certification

Joint Replacement
Lithotripsy
Stroke
Telehealth
Wound Care

[1] CMS deeming authority or recognition
[2] Specialty Distinctions available for ACHC-accredited organizations. See achc.org for more information.

Pronouns used in this publication were chosen for ease of reading and are not intended to exclude additional gender references.

ACHC
139 Weston Oaks Ct.
Cary, NC 27513

www.achc.org
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Foreword

How We Work

Accreditation Commission for Health Care, Inc. (ACHC) offers healthcare organizations an approach to accreditation founded in sharing knowledge and expertise to support improvement in patient care and safety and regulatory compliance.

ACHC offers a range of programs to meet the accreditation, certification, and related education needs of healthcare organizations across the continuum of care. This manual of ACHC Standards is intended for use by Acute Care Hospitals. The intent of the standards is to help the individual hospital and, when applicable, the healthcare system as a whole, maximize its potential to improve outcomes for specific patient populations. We recognize that facilities may find a variety of ways in which to comply with the accreditation requirements. For example, a large hospital or one that is part of a multi-facility system may address issues through policies established at the corporate level. In contrast, a smaller facility may employ a committee of the whole to create individual policies. Either approach may be fully compliant; our goal is to confirm that required policies are relevant to the hospital and followed as defined.

The ACHC process supports customer success throughout the accreditation cycle: before, during, and after the on-site survey.

Account Advisors

Each hospital is assigned an advisor to serve as the primary point of contact with our office. Your Account Advisor will answer process and billing questions, provide helpful timeline and documentation resources, and serve as your contact for reporting changes within your facility.

Standards Interpretation

The Standards Interpretation Team, comprised of clinical professionals experienced in hospital settings and in working with CMS, is easily accessible by phone or email to respond to questions about applicability or interpretation of requirements at any point in the accreditation cycle and will work with you to understand deficiencies identified by ACHC Surveyors in order to develop an effective plan of correction.

Using the Manual

We recommend that you use this manual as a tool for on-going self-assessment of your facility's adherence to ACHC Standards. This ensures that your facility is always ready for external review and avoids the need for a flurry of "ramp up" activities in anticipation of a survey. More importantly, periodic self-assessment supports a culture of quality with regard to the hospital's ability to render care, treatment, and services safely and effectively. At their core, the standards represent a validated risk-reduction strategy for the organization. Compliance will not prevent every adverse event but will diminish the likelihood of their occurrence.

Manual Format

Chapters 1–34 of this manual describe the requirements that must be met for accreditation. Each requirement has four components:

1. **STANDARD** states the requirement to be met. Where applicable, Medicare Conditions and Standards are indicated by the CfR reference (e.g., §482.xx, §483.xx, §485.xx) immediately after the requirement. The exact wording used by CMS for Conditions of Participation (CoP) and standards appears in italics.
2. **REQUIRED ELEMENTS/ADDITIONAL INFORMATION** provides further detail regarding expectations for full compliance. When the standard comes from the CoP, supplementary detail is taken from CMS Interpretive Guidelines in the State Operations Manual (SOM).
3. **SCORING PROCEDURE** identifies how ACHC Surveyors evaluate compliance.
4. **SCORE** identifies the rating options available for the standard.

Scoring

Each standard is identified as Compliant or Not Compliant. Some standards may include an option of 'not applicable' based on the scope of services offered by the facility.

COMPLIANT indicates that there is evidence that the facility fully meets the requirement.

NOT COMPLIANT indicates there is less than full compliance with the requirement or no evidence of compliance with the requirement.

NOT APPLICABLE indicates that the standard does not apply to the facility being surveyed.

Reference to Days

Reference to time frames indicated in "days" refers to calendar days. When the time frame is limited, i.e., Monday through Friday, we will use the term "business days."

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ADMINISTRATION OF THE ORGANIZATIONAL ENVIRONMENT

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.00.00 CONDITION OF PARTICIPATION: Compliance with federal, state, and local laws *The hospital must ensure that all applicable Federal, State, and local law requirements are met.* §482.11	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: Score this Condition based on scoring from 01.00.01 through 01.00.04
01.00.01 Governance plan The administration and governance of all facility services is based upon the stated governance plan of the facility and is appropriate to the scope and complexity of the services offered. There is a written plan for the provision of services, which supports the governance plan.	☐ Compliant ☐ Not Compliant The governance plan, which may be included in the Articles of Incorporation for the facility, is the foundation for the document(s) known as the "plan for the provision of services." Elements within the plan include identification of: 1. Governance and administration 2. Organizational relationships 3. Budget processes, including staffing 4. Scope of services provided 5. Mechanisms for planning 6. Mechanisms for assessing and improving the structure, processes and outcomes of services and care 7. Mission Statement (required) 8. Vision Statement and values (may be included)	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ There is a published governance plan, which is central to the development of the written plan for the provision of services. ▪ The plan for the provision of services effectively outlines at least the first seven of the eight major areas listed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.00.02 Compliance with laws *The hospital must be in compliance with applicable Federal laws related to the health and safety of patients.* §482.11(a)	☐ Compliant ☐ Not Compliant Administrative policies outline the intent to conform to all applicable laws. Reports of surveys, inspections, and complaint investigations are maintained, by the hospital with copies of corrective action plans and follow-up communications to and from the appropriate agency. Review of findings from such reports and follow-up actions and results are acknowledged in minutes of the governing body. The hospital shall be in compliance with its own policies and procedures.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Review all federal, state, and local surveys, inspections and investigations of the hospital that have occurred since the last accreditation survey. ▪ Determine whether: □ required corrective actions have been completed and monitored for compliance. □ the hospital is in compliance with its own policies and procedures. ▪ Interview the CEO or appropriate individual designated by the hospital to determine compliance with federal laws related to patient health and safety. For example, ask if the hospital was cited since its last survey for any violation of section 504 of the rehabilitation act of 1973 related to denying people with Disabilities access to care. □ If so, verify that satisfactory corrections have been made to bring the hospital into compliance with that law). Refer or report noted noncompliance with federal laws and regulations to the appropriate agency having jurisdiction (e.g.,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		accessibility issues, blood-borne pathogens, standard precautions, and TB control to OSHA; hazardous chemical/waste issues to EPA; etc.)
01.00.03 Hospital licensure *The hospital must be –* *1. Licensed; or* *2. Approved as meeting standards for licensing established by the agency of the State or locality responsible for licensing hospitals.* §482.11(b)(1-2)	☐ Compliant ☐ Not Compliant As part of the application process, the hospital must submit: 1. A photocopy of the current license issued by the state or local authority in which it operates, or 2. If it is located within a state that does not license hospitals, evidence that the responsible state agency has approved the hospital as meeting the state's established standards for the licensing of hospitals.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify the hospital has: ▪ A current license from the state or local authority in which it operates OR ▪ If located in a state that does not license hospitals, evidence that the responsible State agency has approved the hospital as meeting the State's established standards for the licensing of hospitals. ▪ Verify that all other required licenses are current (e.g., pharmacy, incinerator, CLIA, etc.).
01.00.04 Licensure of personnel *The hospital must assure that personnel are licensed or meet other applicable standards that are required by State or local laws.*	☐ Compliant ☐ Not Compliant All staff that are required by the State to be licensed must possess a current license. The hospital must assure that these personnel are in compliance with the State's licensure laws. The laws requiring licensure vary from state to state. Examples of healthcare professionals that a state may require to be licensed	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that: □ The hospital has established and follows procedures for determining licensure, certification and/or permit

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.11(c)	include nurses, MDs/DOs, physician assistants, dieticians, X-ray technologists, dentists, physical therapists, occupational therapists, respiratory therapists and hospital administrators. All staff must meet all applicable standards required by the State or local law for hospital personnel. This would include, at a minimum: ▪ Certification requirements ▪ Minimum qualifications ▪ Training education requirements ▪ Permits (such as food handlers permits. When telemedicine is used and the practitioner and patient are in different states, the practitioner providing the patient care service must be licensed and/or meet the other applicable standards that are required by State or local laws in both the state where the practitioner is located and the state where the patient is located.	by the State for that personnel are required to be licensed, certified and/or permitted. □ Staff and personnel licensed, certified and/or permitted in accordance with State and local requirements includes telemedicine files if applicable. □ Staff and personnel meet all standards (such as continuing education, basic qualifications, etc.) required by State and local laws or regulations. Verify that the hospital has a mechanism established and enforced to ensure compliance. ▪ Review a sample of personnel files to verify that licensure and/or other required credentials information is up to date. Verify State licensure compliance of the direct care personnel as well as administrators and supervisory personnel.
01.00.05 <u>For future use</u>		
01.00.06 <u>Articles of Incorporation and documentation of actions</u> The governing body maintains Articles of Incorporation, bylaws (or governance policies), and a record of deliberations	☐ Compliant ☐ Not Compliant The required documents are preserved and safeguarded so as to provide a reasonable means of evaluating ethical and prudent business decisions impacting patient welfare and safety.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Determine that Articles of Incorporation, bylaws (or governance

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(minutes) leading to actions in specific areas.		policies) exist and are safeguarded. Copies may exist in addition to the original documents. ▪ Request and review records of actions (minutes) of the governing body.
01.00.07 Governing body responsibilities The governance bylaws define the responsibility for at least the following: ▪ Adoption and periodic review of governance bylaws governance policies. ▪ Approval and monitoring of budget(s). ▪ Implementation of effective fiscal accounting system(s). ▪ Provision of an organized professional medical staff structure. ▪ An ongoing hospital-wide quality assessment performance improvement (QAPI) program including a written plan of implementation. ▪ Provision of adequate resources to implement the programs of service. ▪ Provision for the adequacy of the	☐ Compliant ☐ Not Compliant Governance bylaws (or policies) effectively describe these functions. Additional components may include: ▪ How the governance members are selected and maintain their affiliation relationship(s) to any higher authority such as ownership (municipal, city, private, multihospital, etc.). ▪ The process for strategic planning. The governing body has a mechanism in place for the review of the governance bylaws no less than every three years.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the governance bylaws (policies) for acknowledgment and implementation of the listed requirements. ▪ Verify that: □ the bylaws include a provision for periodic review and the governance bylaws have been reviewed within the past three years. □ the governing body has completed a performance evaluation of itself within the past 12 months. **Note**: Responsibilities identified as noncompliant in the bylaws must be listed including the CFR number.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

physical plant.

- An annual performance evaluation by the governing body of itself.

01.01.00 CONDITION OF PARTICIPATION: Governing body

There must be an effective governing body that is legally responsible for the conduct of the hospital.

If a hospital does not have an organized governing body, the persons legally responsible for the conduct of the hospital must carry out the functions specified in this part that pertain to the governing body.

§482.12

☐ Compliant ☐ Not Compliant

The hospital must have a governing body which is effective in carrying out its responsibilities for the conduct of the hospital. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are legally responsible for the conduct of the hospital operations.

If the hospital is part of a healthcare system that includes several separately certified hospitals, each with its own Medicare provider agreement and CMS Certification Number, the governing body of the healthcare system has the option to act as the governing body of each separately certified hospital, unless doing so would conflict with State law.

A hospital system also has the option to form several governing bodies, each of which is responsible for several separately certified hospitals. For example, a health system operating hospitals in many states might choose to form regional sub-boards each responsible for the hospitals in its region, or a health system that has a mixture of types of hospitals may choose to form one sub-board responsible for its short-term acute care hospitals and another for its long-term care hospitals.

When deciding whether or not to exercise the option to have a single governing body for multiple hospitals in the system, another factor for systems to consider might be Medicare payment requirements at §412.22(e-h) applicable to certain types of hospitals, i.e., non-grandfathered Hospitals-within-Hospitals and Hospital Satellites. In such cases where the hospital system owns both the tenant and the host hospital, using a single governing

This standard is not met as evidenced by:

DOCUMENT REVIEW

- Verify that the hospital has an organized governing body or has written documentation that identifies the individual or individuals that are responsible for the conduct of the hospital operations.
- If the hospital is part of a hospital system which uses one governing body for several of the hospital's separately certified within the system:
  - ☐ Review the governing body minutes to determine if it is clear which actions pertain to which hospitals.
  - ☐ Select for review several policy and procedure documents adopted by the system governing body to determine if it is clear that they apply to the hospital being surveyed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

body for both hospitals would jeopardize the payment status of a hospital that is being paid by Medicare under a payment system excluded from the Hospital Inpatient Prospective Payment System (IPPS). However, surveyors do not assess compliance with or enforce the Medicare payment regulations that govern Hospitals-within-Hospitals or Hospital Satellites.

The Medicare program offers hospital facilities considerable flexibility regarding how they choose to participate. Based on the geographic and other institutional limitations set out in the "provider-based" regulation at §413.65, which addresses provider-based status for hospital facilities in multiple locations, hospital governing bodies make business decisions about how they want to participate in Medicare, and they indicate on their Medicare enrollment application the choices they have made.

It is not uncommon to find multiple hospital campuses with one owner located in the same geographic area enrolled in Medicare as one hospital. Nor is it uncommon to see a hospital system choosing to enroll its various facilities as separately certified hospitals. Various factors enter consideration when the governing body of a system makes these decisions.

For example, some governing bodies prefer to enroll various campuses as separate hospitals, out of a concern that problems at one hospital's campus might jeopardize the Medicare participation of the other campuses if they were a multi-campus hospital covered under one Medicare provider agreement. In other cases, a governing body may see the benefits of integrating clinical services on multiple campuses into one integrated hospital. In still other cases, the deciding factor might be the implications for Medicare reimbursement of graduate medical education, the ease of adding satellite locations, etc.

CMS defers to the governing bodies of hospitals to weigh the pertinent factors and permissible options, and to make business decisions in their best interest when applying to participate in Medicare.

CMS's hospital certification decisions and issuance of a provider agreement

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

and associated CCN follow from these business decisions by a hospital's governing body. But once the "hospital," with whatever component parts, has been certified, that hospital must independently demonstrate its compliance with the CoPs, independent of any other facility. (77 FR 29040, May 16, 2012)

If a hospital system has chosen to have a one body act as the governing body for multiple separately certified hospitals, this does not alter the fact that each hospital must independently demonstrate compliance with the CoPs.

Examples of what this means include, but are not limited to, the following:

- Each separately certified hospital must be separately and independently assessed for its compliance with the CoPs, through either State Survey Agency or approved Medicare hospital accreditation program surveys. There is no survey of a hospital "system," since the Medicare provider agreement and its terms are specific to each certified hospital.
- A system governing body may wish to adopt identical policies and procedures for many aspects of a hospital's operations across all of its hospitals within the system. It has the flexibility to do so, but the documentation of such policies and procedures must be clear that the governing body has chosen to apply them to specifically named hospitals. Also, each hospital must be able to present for inspection the system governing body policies and procedures that clearly apply to that hospital. For example:
  - □ A document that says "XX Healthsystem has adopted the following policy" is not acceptable. Instead, the document must be more specific, such as, "XX health system adopts the following policy and procedure for Hospital A, Hospital B, and Hospital C." Furthermore, the names of each hospital (Hospitals A, B, and C in this example) must correspond to the names used for their provider agreements. For example, if Hospital C is one Medicare-certified hospital with two inpatient campuses, one called "East" and one called "West," it is not acceptable for the policy document to state, "XX health

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

system adopts the following policy and procedure for Hospital A, Hospital B, and Hospital East and Hospital West." It would be acceptable to state, "XX health system adopts the following policy and procedure for Hospital A, Hospital B, and Hospital C."

- □ It also is not acceptable for the policy document to state, "XX health system adopts the following policy and procedure for Hospital A, Hospital B, and Hospital East, but not Hospital West." Since "Hospitals" East and West refer to separate campuses of Hospital C, which participates in Medicare as one multi-campus hospital, it is not appropriate to refer to these separate campuses of C as "hospitals," since the XX health system made a business decision to enroll them as parts of one multi-campus hospital in Medicare. CMS recognizes that, depending on the particular policy topic, it may be acceptable to have policies that vary by type of unit/department within a hospital. The system governing body could achieve this as follows: "XX health system adopts the following policy and procedure requiring that a physician be on-site 24 hours per day, seven days per week on the inpatient campuses of Hospital A and Hospital B, but within Hospital C, only for the East inpatient campus."

- The minutes of the governing body must be written in such a manner so that it is clear when the governing body has taken actions that apply to a specific certified hospital.

- Departments of separately certified hospitals with one system governing body cannot be operationally integrated. For example, if a system has chosen to operate three separately certified hospitals in relatively close proximity to each other rather than to have them certified as one multi-campus hospital, then each hospital must have its own nursing service. It may not have one integrated nursing service with one Director of Nursing who manages one nursing staff for all three hospitals. The system cannot maintain one integrated schedule that assigns nursing staff among the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

different hospitals. The system also cannot move them back and forth between hospitals on an ad hoc, as needed basis, as if they were one hospital.

On the other hand, the policies and procedures the governing body has adopted for the nursing service in each hospital may be identical, so long as the services operate separately. It is also permissible for the same individual to be the Director of Nursing for each hospital, provided that he or she is able to carry out all of the duties of the position in each hospital, such as managing each hospital's separate nursing staff. It is also permissible for one nurse to work at multiple hospitals within the system, in the same way that a nurse may work for multiple hospitals that do not share ownership, but the nurse must have separate work schedules for each hospital. Such schedules cannot overlap.

- Although the system may choose to operate a quality assessment/performance improvement (QAPI) program at the system level which standardizes indicators measured across system hospitals, each separately-certified hospital in the system must have a QAPI program that is specific to that hospital. This is required not only to demonstrate compliance, but also for the governing body to function effectively, since reviewing QAPI program results only at the system level would make it difficult for the governing body to identify and act upon problems that are localized to one hospital.

  For example, the system may choose to use the same quality indicators or the same methodology to track adverse events across all system hospitals. But each certified hospital must have its own QAPI data with respect to these indicators and adverse events. If a system is tracking readmission rates across all of its hospitals, it must be able to separate out the hospital-specific results for the governing body's review and possible action.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The governing body must function effectively and holds the ultimate responsibility for the hospital's compliance not only with the specific standards of the governing body CoP, but with all of the CoPs. This is the case regardless of whether the regulatory text for a condition or a standard within a condition specifically mentions responsibilities of the governing body. Substantial, i.e., condition-level, non-compliance with one of the other hospital CoPs may be an indicator that the governing body is not functioning effectively. However, it is not the policy of CMS that condition-level noncompliance with any other CoP automatically results in a condition-level citation of the governing body CoP. Surveyors must consider whether the manner and degree of the other deficiencies provide sufficient evidence to conclude that the governing body is not functioning effectively.	
01.01.01 Medical Staff: Categories eligible for appointment *The governing body must:* ▪ *Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.* §482.12(a) §482.12(a)(1)	☐ Compliant ☐ Not Compliant The governing body must ensure the medical staff requirements are met. The governing body must determine, in accordance with State law, which categories of practitioners are eligible for appointment to the medical staff. **PHYSICIANS** The medical staff must, at a minimum, be composed of physicians who are doctors of medicine or doctors of osteopathic medicine. In addition, the medical staff may include other types of practitioners included in the definition of a physician in Section 1861 of the Social Security Act: ▪ Doctor of dental surgery or of dental medicine. ▪ Doctor of podiatric medicine. ▪ Doctor of optometry. ▪ Chiropractor.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review documentation and verify that the governing body has determined and stated the categories of physicians and practitioners that are eligible candidates for appointment to the medical staff or to be granted medical staff privileges.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

In all cases, the practitioner included in the definition of a physician must be legally authorized to practice within the State where the hospital is located and providing services within their authorized scope of practice. In addition, in certain instances the Social Security Act and regulations attach further limitations as to the type of hospital services for which a practitioner may be considered to be a "physician." See 42 CFR 482.12(c)(1) [see 01.01.15] for detail on these limitations.

The governing body has the flexibility, consistent with State law, to determine whether practitioners included in the definition of a physician other than an MD/DO are eligible for appointment to the medical staff.

Note: Information only –Not Required/Not to be Cited

CMS expects that all physician practitioners granted privileges are also appointed as members of the medical staff. However, if State law limits the composition of the hospital's medical staff to certain categories of practitioners, e.g., only MDs or DOs, there is nothing in the CoPs that prohibits hospitals and their medical staffs from establishing certain practice privileges for other categories of physician practitioners excluded from medical staff membership under State law, or from granting those privileges to individual practitioners in those categories, as long as such privileges are recommended by the medical staff, approved by the governing body, and in accordance with State law. (79 FR 27114 - 27115, May 12, 2014)

For physician practitioners granted privileges only, the hospital's governing body and its medical staff must exercise oversight, such as through credentialing and competency review, of those other physician practitioners to whom it grants privileges, just as it would for those practitioners appointed to its medical staff.

NON-PHYSICIAN PRACTITIONERS

Furthermore, the governing body has the authority, in accordance with State law, to grant medical staff privileges and membership to non- physician

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

practitioners. The corresponding regulation at 42 CFR 482.22(a) allows hospitals and their medical staffs to take advantage of the expertise and skills of all types of practitioners who practice at the hospital when making decisions concerning medical staff privileges and membership. Granting medical staff privileges and membership to non-physician practitioners is an option available to the governing body; it is not a requirement.

For non-physician practitioners granted privileges only, the hospital's governing body and its medical staff must exercise oversight, such as through credentialing and competency review, of those non-physician practitioners to whom it grants privileges, just as it would for those practitioners appointed to its medical staff.

Practitioners are described in Section 1842(b)(18)(C) of the Act as any of the following:

- Physician assistant (as defined in Section 1861(aa)(5))
- Nurse practitioner (as defined in Section 1861(aa)(5))
- Clinical nurse specialist (as defined in Section 1861(aa)(5))
- Certified registered nurse anesthetist (as defined in Section 1861(bb)(2))
- Certified nurse-midwife (as defined in Section 1861(gg)(2))
- Clinical social worker (as defined in Section 1861(hh)(1))
- Clinical psychologist (as defined in 42 CFR 410.71 for purposes of Section 1861(ii))
- Anesthesiologist's Assistant (as defined at §410.69)
- Registered dietitian or nutrition professional.

Other types of licensed healthcare professionals have a more limited scope of practice and usually are not eligible for hospital medical staff privileges unless their permitted scope of practice in their state makes them comparable to the above types of non-physician practitioners.

Some examples of types of such licensed healthcare professionals who might be eligible for medical staff privileges, depending on state law and medical

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	staff bylaws, rules and regulations include, but are not limited to: ▪ Physical Therapist (as defined at §410.60 and §484.4) ▪ Occupational Therapist (as defined at §410.59 and §484.4); ▪ Speech Language Therapist (as defined at §410.62 and §484.4). Furthermore, some States have established a scope of practice for certain licensed pharmacists who are permitted to provide patient care, services that make them more like the above types of non-physician practitioners, including the monitoring and assessing of patients and ordering medications and laboratory tests. In such States, a hospital may grant medical staff privileges to such pharmacists and/or appoint them as members of the medical staff. There is no standard term for such pharmacists, although they are sometimes referred to as "clinical pharmacists." Practitioners may be granted active, courtesy, emergency, temporary, etc. membership or privileges in accordance with state law and as specified in the medical staff bylaws, rules, and regulations.	
01.01.02 Medical staff appointment *The governing body must:* ▪ *Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.* §482.12(a)(2)	☐ Compliant ☐ Not Compliant The governing body determines whether to grant, deny, continue, revise, discontinue, limit, or revoke specified privileges, including medical staff membership, for a specific practitioner after considering the recommendation of the medical staff. In all instances, the governing body's determination must be consistent with established hospital medical staff criteria, as well as with State and Federal law and regulations. Only the hospital's governing body has the authority to grant a practitioner privileges to provide care in the hospital.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Confirm there is evidence that the governing body considered recommendations of the medical staff before making medical staff appointments. ▪ Review records of medical staff appointments to determine that the governing body is involved in appointments of medical staff members.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.01.03 Assure medical staff bylaws *The governing body must:* ▪ *Assure that the medical staff has bylaws.* §482.12(a)(3)	☐ Compliant ☐ Not Compliant The governing body must assure that the medical staff has bylaws and that those bylaws comply with state and federal law and the requirements of the Medicare hospital Conditions of Participation.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify the medical staff operates under current bylaws that are in accordance with federal and state laws and regulations.
01.01.04 Approve medical staff bylaws *The governing body must:* ▪ *Approve medical staff bylaws and other medical staff rules and regulations.* §482.12(a)(4)	☐ Compliant ☐ Not Compliant The governing body decides whether or not to approve medical staff bylaws submitted by the medical staff. The medical staff bylaws and any revisions must be approved by the governing body before they are considered effective.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ The medical staff operates under current bylaws, rules and policies that have been approved by the governing body. ▪ Any revisions or modifications in the medical staff bylaws, rules and policies have been approved by the medical staff and the governing body, e.g., bylaws are annotated with date of last review and initialed by person(s) responsible. ▪ The governing body has reviewed and approved the medical staff bylaws minimally every three years.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.01.05 Medical staff accountability for quality of care *The governing body must:* ▪ *Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.* §482.12(a)(5)	☐ Compliant ☐ Not Compliant The governing body must ensure that the medical staff as a group is accountable to the governing body for the quality of care provided to patients. The governing body is responsible for the conduct of the hospital and this conduct includes the quality of care provided to patients. All hospital patients must be under the care of a practitioner who meets the criteria of 42 CFR §482.12(c)(1) [01.00.18] and who has been granted medical staff privileges, or under the care of a practitioner who is directly under the supervision of a member of the medical staff. All patient care is provided by or in accordance with the orders of a practitioner who has been granted privileges in accordance with the criteria established by the governing body, and who is working within the scope of those granted privileges.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The governing body is periodically apprised of the medical staff evaluation of patient care services provided hospital wide, at every patient care location of the hospital. ▪ Any individual providing patient care services is a member of the medical staff or is accountable to a member of the medical staff qualified to evaluate the quality of services provided, and in turn, is responsible to the governing body for the quality of services provided.
01.01.06 Selection criteria for appointment to the staff *The governing body must:* ▪ *Ensure the criteria for selection are individual character, competence, training, experience, and judgment.* §482.12(a)(6)	☐ Compliant ☐ Not Compliant The governing body must assure that the medical staff bylaws describe the privileging process to be used by the hospital. The process articulated in the medical staff bylaws, rules, or regulations must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers: ▪ Individual character. ▪ Individual competence. ▪ Individual training.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify: □ Granting of medical staff membership or privileges, both new and renewal, is based upon an individual practitioner's meeting the medical staff's membership privileging criteria. □ At a minimum, criteria for

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Individual experience. ▪ Individual judgment. The governing body must ensure that the hospital's bylaws governing medical staff membership or the granting of privileges apply equally to all practitioners in each professional category of practitioners.	appointment to the medical staff granting of medical staff privileges are individual character, competence, training, experience, and judgment. □ There are written criteria for appointments to the medical staff and granting of medical staff privileges.
01.01.07 Required criteria for appointment *The governing body must:* ▪ *Ensure that under no circumstances is the accordance of staff membership or professional privileges in the hospital dependent solely upon certification, fellowship or membership in a specialty body or society.* §482.12(a)(7)	☐ Compliant ☐ Not Compliant In making a judgment on medical staff membership, a hospital may not rely solely on the fact that an MD or DO is, or is not, board-certified. This does not mean that a hospital is prohibited from requiring board certification when considering an MD or DO for medical staff membership, but only that such certification must not be the only factor that the hospital considers. In addition to matters of board certification, a hospital must also consider other criteria such as training, character, competence, and judgment. After analysis of all of the criteria, if all criteria are met except for board certification, the hospital has the discretion to decide not to select that individual to the medical staff.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that written criteria for appointment to the medical staff and granting of medical staff privileges are not dependent solely upon certification, fellowship, or membership in a specialty body or society.
01.01.08 Telemedicine agreements with distant-site hospital or distant-site telemedicine entity *The governing body must:* ▪ *Ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the agreement is*	☐ Compliant ☐ Not Compliant "**Telemedicine**," as the term is used in this regulation, means the provision of clinical services to patients by physicians and practitioners from a distance via electronic communications. The distant-site telemedicine physician or practitioner provides clinical services to the hospital patient either simultaneously, as is often the case with tele-ICU services, for example, or	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Ask the hospital's leadership whether it uses telemedicine services. If yes: ▪ Ask to see a copy of the written agreement(s) with the distant-site

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written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in accordance with paragraphs (a)(1) through (a)(7) of 42 CFR 482.12 with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(3) of 42 CFR 482.12, grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.

- *Ensure that, when telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the hospital and as such, in accordance with §482.12(e), furnishes the contracted services in a manner that permits the hospital to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in*

non-simultaneously, as may be the case with many teleradiology services.

"**Simultaneously**" means that the clinical services (for example, assessment of the patient with a clinical plan for treatment, including any medical orders needed) are provided to the patient in "real time" by the telemedicine physician or practitioner, similar to the actions of an on-site physician or practitioner.

"**Non-simultaneously**" means that while the telemedicine physician or practitioner still provides clinical services to the patient upon a formal request from the patient's attending physician; such services may involve after-the-fact interpretation of diagnostic tests in order to provide an assessment of the patient's condition and do not necessarily require the telemedicine practitioner to directly assess the patient in "real time." This would be similar to the services provided by an on-site radiologist who interprets a patient's x-ray or CT scan and then communicates his or her assessment to the patient's attending physician who then bases his or her diagnosis and treatment plan on these findings (see 76 FR 25551-25552, May 5, 2011).

A hospital may make arrangements through written agreements either with a distant-site Medicare-participating hospital or a distant-site telemedicine entity for the provision of telemedicine services to the hospital's patients by physicians or practitioners who have been granted privileges by the distant-site hospital or telemedicine entity.

For the purposes of this rule, a distant-site telemedicine entity is defined as an entity that:

1. provides telemedicine services;
2. is not a Medicare-participating hospital; and
3. provides contracted services in a manner that enables a hospital using its services to meet all applicable CoPs, particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of a hospital.

A distant-site telemedicine entity would include a distant-site hospital that

hospital(s) or telemedicine entity(ies). Does each agreement include the required elements concerning credentialing and privileging of the telemedicine physicians and practitioners?

- Does the hospital have documentation indicating that it granted privileges to each telemedicine physician and practitioner?
- Does the documentation indicate that for each telemedicine physician and practitioner there is a medical staff recommendation, including an indication of whether the medical staff conducted its own review or relied upon the decisions of the distant-site hospital or telemedicine entity?

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paragraphs (a)(1) through (a)(7) of 42 CFR 482.12 with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services.

The governing body of the hospital whose patients are receiving the telemedicine services may, in accordance with §482.22(a)(4) of 42 CFR 482.22, grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such hospital's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.

§482.12(a)(8-9)

does not participate in the Medicare program that is providing telemedicine services to a Medicare-participating hospital. (See 76 FR 25553, May 5, 2011).

If a hospital enters into an agreement for telemedicine services with a distant-site hospital or telemedicine entity, the agreement must be in writing.

Furthermore, the written agreement must specify, in the case of a:

- **Distant-site hospital,** that it is the responsibility of the governing body of the distant-site hospital to satisfy the requirements of §482.12(a)(1-7) with respect to those physicians and practitioners at the distant-site hospital who furnish telemedicine services under the agreement. Since the distant-site hospital must also be a Medicare-participating hospital (see §482.22(a)(3)), it has an independent obligation to comply with these governing body requirements concerning medical staff membership and privileging. Nevertheless, the written agreement between the hospital and the distant-site hospital must explicitly include a provision addressing the distant-site hospital's obligation to comply with these provisions.
- **Distant-site telemedicine entity**, that the written agreement specifies that the entity is a contractor providing telemedicine services to the hospital, and that, in accordance with the requirements governing services under arrangement at §482.12(e), the telemedicine entity furnishes the contracted telemedicine services in a manner that permits the hospital to comply with the Conditions of Participation, including, but not limited to, the governing body requirements of §482.12(a)(1-7) with respect to those physicians and practitioners at the distant-site telemedicine entity who furnish telemedicine services under the agreement.

There are additional requirements for the content of the written agreement, specified at §482.22(a)(3-4) under the medical staff Condition of Participation, which are discussed in the interpretive guidelines for those regulations.

The hospital's governing body must grant privileges to each telemedicine physician or practitioner providing services at the hospital under an

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agreement with a distant-site hospital or telemedicine entity before they may provide telemedicine services. The scope of the privileges in the hospital must reflect the provision of the services via a telecommunications system. For example, a surgeon at a distant-site hospital may provide telemedicine consultation services at a hospital under agreement, but obviously would not be able to perform surgery by this means and must not have surgical privileges in the hospital as part of his/her telemedicine services privileges. If the surgeon also periodically performed surgery on-site at the hospital, then he or she would have to have privileges to do so, granted in the traditional manner provided for at §482.12(a)(1-7) and §482.22(a)(1-2).

In granting privileges to telemedicine physicians and practitioners, the hospital's governing body has the option of considering hospital medical staff recommendations that rely, in accordance with §482.22(a)(3-4), upon the credentialing and privileging decisions of the distant-site hospital or telemedicine entity. With respect to the decisions of a distant-site telemedicine entity, the regulation states that this streamlined privileging option is available to the hospital for physicians and practitioners "employed" by the distant-site telemedicine entity. We are interpreting "employed" in this context to mean "utilized by" the distant-site telemedicine entity to provide telemedicine services to the hospital under an agreement. Since it is common for telemedicine entities to contract with, rather than employ, the physicians and practitioners it utilizes to provide telemedicine services, it would not be reasonable or consistent with the regulatory intent to interpret "employed" to mean that the physicians or practitioners are employees of the distant-site telemedicine entity.

When the hospital's governing body exercises the option to grant privileges based on its medical staff recommendations that rely upon the privileging decisions of a distant-site telemedicine hospital or entity, it may, but is not required to, maintain a separate file on each telemedicine physician and practitioner, or may instead have a file on all telemedicine physicians and practitioners providing services at the hospital under each agreement with a distant-site hospital or telemedicine entity, indicating which telemedicine

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services privileges the hospital has granted to each physician and practitioner on the list.

Relying upon the credentialing and privileging decisions of the distant-site hospital or telemedicine entity is an option available to the hospital's governing body, not a requirement. A governing body may, if it so chooses, require its medical staff to independently review the credentials of and make privileging recommendations for each telemedicine physician and practitioner in accordance with §482.22(a)(1-2), rather than permit its medical staff to rely upon the privileging decisions of the distant-site hospital or telemedicine entity.

The agreement with the distant-site hospital or telemedicine entity may not require the hospital to rely upon the distant-site organization's privileging decisions.

01.01.09 For future use

01.01.10 Governing body periodically consults with the medical staff

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The governing body must:

- *Consult directly with the individual assigned the responsibility for the organization and conduct of the hospital's medical staff, or his or her designee.*
- *At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to*

In accordance with §482.22(b)(3), there must be an individual member of the hospital's medical staff who is assigned responsibility for the organization and conduct of the medical staff (the "leader" of the medical staff). §482.12(a)(10) requires that the governing body consult with this individual, or with someone the leader of the medical staff has designated.

"Direct consultation" means that the governing body, or a subcommittee of the governing body, meets with the leader(s) of the medical staff(s) either face-to-face or via a telecommunications system permitting immediate, synchronous communication. (79 FR 27113, May 12, 2014)

This regulation does not preclude a hospital from having a member of the medical staff serve as a member of the hospital's governing body. However,

INTERVIEW AND DOCUMENT REVIEW

Ask the CEO:

- how the hospital complies with the requirement for periodic consultations by the governing body with the leader(s) of the hospital's medical staff, or the leader's designee. Can the CEO provide evidence that such consultations have occurred, e.g., meeting agendas and lists of

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patients of the hospital.

- *For a multi-hospital system using a single governing body, the single multi-hospital system governing body must consult directly with the individual responsible for the organized medical staff (or his or her designee) of each hospital within its system in addition to the other requirements of this paragraph (a) in 42 CFR 482.12.*

§482.12(a)(10)

membership on the governing body by a medical staff member is not sufficient per se to satisfy the requirement for periodic consultation. In such a situation the hospital meets the consultation requirement only if the medical staff member serving on the governing body is the leader of the medical staff, or his or her designee, and only if such membership includes meeting with the board periodically throughout the fiscal or calendar year and discussing matters related to the quality of medical care provided to patients of the hospital.

If there were a change in the medical staff leadership or his or her designee, and the bylaws governing terms and conditions of governing body membership did not allow for substitution of the new leader of the medical staff (or his or her designee) on the governing body, then the governing body would be expected to engage in direct consultation with the individual newly responsible for the organization and conduct of the medical staff, or his or her designee.

If a hospital chooses to have the leader of the medical staff, or his or her designee, serve on the governing body, there is nothing in the regulation which prohibits the hospital from also including other medical staff members on the governing body in addition to the leader of the medical staff, or his or her designee.

In the case of a multi-hospital system that has one single governing body, the governing body must consult with each separately certified hospital's medical staff leader, or his/her designee.

- The consultations do not have to be separate.
- For example, the system governing body could periodically have a meeting that includes the leaders of the medical staff, or his/her designee, from each hospital within the system, so long as there is discussion of matters related to the quality of medical care provided to the patients of each hospital.

If the medical staff members at separately certified hospitals in a multi-

attendees, meeting minutes, etc.

- whether the hospital tracks these consultations by the calendar year or its fiscal year; ask to see a copy of the policy that establishes this.
  - □ Is there evidence that the consultations were "direct?"
  - □ Is there evidence that the governing body met with the medical staff leader or designee at least twice during the previous year?
  - □ Is there evidence that the discussion concerned matters related to the quality of medical care in the hospital?
- Ask the leader of the hospital's medical staff whether he or she has had meetings with either the whole governing body or a subcommittee of it to discuss the quality of medical care in the hospital.
  - □ Has the leader ever requested a meeting in addition to those regularly scheduled, to discuss a matter of urgent concern to the medical staff? If yes, did the governing body respond by setting up a meeting?
  - □ If the hospital shares a unified medical staff with other separately certified hospitals in a multi-hospital

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hospital system and the hospital system's governing body also have opted to have a unified medical staff (see guidance for §482.22(b)(4)) for some or all of the hospitals in the system, then the governing body must consult with the leader of the unified medical staff or his/her designee. In this case, the leader of the unified medical staff, or the designee, as applicable, is expected to be aware of the concerns/views of members of the medical staff practicing at each separately certified hospital using the unified medical staff.

It is up to the governing body as to whether the leader of the medical staff must make the designation in writing when he or she chooses to designate another individual for these periodic consultations, or whether the leader of the medical staff may make informal, ad hoc designations.

It is also up to the governing body as to whether it wishes to establish minimum advance notice of a designation from the leader of the medical staff to the governing body.

The requirement for the governing body to consult periodically throughout the year leaves some flexibility for the governing body to determine how often during the year its consultations with the leader of the medical staff or designee would occur, but it is expected that consultations occur at least twice during either a calendar or fiscal year.

- ("Fiscal year" refers to the Medicare cost-reporting year for the hospital; in the case of a hospital system with multiple, separately certified hospitals that have one single governing body and a unified medical staff, it is possible that individual hospitals have separate fiscal years. In this case, it would be more practical for the governing body to use a calendar year basis for determining the frequency of consultation.)

The governing body is expected to determine the number of consultations needed based on various factors specific to one or more of the hospitals within a multi-hospital system. These factors include, but are not limited to, the scope and complexity of hospital services offered, specific patient

system, the interview with the leader of the medical staff, or designee, may have to be conducted by telephone. Ask the leader how he/she gathers information about the concerns/views of members of the medical staff practicing at the hospital being surveyed about the quality of medical care provided at that hospital.

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populations served by a hospital, and any issues of patient safety and quality of care that a hospital's quality assessment and performance improvement program might periodically identify as needing the attention of the governing body in consultation with its medical staff.

The hospital must also provide evidence that the governing body is appropriately responsive to any periodic and/or urgent requests from the leader of the medical staff or designee for timely consultation on issues regarding the quality of medical care provided to patients of the hospital. (79 FR 27112, May 12, 2014).

The "year" referenced in the regulation may be either the calendar year or the hospital's fiscal year, as identified on its Medicare cost report. It is up to the hospital which approach it will take, but it must document the approach selected and consistently apply it. For example, if a hospital chooses to use the calendar year, and had only one consultation during a calendar year, it could not then point out that it had had two meetings during the time period covered by its fiscal year.

The required consultation must include discussion of matters related to the quality of medical care provided to the hospital's patients, or, in the case of a hospital system with one single governing body and a unified medical staff, the quality of medical care provided to each separately certified hospital's patients.

The hospital's governing body must adopt policies and procedures addressing how it implements the requirement for periodic, direct consultation with the leader of the medical staff, or the designee.

The hospital must have evidence that the required consultations do take place, such as meeting agendas and lists of attendees, or minutes taken of the discussion, including who was present, etc., and that matters related to the quality of medical care provided to patients of the hospital were discussed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.01.11 Chief executive officer (CEO) appointment *The governing body must:* ▪ *Appoint a chief executive officer who is responsible for managing the hospital.* §482.12(b)	☐ Compliant ☐ Not Compliant The Governing Body must appoint one chief executive officer who is responsible for managing the entire hospital. The CEO is accountable for providing an organizational structure, with appropriate resources including support staff, to effectively implement plans to provide ethical, efficient, effective services. This individual is responsible to governance for day-to-day operations of the entire hospital and is guided by a position description. The position description, with defined management objectives, serves as the basic evaluation criteria for the CEO. The CEO is responsible for insuring that all services provided including those by arrangement, agreement or contract complies with all standards requirements.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ the hospital has only one chief executive officer for the entire hospital. ▪ the governing body has appointed the chief executive officer. ▪ the chief executive officer is responsible for managing the entire hospital.
01.01.12 Care of patients *In accordance with hospital policy, the governing body must ensure that the following requirements are met.* *Every Medicare patient is under the care of:* *(i) A doctor of medicine or osteopathic medicine. (This provision is not to be construed to limit the authority of a doctor of medicine or osteopathy to delegate tasks to other qualified health care personnel to the extent*	☐ Compliant ☐ Not Compliant Practitioners other than MDs or DOs may join the medical staff if the practitioners are appropriately licensed and medical staff membership is in accordance with State law. Every Medicare or Medicaid patient must be under the care of a licensed practitioner as defined in this requirement.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that Medicare patients are under the care of a licensed practitioner as defined by 482.12(c)(1).

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recognized under State law or a state's regulatory mechanism.);

(ii) A doctor of dental surgery or dental medicine who is legally authorized to practice dentistry by the State and who is acting within the scope of his or her license;

(iii) A doctor of podiatric medicine, but only with respect to functions which he or she is legally authorized by the State to perform;

(iv) A doctor of optometry who is legally authorized to practice optometry by the State in which he or she practices;

(v) A chiropractor who is licensed by the State or legally authorized to perform the services of a chiropractor, but only with respect to treatment by means of manual manipulation of the spine to correct a subluxation demonstrated by x-ray to exist;

and

(vi) A clinical psychologist as defined in §410.71 of 42 CFR 410.71, but only with respect to clinical psychologist services as defined in §410.71 of 42 CFR 410.71 and only to the extent permitted by State law.

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§482.12(c)
§482.12(c)(1)
§482.12(c)(1)(i-vi)

01.01.13 State privilege requirements

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

In accordance with hospital policy, the governing body must ensure that the following requirements are met:

- *Patients are admitted to the hospital only on the recommendation of a licensed practitioner permitted by the State to admit patients to a hospital.*
- *If a Medicare patient is admitted by a practitioner not specified in paragraph (c)(1) [standard 01.01.15] of 42 CFR 482.12, that patient is under the care of a doctor of medicine or osteopathic medicine.*

§482.12(c)(2)

CMS hospital regulations do permit licensed practitioners (e.g., nurse practitioners, midwives, etc.), as allowed by the State, to admit patients to a hospital, and CMS does not require these practitioners be employed by an MD or DO.

- However, CMS regulations require that Medicare and Medicaid patients admitted by these practitioners be under the care of an MD or DO.
- Evidence of being under the care of an MD/DO must be in the patient's medical record.
- If a hospital allows these practitioners to admit and care for patients, as allowed by State law, the governing body and medical staff would have to establish policies and bylaws to ensure that the requirements of 42 CFR §482 are met.

MIDWIFE PATIENTS

42 CFR §482.1(a)(5) states, "Section 1905(a) of the Act provides that 'medical assistance' (Medicaid) payments may be applied to various hospital services.

Regulations interpreting those provisions specify that hospitals receiving payment under Medicaid must meet the requirements for participation in Medicare (except in the case of medical supervision of nurse midwife services. See §440.10 and §440.165 42 of this chapter)."

- Midwives are not specified at 42 CFR §482.12(c)(1).

Section §482.1(a)(5), when taken together with this requirement (42 CFR §482.12(c)(2)) means that in a State that permits midwives to admit patients

DOCUMENT REVIEW

- Verify that:
  - ☐ admitting privileges are limited to those categories of practitioners as allowed by State law.
  - ☐ patients are admitted only by those practitioners who are currently licensed and have been granted admitting privileges by the governing body in accordance with State laws and medical staff bylaws.
- If the hospital grants admitting privileges to these practitioners (midwives), select Medicare and Medicaid patients (select only Medicare patients for midwives) that are admitted to the hospital by these practitioners.
- Determine if the patient is/was under the care of a physician.

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	(and in accordance with hospital policy and practitioner privileges), CMS requires ONLY Medicare patients of a midwife be under the care of an MD or DO. ▪ CMS DOES NOT require Medicaid or other non-Medicare patients admitted by a midwife to be under the care of an MD or DO.	
01.01.14 Physician availability *The governing body must ensure that the following requirements are met:* ▪ *A doctor of medicine or osteopathic medicine is on duty or on call at all times.* §482.12(c)(3)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview nursing staff. □ How do they know who is on call? □ Are they able to contact and speak with the on-call physician at all times? □ When appropriate, does the on-call physician come to the hospital to provide needed care? ▪ Verify the governing body has established and monitors enforcement of policies that ensure a physician is on duty or on call at all times to provide medical care and onsite supervision when necessary. □ Review the "call" register to ensure that a physician is on duty or on call at all times.

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01.01.15 Medical staff oversight

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The governing body must ensure that the following requirements are met:

A doctor of medicine or osteopathic medicine is responsible for the care of each Medicare patient with respect to any medical or psychiatric problem that—

(i) Is present on admission or develops during hospitalization; and

(ii) Is not specifically within the scope of practice of a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist, as that scope is—

(A) Defined by the medical staff;

(B) Permitted by State law; and

(C) Limited, under paragraph (c)(1)(v) of 42 CFR 482.12, with respect to chiropractors.

§482.12(c)(4)

CMS hospital regulations **do** permit licensed practitioners (i.e., doctors of dental surgery, dental medicine, podiatric medicine, or optometry; chiropractors; or clinical psychologists), as allowed by the State, to admit patients to a hospital.

However, CMS **does require** that Medicare and Medicaid patients who are admitted by a doctor of dental surgery, dental medicine, podiatric medicine, or optometry; a chiropractor; or clinical psychologist be under the care of an MD/DO with respect to any medical or psychiatric problem that is present on admission or develops during hospitalization that is outside the scope of practice of the admitting practitioner.

If a hospital allows a doctor of dental surgery, dental medicine, podiatric medicine, or optometry, a chiropractor, or a clinical psychologist to admit and care for patients, as allowed by State law, the governing body and medical staff must establish policies and bylaws to ensure that the requirements of 42 CFR §482 are met.

As applicable, the patient's medical record must demonstrate MD/DO responsibility/care.

DOCUMENT REVIEW

- Verify that an assigned MD or DO is responsible for and is monitoring the care of each Medicare or Medicaid patient with respect to all medical or psychiatric problems during the hospitalization.
- If non-MD/DOs admit patients, verify that every Medicare/Medicaid patient is being monitored by an MD or DO who is responsible for any medical or psychiatric problem outside the scope of practice of the admitting practitioners.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.01.16 Institutional plan and budget *The institution must have an overall institutional plan that meets the following conditions:* *(1) The plan must include an annual operating budget that is prepared according to generally accepted accounting principles.* *(2) The budget must include all anticipated income and expenses. This provision does not require that the budget identify item by item the components of each anticipated income or expense.* *(3) The plan must provide for capital expenditures for at least a 3-year period, including the year in which the operating budget specified in paragraph (d)(2) of 42 CFR 482.12 is applicable.* *(4) The plan must include and identify in detail the objective of, and the anticipated sources of financing for, each anticipated capital expenditure in excess of $600,000 (or a lesser amount that is established, in accordance with section 1122(g)(1) of the Act (Social Security Act), by the State in which the hospital is located)*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that an institutional plan and budget exist, includes items 1-4 in the standard and complies with all items in this standard. Do not review the specifics or format of the institutional plan or the budget.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

that relates to any of the following:

(i) Acquisition of land.

(ii) Improvement of land, building, and equipment.

(iii) The replacement, modernization, and expansion of the buildings and equipment.

§482.12(d)
§482.12(d)(1-3)
§482.12(d)(4)(i-iii)

01.01.17 Plan submission

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The plan must be submitted for review to the planning agency designated in accordance with section 1122(b) of the Social Security Act (the Act), or if an agency is not designated, to the appropriate health planning agency in the state (See part 100 of this title.)

A capital expenditure is not subject to section 1122 review of the Act (Social Security Act) if 75 percent of the healthcare facility's patients who are expected to use the service for which the capital expenditure is made are individuals enrolled in a health maintenance organization (HMO) or competitive medical plan (CMP) that meets the requirements of section 1876(b) of the

No additional information.

DOCUMENT REVIEW

Determine that the hospital's plan for capital expenditures has been submitted to the planning agency designated to review capital expenditures. In certain cases, facilities used by HMO and CMP patients are exempt from the review process.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Act (Social Security Act), and if the Department determines that the capital expenditure is for services and facilities that are needed by the HMO or CMP in order to operate efficiently and economically and that are not otherwise readily accessible to the HMO or CMP because-

(i) The facilities do not provide common services at the same site.

(ii) The facilities are not available under a contract of reasonable duration.

(iii) Full and equal medical staff privileges in the facilities are not available.

(iv) Arrangements with these facilities are not administratively feasible.

(v) The purchase of these services is more costly than if the HMO or CMP provided the service directly.

§482.12(d)(5)
§482.12(d)(5)(i-v)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.01.18 Plan review and update *The plan must be reviewed and updated annually.* §482.12(d)(6)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the plan and budget are reviewed and updated annually.
01.01.19 Plan preparation *The plan must be prepared—* *(i) Under the direction of the governing body; and* *(ii) By a committee consisting of representatives of the governing body, the administrative staff, and the medical staff of the institution.* §482.12(d)(7) §482.12(d)(7)(i-ii)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the governing body, administrative staff, and medical staff have participated in the development of the institutional plan and budget.
01.01.20 Oversight of the physical environment The governing body must be responsible for providing a physical environment that is constructed, arranged, maintained, equipped, and staffed to meet the needs and services required for patients.	☐ Compliant ☐ Not Compliant The governing body shall receive and review periodic written reports from appropriate internal and external sources regarding the adequacy and deficiencies of the physical environment to assure the well-being of patients. These reports: ▪ Summarize issues relating to the physical environment, construction, equipment, and staffing needs.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Assess leadership's role in evaluating the staff's accountability in performing their duties. ▪ Determine the governance has received physical plant and equipment reports.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Are typically prepared at least quarterly and aggregated into an annual evaluation. The leadership: ▪ Provides resources and support necessary for staff to perform their duties. ▪ Holds staff accountable to their assigned responsibilities.	▪ Determine the governance has acted upon these reports, as necessary.
01.01.21 Oversight of the QAPI Program The governing body shall be responsible for a hospital-wide Quality Assessment Performance Improvement Program that reflects all hospital departments and services. The QAPI plan and its findings are shared with and reviewed by the governance.	☐ Compliant ☐ Not Compliant The QAPI plan reflects final approval of the governing body either by date and signature or by notation as to the date that governance minutes will document such approval. Hospital staff prepares aggregate summaries for reporting to governance; these separate findings, as appropriate, for staff and other providers of care and service. ▪ Such reports are typically documented at least quarterly and aggregated into an annual evaluation. Report formats may vary to include narration, statistical charts, diagrams, and "storyboards."	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that governance has: ▪ Approved the QAPI plan within the last twelve months. ▪ Received and acted upon summary findings at least quarterly for both Staff and other providers. ▪ Received and acted upon an annual QAPI evaluation for both staff and other providers. ▪ If the hospital is subject to "open meetings" requirements due to ownership by a governmental agency, or otherwise, the QAPI reports may be noted in detail in a governance subcommittee such as Joint Conference with action being taken by the full governance in

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

open session.

01.01.22 Contracted services

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The governing body must be responsible for services furnished in the hospital whether or not they are furnished under contracts.

The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the hospital to comply with all applicable conditions of participation and standards for the contracted services.

1. ***The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.***
2. ***The hospital must maintain a list of all contracted services, including the scope and nature of the services provided.***

§482.12(e)
§482.12(e)(1-2)

The governing body is responsible for assuring that hospital services are provided in compliance with the Medicare Conditions of Participation and according to acceptable standards of practice, irrespective of whether the services are provided directly by hospital employees or indirectly by contract.

Consequently, a list of all contracted services, with the scope and nature of such service, is maintained.

The governing body must take actions through the hospital's QAPI program to:

- assess the services furnished directly by hospital staff and those services provided under contract.
- identify quality and performance problems.
- implement appropriate corrective or improvement activities.
- ensure the monitoring and sustainability of those corrective or improvement activities. (See §482.21 QAPI.)

Patient care and patient care associated services, provided under contract are subject to the same hospital-wide quality assessment and performance improvement (QAPI) evaluation as other services provided directly by the hospital.

INTERVIEW AND DOCUMENT REVIEW

Verify:

- All contractor services provided in the hospital are in compliance with the Conditions of Participation for hospitals.
- **The list for contracted services includes all contractual providers (including shared service or joint venture). The list includes the scope and nature of the services provided.**
- **The process used to evaluate the quality of care for each patientcare and patient care associated contracted service.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.01.23 For future use		
01.01.24 For future use		
01.01.25 Policy and procedure review and approval The organization has a formal policy that establishes the process for policy and procedure approval. Unless specifically indicated by state, federal regulations, or elsewhere in this manual, policies and procedures are to be reviewed at least every three years.	☐ Compliant ☐ Not Compliant The organization is responsible to ensure its policies and procedures are current. The policy approval process may vary depending upon the size, type and complexity of the organization. The organization identifies the policies and procedures that require approval by one or more of the following: ▪ Governing Body ▪ Chief Executive Committee ▪ Medical Executive Committee ▪ Chair, Medical Department ▪ Chief Nursing Executive	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The hospital has a formal policy that establishes the approval process and frequency of policy and procedure review. ▪ The hospital ensures all policies are reviewed at least every three years and consistent with the organization's policy.
01.01.26 Medically-related patient care services The hospital shall have an ongoing plan, consistent with available community and hospital resources, to provide or make available social work, psychological, and educational services to meet the medically related needs of its patients.	☐ Compliant ☐ Not Compliant The hospital should have policies and procedures to provide or make available medical related services to meet the needs of patients regarding: ▪ Social work ▪ Psychological, and ▪ Educational services.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review: ▪ The hospital's plan for providing medically related social work, psychological and educational needs of its patients.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ The documentation of the agreements (e.g., contracts, memorandum of understanding, or letters of agreement) to assure that services are available to all patients needing them.
01.02.01 Emergency services *The hospital must ensure the emergency services requirements are met.* §482.12(f)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: ▪ Score compliance based on the outcome of scoring Chapter 20, Emergency Services if an emergency department is present. ▪ If there is no Emergency Department/ Services, score compliance based on standards 01.02.03 and/or 01.02.04.
01.02.02 Emergency services compliance with federal laws *If emergency services are provided at the hospital, the hospital must comply with the requirements of 42 CFR §482.55.* §482.12(f)(1)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: ▪ Score based on the outcome of scoring in Chapter 20, Emergency Services. ▪ If there is no Emergency Department/Services, score this as "not applicable."

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

01.02.03 Policies regarding emergency care when services are not provided

If emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate.

§482.12(f)(2)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

This requirement applies hospital-wide (all on-campus and off-campus locations) to hospitals that do not provide emergency services.

Hospitals without emergency departments must have appropriate policies and procedures in place for addressing individual's emergency care needs 24 hours per day and 7 days per week, including the following:

APPRAISAL OF PERSONS WITH EMERGENCIES

A hospital must have medical staff policies and procedures for conducting appraisals of persons with emergencies. The policies and procedures must ensure that:

- As required by 42 CFR §482.23(b), an RN is immediately available, as needed, to provide bedside care to any patient and that,
- Among such RN(s) who are immediately available at all times, there must be an RN(s) who is/are qualified, through a combination of education, licensure, and training, to conduct an assessment that enables them to recognize the fact that a person has a need for emergency care.

The policies and procedures for appraisal should provide that the MD or DO (on-site or on-call) would directly provide appraisals of emergencies or provide medical direction of on-site staff conducting appraisals.

INITIAL TREATMENT

A hospital must have medical staff policies and procedures for providing the initial treatment needed by persons with emergency conditions.

Among the RN(s) who must be available at all times in a hospital as required by 42 CFR §482.23(b) [see standard 16.00.04], there must be RN(s) who are qualified, through a combination of education, licensure, and training, to provide initial treatment to a person experiencing a medical emergency. The

INTERVIEW AND DOCUMENT REVIEW

- Interview hospital staff at various locations. Can they state their duties and what they are to do if an individual seeks or needs emergency care at their location?
- Verify that the medical staff has adopted written policies and procedures for the management of medical emergencies.
- Review emergency care policies and procedures. Are they consistent with the expectations articulated above for appraisal, initial treatment, and referral? Do they address emergency procedures for all on-campus and off-campus locations?

on-site or on-call physician could provide initial treatment directly or provide medical oversight and direction to other staff. This requirement, taken together with other hospital regulatory requirements, suggests that a prudent hospital would evaluate the patient population the hospital routinely cares for in order to anticipate potential emergency care scenarios and develop the policies, procedures, and staffing that would enable it to provide safe and adequate initial treatment of an emergency.

REFERRAL WHEN APPROPRIATE

A hospital must have medical staff policies and procedures to address situations in which a person's emergency needs may exceed the hospital's capabilities.

The policies and procedures should be designed to enable hospital staff members who respond to emergencies to:

- recognize when a person requires a referral or transfer, and
- assure appropriate handling of the transfer.

This includes arrangement for appropriate transport of the patient.

Further, in accordance with the Discharge Planning CoP at 42 CFR §482.43(d), the hospital must transfer patients to appropriate facilities, i.e., those with the appropriate capabilities to handle the patient's condition.

The regulation also requires that necessary medical information be sent along with the patient being transferred. This enables the receiving hospital to treat the medical emergency more efficiently.

PATIENT TRANSPORTATION AND EMERGENCY MEDICAL SERVICES (EMS)

A hospital may arrange transportation of the referred patient by several methods, including using the hospital's own ambulance service, the receiving hospital's ambulance service, a contracted ambulance service, or, in extraordinary circumstances, alerting EMS via calling 9-1-1. There is no specific Medicare prohibition on a hospital with or without an emergency department calling 9-1-1 in order to obtain transport of a patient to another

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

hospital. Use of 9-1-1 to obtain transport does not, however, relieve the hospital of its obligation to arrange for the patient's transfer to an appropriate facility and to provide the necessary medical information along with the patient.

A hospital policy or practice that relies on calling 9-1-1 in order for EMS to substitute its emergency response capabilities for those the hospital is required to maintain, as described above, is not consistent with the Medicare CoPs. For example, a hospital may not rely upon 9-1-1 to provide appraisal and initial treatment of medical emergencies that occur at the hospital. Such policy or practice should be considered as condition-level non-compliance with the applicable CoP, 42 CFR §482.55 or 42 CFR §482.12(f).

01.02.04 Off-site emergency care

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

If emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff has written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

§482.12(f)(3)

This requirement applies to any off-campus hospital department / location that does not qualify as a dedicated emergency department in accordance with 42 CFR §489.24(b) and is part of a hospital that provides emergency services. Such departments/locations must have and must implement medical staff policies and procedures for the appraisal of emergencies and referral when appropriate.

APPRAISAL OF PERSONS WITH EMERGENCIES

A hospital must have medical staff policies and procedures for conducting appraisals of persons with emergencies at off-campus departments/locations that are not dedicated emergency departments.

The policies and procedures must ensure that clinical personnel -- who are qualified, through a combination of education, licensure, and training, to conduct an assessment that enables them to recognize the fact that a person has a need for emergency care -- are available during all hours of operation at the off-campus department/location.

INTERVIEW AND DOCUMENT REVIEW

- Interview off-campus hospital department staff. Can they state their duties and what they are to do if an individual seeks emergency care?
- Review emergency care policies and procedures. Determine if they address emergency procedures for all off-campus locations.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

REFERRAL WHEN APPROPRIATE

A hospital must have medical staff policies and procedures to address situations in which a person's emergency needs may exceed the capabilities of the off-campus departments/locations that are not dedicated emergency departments.

The policies and procedures should be designed to enable staff members at such locations to:

- recognize when a person requires a referral or transfer, and
- assure appropriate handling of the transfer.

  This includes arrangement for appropriate transport of the patient along with the transfer of the patient's medical information so that the receiving hospital may treat the medical emergency more efficiently.

INITIAL TREATMENT

Although there is no specific regulatory requirement for such off-campus departments or locations to provide initial treatment of emergencies, nevertheless they are expected to provide treatment and stabilization consistent with the complexity of services, the type and qualifications of clinical staff, and the resources available at that location.

This expectation is based on the requirements of the Outpatient Services CoP that hospital outpatient services meet the needs of the patients in accordance with acceptable standards of practice, outpatient services must be appropriately organized and integrated with inpatient services, and outpatient services must have appropriate professional and nonprofessional personnel available. For example, an off-campus cardiac rehabilitation clinic would be expected to have the appropriate qualified staff, equipment (such as a crash cart), and policies and procedures in place to appropriately provide appraisal, initial interventions, and referral of a patient who experiences a cardiac emergency.

A hospital policy or practice that relies on calling 9-1-1 in order for EMS to substitute its emergency response capabilities for those the hospital is

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	required to maintain at its off-campus departments/locations, as described above, is not consistent with the Medicare CoPs. However, given the more limited emergency capabilities that may be present in some off-campus departments or locations, calling 9-1-1 to respond to an emergency might be appropriate. See the hospital emergency services CoP (42 CFR §482.55) for the emergency requirements for the hospital's locations that provide emergency services.	

02

BASIC HOSPITAL REQUIREMENTS

INTRODUCTION: §482.1 Basis and Scope

HOSPITAL DEFINITION AND REGULATORY ENFORCEMENT AUTHORITIES

"In order to qualify for a provider agreement as a hospital (other than a psychiatric hospital as defined at section 1861(f) of the Act) under Medicare and Medicaid, an entity must meet and continue to meet all of the statutory provisions of §1861(e) of the Act, including the Condition of Participation requirements. See also 42 CFR 488.3(a)(1) and 42 CFR 489.12. This means the entity must:

- Be primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;
- Maintain clinical records on all patients [addressed in 42 CFR 482.24, Medical Records];
- Have medical staff bylaws [42 CFR 482.12, Governing Body, and 42 CFR 482.22, Medical Staff];
- Have a requirement that every patient with respect to whom payment may be made under Title XVIII must be under the care of a physician except that a patient receiving qualified psychologist services (as defined in section 1861(ii) of the Act) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law [42 CFR 482.12, Governing Body];
- Provide 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times…[42 CFR 482.23, Nursing Services];
- Have in effect a hospital utilization review plan which meets the requirements of section 1861(k) of the Act [42 CFR 482.30, Utilization Review];
- Have in place a discharge planning process that meets the requirements of section 1861(ee) of the Act [42 CFR 482.43, Discharge Planning];
- If located in a state in which state or applicable local law provides for the licensing of hospitals, be licensed under such law or be approved by the agency of the State or locality responsible for licensing hospitals as meeting the standards established for such licensing [42 CFR 482.11, Compliance with Federal, State, and Local Laws];
- Have in effect an overall plan and budget that meets the requirements of section 1861(z) of the Act [42 CFR 482.12, Governing Body]; and
- Meet any other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution [42 CFR Parts 482 and 489, among others]."

Considerations:

Generally, a hospital is primarily engaged in providing inpatient services under section 1861(e)(1) of the Act when it is directly providing such services to inpatients. Having the capacity or potential capacity to provide inpatient care is not the equivalent of actually providing such care. Inpatient hospital services are defined under section 1861(b) of the Act and in the regulations at 42 CFR Part 409, Subpart B. CMS guidance describes an inpatient as "a person who has been admitted to a hospital for bed occupancy for purposes of receiving inpatient hospital services …. Generally, a patient is considered an inpatient if formally admitted as an inpatient with the expectation that he or she will require hospital care that is expected to span at least two midnights and occupy a bed even though it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight." (Medicare Benefit Policy Manual, Chapter 1, §10,

https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c01.pdf)

The "expectation of a two midnight stay" for an inpatient is that the intent of the physician was that the patient be admitted to the hospital for an inpatient stay as opposed to that of observation status which is an outpatient service.

Therefore, an average length of stay (ALOS) of two midnights would be one of the benchmarks considered for certification as a hospital.

- In making a determination of whether a facility meets the CMS definition of a hospital, CMS considers multiple factors and will make a final determination based on an evaluation of the facility in totality. Such factors include, but are not limited to, average daily census (ADC), average length of stay (ALOS), the number of off-campus outpatient locations, the number of provider-based emergency departments, the number of inpatient beds related to the size of the facility and scope of services offered, volume of outpatient surgical procedures compared to inpatient surgical procedures, staffing patterns, patterns of ADC by day of the week, etc. Hospitals are not required to have a specific inpatient to outpatient ratio to meet the CMS definition of a hospital.

For surveyors to determine whether or not a hospital is in compliance with the statutory and regulatory requirements of Medicare participation, including the definition of a hospital, they must observe the provision of care. Medicare requirements at 42 CFR 488.26(c)(2) state that "The survey process uses resident and patient outcomes as the primary means to establish the compliance process of facilities and agencies. Specifically, surveyors will directly observe the actual provision of care and services to residents and/or patients, and the effects of that care, to assess whether the care provided meets the needs of individual residents and/or patients."

Because §488.26(c)(2) and section 1861(e) of the Act refer to patients (plural), hospitals must have at least two inpatients at the time of the survey in order for surveyors to conduct the survey. However, two inpatients at the time of a survey does not necessarily mean that the facility is primarily engaged in inpatient care and satisfies all of the statutory requirements to be considered a hospital for Medicare purposes. Having two patients at the time of a survey is merely a starting point in the overall survey and certification process.

If a hospital does not have at least two inpatients at the time of a survey, a survey will not be conducted at that time and an initial review of the facility's admission data will be performed by surveyors while onsite to determine if the hospital has had an average daily census (ADC) of at least two and an average length of stay (ALOS) of at least two midnights over the last 12 months.

- Average daily census is calculated by adding the midnight daily census for each day of the 12-month period and then dividing the total number by the number of days in the year.
- For facilities that have multiple campuses operating under the same CMS Certification Number (CCN), the ADC is not calculated individually at each campus. All locations make up the entire facility and the ADC will be based on the total inpatient census from all campuses. This also includes PPS excluded psychiatric and rehabilitation units that are part of the facility.
- The ALOS is calculated by dividing the total number of inpatient hospital days (day of admission to day of discharge, including day of death) by the total number of discharges in the hospital over 12 months.
- For facilities that have not been operating for 12 months at the time of the survey, an ADC calculated using 12 months as the denominator may falsely result in an ADC of less than two. Therefore, facilities that have been operating for fewer than 12 months at the time of the survey should calculate ADC based on the

number of months the facility has been operational but no less than three months. This does not mean that a facility must be operational for at least three months before a survey can be completed. It merely means that the ADC cannot be calculated using a denominator of less than three months.

- If the ADC and ALOS is two or more, the State Survey Agency (SA) or Accrediting Organization (AO) makes the determination that a second survey will be attempted at a later date.
- If the facility does not have a minimum ADC of two inpatients and an ALOS of two over the last 12 months (or less than 12 months for facilities that have not been operational for at least 12 months), the facility is most likely not primarily engaged in providing care to inpatients and the SA or AO may not conduct the survey. The SA or AO must immediately contact the CMS Regional Office (RO) to inform them that a survey could not be completed and the RO will review additional information provided by the SA or AO to determine whether a second survey should be attempted.

  When the ADC and ALOS are NOT a minimum of two, the SA or AO do not make the final determination whether a second survey will be attempted. Instead, the SA or AO must obtain further information from the facility (other factors described below), review the information and make a recommendation to the RO regarding whether a second survey should be attempted. The SA or AO must provide its recommendation in writing to the RO along with the supporting information used to make the recommendation. The RO must review the recommendation and information and make a determination on whether a second survey will be conducted and communicate its decision to the SA or AO within seven business days of receipt of the recommendation. AO communication to the RO must be via the current established process used for all other written communication to the RO.
- If, during a second survey attempt, the facility does not have two inpatients, the survey will not be conducted and the SA or AO must cite condition level non-compliance with §482.1. In addition, the SA or AO must immediately notify the RO of the situation. The RO will then proceed with either denial of certification (for initial applicants) in the Medicare program or termination of the provider agreement (for currently participating hospitals). For currently participating hospitals, the RO will base any termination action on the totality of the situation including consideration of any access to care issues.

Other factors:

Other factors that the CMS Regional Office should consider in determining whether to (1) conduct a second survey or (2) recommend denial of an initial applicant or termination of a current provider agreement, include but are not limited to:

- The number of provider-based off-campus emergency departments (EDs).
- The number of inpatient beds in relation to the size of the facility and services offered.
- The volume of outpatient surgical procedures compared to inpatient surgical procedures.
- If the facility considers itself to be a “surgical” hospital, are procedures mostly outpatient?
- Patterns and trends in the ADC by the day of the week.
- Staffing patterns. A review of staffing schedules should demonstrate that nurses, pharmacists, physicians, etc. are scheduled to work to support 24/7 inpatient care versus staffing patterns for the support of outpatient operations.
- How does the facility advertise itself to the community? Is it advertised as a “specialty” hospital or “emergency” hospital? Does the name of the facility include

terms like, “clinic” or “center” as opposed to “hospital”?

The CMS RO should consider all of these factors (and others as necessary) to make a determination as to whether or not a facility is truly operating as a hospital for Medicare purposes. A determination of non-compliance with §482.1 will not be based on a single factor, such as failing to have two inpatients at the time of a survey.

It is important to note that CMS has the final authority to make the determination of whether or not a facility has met the statutory definition of a hospital after considering the facility’s entire situation, the recommendations of the State Agency surveyors as well as the evidence submitted by the SAs and AOs.

As stated previously, a facility that meets state requirements for obtaining state status as a hospital is not AUTOMATICALLY considered a hospital for federal survey and certification purposes without further evaluation and consideration of all relevant CMS requirements.

In addition, approval by the Medicare administrative contractor of an enrollment application does not convey hospital status for CMS purposes.

Hospital status is only conveyed and approved by the CMS RO after a survey has been completed and the results clearly demonstrate that the facility has met all the federal requirements, including the statutory definition.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

02.00.00 CONDITION OF PARTICIPATION: Basis and Scope

STATUTORY BASIS

Section 1861(e) of the [Social Security] Act provides that—

(i) *Hospitals participating in Medicare must meet certain specified requirements; and*

(ii) *The Secretary may impose additional requirements if they are found necessary in the interest of the health and safety of the individuals who are furnished services in hospital.*

SCOPE

Except as provided in 42 CFR 488 subpart A, the provisions of this part serve as the basis of survey activities for the purpose of determining whether a hospital qualifies for a provider agreement under Medicare and Medicaid.

§482.1
§482.1(a)(1)
§482.1(a)(1)(i)
§482.1(a)(1)(ii)
§482.1(b)(1)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

DEFINITION OF A HOSPITAL

Refer to the INTRODUCTION (above) for the statutory definition of a hospital in accordance with Social Security Act 1861(e) (the Act).

QUALIFICATION FOR MEDICARE CERTIFICATION

In order to qualify for a provider agreement as a hospital under Medicare and Medicaid, an entity must meet and continue to meet all of the statutory provisions of §1861(e) of the Act, including the Condition of Participation requirements. See also 42 CFR§ 488.3(a)(1) and 42 CFR §489.12.

This means the entity "must be primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;"

"Generally, a hospital is primarily engaged in providing inpatient services under 1861(e)(1) of the Social Security Act when it is directly providing such services to inpatients."

1. The facility must have at least two inpatients for a survey to be conducted.

   However, just because a facility has two inpatients at the time of a survey does not necessarily mean that the facility satisfies all of the statutory requirements to be considered a hospital for Medicare purposes.

   Having two patients at the time of a survey is merely a starting point in the overall survey and certification process.

   An assessment of 'other factors' that support the requirements is required. The list of those 'other factors' is provided above in the INTRODUCTION.

OBSERVATION AND DOCUMENT REVIEW

- Collect morning census report.
- Verify there are at least two inpatients at the time of survey. If yes:
  - ☐ Request and verify:
    1) Average Daily Census (ADC) from previous 12 months is two or more patients.
    2) Average Length of Stay (ALOS) from previous 12 months is two or greater midnights. (For facilities in operation fewer than 12 months, collect data for the duration of operation, but not less than three months.)
  - ☐ The facility meets the CMS definition of a hospital, and
    - Provides the requisite services of a hospital, and
    - Demonstrates compliance with the Conditions of Participation.
- Conduct an assessment of the 'other factors' (see INTRODUCTION for list). If no:
  - ☐ The survey cannot be conducted.
  - ☐ Ask for the following data. Each

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2. Upon verification that the facility has two inpatients at the time of survey, the survey will commence and will begin to evaluate whether the facility meets the definition of a hospital and is in compliance with ALL of the hospital Conditions of Participation (CoP).
3. If a facility does not have two inpatients, the survey cannot be conducted.

HOSPITAL LICENSURE INFORMATION

Section 1861(e)(7) of the Social Security Act requires that for a hospital located in a state which provides for the licensing of hospitals, the hospital must be licensed in accordance with state law or approved as meeting standards for licensing as established by the agency of the state or locality responsible for the licensing of hospitals.

1. A facility that meets state requirements for obtaining state status as a hospital is NOT AUTOMATICALLY considered a hospital for federal survey and certification purposes without further evaluation and consideration of all relevant CMS requirements.
2. While a facility may have a license from a state to operate as a hospital or may have been approved by a state as a hospital under state or local standards and authorities, that facility MAY STILL NOT MEET the Medicare definition of a hospital as per the Social Security Act.
3. The criteria used by a state to determine that a hospital meets the requirements for state licensure as a hospital IS NOT THE SAME CRITERIA used to define a hospital for the purpose of participation in Medicare, and each state has its own criteria and standards for licensure.

report must be printed or sent electronically to the ACHC office for review prior to surveyor departure.

1) Average Daily Census (ADC):
   - Request daily data x 12 months demonstrating inpatients Monday through Sunday.
   - Look for patterns and trends in the ADC by day of week. Does the ADC consistently drop to zero on Saturdays? Sundays?
2) Average Length of Stay (ALOS):
   - Request daily data x 12 months
   - For facilities in operation fewer than 12 months, collect data for duration of its operation, but not less than 3 months.
3) The number of provider-based off-campus emergency departments.
4) The volume of surgical procedures for last 12 months:
   - Inpatient surgical procedures
   - Outpatient surgical procedures
5) Staffing schedules by day of week and shift for the last 12 months. (For facilities in operation less than 12 months, collect data for the duration of operation, but

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

not less than 3 months.)

- Verify the facility is providing the appropriate types and adequate numbers of staff to support 24/7 inpatient services (i.e., nursing, pharmacy, physicians, etc.)

6) Number of inpatient beds in relation to the size of the facility and services offered.

- Determine if the number of inpatient beds could support emergency or unplanned admissions from the volumes of other services offered by the facility, such as ED patients or outpatient surgery patients?

▪ Score at the condition level if the morning census does not reflect two inpatients at time of survey.

Note: The ACHC office will review the administrative data and score at the condition level, if the facility fails to demonstrate it meets the CMS definition of a hospital.

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03

MEDICAL STAFF

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.00.00 CONDITION OF PARTICIPATION: Medical Staff *The hospital must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the hospital.* §482.22	☐ Compliant ☐ Not Compliant The hospital may have only one medical staff for the entire hospital (including all campuses, provider-based locations, satellites, remote locations, etc.). The medical staff must be organized and integrated as one body that operates under one set of bylaws. These bylaws must apply equally to all practitioners within each category, at all locations of the hospital, and to the care provided at all locations of the hospital. For example, a multi-campus hospital may not have a separately organized medical staff for each campus. In the case of a hospital system, it is permissible to have a unified medical staff for multiple, separately certified hospitals. The single medical staff is responsible for the quality of medical care provided to patients by the hospital.	This standard is not met as evidenced by: **Note:** Score based on the aggregate results of scoring of ONLY the §482.22 standards and sub-standards in this chapter.
03.00.01 Eligibility and process for appointment to the Medical Staff *The medical staff must be composed of doctors of medicine or osteopathy. In accordance with State law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at* standard 01.01.12 *[42 CFR §482.12(c)(1)]) and non-physician practitioners who are determined to be eligible for appointment by the governing body.* §482.22(a)	☐ Compliant ☐ Not Compliant The hospital's governing body is responsible for determining which types/categories of physicians and non-physician practitioners or other licensed healthcare professionals (collectively referred to in this guidance as "practitioners"), may be privileged to provide care to hospital patients. ▪ All practitioners who require privileges to furnish care to hospital patients must be evaluated under the hospital's medical staff privileging system before the hospital's governing body may grant them privileges. ▪ All practitioners granted hospital privileges must function under the bylaws, rules, and regulations of the hospital's medical staff. ▪ The privileges granted to an individual practitioner must be consistent	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Hospital and medical staff leadership can describe the categories of practitioners who are members of the medical staff or who may be granted medical staff privileges. □ Review supporting documentation. ▪ If the hospital grants medical staff privileges and/or membership to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

with state scope of practice laws.

PHYSICIANS

The medical staff must be composed, at minimum, of physicians who are MDs/DOs. In addition, the medical staff may include other healthcare professionals included in the definition of a "physician" in Section 1861(r) of the Social Security Act:

- Doctor of dental surgery or of dental medicine.
- Doctor of podiatric medicine.
- Doctor of optometry.
- Chiropractor.

In all cases the healthcare professionals included in the definition of a physician must be legally authorized to practice within the state in which the hospital is located and must provide services within their authorized scope of practice. In certain instances, the Social Security Act and regulations attach further limitations as to the type of hospital services for which healthcare professionals may be considered a "physician." See §482.12(c)(1) for more detail on these limitations.

Note: For Information – Not Required/ Not to be Cited
CMS expects that all physician practitioners granted privileges are also appointed as members of the medical staff. However, if state law limits the composition of the hospital's medical staff to certain categories of practitioners, e.g., only MDs or DOs, there is nothing in the CoPs that prohibits hospitals from establishing certain practice privileges for other categories of physician practitioners excluded from medical staff membership under state law, or from granting those privileges to individual practitioners in those categories, as long as such privileges are recommended by the medical staff, approved by the governing body, and in accordance with state law. (79 FR 27114 – 27115, May 12, 2014)

For physician practitioners granted privileges only, the governing body and physicians who are not MDs/DOs or to non-physician practitioners, the process used ensures that any privileges granted is consistent with state law.

□ Review supporting documentation.

- Hospital and medical staff leadership can describe the process by which they exercise oversight of practitioners granted privileges only.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

medical staff must exercise oversight through credentialing and competency review just as they would for physicians appointed to the medical staff.

NON-PHYSICIAN PRACTITIONERS

Any privileges granted to non-physician practitioners must be in accordance with state law, regulations, and scope of practice.

The governing body has the authority, in accordance with state law, to appoint non-physician practitioners to the medical staff. The regulation allows hospitals to take advantage of the expertise and skills of all types of practitioners at the hospital when making recommendations and decisions concerning medical staff privileges and membership.

Note: For Information Only – Not Required/Not to be Cited
CMS expects that all practitioners granted privileges are also appointed as members of the medical staff. However, if state law limits the composition of the hospital's medical staff to certain categories of practitioners, e.g., only physician practitioners, there is nothing in the CoPs that prohibits hospitals from establishing certain practice privileges for those specific categories of non-physician practitioners excluded from medical staff membership under state law, or from granting those privileges to individual practitioners in those categories, as long as such privileges are recommended by the medical staff, approved by the governing body, and in accordance with state law. (79 FR 27114 - 27115, May 12, 2014)

For non-physician practitioners granted privileges only, the hospital's governing body and its medical staff must exercise oversight just as they would for those practitioners appointed to the medical staff.

Practitioners are described in Section 1842(b)(18)(C) of the Social Security Act as any of the following:

- Physician assistant (as defined in Section 1861(aa)(5) of the Act).
- Nurse practitioner and clinical nurse specialist (as defined in Section

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

1861(aa)(5)).

- Certified registered nurse anesthetist (as defined in Section 1861 (bb)(2)).
- Certified nurse-midwife (as defined in Section 1861(gg)(2)).
- Clinical Social Worker (as defined in Section 1861(hh)(1)).
- Clinical psychologist (as defined in 42 CFR §410.71 for purposes of Section 1861(ii) of the Act).
- Anesthesiologist's Assistant (as defined in §410.69).
- Registered dietitian or nutrition professional.

Other types of licensed healthcare professionals have a more limited scope of practice and are generally not eligible for hospital medical staff privileges unless the permitted scope of practice in their state makes them more comparable to the above types of non-physician practitioners.

Examples of such licensed healthcare professionals who might be eligible for medical staff privileges include, but are not limited to:

- Physical Therapist (as defined at §410.60 and §484.4).
- Occupational Therapist (as defined at §410.59 and §484.4).
- Speech Language Therapist (as defined at §410.62 and §484.4).

Some states have established a scope of practice for certain licensed pharmacists permitting patient care services including the monitoring and assessing of patients and ordering medications and laboratory tests that make them more like the above types of non-physician practitioners.

- In such states, a hospital may grant medical staff privileges to such pharmacists and/or appoint them as members of the medical staff. There is no standard term for such pharmacists, although they are sometimes referred to as "clinical pharmacists."

Practitioners may be granted active, courtesy, emergency, temporary, etc.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	membership or privileges in accordance with state law and as specified in the medical staff bylaws, rules, and regulations.	
03.00.02 Periodic appraisal of members *The Medical Staff must periodically conduct appraisals of its members*. §482.22(a)(1)	☐ Compliant ☐ Not Compliant The medical staff must at regular intervals appraise the qualifications of all practitioners appointed to the medical staff/granted medical staff privileges. In the absence of a state law that establishes a time frame for periodic reappraisal, an appraisal is conducted at a minimum, every **36 months** for each practitioner. The purpose of the appraisal is for the medical staff to verify the suitability of continuing the medical staff membership or privileges of each individual practitioner, identifying if that individual's membership or privileges should be continued, discontinued, revised, or otherwise changed. Appraisal procedures must evaluate each individual practitioner's qualifications and demonstrated competencies to perform each task or activity for which he/she has been granted privileges within the applicable scope of practice or privileges for that type of practitioner. Components of practitioner qualifications and demonstrated competencies would include at least: current work practice, special training, quality of specific work, patient outcomes, education, maintenance of continuing education, adherence to medical staff rules, certifications, appropriate licensure, and currency of compliance with licensure requirements. ▪ In addition to the periodic appraisal of members, any procedure/ task/activity/privilege requested by a practitioner that goes beyond the specified list of privileges for that particular category of practitioner requires an appraisal by the medical staff and approval by the governing body. ▪ The appraisal must consider evidence of qualifications and	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The medical staff has a system in place to reappraise each of its current members and their qualifications at regular intervals, or, if applicable, as prescribed by state law. ▪ The medical staff bylaws identify the process and criteria to be used for the periodic appraisal. ▪ The criteria used for reevaluation comply with the requirements of this section, state law and hospital bylaws, rules, and regulations. ▪ The medical staff has a system to ensure that practitioners seek approval to expand their privileges for tasks/activities/ procedures that go beyond the specified list of privileges for their category of practitioner. ▪ The medical staff conducts the periodic appraisals of any current member of the medical staff who has not provided patient care at the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	competencies specific to the nature of the request. It must also consider whether the activity/task/procedure is one that the hospital can support when it is conducted within the hospital. ▪ Privileges cannot be granted for tasks/procedures/activities that are not conducted within the hospital, regardless of the individual practitioner's ability to perform them. ▪ After the medical staff conducts its reappraisal of individual members, the medical staff makes recommendations to the governing body to continue, revise, discontinue, limit, or revoke some or all of the practitioner's privileges, and the governing body takes final appropriate action. A separate credentials file must be maintained for each medical staff member. ▪ The hospital must ensure that the practitioner and appropriate hospital patient care areas/departments are informed of the privileges granted to the practitioner, as well as of any revisions or revocations of the practitioner's privileges. ▪ Whenever a practitioner's privileges are limited, revoked, or in any way constrained, the hospital must report those constraints to the appropriate state and federal authorities, registries, and/or data bases, such as the National Practitioner Data Bank.	hospital or who has not provided care for which he/she is privileged to patients at the hospital during the appropriate evaluation time frames. □ Does this method meet state law and the hospital's written criteria for medical staff membership and for granting privileges? □ **The reappraisal period is conducted at a minimum every 36 months, or sooner if required by state law or other regulation.**
03.00.03 **For future use**		
03.00.04 **For future use**		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.00.05 Responsibilities of privileged professionals The responsibilities for all privileged practitioners must include: A. Participating in medical staff functions, committee activity, educational, and Quality Assessment and Performance Improvement (QAPI) activities. B. Abiding by Medical Staff bylaws, rules and regulations. C. Adhering to ethical practice guidelines.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Medical staff bylaws, rules and regulations include these responsibilities. ▪ Through review of sample files, practitioners attest to these responsibilities at appointment/ reappointment.
03.00.06 Recommendation for appointment to governing body *The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with State law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations.* *A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the*	☐ Compliant ☐ Not Compliant An established process includes examining credentials of individual prospective members (new appointments or reappointments) by the medical staff including, at least: ▪ A request for clinical privileges. ▪ Evidence of current licensure. ▪ Evidence of training and professional education. ▪ Documented experience. ▪ Supporting references of competence. The medical staff bylaws may require board certification when considering membership or privileges for an MD/DO but such certification may not be the only factor that the medical staff considers.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Medical staff bylaws identify the process and criteria to be used for the evaluation of candidates for medical staff membership/privileges. ▪ Criteria used for evaluation comply with the requirements of this section, state law, and hospital bylaws, rules and regulations. ▪ Leadership of the medical staff can describe methods used to ensure that

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
requirements contained in 42 CFR 482.22. §482.22(a)(2)	The medical staff makes recommendations to the governing body for each candidate that are specific to type of appointment and extent of the individual practitioner's specific clinical privileges, and the governing body takes final appropriate action. Each practitioner who is a member of the medical staff or who holds medical staff privileges is subject to all the requirements of the Medical Staff Condition of Participation. The medical staff and the governing body must enforce its medical staff requirements and take appropriate actions when individual members or other practitioners with privileges fail to adhere to the bylaws, rules or regulations. They must likewise afford all members/practitioners who hold privileges the protections and due process rights provided for in the bylaws, rules and regulations. A separate credentials file must be maintained for each individual medical staff member or applicant.	all medical staff members and non-member practitioners who hold privileges adhere to the medical staff bylaws, rules and regulations and are afforded the due protections and process rights provided for under the bylaws, rules and regulations. □ Ask for specific examples of actions taken. ▪ Practitioners are made aware of their rights and responsibilities with respect to medical staff bylaws, rules and regulations.
03.00.07 <u>Duties and responsibilities to patients</u> The duties and privileges for all privileged practitioners include: A. Provision of continuous care/supervision of his/her patients. B. Calling for, or responding to, consultations when required by patient condition or hospital requirement.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** Verify: ▪ Credentialing documentation describes duties and obligations for all credentialed provider categories that address these requirements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

03.00.08 Telemedicine privileging provisions through distant-site hospital agreement

When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site hospital, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in lieu of the requirements in standards 03.00.02 and 03.00.06 (*42 CFR 482.22(a)(1) and (a)(2)), to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:*

(i) The distant-site hospital providing the telemedicine services is a Medicare participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital.

☐ Compliant ☐ Not Compliant ☐ Not Applicable

This standard is not met as evidenced by:

This standard is only applicable if the hospital uses telemedicine services through an agreement with a distant-site hospital.

The hospital's governing body has the option, when considering granting privileges to telemedicine physicians and practitioners, to have the hospital's medical staff rely upon the credentialing and privileging decisions of the distant-site hospital for these physicians and practitioners. This process would be in lieu of the traditional process required under 42 CFR §482.22(a)(1) and 42 CFR §482.22(a)(2), whereby the hospital's medical staff conducts its own review of each telemedicine physician's or practitioner's credentials and makes a recommendation based on that individualized review.

In order to exercise this alternative credentialing and privileging option, the hospital's governing body must ensure through its written agreement with the distant-site hospital that all of the following requirements are met:

- The distant-site hospital participates in the Medicare program. If the distant-site hospital's participation in Medicare is terminated, either voluntarily or involuntarily, at any time during the agreement, then, as of the effective date of the termination, the hospital may no longer receive telemedicine services under the agreement.
- The distant-site hospital provides a list of all its physicians and practitioners covered by the agreement, including their privileges at the distant-site hospital. The list may not include any physician or practitioner who does not hold privileges at the distant-site hospital. The list must be current, so the agreement must address how the distant-site hospital will keep the list current.
- Each physician or practitioner who provides telemedicine services to the hospital's patients under the agreement holds a license issued or recognized by the state in which the hospital (not the distant-site

INTERVIEW AND DOCUMENT REVIEW

- If the hospital provides telemedicine services to its patients under an agreement with a distant-site hospital, ask whether the hospital's governing body has exercised the option to have the medical staff rely upon the credentialing and privileging decisions of the distant-site hospital in making privileging recommendations on telemedicine physicians and practitioners.

  If yes, verify:

  ☐ The written agreement with the distant-site hospital addresses the required elements concerning the distant-site hospital's Medicare participation, licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners with privileges, and review by the hospital of the telemedicine physicians' and practitioners' services and provision of this information to the distant-site hospital.

  ☐ There is a list provided by the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the State in which the hospital whose patients are receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the hospital's patients and all complaints the hospital has received about the distant-site physician or practitioner.

§482.22(a)(3)
§482.22(a)(3)(i-iv)

hospital) is located. States may have varying requirements as to whether they will recognize an out-of-state license, and they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements in the state where the hospital whose patients are receiving the telemedicine services is located must be satisfied, whatever they may be.

- The hospital has evidence that it reviews the telemedicine services provided to its patients and provides feedback based on this review to the distant-site hospital for the latter's use in its periodic appraisal of each physician and practitioner providing telemedicine services under the agreement. At a minimum, the hospital must review and send information to the distant-site hospital on all adverse events that result from a physician or practitioner's provision of telemedicine services under the agreement and on all complaints it has received about a telemedicine physician or practitioner covered by the agreement.

Note: Refer to standards 03.00.02 for reference to §482.22 (a)(1) and 03.00.06 for reference to §482.22(a)(2), as mentioned above.

distant-site hospital of the telemedicine physicians and practitioners, including their current privileges and pertinent licensure information.

□ Evidence that the hospital reviews the services provided by the telemedicine physicians and practitioners, including any adverse events and complaints, and provides feedback to the distant-site hospital.

□ Telemedicine credentialing files reflect compliance with the credentialing process as outlined in the agreement and governing body bylaws.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

03.00.09 Telemedicine privileging provisions through distant-site telemedicine entity agreement

When telemedicine services are furnished to the hospital's patients through an agreement with a distant-site telemedicine entity, the governing body of the hospital whose patients are receiving the telemedicine services may choose, in accordance with the requirements at standards 03.00.02 and 03.00.06 (*42 CFR §482.22(a)(1) and 42 CFR §482.22(a)(2)), to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the hospital's governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with 42 CFR §482.12(e), permit the hospital to comply with all applicable conditions of participation for the contracted services.*

The hospital's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:

☐ Compliant ☐ Not Compliant ☐ Not Applicable

This standard is not met as evidenced by:

This standard is only applicable if the hospital uses telemedicine services through an agreement with a distant-site telemedicine entity.

For the purposes of this rule, a distant-site telemedicine entity is defined as an entity that:

1. Provides telemedicine services.
2. Is not a Medicare-participating hospital.
3. Provides contracted services in a manner that enables a hospital using its services to meet all applicable Conditions of Participation, particularly those requirements related to the credentialing and privileging of practitioners providing telemedicine services to the patients of a hospital.

A distant-site telemedicine entity would include a distant-site hospital that does not participate in the Medicare program that is providing telemedicine services to a Medicare-participating hospital. (See 76 FR 25553, May 5, 2011)

The hospital's governing body has the option, when considering granting privileges to telemedicine physicians and practitioners, to have the hospital's medical staff rely upon the credentialing and privileging decisions of the distant-site entity for these physicians and practitioners. This process would be in lieu of the traditional process required under 42 CFR §482.22(a)(1) and §482.22(a)(2), whereby the medical staff conducts its own review of each telemedicine physician's or practitioner's credentials and makes a recommendation based on that individualized review.

In order to exercise this alternative credentialing and privileging option, the hospital's governing body must ensure through its written agreement with the distant-site entity that all of the following requirements are met:

INTERVIEW AND DOCUMENT REVIEW

- If the hospital provides telemedicine services to its patients under an agreement with one or more distant-site telemedicine entities, ask whether the hospital's governing body has exercised the option to have the medical staff rely upon the credentialing and privileging decisions of the distant-site telemedicine entity in making privileging recommendations on telemedicine physicians and practitioners.

  If yes, verify:

  □ The written agreement with each distant-site telemedicine entity addresses the required elements concerning the distant-site telemedicine entity's use of a medical staff credentialing and privileging process that meets the requirements of the hospital CoPs, appropriate licensure of telemedicine physicians and practitioners, providing a current list of telemedicine physicians and practitioners and specifying their privileges, and review by the hospital

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at 42 CFR §482.12(a)(1) through (a)(7) and 42 CFR §482.22(a)(1) through (a)(2).

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the hospital with a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the state in which the hospital whose patients are receiving such telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the hospital whose patients are receiving the telemedicine services, the hospital has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site

- The distant-site telemedicine entity uses a medical staff credentialing and privileging process and standards that at least meet the standards for the medical staff of a hospital established at 42 CFR §482.12(a)(1) through (a)(7) and 42 CFR §482.22(a)(1) through (a)(2).
- The distant-site telemedicine entity provides a list to the hospital of all physicians and practitioners covered by the agreement, including their privileges at the distant-site telemedicine entity. The list may not include any physician or practitioner who does not hold privileges at the distant-site telemedicine entity. The list must be current, so the agreement must address how the distant-site telemedicine entity will keep the list current.
- Each physician or practitioner who provides telemedicine services to the hospital's patients under the agreement holds a license issued or recognized by the state where the hospital (not the distant-site entity) is located. States may have varying requirements as to whether they will recognize an out-of-state license and they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements governing in the state where the hospital whose patients are receiving the telemedicine services is located must be satisfied, whatever they may be.
- The hospital has evidence that it reviews the telemedicine services provided to its patients and provides a written copy of this review to the distant-site telemedicine entity for the latter's use in its periodic appraisal of the physicians and practitioners providing telemedicine services under the agreement. At a minimum, the hospital must review and send information to the distant-site telemedicine entity on all adverse events that result from a physician or practitioner's provision of telemedicine services and on all complaints it has received about a telemedicine physician or practitioner.

of the telemedicine physicians' and practitioners' services and provision of this information to the distant-site entity.

□ There is a list provided by the distant-site telemedicine entity of the telemedicine physicians and practitioners covered by the agreement, including their current privileges and pertinent licensure information.

□ Evidence that the hospital reviews the services provided by the telemedicine physicians and practitioners, including any adverse events and complaints, and provides written feedback to the distant-site telemedicine entity.

□ The hospital confirms that the telemedicine entity employs a credentialing and privileging process that meets or exceeds what is required for hospitals under the Medicare CoPs?

Note: Surveyors do not attempt to independently verify whether or not the distant-site telemedicine entity's credentialing and privileging process fulfills the regulatory requirements. Surveyors focus only on whether the hospital takes steps to ensure that the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner. §482.22(a)(4) §482.22(a)(4)(i-iv)		distant-site telemedicine entity complies with the terms of the written agreement.
03.00.10 <u>Medical staff responsibilities to the governing body</u> *(1) The Medical Staff must be well organized and accountable to the governing body for the quality of the medical care provided to the patients. The medical staff must be organized in a manner approved by the governing body.* *(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathic medicine.*	☐ Compliant ☐ Not Compliant The conditions of participation create a system of checks and balances within an overall framework of collaboration between the governing body and the medical staff (and, to a certain degree, also between an individual practitioner and the hospital's medical staff and governing body). Each has its own areas of authority. The medical staff has oversight of all practitioners practicing in the hospital through processes such as peer review and making recommendations concerning privileging and re-privileging. The governing body has the authority to establish the categories of healthcare professionals (regardless of the terms used to describe those categories) eligible for privileges and medical staff appointment.	This standard is not met as evidenced by: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** Verify: ▪ The medical staff has a formal, organized structure reflected in its bylaws, rules and regulations. Functions and responsibilities within the medical staff and with respect to the governing body and other parts of the hospital are addressed. ▪ If there is active medical staff executive committee (MEC), a majority of the

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(3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:

(i) An individual doctor of medicine or osteopathic medicine.

(ii) A doctor of dental surgery or dental medicine, when permitted by State law of the State in which the hospital is located.

(iii) A doctor of podiatric medicine, when permitted by State law of the State in which the hospital is located.

§482.22(b)
§482.22(b)(1-3)
§482.22(b)(3)(i-iii)

However, the governing body must rely on the medical staff to apply the criteria for privileging and appointment to those eligible candidates and to make recommendations before the governing body makes a final decision regarding appointment of a practitioner to the medical staff. (77 FR 29042 May 16, 2012).

If the hospital uses a unified medical staff that it shares with other hospitals that are part of a multi-hospital system, this does not change the requirement for the medical staff to be well organized and accountable to the system's governing body for the quality of care in each separately certified hospital.

LEADERSHIP OF THE MEDICAL STAFF

The members of the hospital's medical staff must select, in accordance with the medical staff bylaws, rules or regulations approved by the governing body, a single individual to lead the medical staff and be responsible for the organization and conduct of the medical staff.

- This individual must be an MD or DO or, if permitted by state law where the hospital is located, a doctor of dental surgery, dental medicine, or podiatric medicine.
- Removal of the leader of the medical staff may only occur in accordance with medical staff bylaws, rules or regulations.
- If the hospital uses a unified medical staff, only one individual may be responsible for the organization and conduct of the unified medical staff; that individual may or may not hold privileges and practices at the hospital being surveyed.
- When the individual does not practice at the hospital being surveyed and it is necessary to interview this individual as part of a survey, a telephone interview must be arranged.

EXECUTIVE COMMITTEE

The medical staff bylaws, rules and regulations may provide for the members of the medical staff to select a smaller executive committee to which it members are physicians.

- An individual MD or DO (or if permitted by state law, a doctor of dental surgery, dental medicine, or podiatric medicine, selected by the medical staff), is responsible for the conduct and organization of the medical staff.
- The CEO and medical staff leadership can describe the mechanisms by which the medical staff fulfills its responsibility to be accountable for the quality of medical care in the hospital.
- Members of the medical staff, including both practitioners who hold leadership or executive committee positions and ones who do not can describe:
  - □ Their medical staff duties and responsibilities and how they are performed.
  - □ How the medical staff is accountable for the quality of medical care provided to patients.

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delegates many of the functions of the medical staff, in order to increase the efficiency of its operations.

If the medical staff has an executive committee (MEC), the majority of the voting members must be MDs or DOs.

Note: For Information Only – Not Required/Not to be Cited

A hospital is not required to have an executive committee. However, use of an executive committee may facilitate efficient and effective functioning of the medical staff in hospitals systems that use a unified medical staff, particularly if the executive committee includes members from each hospital that shares the unified medical staff.

ACCOUNTABILITY OF THE MEDICAL STAFF

The medical staff must be accountable to the hospital's governing body for the quality of medical care provided to the patients.

The medical staff demonstrates its accountability through exercise of its duties related to appointment of members, its conduct of reappraisals (including peer reviews), its approval of policies and procedures as required under other conditions of participation and its leadership participation in the organization and implementation of the hospital's quality assessment and performance improvement program required in accordance with 42 CFR §482.21.

Under a unified medical staff structure, the medical staff continues to be accountable for the quality of care in each separately certified hospital.

The organization of the medical staff must include:

A. Acting on the reports of services, departments, and committees of the medical staff;

B. Direct reporting to governance regarding medical staff appointments, reappointments, and privilege delineations;

C. Direct reporting to governance regarding medical staff behaviors

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resulting in suspension, or other corrective action, and any fair hearing results;

D. Direct reporting to governance of organizational proposals including revisions in Bylaws, rules and regulations and medical staff officers;

E. Accountability to governance for the findings from ongoing evaluation of the clinical work of the medical staff; and

F. Collaborating with administration and governance regarding institutional planning, budgeting and appropriate utilization of available resources.

03.00.11 Multiple-hospital systems: Unified and integrated medical staff

If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that…

§482.22(b)(4)

☐ Compliant ☐ Not Compliant ☐ Not Applicable for non-system hospitals

This standard is not met as evidenced by:

MULTI- HOSPITAL SYSTEM

A hospital that is part of a system consisting of multiple, separately certified hospitals may use a single unified and integrated medical staff (hereafter referred to as a "unified medical staff") that is shared with one or more of the other hospitals in the system. As long as the requirements of the standard are met, it is not necessary for each separately-certified hospital within the system to have its own distinct medical staff organization and structure, including hospital-specific medical staff bylaws, rules and requirements, hospital-specific medical staff leadership, hospital-specific credentialing and peer review, etc.

However, separately certified hospitals which share a single unified and integrated medical staff must also share a system governing body, in accordance with the provisions of 42 CFR §482.12, since only one governing body may carry out the governing body's medical staff responsibilities for a unified medical staff.

MULTI-CAMPUS HOSPITAL

A multi-campus hospital that has several inpatient campuses that are

INTERVIEW AND DOCUMENT REVIEW

- Ask the hospital and medical staff leadership if the hospital is part of a multi-hospital system of separately certified hospitals.

  If no, it is not necessary to assess compliance with this regulation.

  If yes, ask if the hospital also shares its governing body and medical staff with one or more other separately certified hospitals in the system. If yes:

  □ Does the use of the unified medical staff predate July 11, 2014?

  If yes, review documentation of the governing body's determination that use of a unified medical staff

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provider-based, remote locations of the hospital is not a multi-hospital system.

A multi-campus hospital is one certified hospital, NOT several separately certified hospitals.

- A multi-campus hospital may not have separate medical staffs at each campus since each hospital must have no more than one medical staff.
- A multi-campus hospital with one medical staff separate from that of other certified hospitals is not employing a unified medical staff as that term is used in this regulation.
- However, a multi-campus hospital that is part of a hospital system consisting of multiple separately certified hospitals may share a unified medical staff with other separately certified hospitals within the system.

A hospital system that includes certain types of hospitals, i.e., hospitals-within-hospitals or hospital satellites, that are being paid under a Medicare payment system other than the Hospital Inpatient Prospective Payment System (IPPS) might jeopardize the Medicare payment status of those excluded hospitals if it owns both the tenant and host hospitals and uses a unified medical staff for both. This is the case even if the requirements of §482.22(b)(4) are met. However, surveyors do not assess compliance with or enforce the Medicare payment regulations that govern hospitals-within-hospitals or hospital satellites.

When granting practitioners privileges to provide patient care, a hospital's governing body must specify those hospitals in the system where the privileges apply, since, in addition to the qualifications of individual practitioners, the services provided at each hospital must be considered when granting privileges.

- For example, psychiatric hospitals do not offer surgical services, labor and delivery services, nuclear medicine, etc., so it would not be

does not conflict with state or local law.

□ Did the use of the unified medical staff start after July 11, 2014?

If yes, review documentation of the governing body's decision to elect use of a unified medical staff and of its determination that use of a unified medical staff does not conflict with State or local law.

□ Can the hospital produce documentation that practitioners who practice at the hospital have been granted privileges by the hospital's governing body that specify the practitioner's privileges apply to specific hospital(s), which include the hospital being surveyed?

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appropriate for practitioners practicing in these areas to hold privileges at psychiatric hospitals in a multi-hospital system that uses a unified medical staff.

- Likewise, if a multi-hospital system covers a wide geographic area, many of its practitioners may have no interest in practicing on site at hospitals that are distant from their usual practice location(s).
- In addition, in order for the approval or opt-out provisions of 42 CFR §482.22(b)(4)(i) and (ii) to be workable, privileges must be granted on a hospital-specific basis to practitioners who actually practice or are likely to practice at the hospital.

MULTI–HOSPITAL SYSTEM

The governing body in a multi-hospital system must elect to exercise this option.

The existence of a unified medical staff prior to July 11, 2014, is considered evidence of the hospital's governing body's election of this option.

- This does not relieve the governing body of the responsibility to conduct a review of all applicable state and local laws, including regulations, and make a determination that use of a unified medical staff that is shared by multiple hospitals does not conflict with those laws.
- The hospital must maintain documentation of this determination by its governing body.
- Nor does it relieve the governing body of the obligation to inform the medical staff of the right to vote to opt out of a unified medical staff arrangement. (See discussion of 42 CFR §482.22(b)(4)(ii), which requires notification of all members of this right. Failure to comply would be cited under the tag for 42 CFR §482.22(b)(4)(ii).)

If a hospital is part of a multi-hospital system that wishes to establish a unified medical staff for some or all of its separately certified hospitals after the July 11, 2014 effective date of the final rule at 42 CFR §482.22(b)(4), then

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the hospital's system governing body must document in writing its decision to elect to use the unified medical staff option, conditioned upon acceptance of a unified medical staff by the hospital's medical staff in accordance with 42 CFR §482.22(b)(4)(i).

- The governing body must also document its determination that such election does not conflict with state or local laws, including regulations.

Note: Surveyors are not expected, as part of their assessment of compliance with the Medicare CoPs, to evaluate whether the governing body's determination of compliance with state and local law is accurate. This would be handled by the appropriate state or local authorities.

03.00.12 Voting requirements for separately certified hospitals

☐ Compliant ☐ Not Compliant ☐ Not Applicable for non-system hospitals

This standard is not met as evidenced by:

If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:

(i) The medical staff members of each separately certified hospital in the system (that is, all medical staff members who hold specific privileges to practice at that hospital) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff

The decision for a particular certified hospital in a multi-hospital system to use a unified medical staff is a joint one arrived at by both:

- Election of the unified medical staff option by the hospital's governing body.
- Acceptance by a majority of the medical staff members who hold privileges to practice at that particular hospital, voting in accordance with the medical staff bylaws.

The medical staff of each hospital also has the option to opt out of an existing unified medical staff, when a majority of the medical staff members who hold privileges to practice at that particular hospital, voting in accordance with the medical staff bylaws, vote to do so.

- For purposes of voting on whether to use or opt out of a unified medical staff, the term "privileges to practice at that particular hospital" is interpreted to mean only those practitioners who hold privileges to practice on-site at the hospital.

INTERVIEW AND DOCUMENT REVIEW

Note: Assess compliance with this regulation only if the hospital uses a unified medical staff. (See survey procedures for standard 03.00.11.)

- If the hospital uses a unified medical staff, ask the hospital's leadership when it began to do so.
  - ☐ Is there any documentation to support the response?
- If the hospital began using a unified medical staff after July 11, 2014, is there evidence that a majority of the medical staff holding privileges at the hospital voted in favor of using a

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structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective hospital; §482.22(b)(4) §482.22(b)(4)(i)	▪ Practitioners who hold only telemedicine privileges at a hospital are not included when identifying which practitioners are eligible to vote or what constitutes a majority of the practitioners holding privileges at the hospital. A hospital that is part of a hospital system is expected to have medical staff bylaws, rules and requirements that address the regulatory requirements of 42 CFR §482.22(b)(4)(i) – (iv) related to using a unified medical staff, including the processes under the bylaws for voting to accept or opt out of a unified medical staff. ▪ This is the case even if the hospital currently does not use a unified medical staff. If the hospital uses a unified medical staff, depending on state law requirements, the unified medical staff bylaws, rules and requirements required at §482.22(b)(4)(ii) may substitute for hospital-specific medical staff bylaws, rules and requirements. Hospitals that were part of a hospital system using a unified medical staff as of July 11, 2014, are expected to have initiated the process before December 31, 2014, to effect the necessary amendments, even if the process is not completed until after that date. Likewise, when a hospital is acquired by a system but maintains separate participation in Medicare, if the hospital's governing body elects to use a unified medical staff and the medical staff accepts such election, the hospital is expected to initiate the necessary changes to its medical staff bylaws, rules and requirements no later than six months after the effective date of its acquisition. In establishing medical staff bylaws governing voting on the questions of a unified medical staff, the medical staff and the governing body, which must approve the revised bylaws in accordance with 42 CFR §482.12(a)(4), have the flexibility to determine the details of the voting process including:	unified medical staff? ▪ If the hospital uses a unified medical staff, do the bylaws clearly describe a process by which a vote to opt out of using a unified medical staff may be requested and conducted? □ Are there provisions that are described in the guidance above unduly limiting the rights of medical staff members to vote on whether to accept or opt out of the unified medical staff? □ If there are requirements in the voting process that appear to limit opt-out voting, ask the medical staff leadership to explain why the limitations are reasonable and not unduly restrictive. ▪ Ask members of the medical staff whether there has ever been a vote on the question of opting out. □ If yes, ask the hospital to produce evidence that a majority of the practitioners holding privileges at the hospital voted against opting out. ▪ Can the hospital readily identify the members of the unified medical staff who are eligible to vote to approve or to opt out of a unified medical staff?

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- how an acceptance or opt-out vote can be requested.
- whether all categories of members holding privileges to practice on-site at the hospital are afforded medical staff voting rights.
- whether voting will be in writing and open or by secret ballot, etc.

A hospital may not set up bylaws that unduly restrict the rights of medical staff members when voting on the issue of accepting or opting out of a unified medical staff structure. For example:

- Hospitals may not establish different criteria as to which categories of medical staff members have voting rights with respect to a vote on a unified medical staff than are used for other amendments to the medical staff's bylaws, except as required under the regulation at 42 CFR §482.22(b)(4) that only members holding privileges to practice at the hospital may vote. (See also the discussion below concerning delegation of authority to the medical staff executive committee.)
- Hospitals may not require as a condition for holding an opt-out vote that there be a petition signed by the same number of voting members as would be required for a successful vote to opt out.
- Hospitals may require for a successful acceptance or opt-out vote a "supermajority," that is, a majority that is greater than a simple majority of more than 50% of the medical staff members with voting rights, so long as the same type of supermajority is otherwise generally required to amend the medical staff's bylaws, rules and requirements.
- In the case where a hospital system has a unified medical staff and members of the staff at a hospital in the system exercise their right to hold a vote on the question of opting out, the hospital may not permit delegation of an opt-out decision to the unified medical staff's executive committee.

  This is the case even when the executive committee has otherwise delegated authority to amend unified medical staff bylaws, rules and

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requirements that it recommends for approval to the governing body.

Where the bylaws permit such delegation to the unified medical staff's executive committee for other purposes, a "majority" for purposes of conducting a vote on whether to opt out of a unified medical staff consists of a simple majority, that is, any number which is greater than 50% of the medical staff members practicing at the hospital who have voting privileges.

- Where a hospital that is part of a hospital system but has a separate medical staff is holding a vote on whether to accept participating in a unified medical staff, the hospital may permit a vote by members of the hospital's medical staff executive committee only if this is consistent with the hospital's medical staff bylaws governing amendments in effect at the time of the vote.
- A hospital may establish a minimum interval between acceptance or opt-out votes, such as not permitting a vote more than once every two years. However, a minimum interval between votes longer than two years might unduly restrain the rights of the members of the medical staff and would not be permissible.

03.00.13 Medical Staff: Bylaws of the unified medical staff

If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:

☐ Compliant ☐ Not Compliant ☐ Not Applicable for non-system hospitals

This standard is not met as evidenced by:

ONE SET OF BYLAWS, RULES AND REQUIREMENTS

A hospital that uses a unified medical staff must ensure that the unified medical staff has one set of bylaws, rules and requirements that describe the medical staff's processes for self-governance, appointment, credentialing, privileging, oversight, peer review, and due process rights guarantees.

- Consistent with the requirements for a system governing body in 42 CFR §482.12, the documentation of the bylaws, rules and requirements that apply to the unified medical staff must identify each separately certified

INTERVIEW AND DOCUMENT REVIEW

Note: Assess compliance with this regulation only if the hospital uses a unified medical staff. (See survey procedures for standard 03.00.11.)

- Review evidence that the unified medical staff's bylaws, rules and requirements are readily available, and

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(ii) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified hospital (that is, all medical staff members who hold specific privileges to practice at that hospital) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their hospital.

§482.22(b)(4)(ii)

hospital that has elected to use a unified medical staff and which, therefore, is covered by the unified medical staff bylaws, rules and regulations.

- Depending on state law requirements, the unified medical staff bylaws, rules and requirements may be in addition to or instead of hospital-specific medical staff bylaws, rules and requirements.
- The unified medical staff bylaws, rules and regulations must not conflict with any of the specific requirements for medical staff found elsewhere in 42 CFR §482.12 or 42 CFR §482.22, or under any other hospital CoPs which assign responsibilities to the hospital's medical staff.

The unified medical staff's bylaws, rules and requirements addressing its self-governance processes must provide for a process by which members of the unified medical staff holding privileges to practice on site at each separately certified hospital are advised that they have the right to vote on whether to opt out of participation in the unified medical staff, and that if a majority vote to opt out, then the hospital must establish a separate medical staff.

- At a minimum, the hospital must advise medical staff members in writing of their right to vote by majority to opt out when medical staff membership is first granted, and when it is renewed.

The bylaws must address the process by which a vote to opt out of the unified medical staff is conducted. In establishing the unified medical staff bylaws governing opting out, the unified medical staff, and the system governing body, which must approve the medical staff's bylaws, rules or regulations in accordance with 42 CFR §482.12(a)(4), have the flexibility to determine the details of the voting process, such as how an acceptance or opt-out vote can be requested; whether all categories of members holding privileges to practice on-site at the hospital are afforded medical staff voting rights; whether voting will be in writing and open or by secret ballot, etc.

- However, the unified medical staff and system governing body may not set up bylaws that unduly restrict the rights of medical staff members at that it is clear that they apply to that hospital.
- Review evidence that the unified medical staff bylaws, rules or requirements address the rights of members holding privileges at the hospital to vote by majority to opt out of using the unified medical staff, including notification of these rights.
- Ask how the unified medical staff bylaws define a majority for the purpose of an opt-out vote. If the unified medical staff bylaws require a super-majority, ask for evidence that this is consistent with the way "majority" is defined for other amendments to the bylaws.
- Do the bylaws, rules or requirements clearly describe how and when members holding privileges at the hospital will be advised of their rights?
- Can the hospital readily identify the members of the unified medical staff who are eligible to vote to opt out and therefore must be advised of their rights?
- Do the credentialing and privileging files of members of the medical staff have any evidence of their being notified of their right to vote by majority to opt out?

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	each separately certified hospital to vote whether to accept or opt out of a unified medical staff structure. For example: ▪ The bylaws, rules and requirements may not establish different criteria as to which categories of medical staff members have voting rights with respect to a vote to accept or opt out of a unified medical staff than are used for any other type of voting the medical staff engages in, except as required under the regulation at 42 CFR §482.22(b)(4) that only members holding privileges to practice at the hospital may vote. (See also the discussion below concerning delegation of authority to the medical staff executive committee.) ▪ The bylaws, rules and requirements may not require as a condition for holding an opt-out vote that there be a petition signed by the same number of voting members as would be required for a successful vote to opt out. ▪ The bylaws, rules and requirements may require for a successful acceptance or opt-out vote a "super-majority," that is, a majority that is greater than a simple majority of more than fifty percent of the medical staff members with voting rights holding privileges to practice at the hospital, so long as the same type of supermajority is otherwise required to amend the unified medical staff's bylaws, rules and requirements. ▪ In the case where a hospital system has a unified medical staff and members of the staff at a hospital in the system exercise their right to hold a vote on the question of opting out, the unified medical staff bylaws may not permit delegation of an opt-out decision to the unified medical staff's executive committee. This is the case even when the executive committee is otherwise delegated authority to amend unified medical staff bylaws, rules and requirements that it recommends for approval to the governing body. In cases where the bylaws permit such delegation to the unified medical staff's executive committee for other purposes, a "majority" for purposes of conducting a vote on whether to	▪ Interview several members of the medical staff to determine if they recall being notified of their right to vote by majority to opt out.

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opt out of a unified medical staff consists of a simple majority, that is, any number which is greater than fifty percent of the medical staff members practicing at the hospital who have voting privileges.

- The bylaws, rules and requirements may establish a minimum interval between acceptance or opt-out votes, such as not permitting a vote more than once every two years. However, minimum interval between votes longer than two years might unduly restrain the rights of the members of the medical staff and would not be permissible.

03.00.14 Multiple hospital systems: Unique circumstances

If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:

(iii) The unified and integrated medical staff is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and service.

§482.22(b)(4)(iii)

☐ Compliant ☐ Not Compliant ☐ Not Applicable for non-system hospitals

This standard is not met as evidenced by:

SEPARATELY CERTIFIED HOSPITALS

The separately certified hospitals belonging to a multi-hospital system and using a single unified medical staff may be very different from each other, presenting different needs and challenges for the medical staff.

As a result, the unified medical staff is expected to take these differences into account rather than using a one-size-fits-all approach for all of its policies and procedures.

For example, a multi-hospital system may:

1. Consist of a mixture of different types of hospitals, such as short-term acute care hospitals, psychiatric hospitals, rehabilitation hospitals, children's hospitals, and long-term care hospitals. As a result, they would offer different types of services to different patient populations.
   - This could have implications for medical staff functions such as the periodic review of credentials and privileges and ongoing peer review of the quality of medical care.
   - It could also have implications for other responsibilities the medical staff has under various CoPs.

INTERVIEW AND DOCUMENT REVIEW

Note: Assess compliance with this regulation only if the hospital uses a unified medical staff. (See survey procedures for standard 03.00.11.)

- Ask the hospital and medical staff leadership to describe the other types of hospitals in the system with which it shares a unified medical staff, and how the hospital's unique circumstances are addressed.

  For example, how does the unified medical staff assure that:

  □ Standing orders it has approved are also approved by the nursing and pharmacy leadership in each separately certified hospitals? (*See §482.24(c)(3)(i).*)

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- For example, the medical staff has a key role in the development and oversight of the use of standing orders/protocols, but these orders/protocols must be specific to each hospital, reflecting the types of services a hospital offers and its patient population;

2. Consist of hospitals that differ in size, ranging from comparatively small hospitals in rural areas, or which provide specialized rehabilitation or long-term care hospital services, to very large, short term acute care service hospitals. Such differences could have implications for various medical staff requirements, such as on-call requirements.
3. Consist of hospitals that differ as to whether they are teaching hospitals or not, which would have implications for policies concerning the roles and supervision of residents.
4. Consist of hospitals located in different states which have different licensure requirements affecting the organization and composition of the medical staff. For example, in one state it might be permissible for non-physician practitioners to be members of the medical staff, while in another the medical staff is limited to physicians.

   On the other hand, a multi-hospital system may have a conscious strategy of having hospitals that are very similar to each other in terms of size, services, patient populations served, and type of location. In this case, the unified medical staff would have fewer challenges in addressing the needs of each hospital and might have more policies that are uniform across the medical staff.

HOSPITAL LEADERSHIP

In all cases the hospital's leadership and the medical staff leadership must be able to explain how the way in which the unified medical staff is organized and functions takes account of and responds to the unique circumstances of the hospital that is being surveyed.

□ Policies and procedures developed by the medical staff to minimize drug errors, if this function has not been delegated to the hospital's pharmaceutical service, take into account any unique hospital circumstances? (*See §482.25.*)

□ The formulary system established by the medical staff takes into account any unique hospital circumstances? (*See §482.25(b)(9).*)

□ The medical staff's specification of procedures and treatments requiring a properly executed informed consent reflects any unique hospital circumstances? (*See §482.24(c)(4)(v).*)

□ The medical staff carries out its joint responsibility with the CEO and Director of nursing for ensuring that hospital-specific infection control problems identified by the hospital's infection control officer(s) are addressed in the hospital's QAPI and training programs? (*See §482.42(b).*)

□ The medical staff fulfills its joint executive responsibilities, along with the hospital's governing body and administrative officials, for ensuring that the hospital-specific

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QAPI program:

- Is ongoing, defined, implemented and maintained.
- Addresses hospital-specific priorities for improved quality of care and patient safety, and that all improvements are evaluated.
- Establishes clear expectations for safety in the hospital.
- Allocates adequate resources for the hospital specific QAPI program.
- Determines annually the number of distinct improvement projects conducted in the hospital. (*See §482.21(e).*)

□ Medical staff policies governing ordering of outpatient services address any unique hospital circumstances? (*See §482.54(c)(4).*)

□ Medical staff policies and recommendations governing which practitioners may be authorized to write orders and be responsible for the care of the patient conform to state law, including scope of practice law, for the state in which the hospital is located? (*Multiple citations in various CoP.*)

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03.00.15 Policies of the unified medical staff

If a hospital is part of a hospital system consisting of multiple separately certified hospitals and the system elects to have a unified and integrated medical staff for its member hospitals, after determining that such a decision is in accordance with all applicable State and local laws, each separately certified hospital must demonstrate that:

(iv) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

§482.22(b)(4)(iv)

☐ Compliant ☐ Not Compliant ☐ Not Applicable for non-system hospitals

This standard is not met as evidenced by:

MEDICAL STAFF POLICIES

This provision is not about an individual medical staff member's concerns with privileges granted or not granted to him/her, peer review results, due process issues, etc. This provision addresses a requirement for the unified medical staff to consider and address concerns that practitioners have concerning their own hospital's needs.

- For example, physicians practicing in a children's hospital may have concerns about having protocols for medication administration that reflect specific pediatric patient concerns, or physicians practicing in a small rural hospital may have concerns about how to get timely telemedicine consults from their colleagues in urban areas.

The medical staff has flexibility in establishing its written policies and procedures for addressing these local concerns, but at a minimum they must cover:

1. A process by which members who practice at a hospital can raise their local concerns and needs with the unified medical staff's leadership.
2. How members are informed of the process by which they can raise their local concerns and needs.
3. A process for referring the concerns and needs raised to the appropriate committee or other group within the medical staff for due consideration.
4. Documentation of the outcome of the medical staff's review of the concerns and needs raised.

INTERVIEW AND DOCUMENT REVIEW

Assess compliance with this regulation only if the hospital uses a unified medical staff.

- Determine that the unified medical staff has policies and procedures addressing how members can raise local concerns and needs.
  - ☐ Do the written policies and procedures cover the minimum elements?
- Ask the hospital and the medical staff leadership whether any members practicing at the hospital have raised concerns or needs.
  - ☐ If yes, ask for documentation on how the concern/need was considered and addressed by the unified medical staff.
- Ask members of the medical staff if they are aware they can raise local concerns or needs with the leadership of the unified medical staff.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.01.01 Medical staff bylaws	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The medical staff must adopt and enforce bylaws to carry out its responsibilities. §482.22(c)	The medical staff must regulate itself by bylaws that are consistent with the requirements of this and other CoPs that mention medical staff bylaws, as well as state laws. The bylaws must be enforced and revised as necessary.	**DOCUMENT REVIEW** Verify: ▪ The medical staff has bylaws that comply with the CoPs and state law. ▪ The bylaws describe a mechanism for ensuring enforcement of its provisions along with rules and regulations of the hospital. ▪ The medical staff enforces the bylaws.
03.01.02 Medical staff bylaws: Approval by governance	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The bylaws must: ▪ *Be approved by the governing body.* §482.22(c)(1)	Medical staff bylaws and any revisions of those bylaws must be submitted to the governing body for approval. The governing body has the authority to approve or disapprove bylaws suggested by the medical staff. The bylaws and any revisions must be approved by the governing body before they are considered effective.	**DOCUMENT REVIEW** ▪ Verify that the medical staff bylaws have been approved by the medical staff and the governing body.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.01.03 Medical staff bylaws: Categories, duties, and responsibilities *The bylaws must:* ▪ *Include a statement of the duties and privileges of each category of medical staff (e.g., active, courtesy, etc.).* §482.22(c)(2)	☐ Compliant ☐ Not Compliant The medical staff bylaws must clearly and completely list the specific privileges or limitations for that category of practitioner. The specific privileges must reflect activities that the majority of practitioners in that category can perform competently and that the hospital can support. Although the medical staff bylaws must address the duties and scope for each category of practitioner, this does not mean that each individual practitioner within the category may automatically be granted the full range of privileges. It cannot be assumed that every practitioner can perform every task/activity/privilege that is specified for the applicable category of practitioner. The individual practitioner's ability to perform each task/activity/privilege must be individually assessed.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the bylaws specify the duties and scope of medical staff privileges for each category of practitioner eligible for medical staff membership or privileges.
03.01.04 Medical staff bylaws: Organization of the medical staff *The bylaws must:* ▪ *Describe the organization of the medical staff.* §482.22(c)(3)	☐ Compliant ☐ Not Compliant The medical staff bylaws must describe the organizational structure of the medical staff and lay out the rules and regulations of the medical staff to make clear acceptable standards of patient care for all diagnostic, medical, surgical, and rehabilitative services.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the bylaws specify the organization and structure of the medical staff, and a mechanism that delineates accountability to the governing body. ▪ Verify that the bylaws describe who is responsible for regularly scheduled review and evaluation of the clinical work of the members of the medical staff and describe the formation of medical staff leadership.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.01.05 Attestation statements in bylaws The medical staff demonstrates high standards of ethical conduct; bylaws provide for: A. Corrective action. B. A fair hearing mechanism C. Physician adherence to the Code of Ethics prescribed by his/her profession.	☐ Compliant ☐ Not Compliant Ethical conduct of the medical staff organization is demonstrated in its stated expectations and mechanisms for placing these into operation. The bylaws make provision for each of these elements. Codes of Ethics may include AOA, AMA, ADA, or APMA.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify that the medical staff bylaws include all elements described.
03.01.06 Medical staff bylaws: Application, reapplication, and criteria for membership *The bylaws must:* ▪ *Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.* §482.22(c)(4)	☐ Compliant ☐ Not Compliant The bylaws must describe the privileging process to be used in the hospital. The process articulated in the medical staff bylaws must include criteria for determining the privileges that may be granted to individual practitioners and a procedure for applying the criteria to individual practitioners that considers: ▪ Individual character. ▪ Individual competence. ▪ Individual training. ▪ Individual experience. ▪ Individual judgment. The medical staff may not rely solely on the fact that an MD/DO is, or is not, board-certified in making a judgment on medical staff membership. This does not mean that the medical staff is prohibited from requiring board certification when considering an MD/DO for medical staff membership; only	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The medical staff bylaws describe the qualifications such as licensure, specific training, experience, current competence, judgment, character, and health status to be met by an individual candidate for the medical staff to recommend appointment or reappointment. ▪ The process for granting of privileges is clearly defined. ▪ All practitioner categories are included in the process.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	that such certification is not the only factor that the hospital considers. After analysis of all of the criteria, if all criteria are met except for board certification, the medical staff has the discretion to not recommend that individual for medical staff membership/privileges. The bylaws must apply equally to all practitioners in each professional category of practitioners. The medical staff then recommends individual candidates that meet those requirements to the governing body for appointment to the medical staff.	▪ There are written criteria for appointments to the medical staff and granting of medical staff privileges. ▪ Granting of medical staff membership or privileges, is based upon an individual practitioner's meeting these criteria. ▪ At a minimum, criteria for appointment to the medical staff/ granting of medical staff privileges are individual character, competence, training, experience, and judgment. ▪ Written criteria for appointment to the medical staff and granting of medical staff privileges are not dependent solely upon certification, fellowship, or membership in a specialty body or society.
03.01.07 <u>Medical Staff Bylaws: History and physical requirement</u> *The bylaws must include a requirement that:* *A medical history and physical be completed and documented for each patient no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, and except as*	☐ Compliant ☐ Not Compliant The purpose of a medical history and physical examination (H&P) is to determine whether there is anything in the patient's overall condition that would affect the planned course of the patient's treatment, such as a medication allergy, or a new or existing co-morbid condition that requires additional interventions to reduce risk to the patient. The medical staff bylaws must include a requirement that an H&P be completed and documented for each patient no more than 30 days prior to or 24 hours after hospital admission or registration, but prior to surgery or a	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review the medical staff bylaws to determine whether they require that a physical examination and medical history be done for each patient no more than 30 days before or 24 hours after admission or registration by a physician (as defined in section 1861(r) of the Act), an oral maxillofacial

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

provided under standard 03.01.09.

The medical history and physical examination must be completed and documented by a physician (as defined in section 1861 (r) of the Act) (Social Security Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with state law and hospital policy.

§482.22(c)(5)(i)

procedure requiring anesthesia services.

The H&P may be handwritten or transcribed, but always must be placed within the patient's medical record within 24 hours of admission or registration, or prior to surgery or a procedure requiring anesthesia services, whichever comes first.

An H&P is required prior to surgery and prior to procedures requiring anesthesia services, regardless of whether care is being provided on an inpatient or outpatient basis. An H&P that is completed within 24 hours of the patient's admission or registration, but after the surgical procedure, procedure requiring anesthesia, or other procedure requiring an H&P would not be in compliance with this requirement.

The medical history and physical examination must be completed and documented by a physician, oral maxillofacial surgeon, or other qualified licensed individual in accordance with state law and hospital policy.

Section 1861(r) defines a physician as a:

- Doctor of medicine or osteopathic medicine.
- Doctor of dental surgery or of dental medicine.
- Doctor of podiatric medicine.
- Doctor of optometry.
- Chiropractor.

In all cases the practitioners included in the definition of a physician must be legally authorized to practice within the state where the hospital is located and providing services within their authorized scope of practice. In certain instances, the Social Security Act attaches further limitations as to the type of hospital services for which a practitioner is considered to be a "physician." For example, a chiropractor is considered a physician only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation).

surgeon, or other qualified licensed individual in accordance with state law and hospital policy. Verify whether the bylaws require the H&P be completed prior to surgery or a procedure requiring anesthesia services.

- Review the hospital's policy, if any, to determine whether other qualified licensed individuals are permitted to conduct H&Ps to ensure that it is consistent with the state's scope of practice law or regulations.
- Verify that non-physicians who perform H&Ps within the hospital are qualified and have been credentialed and privileged in accordance with the hospital's policy.
- Determine that hospital policies (including Medical Staff Rules/ Regulations) address the use of physician extenders in documenting admission assessment data for the physician's H&P.
- Review a sample of inpatient and outpatient medical records that include a variety of patient populations undergoing both surgical and non-surgical procedures to verify that:
  - □ There is an H&P that was completed no more than 30 days before or 24

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Other qualified licensed individuals are those licensed practitioners who are authorized in accordance with their state scope of practice laws or regulations to perform an H&P and who are also formally authorized by the hospital to conduct an H&P. Other qualified licensed practitioners could include nurse practitioners and physician assistants. More than one qualified practitioner can participate in performing, documenting, and authenticating an H&P for a single patient. When performance, documentation, and authentication are split among qualified practitioners, the practitioner who authenticates the H&P will be held responsible for its contents. A hospital may adopt a policy allowing submission of an H&P prior to the patient's hospital admission or registration by a physician who may not be a member of the hospital's medical staff or who does not have admitting privileges at that hospital, or by a qualified licensed individual who does not practice at that hospital but is acting within his/her scope of practice under state law or regulations. Generally, this occurs where the H&P is completed in advance by the patient's primary care practitioner. When the H&P is conducted within 30 days before admission or registration, an update must be completed and documented by a licensed practitioner who is credentialed and privileged by the hospital's medical staff to perform an H&P. (See discussion of H&P update requirements at standard 03.01.08.)	hours after admission or registration, but, in all cases, prior to surgery or a procedure requiring anesthesia services. □ The H&P was performed by a physician, an oral maxillofacial surgeon, or other qualified licensed individual authorized in accordance with state law and hospital policy. **Note**: Score chart review deficiency at standard 10.01.07.
03.01.08 <u>Medical staff bylaws: Update to the history and physical prior to admission</u> *The bylaws must include a requirement that:* *An updated examination of the patient, including any changes in the patient's*	☐ Compliant ☐ Not Compliant The medical staff bylaws must include a requirement that when a medical history and physical examination has been completed within 30 days before admission or registration, an updated medical record entry must be completed and documented in the patient's medical record within 24 hours	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review the medical staff bylaws to verify that they include provisions requiring an updated medical record

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

condition, be completed and documented within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services, when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under standard 03.01.09.

The updated examination of the patient, including any changes in the patient's condition, must be completed and documented by a physician (as defined in section 1861 (r) of the Act) (Social Security Act), an oral and maxillofacial surgeon, or other qualified licensed individual in accordance with state law and hospital policy.

§482.22(c)(5)(ii)

after admission or registration.

The examination must be conducted by a licensed practitioner who is credentialed and privileged by the hospital's medical staff to perform an H&P. In all cases, the update must take place prior to surgery or a procedure requiring anesthesia services.

The update note must document an examination for any changes in the patient's condition since the patient's H&P was performed that might be significant for the planned course of treatment. The physician or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient's condition and co-morbidities, if any, in relation to the patient's planned course of treatment to decide the extent of the update assessment needed as well as the information to be included in the update note in the patient's medical record.

If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed (71 FR 68676).

- Any changes in the patient's condition must be documented by the practitioner in the update note and placed in the patient's medical record within 24 hours of admission or registration, but prior to surgery or a procedure requirement anesthesia services.
- Additionally, if the practitioner finds that the H&P done before admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update may disregard the existing H&P, and conduct and document in the medical record a new H&P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia.

entry documenting an examination for changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration when the medical history and physical examination was completed within 30 days before admission or registration.

- Determine whether the bylaws require that, in all cases involving surgery or a procedure requiring anesthesia services, the update to the H&P must be completed and documented prior to the surgery or procedure.

  In the sample of medical records selected for review, look for cases where the medical history and physical examination was completed within 30 days before admission or registration.
- Verify that an updated medical record entry documenting an examination for any changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration.
- Verify that in all cases involving surgery or a procedure requiring anesthesia services, the update was completed and documented prior to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		the surgery or procedure. **Note**: Score chart review deficiency at standard 10.01.07.
03.01.09 Exception for outpatient surgical procedures The medical staff may choose to develop and maintain a policy that identifies specific outpatient surgical or procedural services requiring anesthesia services for which patients may be eligible for a modified *medical history and physical examination prior to specific outpatient surgical or procedural services.* A written medical staff policy - 1. Requires a history and physical to be completed no more than 30 days prior to the date of a procedure. The policy defines the required elements of the history and physical to be completed and documented in the medical record. 2. *Identifies the specific outpatient surgical or procedural services for which patients may be eligible for a modified medical history and physical.* 3. *Must apply only to specific patients based on, but not limited to:* a. *Patient age*	☐ Compliant ☐ Not Compliant ☐ NA In lieu of the comprehensive history and physical (H&P) and update to the H&P (standards 03.01.07 and 03.01.08), the hospital and its medical staff have the flexibility to establish a policy for selected groups of patients that would require a modified or less comprehensive presurgical or pre-procedural assessment of the patient. In accordance with the medical staff policy: ▪ A history and physical is required within 30 days of the procedure. ▪ The update to the H&P would be replaced with a patient assessment. The medical staff policy defines the elements of the patient assessment to be completed immediately prior to the outpatient surgery. At a minimum, this brief physical examination includes an assessment of the airway, lungs and heart. The pertinent history must be verified with the patient. Based on the assessment, a statement of verification signed by a physician is required indicating that there have been no interval changes. For patient safety, even for healthy patients undergoing "low risk" surgery, a medical history is critical to plan the appropriate anesthesia and/or to react to adverse events that might occur during surgery and anesthesia. It is the responsibility of the healthcare system to, at a minimum, provide pertinent information to the anesthesia provider for the appropriate assessment of the severity of medical condition of the patient and invasiveness of the proposed surgical procedure well in advance of the anticipated day of procedure for all elective patients.	This standard is not met as evidenced by: DOCUMENT REVIEW ▪ If the hospital has elected to establish a policy for a presurgical or pre-procedural assessment of the patient (in lieu of the requirements for a comprehensive pre-surgical or preprocedural H&P and its update), review the policy to determine it requires: □ the patient assessment is completed and documented after registration and immediately prior to surgery or a procedure requiring anesthesia services. □ the patient is receiving a specific outpatient surgical or procedural services as outlined in the policy. □ The policy for each procedure takes into consideration patient age, diagnoses, the type and number of surgeries and procedures scheduled to be performed, comorbidities, and level of anesthesia required for the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	b. *Diagnoses* c. *The type and number of procedures scheduled to be performed on the same surgery date* d. *Comorbidities* *and* e. *Level of anesthesia required for the surgery or procedure.* 4. *Must be based on nationally recognized guidelines and standards of practice for assessment of specific outpatient surgeries and procedures, and applicable State and local health and safety laws.* 5. *Establishes that an assessment of the patient must be completed and documented after registration* and performed immediately *prior to the* outpatient *surgery or a procedure requiring anesthesia services.* 6. Defines the elements of the patient assessment to be completed and documented in the medical record prior to the outpatient procedure. 7. *The assessment must be completed and documented by a physician (as defined in section 1861(r) of the Act), an oral and maxillofacial surgeon, or other qualified licensed individual in*	surgery or procedure, nationally recognized guidelines and standards of practice for assessment of specific types of patients prior to specific outpatient surgeries and procedures, and applicable state and local health and safety laws. Note: Score chart review deficiency at standard 10.01.07.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

accordance with State law and hospital policy.

If *the medical staff chooses* to have a modified H&P*, the medical staff must demonstrate evidence that the policy applies only to those patients receiving specific outpatient surgical or procedural services.*

This standard is not applicable if the medical staff does not approve a policy for a modified History and Physical for outpatient surgical procedures.

§482.22(c)(5)(iii-v)
§482.22(c)(5)(v)(A-C)

03.01.10 Medical staff bylaws: Granting of privileges

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The bylaws must:

- *Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges.*

  For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in

All patient care is provided by or in accordance with the orders of a physician or practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted privileges in accordance with those criteria by the governing body, and who is working within the scope of those granted privileges.

Privileges are granted by the hospital's governing body to individual practitioners based on the medical staff's review of that individual practitioner's qualifications and the medical staff's recommendations for that individual practitioner to the governing body.

However, in the case of telemedicine physicians and practitioners providing telemedicine services under an agreement, the governing body has the option of having the medical staff rely upon the credentialing and privileging

DOCUMENT REVIEW

- Verify that the medical staff bylaws contain criteria for granting, withdrawing, and modifying clinical privileges to individual practitioners of the medical staff and that a procedure exists for applying these criteria.
- In the case of telemedicine physicians and practitioners providing telemedicine services under an agreement with the hospital where the hospital's governing body has

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
42 CFR §482.12(a)(8) and (a)(9), and 42 CFR §482.22(a)(3) and (a)(4). §482.22(c)(6)	decisions of the distant-site hospital or telemedicine entity with which the hospital has entered into an agreement. When the governing body has exercised this option, the medical staff's bylaws must include a provision allowing the medical staff to rely upon the credentialing and privileging decisions of a distant-site hospital or telemedicine entity when that distant-site hospital or entity is required under the terms of its agreement with the hospital to employ a credentialing and privileging process that conforms to the provisions of 42 CFR §482.12(a)(8) and (a)(9), and 42 CFR §482.22(a)(3) and (a)(4).	opted to have the medical staff rely upon the credentialing and privileging decisions of the distant-site hospital or telemedicine entity, verify that the bylaws include a provision permitting such reliance. ▪ Verify that physicians and practitioners who provide care to patients are working within the scope of the privileges granted by the governing body.
03.01.11 Medical staff policies and procedures Policies of the medical staff shall be supportive of and congruent with the medical staff bylaws, rules and regulations.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the bylaws for conflicting position statements. A statement in the bylaws of congruency of all medical staff policies to the bylaws would be acceptable.
03.01.12 Medical staff bylaws: Periodic review The medical staff bylaws, rules and regulations shall be reviewed and updated as necessary to assure congruence with medical staff practice and contain a mechanism for review at least every three years.	☐ Compliant ☐ Not Compliant Processes are in place that ensures the governing body approves all changes to the medical staff bylaws.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ The provision for periodic review is present in the medical staff bylaws. ▪ The medical staff bylaws have been reviewed within the last three years.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.01.13 Uniform application of membership criteria Criteria for membership and/or privileging shall be uniformly applied to all applicants for initial appointment and reappointment.	☐ Compliant ☐ Not Compliant There are to be no "waivers" to the criteria for membership and/or privileging; this includes the period of initial (associate/provisional) appointment.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine that the document(s) provide for uniform application of criteria and provisional periods for appointments and privileging for ALL providers, not just medical staff.
03.01.14 Nondiscrimination in application of membership criteria Criteria shall not include: ▪ Sex ▪ Race ▪ Creed ▪ National origin ▪ Handicap or other considerations not impacting the applicant's ability to discharge the privileges for which he/she has applied.	☐ Compliant ☐ Not Compliant The medical staff bylaws, or the credentials manual, contain a statement of nondiscrimination.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine that the medical staff bylaws or the credentials manual contain a statement of nondiscrimination.
03.01.15 Application and reapplication requirements Each of the following areas must be reviewed for each applicant/reapplicant during the review and approval process.	☐ Compliant ☐ Not Compliant The application/reapplication, including all verified information, is reviewed, evaluated, and summarized by credentialing professionals. Discrepancies or unusual or problematic areas are reviewed and discussed by committee	This standard is not met as evidenced by: **DOCUMENT REVIEW** Using no fewer than ten files, verify that: ▪ The credentialing criteria were

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

A. Licensure History: current license(s), licensure sanction(s), state(s) of current practice or intended practice, and all previous licenses held.

For Nurse Practitioners and Physician Assistants, a collaborative agreement or supervisory agreement is required, per State regulations.

B. Medical Education and Postgraduate Training

C. Malpractice Insurance and History: 5-year history.

D. Specialty Board Status (if applicable).

E. Sanctions or Disciplinary Actions taken by healthcare facilities, specialty boards, federal or state agencies, malpractice carriers.

F. Criminal History: Initial application - felony convictions/criminal history (7-10 years).

G. History of Hospital Employment & Affiliations:

(1) Healthcare employment history for hospital-employed physicians and non-physician practitioners.

(2) History of medical staff appointments and affiliations where privileges have been granted.

members and appropriate members of the medical staff leadership.

A CVO may be used to perform the primary source verification function for a hospital, but the process for credentialing by the organization must reflect the requirements as stated in the applicable standards.

A. Primary Source Verification (PSV) from State Licensing Agency(ies) and query from the National Practitioner Data Bank (NPDB).

□ Information regarding previously successful and/or currently pending (if available) challenges to any license, and/or voluntary or involuntary relinquishment of his/her license.

□ Results from search of Federation of State Medical Boards (FSMB) Disciplinary Action Databank or Fraud and Abuse Control Information Systems (FACIS).

□ If telemedicine is utilized, review the process for validation of licensure and validate it is being enforced.

□ Evidence of current collaborative agreement for Nurse Practitioners, or Supervisory agreement for Physician Assistants, with a physician that has the same privileges being requested.

B. Primary Source Verification (PSV) includes AMA Physicians Profile, AOA Official Osteopathic Physician Profile, and Educational Commission for Foreign Medical Graduates (ECFMG), as applicable; documentation regarding training and education sufficient to support requested privileges; evidence of continuing educational activities every two years may be requested.

C. Evidence of professional liability insurance including current certificates showing amount insurance; malpractice litigation history from insurance carrier; National Practitioner Data Bank (NPDB) query on professional liability actions resulting in final settlements or judgments within the past 5 years.

D. Documentation regarding specialty board status.

consistently applied in recommendations for membership and privilege delineations.

- A summary provides a clear report of the review of all submitted information (both application information and verified information).
- Appropriate physician leaders, committees, as well as the Governing Body review the summary.
- Practitioners who provide care to patients are working within the scope of the privileges granted by the governing body.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

H. Professional References: current competence and peer recommendations/references, ability to perform privileges requested (health status). For physicians seeking reapplication, peer references include: peers familiar with their practice of medicine, reviews under the hospital's peer review activities, reviews by the hospital's Credentials Committee, Department Chair, or Medical Executive Committee.

I. Clinical Activity: procedure logs with outcomes to support privilege requests for procedures not attested to in postgraduate references.

J. Information Verified for Comparison: comparison of applicant - provided information and verified information.

K. Meeting attendance is consistent with requirements established in the medical staff bylaws.

□ If certified by a member of board ABMS, verify with ABMS; and/or

□ If certified by a specialty board of AOA, verify with AOA Official Osteopathic Physician Profile.

E. The application requests information regarding:

□ Disciplinary actions taken or investigations pending by hospitals or other healthcare facilities, specialty boards, Medicare/Medicaid

□ Actions against the Federal Drug Enforcement Agency (DEA) certificate or state Controlled Dangerous Substances (CDS) certificate

□ Actions listed in the National Practitioner Data Bank (NPDB).

F. Minimally, criminal background check is conducted with the initial application; thereafter, perform in accordance with medical staff bylaws. The application requests information regarding any criminal history. The hospital conducts criminal background investigation based on information provided in the application or as required by federal and state regulations.

G. Information regarding other facilities where the applicant has or had privileges, other clinical/medical staff appointments, etc.

Verification of this information, including a confirmation of the applicant's appointment and privilege history, and any pending investigations of disciplinary actions, voluntary resignations, or relinquishments of membership/ clinical privileges/contracts.

Verification of employment history for hospital-employed physicians and non-physician practitioners.

H. References from at least one but preferably three peers, one of which shall be an individual with the same professional credential as the applicant/re-applicant. With initial applications, references should be obtained from the Residency Program Director or a Department Chair. If someone with the same professional credential is not available, then a person in the same practice area who can speak to the applicant/re-

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

applicant's professional competence and ethical standards may be used as a reference. Include a statement relative to the physician's physical and mental health in relation to privileges requested.

REAPPLICANTS DO NOT NEED TO PROVIDE LETTERS OF REFERENCE

- For re-applicants, peer review via routine review (e.g., clinical peer review, medical records review, credentials function, Medical Executive Committee) is sufficient.
- However, clinical competence review must be a component of re-credentialing.

I. Clinical Activity: Applicants must provide documentation regarding clinical activity (from residency, fellowship program, or facilities where the applicant has been practicing medicine) and competency for consideration of privileges requested.

J. Re-applicants must provide recommendations from the Department Chair in which privileges are sought; (if volume is low, this may require review of procedure logs/ competency from other institutions to verify competency) including:

□ Scope of specific privileges based upon recent experience and

□ Recommendations from quality assurance committee and/or other staff committees based upon peer review findings.

K. Meeting attendance is evaluated at time of reappointment against the requirements of the medical staff bylaws.

03.01.16 Medical staff bylaws: Emergency privileges

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Medical staff bylaws provide for the granting of emergency privileges.

The medical staff bylaws provide for a medical staff chief and/or the CEO to grant emergency privileges to a practitioner to accomplish life saving procedures, within the scope of his/her license, during such times that reasonably suggest that a staff member who is a credentialed practitioner

DOCUMENT REVIEW

- Determine that the medical staff bylaws, or credentialing procedures

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	with appropriate privileges is not available. This practice is generally limited to circumstances within an overwhelming disaster; it is not utilized to "cover" a practitioner who has failed to follow Medical Staff guidelines in applying for privileges.	manual, describe mechanisms to grant emergency privileges per the standard. ▪ Verify that the process is followed.
03.01.17 <u>Medical staff bylaws: Temporary privileges</u> Medical staff bylaws provide for the granting of temporary privileges. Upon recommendation from the president of the medical staff or the applicable department chief/medical director, the CEO or designee, acting on behalf of the governing body, may grant temporary privileges, consistent with state law, for: 1. An initial application that is complete and contains all required elements and waiting to go to the Medical Executive Committee and the governing body for final approval, 2. The care of specific patient(s) 3. Locum tenens 4. Times of emergency and/or disaster Temporary privileges are time limited. The governing body is notified of all practitioners granted temporary privileges, locum tenens privileges, or	☐ Compliant ☐ Not Compliant The granting of temporary privileges is not precipitous and must be consistent with state law. Temporary privileges must not be granted for reasons of convenience. Temporary privileges may only be considered if the application is complete and contains all required elements including: 1. Verification of current professional licensure, Drug Enforcement Administration (DEA) registration, medical malpractice insurance, and 2. Query of the National Practitioner Data Bank (NPDB), and 3. At least one recent reference from a previous hospital, chief or department chair. Limits to the number of "specific patients" which may be cared for are identified. **LOCUM TENENS** Locum tenens privileges may be granted for specific periods of time, which are not typically sequential so as to bypass the need for submitting an application for provisional appointment. **EMERGENCY/DISASTER PRIVILEGES** The hospital should have a plan for dealing with clinical volunteers during times of emergency and/or disaster. This plan should provide for primary source identification from the volunteer's hospital. (A documented phone call is acceptable.) The hospital should use such volunteers as appropriate within	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Verify that the medical staff bylaws, or credentials manual, describe mechanisms for the granting of temporary privileges in the four described situations. ▪ Review at least one file where temporary privileges were granted to verify the process was followed.

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emergency/disaster privileges.	the scope of their license or certification. (For more information, refer to Chapter 9 Emergency Management.)	
03.01.18 Suspension of privileges Provision for corrective action(s) with suspension of privileges shall occur where appropriate.	☐ Compliant ☐ Not Compliant Automatic Suspension of privileges is invoked for: ▪ Lapsed professional liability coverage. ▪ Suspensions, revocations, or limitations imposed on the insurance coverage or license or narcotic certificate of the practitioner. ▪ In congruence with medical staff rules regarding delinquent medical records. Summary Suspension of privileges is invoked when there is real potential danger to a patient due to the behavior or condition of a practitioner. The corrective action mechanism shall address the disruptive and/or impaired practitioner.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the medical staff bylaws to determine that the provisions for corrective action include: □ Automatic suspension for each of the described elements. □ Summary suspension. ▪ Determine that definitions, with correlating medical staff activities, exist for disruptive and impaired practitioners; and, that these are consistent with any state regulations regarding impaired licensees. ▪ Interview medical staff leadership to validate the process is in place and that the defined process is followed.
03.01.19 Fair hearing process The hospital shall have a fair hearing plan for members of the medical staff. Individuals involved in peer review activities shall be impartial peers and shall	☐ Compliant ☐ Not Compliant The fair hearing plan outlines the circumstances under which a practitioner may request (or waive) this mechanism: ▪ Denial	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine that the fair hearing mechanism is descriptive of the

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not have an economic interest in and/or a conflict of interest with the subject of the peer review activity. Impartial peers would also exclude individuals with blood relationships, employer/employee relationships, or other potential conflicts that might prevent the individual from giving an impartial assessment or give the appearance for the potential of bias for or against the subject of the peer review.	▪ Modification or changes in appointment/reappointment category ▪ Initial or re-granting of privileges with final review/action by the governing body	required elements.
03.01.20 For future use		
03.01.21 For future use		
03.01.22 Medical staff bylaws: Meeting frequency and attendance Medical staff bylaws outline the requirements for meeting frequency and attendance. Such requirements may be more stringent for provisional (associate) and active staff than for other categories. If there are departments and services, separate requirements are outlined. Meeting attendance is considered as one parameter in the credentialing process.	☐ Compliant ☐ Not Compliant Active staff should be expected to attend staff, department/service, and committee meetings. The medical staff bylaws address the definition of a quorum for the various meetings. Staff membership, with resulting privileging, carries obligations to reasonably participate in medical staff self-governance.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the medical staff bylaws and summaries of medical staff attendance rosters to determine conformance with attendance requirements. □ Is a quorum defined? □ Were actions taken without a quorum present? ▪ Was attendance considered in the

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		reappointment files reviewed in credentialing/recredentialing?
03.01.23 Medical staff bylaws: Clinical department structure Medical staff bylaws may provide for the organization of clinical departments or services. When such exist, the bylaws provide for the organizational requirements of: A. Structure – officers and meeting frequency; B. No fewer than three physicians on active status to organize a separate department service; C. The criteria for membership; and D. The duties and obligations of departments or services. (a) Selection of chairperson; and (b) Duties and responsibilities of chair.	☐ Compliant ☐ Not Compliant Smaller facilities often operate effectively non-departmentalized to reduce the incremental meeting attendance requirements. When departments/services exist, they are accountable to the Medical Executive Committee (MEC) and the full medical staff, for their portion of the responsibilities outlined above.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Determine that if departments or services exist, the functions are effectively accomplished for each listed department or service. ▪ Determine that the bylaws accurately reflect the organizational structure of the medical staff. ▪ The medical staff which functions as a "staff of the whole" with medical staff bylaws describing a non-departmentalized organization, is scored as Compliant.
03.02.01 Required committees There are two required committees: 1. Medical Executive Committee 2. Utilization Review Committee	☐ Compliant ☐ Not Compliant The medical staff is structured to provide the governing body with assurance that appropriate care has been provided to the patients. Although no other committees are required, hospitals must establish either a	**Scored at 03.03.01 and 03.04.01**

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	committee or a function of another committee at the determination of the medical staff for the purpose of doing the work of the following: ▪ Credentials Committee ▪ Mortality Review Committee ▪ Infection Control Committee ▪ Transfusion Committee ▪ Pharmacy and Therapeutics Committee (P&T Committee) In small hospitals, designated members of the professional staff or the staff serving as a committee-of-the-whole may perform these functions. In all instances, these functions shall be performed and recorded by the active staff.	
03.03.01 Medical Executive Committee	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The medical staff bylaws require, even if the medical staff functions as a "committee of the whole," a Medical Executive Committee function or process. The determination of the meeting frequency and attendance requirements for the Medical Executive Committee shall be responsibility of the hospital.	When the medical staff functions as a "committee of the whole," there is a provision to enter executive session with at least one member of administration present in order to act with a degree of freedom in order to address extremely sensitive issues of self-governance.	**DOCUMENT REVIEW** ▪ Verify that the medical staff bylaws provide for a Medical Executive Committee/function (MEC) or process when a "committee of the whole," which meets the requirements of this standard.
03.03.02 Medical Executive Committee scope	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The Medical Executive Committee (MEC) is empowered to act on behalf of the	When the medical staff functions as a committee of the whole, there shall be a mechanism to convene between meetings; this may be accomplished by ad	**DOCUMENT REVIEW**

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medical staff when the medical staff cannot be assembled or between their regular meetings.	hoc meetings of an identified MEC when the entire active medical staff is unable to be assembled or for executive session.	▪ Verify that the medical staff bylaws indicate that the MEC is empowered to act on behalf of the medical staff.
03.04.01 Utilization Review Committee	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The medical staff bylaws require, even if the medical staff functions as a "committee of the whole," a Utilization Review Committee.	Note: see chapter 6 for additional information regarding UR.	**DOCUMENT REVIEW** ▪ Verify that the medical staff bylaws provide for a Utilization Review Committee or process when Medical Staff functions as a "committee of the whole."
03.04.02 Utilization Review Committee meeting documentation	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Meetings shall have written minutes reflecting the activities of the committee.	Determination of the meeting frequency and attendance requirements for the Utilization Review Committee is a responsibility of the hospital.	**DOCUMENT REVIEW** ▪ Verify that UR Committee meetings are documented with meeting minutes.
03.05.01 For future use		
03.06.01 Credentials Committee/ Function	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The Credentials Committee/function reviews as an investigative and recommending body.	No additional information.	**DOCUMENT REVIEW** ▪ Review minutes of the Credentials

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		Committee/function. **Note**: This may be part of Medical Staff minutes if it meets as a committee-of-the-whole.
03.06.02 Credentials Committee responsibility The Credentials Committee/function makes recommendations to the executive committee on applications received for staff membership and requests for privileging for members and non-members.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review minutes of the Credentials Committee (function) or medical staff minutes if it meets as a committee-of-the-whole.
03.06.03 Credentials Committee scope The Credentials Committee/function recommends expansion or limitation of privileges of staff members and all categories of credentialed staff based on a thorough review of credentials.	☐ Compliant ☐ Not Compliant The Credentials Committee (function) is responsible for credentialing the medical staff as well as non-physician practitioners who provide a medical level of care, as applicable.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review minutes of the Credentials Committee (function) or medical staff minutes if it meets as a committee-of-the-whole.
03.06.04 For future use		
03.06.05 For future use		

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03.06.06 Incomplete applications The Credentials Committee/function members shall return incomplete applications to the applicant for corrections before consideration.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review minutes of the Credentials Committee/function or medical staff minutes to ensure applications are complete.
03.06.07 For future use		
03.06.08 Time frame for processing applications A recommendation shall be made to the Medical Executive Committee (MEC) within 60 days of receipt of completed application. The recommendations of the Credentials Committee/function will be based on individual practitioner's qualifications and competency at the time the privileges are requested.	☐ Compliant ☐ Not Compliant All recommendations to the MEC shall contain a delineation of the privileges to be extended to the applicant.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the Credentials Committee minutes or MEC minutes to verify that recommendations are: □ Made to the governing body. □ Within the required time frame. □ Based on individual practitioner qualifications and competency.
03.06.09 Meeting frequency and attendance The hospital shall determine the meeting frequency and attendance requirements for the Credentials Committee.	☐ Compliant ☐ Not Compliant No additional information	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review hospital requirements for

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		meeting attendance/frequency. ▪ Review Credentials Committee minutes.
03.07.01 For future use		
03.08.01 For future use		
03.09.01 For future use		
03.10.01 Mortality Review The organization has a process to review all inpatient deaths.	☐ Compliant ☐ Not Compliant A formal committee is not required to perform this function but the organization must evaluate all cases to determine that the patient received appropriate evaluation and care. The attending physician was aware of the critical nature of the case as noted in: 1. the physician's orders. 2. laboratory procedures ordered. 3. timeliness of consultation orders. The hospital determines the meeting frequency and attendance requirements for mortality review. The results of the inpatient death review are: ▪ Integrated into the hospital QAPI program, and ▪ Considered as a part of the medical staff peer review process.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review requirements for meeting frequency and attendance. ▪ Verify the mortality review data is integrated with the hospital QAPI committee. ▪ Ask the medical staff leaders how the mortality review results are incorporated with the medical staff peer review process. ▪ Review the Mortality Review Committee (or function) minutes or the Medical Staff minutes when it acts as a committee-of-the-whole.

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03.10.02 For future use		
03.10.03 For future use		
03.10.04 For future use		
03.10.05 For future use		
03.10.06 For future use		
03.11.01 For future use		
03.12.01 For future use		
03.13.01 Transfusion Utilization Review The medical staff has a process to: ▪ Review all transfusions of blood and blood products to determine appropriateness of orders based on protocols. ▪ Analyze transfusion reactions. ▪ Review blood transfusion policies and practices.	☐ Compliant ☐ Not Compliant A formal committee is not required to perform this function; these activities may be a function of another committee. The medical staff shall adopt blood and blood products administration practices based on current national guidelines. A process is in place to review all transfusion reactions. If a screening tool is used, the medical staff has approved the tool. The results of the transfusion utilization review are: ▪ Integrated into the hospital QAPI program	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Ask which national guidelines are used for blood and blood product administration. ▪ Review transfusion of blood and blood product related polices to determine these are in place and reviewed at least every three years. ▪ Verify that transfusion reactions are reported through the QAPI program.

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	▪ Reported to the medical staff Transfusion and blood product policies are reviewed at least every three years and updated more frequently, as necessary.	Are identified issues being resolved?
03.14.01 Pharmacy and therapeutics review The medical staff has a process to monitor the use of medications throughout the organization. Responsibilities include: ▪ Reporting on acquisition costs. ▪ Development of standard dosing regimen. ▪ Review of adverse drug reactions and medication errors. ▪ Review of medication preparation and administration policies and practices.	☐ Compliant ☐ Not Compliant A formal committee is not required to perform this function; these activities may be a function of another committee. The reports of pharmacy acquisition costs are: ▪ Integrated into the hospital QAPI program, and ▪ Reported to the medical staff Medication preparation and administration policies are reviewed by the Pharmacy and Therapeutics committee or function of another committee at least every three years and updated more frequently, as necessary.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Policies are reviewed at least every three years. ▪ The medical staff has a process to monitor the use of medication throughout the organization. ▪ Pharmacy acquisition costs are integrated into the hospital QAPI program and reported to the medical staff.
03.15.01 Ongoing professional practice evaluation Ongoing professional practice evaluation (OPPE) information is factored into the decision to maintain existing privilege(s), to revise existing privilege(s), and/or to revoke an existing privilege prior to or at the time of renewal.	☐ Compliant ☐ Not Compliant The medical staff must have a process to monitor the competency of its members. Through an ongoing review of performance measurements, negative trends are tracked and trended in a manner that allows the leadership to identify performance issues and implement strategies that will effect change. Prospective and real-time evaluation is important to ensure the delivery of	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ The medical staff bylaws address the ongoing professional practice evaluation process. ▪ The medical staff have identified and approved performance measures.

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safe and competent care.

The medical staff develop an ongoing professional practice evaluation plan that is applicable to all practitioners with privileges granted by the governing body.

The plan for the evaluation of each practitioner's professional practice is clearly defined. This medical staff approved plan addresses each of the following:

1. Reasons for ongoing professional practice performance evaluations
2. Identification of performance indicators specific to each department of the medical staff
3. Data collection methods
4. Individual(s) responsible for data collection
5. Sources of data, e.g., medical records
6. Frequency of data collection
7. Methods for evaluation and analysis of data
8. Confidentiality and security of data
9. Individuals that may access individual practitioner's professional practice data
10. Explanation that data will be used as a measure of competency and will be reviewed at time of reappointment to determine eligibility
11. Evaluation of low volume practitioners
12. Triggers for additional, focused monitoring

Processes are established to ensure the confidentiality and security of the ongoing professional practice evaluation data. The medical staff identify individuals that may access and review the data, for example:

- Respective department chair.

- Credential files reflect the ongoing professional practice evaluation is performed at least three times during the **three**-year appointment cycle. This quality data is reviewed as part of the reappointment process.

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- Credentials committee.
- Medical Executive Committee (MEC).
- Special committees.
- Chief of Staff.
- Chief Medical Officer/Vice President of Medical Affairs (VPMA).
- Personnel working in the Medical Staff Office, Quality Department, or Medical Records Department.

Data will be collected on an ongoing basis and summarized at least three times during each **three**-year appointment cycle. It is recommended that individual data reports be distributed to the practitioners.

When possible, data collection systems that are currently in place should be accessed to measure individual practitioner outcomes. Electronic billing data, for example, often provides information according to the admitting and attending physician, primary surgeon, consultants and other practitioners. Billing data, however, may have limited usefulness for the non-physician providers, as traditional coding practices may not identify this group of practitioners.

At least every **36 months**, the medical staff identify and approve performance measurements that are specific to the services provided by the practitioners.

- At least two performance measures are administrative indicators to evaluate compliance with medical staff bylaws, rules and regulations, and hospital policies. Examples include:
  - □ Number of admissions
  - □ Number of consultations
  - □ Number of weeks on surgery suspension list
  - □ Medical record delinquency rate
  - □ Compliance with bylaws, rules and regulations, and policies

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- At least two performance measures are clinical indicators to evaluate current competence of privileges granted. Examples include:
  - □ Core measures (Heart Failure, Acute Myocardial Infarction, Pneumonia, Stroke, and etc.)
  - □ SCIP (Surgical Care Improvement Project)
  - □ Returns to surgery
  - □ Surgical infection rate
  - □ Procedural complication data
  - □ Administration of corticosteroids within 24 hours of admission for asthma
  - □ Cesarean section births, not medically necessary
  - □ Turnaround time for simple/complicated autopsy reports

The medical staff determines data to be collected for the non-physician practitioners (e.g., nurse practitioners, physician assistants, certified nurse anesthetists, and certified nurse midwifes) granted privileges that are relevant to their practice.

03.15.02 Focused professional practice evaluation

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The organized medical staff defines the circumstances requiring additional, focused monitoring and evaluation of a practitioner's professional performance.

Indications for Focused Professional Practice Evaluation (FPPE) include:

1. All initial privileges granted.
2. All new privileges granted following

The focused professional practice evaluation (FPPE) process is designed to be a fair, balanced, and educational approach to ensure the competency of the staff. FPPE is consistently implemented in accordance with the criteria and requirements defined by the organized medical staff.

The medical staff bylaws address:

1. The period of focused professional practice evaluation (FPPE) implemented for all new privileges granted by the Board either:

DOCUMENT REVIEW

- The medical staff bylaws address the focused professional practice evaluation process.
- The medical staff bylaws clearly define the triggers requiring a focused review, as well as indications for an external reviewer.

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initial appointment. 3. Unacceptable levels of performance or quality of care concerns.	▪ upon initial appointment or ▪ requests for additional privileges. 2. The criteria for evaluating the performance of practitioners when issues affecting the provision of safe, high-quality patient care are identified. The medical staff bylaws clearly define the professional practice evaluation process and addresses each of the following: ▪ Criteria (triggers) for conducting focused performance monitoring. ▪ Methods for determining the duration of focused performance monitoring. ▪ Indications for an external reviewer. The department chair is responsible to assign the focused evaluation. The focused evaluation may be defined as either a period of time (e.g., six months) or a specific number of cases. The focused evaluation may be extended, as defined in the bylaws. Data sources for the focused evaluation are defined and may include: ▪ Chart review. ▪ Direct observation. ▪ Simulation. ▪ Discussion with others involved in the care of each patient. The medical staff bylaws define the unacceptable levels of performance that trigger the need for focused performance monitoring. Triggers may be a single incident or evidence of a clinical practice trend. Examples of performance triggers include: ▪ Number of adverse events. ▪ Number of peer review events with adverse determination. ▪ Infection rates higher than most practitioners.	▪ Credential files reflect the period of focused professional practice evaluation.

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- Sentinel events.
- Low volume admissions/procedures over an extended period of time.
- Increased length of stay (LOS).
- Increased number of returns to surgery.
- Frequent/repeat readmission for same issue
- Patterns of unnecessary diagnostic testing/treatments.
- Failure to follow approved clinical practice guidelines.
- Patient, family, or staff complaints.

The medical staff bylaws define the methods to be implemented to resolve performance issues. The measures employed to resolve performance issues are consistently implemented and may include:

- Education.
- Proctoring/assisting for defined privilege.
- Counseling.
- Physician/practitioner assistance programs.
- Suspension of specific privileges.
- Revocation of specific privileges

The improvement plan must be documented and include the requirements, who is accountable, and how the improvement will be measured and documented.

The individual is provided written notification of the FPPE with a copy in the individual's credential file.

The outcome of FPPE is to be documented and analyzed. Processes are developed to allow the practitioner to review findings and submit opinions.

The medical staff leadership is responsible to submit recommendations to the

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governing body regarding:

- The need to continue the FPPE.
- Continuation or limiting of the privilege.

04

HUMAN RESOURCES MANAGEMENT

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
04.00.01 Governance responsibility for staffing The hospital Governance Plan is supported by a written description of the "Plan for the Delivery of Care and Services." This plan describes the mechanisms to provide appropriate staffing for these services.	☐ Compliant ☐ Not Compliant The plan for staffing addresses the recruitment and retention of qualified persons to provide services. The plan also addresses staffing patterns by department and by shift. Processes and mechanisms for determining the need for staffing adjustments are also defined. "Appropriate staffing" is impacted by both quantity and quality of persons providing care and those supporting direct care providers.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the "Plan for the Delivery of Care and Services" document addresses staffing, plans for staffing adjustments based on need and type of staffing available, recruitment, and retention.
04.00.02 Licensure The hospital must verify that all employees meet licensure and all other applicable standards for employment. This includes certification, minimum qualifications, training and education requirements, and permits (such as food handlers permits). This standard applies to contract or agency staff as well as hospital employees. §482.11(c)	☐ Compliant ☐ Not Compliant Mechanisms are established to verify with the appropriate licensing agency that all initial and renewal licenses and certificates conform to state practice acts. Practice in a facility by an individual without appropriate state license or certification is grounds for loss of accreditation by the facility.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that there is mail, electronic or telephone verification with the appropriate licensing authority for all new personnel and for licensure or certificate renewals. □ This will include all disciplines defined in the state practice acts or association standards that require certification/ licensure/registration for facility employment. ▪ Verify that the hospital has established a policy and follows procedures for ensuring that all personnel required to be licensed, certified and/or permitted by the state are properly licensed and meet the basic requirements for the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		positions they hold. ▪ Review a sampling of personnel files to verify that all required information is current. □ Review administrative and supervisory personnel as well as direct care personnel. Also sample contract and agency staff files.
04.00.03 For future use		
04.00.04 License pending and lapse or restriction of licensure/certification New graduate providers provide services within the scope of their practice acts. If the state or territory permits new graduates to function as "license pending," all mandated provisions are enforced. Providers whose licensure, certification or registration lapses or is placed under revocation, suspension, stipulation, etc., conform to all such provisions.	☐ Compliant ☐ Not Compliant The facility retains the authority while delegating to the department or service manager the accountability for assuring that all such mandated provisions are enforced. Typically, nonpayment, late payment, and registration lapses result in prohibition of providing service, as does failure to "pass" the licensing examination.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that facility policy is explicit regarding actions to be taken with examination failures and registration lapses/revocations/suspensions/ stipulations. **Note:** Licensure and registration are not the same as certification.

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04.00.05 Competency The facility develops policies and procedures identifying those patient care and/or diagnostic procedures, which require staff to have evidence of specific competence. Some of these may result in external or internal mechanisms for certification. Maintenance of such competence is considered in the design of these policies and procedures.	☐ Compliant ☐ Not Compliant Hospital policies identify required certifications such as ACLS or Basic Life Support (BLS) certification versus "basic CPR" or rescue training. External certifications may be indicated by subspecialty such as for operating room, emergency room, psychiatric, critical care nursing, etc., or may be technique-specific such as "chemotherapy," "mammography," etc. Internal certifications may include processes for minimal sedation, moderate sedation (conscious sedation), deep anesthesia, Monitored Anesthesia Care (MAC) or fetal scalp electrode placement.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the staffing protocols outline those positions or processes for which the facility has determined that external or internal certification is required. □ If such exist, determine that there are mechanisms to maintain current skill competence. Job descriptions may be a source for this information.
04.00.06 Federal employment regulations Hospital wide policies and procedures identify adherence to federal, state and local requirements. Statements of facility compliance are posted regarding fair labor practices, equal employment opportunity standards, etc. Employee handbooks, human resource manuals, and other documents outline facility standards regarding nondiscrimination practices with concomitant personnel expectations.	☐ Compliant ☐ Not Compliant These documents are accessible and applicable to all providers (medical staff, employee, contractual and volunteer). Detailed explanations may be reserved for department/service managers to share with staff as needed. Summary formats are made available upon hire or initial orientation for all categories of staff. Disciplinary and grievance mechanisms are outlined and may be impacted by existing labor organization contracts.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ All appropriate documents are accessible to all providers. ▪ Staff is oriented to specific mechanisms regarding discipline and grievance with specific emphasis on discrimination (sexual, ethnic harassment, etc.). ▪ Policies and procedures regarding the workday/week and overtime are enforced.

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		□ Interview managers regarding their knowledge of nondiscriminatory policies.
04.00.07 Staffing plans Hospital and service specific policies and procedures identify basic/core staffing for usual patient care needs and reflect mechanisms for altering these levels for changes in the volume, complexity or intensity of services.	☐ Compliant ☐ Not Compliant Staffing assignment policies for each department/service identify the principles of matching the mix of skills possessed by the staff to the identified patient needs, or for the specific task, relating to: ▪ Physical care. ▪ Equipment/technology/environment. ▪ Emotional support. ▪ Education for the procedure and/or self-care. The mechanisms for non-nursing providers may be similar to the nursing department, yet not as complex. (Refer to 16.00.11 Care Assignments for more information.)	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that staffing policies address basic/core staffing with criteria-based modifications for changing/ augmenting that level. ▪ Interview managers and selected staff to determine if policies are implemented and that there is a sufficient number of qualified staff to provide the care, treatment and services required.
04.00.08 Staffing assignment criteria Staffing policies and procedures identify any constraints regarding assignment to certain types of patients or processes, which require specific skill from a provider. Providers do not provide services beyond their capability; this does not preclude provision of such services under formal preceptorship/supervision within licensure/registration parameters.	☐ Compliant ☐ Not Compliant Note the requirements in standard 04.00.05 above regarding skill, competence and certifications. Staffing shall be sufficient in numbers and qualification so that individuals are not providing care, treatment or services beyond their education, experience, or training.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review assignment mechanisms and interview sufficient numbers of managers and staff to determine that patient care is not jeopardized.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
04.00.09 Evaluation of competence	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Staff is competent in knowledge, skills and ability to perform their responsibilities. An objective process for assessing and evaluating the competence of all employees is performed at defined intervals. Competency assessment is an ongoing process. The facility will define the competencies to be assessed annually and those competencies to be assessed at shorter defined time intervals.	Prior to beginning the relationship with the facility, the applicant provides information about education, training, and skills relevant to the desired position. During the initial phase of affiliation with the facility there is a period of observation and training as needed to document the competencies required. Written criteria are used for such evaluations. Such criteria include those noted in the facility and Quality Assessment Performance Improvement plan. Evaluation is repeated at specified intervals; this may be upon the discretion of the facility but is at least on an annual basis.	**DOCUMENT REVIEW** ▪ Verify there are criteria-based mechanisms for assessing competency: □ At initial phase of affiliation (during orientation). □ At specified periods thereafter, but at least annually.
04.00.10 New employee orientation	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Providers of care or service who are new in their affiliation are provided an orientation to the facility and their job responsibilities. The period of orientation is documented and may vary according to the classi-fication of the professional: support staff, agency or contractual, volunteer, student, etc., including prior experience(s). The documents related to new orientation are readily retrievable.	Written documentation is maintained for each employee (including contracted employees) to verify that orientation to the facility and role has been accomplished. The documentation may be located in the human resources department, in each department or service, or may be located within the official file for each provider.	**DOCUMENT REVIEW** Verify: ▪ Orientation is available and provided to all categories of personnel. ▪ Mechanisms exist to readily retrieve the documentation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

04.00.11 Required orientation curriculum

The orientation curriculum addresses specific information about the processes expected of the individual (scope of service, the written job description and evaluation tools). Facility wide, department/service and job specific components include:

1. Infection control, including blood borne pathogens and airborne pathogens.
2. Quality Assessment/Performance Improvement (QAPI).
3. Life safety.
4. Equipment/device safety.
5. Hazardous waste and materials safety.
6. Information Management including confidentiality, computer access, and medical records confidentiality.
7. Patient Rights.
8. Restraint use, if applicable to the job type.

☐ Compliant ☐ Not Compliant

An effective process is in place. The standard does not mandate an "education department."

All components of the orientation are included for all categories of personnel; in some instances, this may be via video or booklet material reviewed off-site (such as for agency or student providers).

The orientation program is significantly enhanced when there is documentation of knowledge via post testing of the employee.

The facility may wish to consider the review of falls, incidents, medical errors, etc. within its department/service and job specific reviews.

This standard is not met as evidenced by:

DOCUMENT REVIEW

- Review curriculum content for various providers and affiliates.
- Verify that the orientation program is comprehensive and includes:
  - □ Role expectations.
  - □ Evaluation mechanisms.
  - □ The eight required elements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
04.00.12 Annual required competencies	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The facility provides for ongoing training and education to maintain and improve the competency and knowledge of staff. Annual retraining in the eight areas noted in standard 04.00.11 is documented.	Ongoing training and education for all providers in addition to the mandated areas are related to the identified learning needs of the provider in accomplishing the job-related duties expected by the facility. Training may be provided directly by the facility or from external sources. Learning needs may be determined from results of: ▪ Staff survey. ▪ The findings from Quality Assessment Performance Improvement (QAPI) activities. ▪ The implementation of new or revised technology or practices. This element does not require a facility to provide training for staff to advance to a new career(s) although some facilities may provide tuition assistance without regard to correlation to the present job.	**DOCUMENT REVIEW** ▪ Verify that each provider (staff or contractual) has a record of ongoing training that documents: □ Completion of the required eight elements for annual retraining. □ Education relating to the findings from QAPI activities. □ Education related to the implementation of new or revised technology or practices.
04.00.13 Employee identification system	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Hospital staff and contracted personnel shall be issued and required to wear an identification badge. Hospital policy defines the information to be provided on the identification badge. Minimally, the badge should include: ▪ First name ▪ Job title	All care providers including physicians and agency personnel are expected to wear an identification badge in order to: 1. Comply with the patient's right to know the names of their care providers. 2. To identify employees and allow access to work areas during an emergency or disaster situation. Hospital policy specifies the specific information to be displayed on the identification badge.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Review the Human Resource policy to determine that the requirement was met. ▪ Observe employees when touring the facility to verify that the requirement is met.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Other information to consider include:

- Credentials
- Department
- Photo

04.01.01 Staff Training: Identification of patients at risk for harm

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Hospital staff must be trained to identify environmental safety risks at time of new employee orientation and annually thereafter.

§482.13(c)(2)

Hospitals must provide the appropriate level of education and training to staff regarding:

1. The identification of patients at risk of harm to self or others.
2. The identification of environmental patient safety risk factors.
3. Mitigation strategies.

Staff training is provided for:

- Direct employees.
- Volunteers.
- Contractors.
- Per diem staff.
- Other individuals providing clinical care under arrangement.

Hospitals have the flexibility to tailor the training to the particular services staff provide and the patient populations they serve.

Hospitals are expected to provide education and training to:

1. All new staff initially upon orientation
2. Whenever policies and procedures change
3. Annually, thereafter.

DOCUMENT REVIEW

- Review documents to verify the requirement is included with new employee orientation.
- Review documents to verify the requirement is included with annual training.
- Review employee files to verify the new employee received this information during orientation and annually thereafter.

05

FOR FUTURE USE

06

UTILIZATION REVIEW

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.00.00 Condition of Participation: Utilization Review *The hospital must have in effect a utilization review (UR) plan that provides for review of services furnished by the institution and by members of the Medical Staff to patients entitled to benefits under the Medicare and Medicaid program.* §482.30	☐ Compliant ☐ Not Compliant If it does not satisfy one of the exception criteria (see standard 06.00.01/ §482.30(a)), the hospital UR plan in effect must provide for review of services provided to Medicare and Medicaid beneficiaries. The hospital UR plan should include a delineation of the responsibilities and authority for those involved in the performance of UR activities. It should also establish procedures for the review of the medical necessity of admissions, the appropriateness of the setting, the medical necessity of extended stays, and the medical necessity of professional services.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** **Note:** The manner and degree of noncompliance with one or more of the UR standards is considered when determining whether there is condition-level compliance or non-compliance. Verify: ▪ The hospital has a utilization review plan for those services furnished by the hospital and its medical staff to Medicare and Medicaid patients. ▪ The UR plan has been approved by the medical staff within the past three years or more often as needed for updates. ▪ Through review of records and reports and interviews with the UR chairman and/or members that UR activities are being performed as described in the hospital UR plan. □ Review the minutes of the UR committee to verify that they include dates, members in attendance, extended stay reviews with approval or disapproval noted in a status report of any actions taken.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.00.01 Applicability	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The provisions 42 CFR 482.30 apply except in either of the following circumstances: *1) A Utilization and Quality Control Quality Improvement Organization (QIO) has assumed binding review for the hospital.* 2) *CMS has determined that the UR procedures established by the State under title XIX of the Act (Social Security Act) are superior to the procedures required in this section, and has required hospitals in that State to meet the UR plan requirements under 42 CFR §456.50 through §456.245.* §482.30(a) §482.30(a)(1) §482.30(a)(2)	The regulation permits two exceptions to the requirement for a hospital UR plan: (1) where the hospital has an agreement with a QIO under contract with the Secretary to assume binding review for the hospital or; (2) where CMS has determined that UR procedures established by the State under Medicaid are superior to the UR requirements for the Medicare program and has required hospitals in that State to meet the UR requirements for the Medicaid program at 42 CFR §456.50 through §456.245. According to the regulation at 42 CFR §476.86(e), QIO review and monitoring activities fulfill the requirements for compliance activities of State Survey Agencies under §1861(k) of the Social Security Act (the Act). The statutory requirements for utilization review at §1861(k) of the Act are reiterated in the UR CoP at 42 CFR §482.30. Therefore, a hospital meets the exception requirements of 42 CFR §482.30 if a QIO has assumed binding review for the hospital. (The hospital may not make requests for work to be performed by the QIO that goes beyond the scope of the QIO's contract with the Secretary.) The regulation at 42 CFR §489.20(e) requires a hospital to maintain an agreement with a QIO to review the admissions, quality, appropriateness, and diagnostic information related to inpatient services for Medicare patients, if there is a QIO with a contract with CMS in the area where the hospital is located. CMS anticipates that most hospitals comply with the UR CoP by means of the QIO exception. With regard to the second exception, CMS would have to determine that UR procedures established by a state under Medicaid are superior to the UR requirements for Medicare.	**DOCUMENT REVIEW** Verify that the hospital either: ▪ Has its own UR plan in place and that it meets the regulatory requirements OR ▪ Has an agreement with the QIO that provides for binding UR review. Surveyors should ask to see the signed, dated agreement. If the hospital has an agreement with a QIO, it is not necessary for surveyors to assess the remaining UR standards.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Currently no UR plans established by a state under Medicaid have been approved as exceeding the requirements under Medicare and required for hospital compliance with the Medicare UR CoP within that state.	
06.00.02 Composition of the UR Committee *UR committee consisting of two or more practitioners must carry out the UR function. At least two of the members of the committee must be doctors of medicine or osteopathic medicine. The other members may be any of the other types of practitioners specified in 42 CFR §482.12(c)(1).* *(1) Except as specified in paragraphs (b)(2) and (3) of 42 CFR 482.30, the UR committee must be one of the following:* *(i) A staff committee of the institution;* *(ii) A group outside the institution-* *(a) Established by the local medical society and some or all of the hospitals in the locality; or* *(b) Established in a manner approved by CMS* *(2) If, because of the small size of the institution, it is impracticable to have a properly functioning staff*	☐ Compliant ☐ Not Compliant Under Medicare, a QIO shall perform UR functions for a hospital. The hospital must have a contract with their QIO to perform UR functions. Under Medicaid, the state shall undertake review of UR activities in participating facilities either directly or optionally by a QIO or other contractor. If a QIO contract exists, the state plan shall comply with 42 CFR §431.630. (For risk management purposes many facilities choose to accomplish their own Utilization Review in addition to that accomplished by the QIO).	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine the composition of the UR committee. ▪ Verify that the governing body has delegated authority and responsibility to carry out the UR function to the UR committee. **Note:** Small hospitals may delegate the UR function to an outside group if it is impractical to have a staff committee. ▪ Verify that committee members are neither financially involved in the hospital (ownership of 5 percent or greater) nor participants in the development or execution of the patient's treatment plan.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
committee, the UR committee must be established as specified in paragraph (b)(1)(ii) of 42 CFR 482.30. *(3) The committee or group's reviews may not be conducted by any individual who—* *(i) Has a direct financial interest (for example, an ownership interest) in that hospital; or* *(ii) Was professionally involved in the care of the patient whose case is being reviewed.* §482.30(b) §482.30(b)(1) §482.30(b)(1)(i) §482.30(b)(1)(ii) §482.30(b)(1)(ii)(A-B) §482.30(b)(2) §482.30(b)(3) §482.30(b)(3)(i-ii)		
06.00.03 Utilization Review scope and frequency of review *(1) The UR plan must provide for review for Medicare and Medicaid patients with respect to the medical necessity of:* *(i) Admissions to the institution;* *(ii) The duration of stays;*	☐ Compliant ☐ Not Compliant Admissions may be reviewed before, during, or after hospital admission as stated in the hospital's UR plan. Reviews may be conducted on a sample basis, except for reviews of extended stay cases. In an Inpatient Prospective Payment System (IPPS) hospital, to determine outlier review compliance, "reasonably assumes" is a good faith test. The	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Examine the UR plan and other documentation to verify that the medical necessity for Medicare and Medicaid patients is reviewed with respect to admission, duration of the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(iii) Professional services furnished including, drugs and biologicals.

(2) Review of admissions may be performed before, at, or after hospital admission.

(3) Except as specified in paragraph (e) of 42 CFR 482.30, reviews may be conducted on a sample basis.

(4) Hospitals that are paid for inpatient hospital services under the prospective payment system set forth in 42 CFR 412 must conduct review of duration of stays and review of professional services as follows:

(i) for duration of stays, these hospitals need review only cases that they reasonably assume to be outlier cases based on extended length of stay, as described in 42 CFR §412.80(a)(1)(i); and

(ii) for professional services, these hospitals need review only cases that they reasonably assume to be outlier cases based on extraordinarily high costs, as described in 42 CFR §412.80(a)(1)(ii).

§482.30(c)
§482.30(c)(1)(i-iii)
§482.30(c)(2-4)(i-ii)

question to ask is whether the hospital is reviewing outlier cases.

In instances where there was no other review of outlier cases, the question is whether it was reasonable for the hospital not to have known that the cases were in fact outliers. Some medical judgment might be required to determine whether it is reasonable for the hospital to have assumed that a patient fell into a DRG other than the one eventually assigned by the intermediary. This would be an issue in long stay outlier cases where the hospital did not review because the hospital erroneously assumed that the patient was in a DRG under which the case would not have been an outlier.

stay, and the professional services furnished.

- Determine if the hospital is reimbursed under IPPS. This requirement does not apply to IPPS excluded hospitals or units.
- Verify that in an IPPS hospital the following are being reviewed:

☐ Duration of stay in cases reasonably assumed to be outlier cases; and

☐ Professional services in cases reasonably assumed to be outlier cases.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.00.04 Determination regarding admissions or continued stays	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:

1. *The determination that an admission or continued stay is not medically necessary –*
   (i) *May be made by one member of the UR committee, if the practitioner or practitioners responsible for the care of the patient as specified of 42 CFR §482.12(c) concur with the determination or fail to present their views when afforded the opportunity; and*
   (ii) *Must be made by at least two members of the UR Committee in all other cases.*
2. *Before making a determination that an admission or continued stay is not medically necessary, the URC must consult the practitioner or practitioners responsible for the care of the patient as specified in 42 CFR §482.12(c), and afford the practitioner or practitioners the opportunity to present their views.*
3. *If the committee decides that admission to or continued stay in the hospital is not medically necessary, written notification must be given, no*

When other than a doctor of medicine or osteopathic medicine makes an initial finding that the written criteria for extended stay are not met, the case must be referred to the committee, or subgroup thereof which contains at least one physician.

If the committee or subgroup agrees after reviewing the case that admissions, or extended stay is not medically necessary or appropriate, the attending physician is notified and allowed an opportunity to present his views and any additional information relating to the patient's needs for admissions or extended stay.

- When a physician member of the committee performs the initial review instead of a non-physician reviewer, and he finds that admissions or extended stay is not necessary no referral to the committee or subgroup is necessary and he may notify the attending practitioner directly.
- If the attending practitioner does not respond or does not contest the findings of the committee or subgroup or those of the physician who performed the initial review, then the findings are final.
- If the attending physician contests the committee or subgroup findings, or if he presents additional information relating to the patient's need for extended stay, at least one additional physician member of the committee must review the case.
- If the two physician members determine that the patient's stay is not medically necessary or appropriate after considering all the evidence, their determination becomes final.
- Written notification of this decision must be sent to the attending physician, patient (or next of kin), facility administrator, and the single State agency (in the case of Medicaid) no later than 2 days

DOCUMENT REVIEW

For a sample of "medically unnecessary" decisions involving admissions or continued stay and verify that these decisions are made by:

1. One member of the UR committee, if the practitioner(s) responsible for the patient's care concurs with the determination or fails to present his/her views. The practitioner must be one of those specified in §482.12(c), or

   at least two members of the UR committee in all cases not qualified under the above.
2. Verify that the physician or practitioners, as specified in §482.12(c), were informed of the committees expected decision and were given an opportunity to comment.
3. Verify that all involved parties are notified of the decision that care is medically not necessary no later than two days following the decision.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
later than 2 days after the determination, to the hospital, the patient, and the practitioner or practitioners responsible for the care of the patient. §482.30(d) §482.30(d)(1)(i-ii) §482.30(d)(2-3)	after such final decision and in no event later than 3 working days after the end of the assigned extended stay period. There are only five working days in a given week. Normally these days are Monday through Friday; however, the institution has the option to establish five other days as working days. When a holiday falls on a working day, that day is not counted as a working day. In no case may a non-physician make a final determination that a patient's stay is not medically necessary or appropriate. If, after referral of a questioned case to the committee or subgroup thereof, the physician reviewer determines that an admission or extended stay is justified, the attending physician shall be so notified and an appropriate date for subsequent extended stay review will be selected and noted on the patient's record. Written notification of this final determination must be sent to the attending physician, the patient (or next of kin), the facility administrator and the single State agency (in the case of Medicaid) no later than two days after such final determination and in no event later than three working days after the end of the assigned extended stay period. Where possible, the written notification should be received by all involved parties within the stated time period. Where appropriate and desired, verbal notification may precede written notification.	
06.00.05 <u>Utilization Review scope in Non-PPS hospitals: Extended stay review</u> 1. *In hospitals that are not paid under the prospective payment system, the UR committee must make a periodic*	☐ Compliant ☐ Not Compliant A written Utilization Review Plan is in place and includes a definition of an extended stay.	This standard is not met as evidenced by: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** ▪ Review the facility's definition of extended stay in the UR plan.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
review, as specified in the UR plan, of each current inpatient receiving hospital services during a continuous period of extended duration. *The scheduling of the periodic reviews may –* *(i) be the same for all cases or* *(ii) differ for different classes of cases.* 2. *In hospitals paid under the prospective payment system, the UR committee must review all cases reasonably assumed by the hospital to be outlier cases because of the extended length of stay exceeding the threshold criteria for diagnosis. The hospital is not required to review an extended stay that does not exceed the outlier threshold for the diagnosis.* 3. *The Utilization Review committee must make the periodic review no later than 7 days after the day required in the UR plan.* §482.30(e) §482.30(e)(1)(i-ii) §482.30(e)(2-3)		▪ Verify that the hospital's UR plan requires a periodic review of each current Medicare/Medicaid inpatient receiving hospital services of extended duration and that the review is carried out at the specified time stated in the facility's UR plan. □ The review may be the same for all cases or be different for different classes of care. □ If the committee uses a different number of days for different diagnosis or functional categories for the period of extended stay, the surveyor must verify that there is a written list with lengths of stay designated for each diagnosis of functional category. ▪ Hospitals under IPPS need only review cases reasonably assumed to be outlier cases, and extended stay that exceeds the outlier threshold for the diagnosis. ▪ Review minutes of the UR committee to verify that the periodic reviews of extended stay are carried out on or before the expiration of the stated period or no later than seven days after the day required in the hospital's plan.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.00.06 Review of professional services *The committee must review professional services provided, to determine medical necessity and to promote the most efficient use of available health facilities and services.* §482.30(f)	☐ Compliant ☐ Not Compliant ☐ NA=Not Applicable "Professional" services mean the services provided by practitioners, including both physicians and non-physician practitioners. The review includes medical necessity and efficient use of available health facilities and services. Examples of topics a committee may review are: ▪ Availability and use of necessary services - underused, overuse, appropriate use. ▪ Timeliness of scheduling of services - operating room, diagnostic. ▪ Therapeutic procedures.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the committee performs a review of professional services. ▪ Professional service includes the aspects of care rendered by laboratory personnel, physical therapists, nurses, and others, as well as services provided by anMD/DO. ▪ The review includes medical necessity and efficient use of available health facilities and services. Examples of topics a committee may review are: □ Availability and use of necessary services—underused, overuse, and appropriate use; □ Timeliness of scheduling of services—operating room, diagnostic services; □ Therapeutic procedures.

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07

INFECTION PREVENTION AND CONTROL/ ANTIBIOTIC STEWARDSHIP

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.00.00 CONDITION OF PARTICIPATION: Infection Prevention and Control and Antibiotic Stewardship Programs *The hospital must have active hospital-wide programs for the surveillance, prevention, and control of HAIs and other infectious diseases, and for the optimization of antibiotic use through stewardship.* *The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the hospital-wide quality assessment and performance improvement (QAPI) program.* §482.42	☐ Compliant ☐ Not Compliant The hospital infection control program must be hospital-wide, include all locations, all campuses, all departments, and services. This regulation requires the hospital to develop, implement, and maintain an active, hospital-wide program for the prevention, control, and investigation of infections and communicable diseases. The National Institute of Allergy and Infectious Diseases (NIAID) defines an infectious disease as a change from a state of health to a state in which part or all of a host's body cannot function normally because of the presence of an infectious agent or its product. An infectious agent is defined by the NIAID as a living or quasi-living organism or particle that causes an infectious disease, and includes bacteria, viruses, fungi, protozoa, helminthes, and prions. NIAID defines a communicable disease as a disease associated with an agent that can be transmitted from one host to another (NIAID website glossary). The hospital must provide and maintain a sanitary environment to avoid sources and transmission of infections and communicable diseases. All areas of the hospital must be clean and sanitary. This includes all hospital units, campuses, and off-site locations. The infection prevention and control program must include appropriate monitoring of housekeeping, maintenance (including repair, renovation, and construction activities), and other activities to ensure that the hospital maintains a sanitary environment. Examples of areas to monitor include: food storage, preparation, serving and dish rooms, refrigerators, ice machines, air handlers, autoclave rooms, venting systems, inpatient rooms, treatment areas, labs, waste handling, surgical areas, supply storage, equipment cleaning, etc. The hospital's program for prevention, control and investigation of infections and communicable diseases should be conducted in accordance with	This standard is not met as evidenced by: NOTE: Score based on the aggregate results of scoring of the §482.42 standards and sub-standards in this chapter.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

nationally recognized infection control practices or guidelines, as well as applicable regulations of other federal or state agencies. Examples of organizations with such guidelines and/or recommendations include: the CDC, the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of periOperative Registered Nurses (AORN). The U.S. Occupational Health and Safety Administration (OSHA) also issues federal regulations applicable to infection control practices.

To prevent, control and investigate infections and communicable diseases, the hospital's program must include an active surveillance component that covers both hospital patients and personnel working in the hospital. Surveillance includes infection detection, data collection and analysis, monitoring, and evaluation of preventive interventions.

The hospital must conduct surveillance on a hospital-wide basis to identify infectious risks or communicable disease problems at any particular location. This does not imply "total hospital surveillance," but it does mean that hospitals must have reliable sampling or other mechanisms in place to permit identifying and monitoring infections and communicable diseases occurring throughout the hospital's various locations or departments. The hospital must document its surveillance activities, including the measures selected for monitoring, and collection and analysis methods. Surveillance activities should be conducted in accordance with recognized infection control surveillance practices, such as, for example, those used by the CDC's National Healthcare Safety Net (NHSN).

The hospital must develop and implement appropriate infection control interventions to address issues identified through its detection activities, and then monitor the effectiveness of interventions through further data collection and analysis.

The infection control program includes processes to reduce the risk of growth and spread of legionella and other opportunistic pathogens in

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

building water systems.

The hospital's infection prevention and control program must be integrated into its hospital-wide Quality Assurance and Performance Improvement (QAPI) program. (See 42 CFR 482.42(b)(1).)

SPECIAL CHALLENGES IN INFECTION CONTROL

Multi-drug Resistant Organisms (MDRO)

MDROs are microorganisms that are resistant to one or more antimicrobial agents. The CDC provides a summary of recommendations to manage MDROs here: https://www.cdc.gov/infectioncontrol/guidelines/mdro/index.html. Hospitals must have mechanisms in place for the early identification of patients with targeted MDROs prevalent in their hospital and community, and for the prevention of transmission of such MDROs. When ongoing transmission of targeted MDROs in the hospital is identified, the infection prevention and control program uses this event to identify potential breaches in infection control practice.

Ambulatory Care

Ambulatory care settings, including emergency departments, present unique challenges for infection control, because patients may remain in common areas for prolonged periods of time, until they can be seen by a healthcare practitioner; examination or treatment rooms are turned around quickly with minimal cleaning; and infectious patients may not be recognized immediately. Furthermore, immuno-compromised patients may receive treatments in rooms among other patients who pose risks of infection.

The hospital's infection prevention and control program is designed with these ambulatory care setting challenges in mind. After assessing the likely level of risk in its various ambulatory care settings, including off-site settings, a hospital might identify particular settings, such as the emergency department, where it would be appropriate to employ measures for screening individuals with potentially contagious diseases during their initial patient encounter, and taking appropriate control measures for those

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

individuals who may present risk for the transmission of infectious agents by the airborne or droplet route. Guidelines from the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC) are a resource for hospitals in developing their infection control program for ambulatory care.

Communicable Disease Outbreaks

Community-wide outbreaks of communicable diseases (such as measles, SARS, or influenza) present many of the same issues and require many of the same considerations and strategies as other hospital infectious disease threats. If a communicable disease outbreak occurs, an understanding of the epidemiology, likely modes of transmission, and clinical course of the disease is essential for responding to and managing the event.

Among the infection control issues that may need to be addressed are:

- Preventing transmission among patients, healthcare personnel, and visitors.
- Identifying persons who may be infected and exposed.
- Providing treatment or prophylaxis to large numbers of people.
- Logistics issues (staff, medical supplies, resupply, continued operations, and capacity).

Pandemics present additional challenges due to the potential impact on the availability of back-up resources that would typically be available to address an outbreak confined to a smaller geographic area.

Bioterrorism

A bioterrorism event presents issues similar to naturally occurring communicable disease threats. An appropriate response is likely to differ based on whether exposure is a result of a biological release or person-to-person transmission.

A variety of sources offer guidance for the management of persons exposed to likely agents of bioterrorism, including federal agency websites.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Because of the many similarities between man-made and naturally occurring threats, an all-hazards approach to emergency response is preferred, and hospitals are encouraged to work with their state and local emergency response agencies when developing their plans.	
07.00.01 Responsibilities of the governing body The governing body must ensure all of *the following:* *(i) Systems are in place and operational for the tracking of all infection surveillance, prevention and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.* *(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with the hospital's QAPI leadership.* §482.42(c)(1) §482.42(c)(1)(i-ii)	☐ Compliant ☐ Not Compliant The governing body ensures the resources are available to implement an effective infection prevention and control program, including an antibiotic stewardship program. The governing body regularly receives information on the effectiveness of the program and corrective action plans when needed as determined though the reporting mechanisms.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview members of leadership to discuss the implementation issues of the infection prevention and control program and antibiotic stewardship program. ▪ Determine whether the hospital's infection prevention and control program is integrated into its hospital-wide QAPI program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

07.00.02 Infection prevention and control leadership

The hospital must demonstrate that:

- *An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body as the infection preventionist(s)/ infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership.*

A person or persons must be designated as Infection Control Officer (ICO) or officers to develop and implement policies governing control of infections and communicable diseases.

§482.42(a)(1)

☐ Compliant ☐ Not Compliant

The hospital must designate in writing an individual or group of individuals as its infection preventionist(s)/infection control officer(s). In designating infection preventionist(s)/infection control officer(s), hospitals should assure that the individuals so designated are qualified through education, training, experience, or certification (such as that offered by the Certification Board of Infection Control and Epidemiology (CBIC), or by the specialty boards in adult or pediatric infectious diseases offered for physicians by the American Board of Internal Medicine (for internists) and the American Board of Pediatrics (for pediatricians)). Infection control officers should maintain their qualifications through ongoing education and training, which can be demonstrated by participation in infection control courses, or in local and national meetings organized by recognized professional societies, such as APIC and SHEA.

The number of infection preventionist(s)/infection control officer(s) to be designated or the number of that must be devoted to the infection prevention and control programs are not quantified. However, resources must be adequate to accomplish the tasks required for the infection control program. A prudent hospital would consider patient census, characteristics of the patient population, and complexity of the healthcare services it offers in determining the size and scope of the resources it commits to infection control. The CDC's HICPAC as well as professional infection control organizations such as the APIC and the SHEA publish studies and recommendations on resource allocation that hospitals may find useful.

The infection preventionist(s)/infection control officer(s) must develop and implement policies governing the control of infections and communicable diseases. Infection control policies should address the roles and responsibilities for infection control within the hospital; how the various hospital committees and departments interface with the infection control program; and how to prevent infectious/communicable diseases; and how to

This standard is not met as evidenced by:

DOCUMENT REVIEW

- Verify infection preventionist(s)/ infection control officer(s) is(are) designated with assigned responsibility for the infection prevention and control program.
- Verify the infection preventionist(s)/ infection control officer(s) developed and implemented hospital infection control policies.
- Review the personnel file of the infection preventionist(s)/infection control officer(s) to determine qualifications to oversee the infection control program through ongoing education, training, experience, or certification.

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report infectious/communicable diseases to the infection control program.

07.00.03 Responsibilities of the infection prevention and control professional

The infection prevention and control professional(s) is responsible for:

(i) The development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

(iii) Communication and collaboration with the hospital's QAPI program on infection prevention and control issues.

(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of infection prevention and control guidelines, policies and procedures.

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control

☐ Compliant ☐ Not Compliant

The job description for the infection prevention and control professional(s) describes all requirements listed in the standard.

The hospital provides evidence of the required policies, surveillance reports, and staff training.

Infection prevention and control issues are integrated into the hospital's Quality Assurance Performance Improvement program (QAPI).

The successful development, implementation and evaluation of a hospital-wide infection prevention and control program requires frequent collaboration with persons administratively and clinically responsible for inpatient and outpatient departments and services, as well as, non-patient-care support staff, such as maintenance and housekeeping staff.

The infection preventionist(s)/infection control officer(s) responsibility for measures to identify, investigate, report, prevent and control infections and communicable diseases include the following activities:

1. Maintenance of a sanitary hospital environment.
2. Development and implementation of infection control measures related to hospital personnel; hospital staff, for infection control purposes, includes all hospital staff, contract workers (e.g., agency nurses, housekeeping staff, etc.), and volunteers.
3. Mitigation of risks associated with patient infections present upon admission.
4. Mitigation of risks contributing to healthcare-associated infections.
5. Active surveillance.

This standard is not met as evidenced by:

DOCUMENT REVIEW

Verify:

- The job description for the infection prevention and control professional reflects the required elements of this standard.
- The written infection prevention and control policies reference national guidelines.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
policies and procedures by hospital personnel. *(vi) Communication and collaboration with the antibiotic stewardship program.* §482.42(c)(2) §482.42 (c)(2)(i-vi)	6. Monitoring compliance with all policies, procedures, protocols, and other infection control program requirements. 7. Program evaluation and revision of the program, when indicated. 8. Coordination as required by law with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks. 9. Complying with the reportable disease requirements of the local health authority.	
07.00.04 Committee (function) structure	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The chairperson of the infection control committee (function) is a physician (Doctor of Medicine/Doctor of Osteopathic Medicine) member of the active Medical Staff. Other members of the professional staff are active in the infection control function. The hospital shall determine the meeting frequency and attendance requirements for the Infection Control Committee. The committee must meet, at a minimum, quarterly. One person may represent more than one area, but the areas represented must be reflected in the minutes.	Physician members of the function should be representative of the Medical Staff. Minimum attendance will include the following: ▪ MD/DO program coordinator. ▪ infection preventionist(s)/infection control officer(s). ▪ Administration. ▪ Medical staff participation by department, as appropriate. ▪ Appropriate clinical staff (OB, ICU, etc.). ▪ Microbiology department representation. ▪ Housekeeping department representation. ▪ Central/sterile supply representation. ▪ Surgery department management and/or clinical representative. ▪ Other appropriate clinical departments as identified. The Infection Control Committee (function) has determined a regular reporting schedule and reviews healthcare-associated infections. The	**DOCUMENT REVIEW** ▪ Determine the appointments and attendance of physicians for this function. Is a pathologist or an infection disease specialist available for consult to the Medical Staff? ▪ Does the committee have representation across the facility? ▪ Verify the hospital conducts an annual review of the infection prevention and control plan in the Infection Prevention and Control Committee minutes or the Medical Staff minutes.

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	committee is responsible to: 1. Establish techniques of discovering and reporting infections and tracing sources of infection of patients and hospital personnel. 2. Establish techniques for prevention, handling, and control of institutional infections. 3. Review findings of conditions within the hospital. The annual Employee Health Plan is approved by the Infection Control Committee (function).	
07.00.05 Infection control plan The Infection Control Committee shall develop and implement an infection control plan for the hospital.	☐ Compliant ☐ Not Compliant The facility has an annual Infection Control Plan approved by the Infection Control Committee (function). The Infection Prevention and Control Committee develops and implements a hospital-wide coordinated plan, which includes the following: ▪ All departments and patient services located within the hospital. The combination of plans of all the departments/services may serve as the infection control manual for the hospital. ▪ Development of policies and procedures in each department/service relative to infection prevention and control with assistance and approval of the infection control committee. ▪ Provision for cleaning and care of all equipment including a formula for every mixture prepared in the department/service for use in the cleaning procedures. Each solution shall have a proven effective spectrum of germicidal action. ▪ Provides for an annual review of the plan. Activity reports from the infection prevention and control committee are	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the Infection Control Committee minutes or the Medical Staff minutes when it acts as a committee-of-the-whole. ▪ Verify the hospital has an annual infection control plan. ▪ Verify there are hospital-wide policies and procedures for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases of patients and hospital personnel, including contract personnel and volunteers. ▪ Verify the policies and procedures have been implemented correctly in an active infection control program.

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	discussed by the professional medical staff at least quarterly.	
07.00.06 Scope and complexity of services *The infection prevention and control program reflects the scope and complexity of the hospital services provided.* §482.42(a)(4)	☐ Compliant ☐ Not Compliant Infection control policies address the roles and responsibilities for infection control within the hospital and considers patient census, characteristics of the patient population, and complexity of the healthcare services it offers in determining the size and scope of the resources it commits to infection control.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ The infection prevention and control program is hospital-wide and program specific in gathering and assessing infection and communicable disease data. ▪ The infection control program can identify all hospital locations and that the policies and procedures take the various hospital locations into account.
07.00.07 Unified multi-hospital Infection Prevention and Control Program *If a hospital is part of a hospital system consisting of multiple separately certified hospitals using a system governing body that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is*	☐ Compliant ☐ Not Compliant ☐ Not Applicable (not part of a system) The governing body is expected to ensure the various factors specific to one or more of the hospitals within a multi-hospital system are addressed. These factors include, but are not limited to, the scope and complexity of hospital services offered, specific patient populations served by a hospital, and any issues regarding the infection prevention and control and antibiotic stewardship programs. Each hospital must independently meet the requirements of the standards in this chapter. The hospital must also provide evidence that the governing body is appropriately responsive to any periodic and/or urgent issues identified by the individual hospital.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ The programs reflect the patient population, services, etc. of the hospital. ▪ Information specific to the hospital is communicated to the multi-hospital system governing body.

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responsible and accountable for ensuring that each of its separately certified hospitals meets all the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital;

(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular hospitals are duly considered and addressed.

§482.42(d)(1-3)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.00.08 Unified multi-hospital Infection Prevention and Control Program leadership *A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the hospital as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to hospital staff.* *§482.42(d)(4)*	☐ Compliant ☐ Not Compliant ☐ Not Applicable (not part of a system) The infection prevention and control professional(s) has an established communication channel to the governing body of the multi-hospital system.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that information about the hospital's infection prevention and control and antibiotic stewardship programs is communicated to the governing body.
07.00.09 COVID-19 reporting *During the Public Health Emergency, as defined in §400.200, the hospital must report information in accordance with a frequency as specified by the Secretary of the Department of Health and Human Services (HHS) on COVID–19 in a*	☐ Compliant ☐ Not Compliant **Note: This standard was added by addendum in 2021.** Medicare and Medicaid participation requires that CAHs report data critical to the management and mitigation of COVID-19. Data submission as specified by the Secretary is subject to change, but may include: ▪ The number of staffed beds and the number of those that are occupied.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview members of the leadership team to discuss the reporting process. Verify: ▪ Hospital policy provides details of the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
standardized format specified by the Secretary. *This report must include, but not be limited to, the following data elements:* *(1) The hospital's current inventory of supplies of any COVID–19-related therapeutics that have been distributed and delivered to the hospital under the authority and direction of the Secretary; and* *(2) The hospital's current usage rate for any COVID–19-related therapeutics that have been distributed and delivered to the hospital under the authority and direction of the Secretary.* §482.42(e) §482.42(e)(1-2)	▪ Information about ventilator and personal protective equipment (PPE) supplies. ▪ A count of patients currently hospitalized who have laboratory confirmed COVID–19. Hospital policy defines the process for reporting the required information at the frequency and in the format specified by the Secretary, Department of Health and Human Services, during the COVID–19 PHE. All Medicare participating hospitals will track their inventory supplies and usage rates in real time for those COVID–19-related therapeutics that have been distributed and delivered by HHS so that public health officials can maintain a robust and accurate database to efficiently and effectively manage the distribution and delivery of these therapeutics, particularly to regions of the country that might be experiencing shortages of these supplies. HHS has approved options for submitting data: 1. To the state. 2. To the organization's authorized health IT vendor or other third-party to share directly with HHS. 3. To TeleTracking™ □ https://teletracking.protect.hhs.gov. □ All instructions on data submission are provided on that site. 4. Publish to the hospital or facility's website in a standardized format, such as schema.org. Use one of the methods in items 1-3 above until your ASPR Regional Administrator or HHS Protect notifies you that this implementation is being received.	reporting process. ▪ The hospital has implemented its policy for reporting data in accordance with the frequency and format in accordance with the Secretary, HHS.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

07.00.10 Reporting of acute respiratory illness, including seasonal influenza virus, influenza-like illness, and severe acute respiratory infection

During the Public Health Emergency, as defined in §400.200 the hospital must report information, in accordance with a frequency as specified by the Secretary of the Department of Health and Human Services (HHS), on acute respiratory illness (including, but not limited to, seasonal influenza virus, influenza-like illness, and severe acute respiratory infection) in a standardized format specified by the Secretary.

§482.42(f)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Note: This standard was added by addendum in 2021.

New reporting requirements at §482.42(f) do not relieve a hospital of its obligation to comply with §482.42(a)(3) (Standard 07.02.02) which requires a facility to address any infection prevention and control issues identified by public health authorities.

Hospital policy must define the process for reporting the required information at the frequency and in the format specified by the Secretary, during the COVID–19 PHE.

Examples of data elements that may be required include:

- Diagnoses.
- Admissions.
- Counts of patients currently hospitalized who have diagnoses of acute respiratory illnesses.

ENFORCEMENT OF REQUIREMENTS

Should a hospital consistently fail to report data related to patient diagnoses of acute respiratory illness throughout the duration of the public health emergency (PHE) for COVID–19, it will be noncompliant with the hospital CoPs set forth at § 482.42(f) and subject to termination as defined at 42 CFR 489.53(a)(3).

INTERVIEW AND DOCUMENT REVIEW

- Interview members of the leadership team to discuss the reporting process.

Verify:

- Hospital policy provides details of the reporting process.
- The hospital has implemented its policy for reporting data in accordance with the frequency and format defined by the Secretary, HHS.

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07.01.01 Responsibilities of the Antibiotic Stewardship Program leader *The leader(s) of the antibiotic stewardship program is responsible for:* *(i) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.* *(ii) All documentation, written or electronic, of antibiotic stewardship program activities.* *(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the hospital's infection prevention and control and QAPI programs, on antibiotic use issues.* *(iv) Competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospitals, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.* §482.42(c)(3) §482.42(c)(3)(i-iv)	☐ Compliant ☐ Not Compliant The job description for the Antibiotic Stewardship Program professional(s) describes all requirements listed in the standard. The hospital provides evidence of the required policies, surveillance reports, and staff training. Antibiotic stewardship activities and issues are integrated into the hospital's Infection Prevention and Control Program.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ The job description for the antibiotic stewardship professional reflects the required elements of this Standard. ▪ The written antibiotic stewardship policies reference national guidelines.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.01.02 Antibiotic Stewardship Program leadership	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital must demonstrate that: ▪ *An individual (or individuals), qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body, or responsible individual, as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership.* §482.42(b)(1)	The hospital must designate in writing an individual to lead its antibiotic stewardship program. The hospital defines the qualifications required for the individual responsible for the antibiotic stewardship program. This individual may or may not be a physician. This person may or may not be the Infection Prevention and Control Officer/Coordinator responsible for the infection control program of the facility.	**DOCUMENT REVIEW** ▪ The job description for the antibiotic stewardship professional reflects the required elements of this standard. ▪ Verify the appointment is based on the recommendations of the medical staff leadership and pharmacy leadership.
07.01.03 Facility-wide Antibiotic Stewardship Program	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The facility-wide antibiotic stewardship program: (i) *Demonstrates coordination among all components of the hospital responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;* (ii) *Documents the evidence-based use of antibiotics in all departments and*	The hospital implements an antibiotic stewardship program to help reduce inappropriate antibiotic use and antimicrobial resistance in the facility. The hospital plays an important role in combatting antimicrobial resistance through implementation of a robust stewardship program that follows nationally recognized guidelines for appropriate antibiotic use.	**DOCUMENT REVIEW** Verify: ▪ Information from the antibiotic stewardship program is integrated into the Infection Prevention and Control Program and communicated to the QAPI Program and appropriate services/ departments. ▪ The hospital has reviewed evidence-based use of antibiotics and incorporated the findings into its practices.

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services of the hospital; and (iii) *Documents any improvements, including sustained improvements, in proper antibiotic use.* §482.42(b)(2) §482.42(b)(2)(i-iii)		▪ Program improvements are documented.
07.01.04 Antibiotic stewardship guidelines *The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use.* §482.42(b)(3)	☐ Compliant ☐ Not Compliant The hospital's program demonstrates adherence to nationally recognized infection prevention and control guidelines for reducing the transmission of infections, as well as best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. The hospital selects the nationally recognized guidelines to follow such as those established by the Association for Professionals in Infection Control and Epidemiology (APIC), the Society for Healthcare Epidemiology of America (SHEA), and the Association of perioperative Registered Nurses (AORN). The U.S. Occupational Health and Safety Administration (OSHA) also issues federal regulations applicable to infection control practices. This approach will provide hospitals the flexibility they need to select and integrate those standards that best suit their individual infection prevention and control and antibiotic stewardship programs. This approach will allow hospitals the flexibility to adapt their policies and procedures in concert with any updates in the guidelines they have elected to follow.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the program bases antibiotic use on nationally recognized guidelines.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.01.05 Scope and complexity of the Antibiotic Stewardship Program *The antibiotic stewardship program reflects the scope and complexity of the hospital services provided.* §482.42(b)(4)	☐ Compliant ☐ Not Compliant The Antibiotic Stewardship Program is reflective of all departments of the facility and all outpatient areas.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ The Antibiotic Stewardship Program is hospital-wide. ▪ The Antibiotic Stewardship Program can identify all hospital locations and that the policies and procedures take the various hospital locations into account.
07.02.01 Risk mitigation measures for infection prevention The hospital has identified activities to mitigate risks associated with acquiring infections. *The hospital infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings.* §482.42(a)(2)	☐ Compliant ☐ Not Compliant The infection prevention program implements and evaluates measures governing the identification, investigation, reporting, prevention and control of infections and communicable diseases within the hospital, including both healthcare–associated infections and community-acquired infections. Infection prevention and control policies should be specific to each department, service, and location, including off-site locations, and be evaluated and revised when indicated. **MAINTENANCE OF A SANITARY PHYSICAL ENVIRONMENT** A hospital with a comprehensive hospital-wide infection control program should have and implement policies and procedures, based as much as possible on national guidelines, that address the following: ▪ Ventilation and water quality control issues, including measures taken to maintain a safe environment during internal or external construction/renovation. ▪ Maintaining safe air handling systems in areas of special ventilation, such	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify that the hospital: ▪ Maintains a sanitary environment. ▪ Develops and implements infection control measures related to hospital personnel. ▪ Mitigates risks associated with patient infections present upon admission. ▪ Mitigates risks contributing to healthcare-associated infections (for example, observe whether staff exhibit good hand washing hygiene). ▪ Conducts active surveillance. ▪ Coordinates as required by law with federal, state, and local emergency

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	as operating rooms, intensive care units, and airborne infection isolation rooms. ▪ Techniques for food sanitation. ▪ Techniques for cleaning and disinfecting environmental surfaces, carpeting and furniture. ▪ Techniques for textiles reprocessing, storage, and distribution. ▪ Techniques for disposal of regulated and non-regulated waste. ▪ Techniques for pest control. ▪ Techniques for infection control risk mitigation for corrugated cardboard boxes. **HOSPITAL STAFF-RELATED MEASURES** ▪ Measures—and authority—for evaluating hospital staff immunization status for designated infectious diseases, as recommended by the CDC and its Advisory Committee on Immunization Practices (ACIP). ▪ Policies articulating the authority and circumstances under which the hospital screens hospital staff for infections likely to cause significant infectious disease or other risk to the exposed individual, and for reportable diseases, as required under local, state, or federal public health authority. ▪ Policies articulating when infected hospital staff are restricted from providing direct patient care and/or are required to remain away from the healthcare facility entirely. ▪ New employee and regular update training in preventing and controlling healthcare-associated infections and methods to prevent exposure to and transmission of infections and communicable diseases. ▪ Measures to evaluate staff and volunteers exposed to patients with infections and communicable disease. ▪ **Risk mitigation measures are implemented to decrease infectious risk**	preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks. ▪ Complies with the reportable disease requirements of the local health authority.

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associated with corrugated containers to ensure a safe, sanitary environment. Diligence is demonstrated to remove corrugated containers throughout the facility, including from high-risk areas, such as Central Sterile, Procedural Areas, Compounding Pharmacy, specialty patient care units, etc. Receiving, breakdown, and distribution of supplies is an important aspect of sterility. Infection risk assessments should be conducted for specific items which cannot be removed from corrugated boxes which stratifies the risk of potential infection to the loss or damage of product.

MITIGATION OF RISKS ASSOCIATED WITH PATIENT INFECTIONS PRESENT UPON ADMISSION

- Measures for the early identification of patients who require isolation in accordance with CDC guidelines.
- Appropriate use of personal protective equipment including gowns, gloves, masks and eye protection devices.
- Use and techniques for "isolation" precautions as recommended by the CDC.

MITIGATION OF RISKS CONTRIBUTING TO HEALTHCARE-ASSOCIATED INFECTIONS

1. **Surgery-related infection risk mitigation measures:**
   - □ Implementing appropriate prophylaxis to prevent surgical site infection (SSI), such as a protocol to assure that antibiotic prophylaxis to prevent surgical site infection for appropriate procedures is administered at the appropriate time, done with an appropriate antibiotic, and discontinued appropriately after surgery;
   - □ Addressing aseptic technique practices used in surgery and invasive procedures performed outside the operating room, including sterilization of instruments.
2. **Other Healthcare-Associated Infection Risk Mitigation Measures:**

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- ☐ Promotion of hand-washing hygiene among staff and employees, including utilization of alcohol-based hand sanitizers.
- ☐ Measures specific to prevention of infections caused by organisms that are antibiotic-resistant.
- ☐ Measures specific to prevention of device-associated bloodstream infection (BSI), such as a protocol for reducing infections of central venous catheters specifying aseptic precautions for line insertions, care of inserted lines, and prompt removal when a line is no longer needed.
- ☐ Measures specific to prevention of other device-associated infections, e.g., those associated with ventilators, tube feeding, indwelling urinary catheters, etc.
- ☐ Isolation procedures and requirements for highly immuno-suppressed patients who require a protective environment.
- ☐ Care techniques for tracheostomy care, respiratory therapy, burns and other situations that reduce a patient's resistance to infection.
- ☐ Requiring disinfectants, antiseptics, and germicides to be used in accordance with the manufacturers' instructions.
- ☐ Appropriate use of facility and medical equipment, including negative and positive pressure isolation room equipment, portable air filtration equipment, treatment booths and enclosed beds, UV lights, and other equipment used to control the spread of infectious agents.
- ☐ Adherence to nationally recognized infection prevention and control precautions, such as current CDC guidelines and recommendations, for infections/communicable diseases identified as present in the hospital.
- ☐ Educating patients, visitors, caregivers, and staff, as appropriate, about infections and communicable diseases and methods to reduce transmission in the hospital and in the community.

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07.02.02 Surveillance *The infection prevention and control includes surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also addresses any infection control issues identified by public health authorities.* §482.42(a)(3)	☐ Compliant ☐ Not Compliant The hospital is expected to identify and track infections and communicable diseases in any of the following categories occurring throughout the hospital, whether in patients or staff (patient care staff and non-patient care staff, including employees, contract staff and volunteers). ▪ Healthcare-associated infections selected by the hospital's Infection Prevention and Control Program as part of a targeted surveillance strategy based on nationally recognized guidelines and periodic risk assessment. ▪ Patients or staff with identified communicable diseases that local, State, or Federal health agencies require be reported. ▪ Patients identified by laboratory culture as colonized or infected with multi-drug-resistant organisms (MDROs), as defined by the hospital's Infection Prevention and Control Program. ▪ Patients who meet CDC criteria for requiring isolation precautions (other than "Standard Precautions" or a protective environment) during their hospitalization. Definitions of healthcare-acquired and community-acquired infections are based upon current CDC criteria and are applicable to both patient and staff infections.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify that: ▪ The hospital performs active surveillance to identify infections. ▪ The hospital documents surveillance activities, including the measures selected for monitoring, and collection and analysis methods. ▪ The hospital implements appropriate infection control interventions to address issues identified. ▪ The parameters of the active surveillance program are consistent with infection control standards of practice and suitable to the scope and complexity of the hospital's services. ▪ The facility coordinates with federal, state, and local health authorities, as required by law, regarding reportable diseases and other infection control issues.

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07.02.03 Environmental Surveillance In addition to reports of actual infections and communicable diseases, the infection prevention and control leader submits reports to the Professional Medical Staff, Safety Committee, and the Infection Control Committee (function) regarding environmental surveillance activities.	☐ Compliant ☐ Not Compliant "Walking rounds" are conducted to assess conformance with standard precautions and aseptic principles. Environmental surveillance reports are submitted to the Professional Medical Staff, Safety Committee, and Infection Control Committee (function) for review. Environmental surveillance reports are communicated to clinical areas, as appropriate. Collecting cultures of the environment is discouraged unless a specific problem is being monitored.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Observe for sanitary condition of the environment of care (cleanliness of patient rooms, floors, horizontal surfaces, patient equipment, air inlets, mechanical rooms, food service activities, treatment and procedure areas, surgical areas, central supply, storage areas, etc.) ▪ Review the parameters of the surveillance program to verify suitability to the scope and complexity of the hospital's services. Verify: ▪ Meeting minutes include evidence that summaries of such surveillance have been discussed. ▪ Environmental surveillance activities are included in the hospital wide QAPI program.
07.02.04 Personal protective equipment (PPE) The healthcare organization, in accordance with nationally recognized standards of practice (OSHA, CDC, APIC), must: ▪ Define in policies and procedures the	☐ Compliant ☐ Not Compliant PPE in the healthcare setting includes the use of specialized clothing or equipment worn by an employee for protection against infectious material. The purpose of PPE is for infection prevention and control and to improve safety in the healthcare environment. The healthcare organization, in accordance with nationally recognized	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Observe staff donning and removing PPE. Verify: ▪ Policies and procedures are based on national guidelines.

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circumstances in which PPE must be worn and specifies the clinical conditions for which specific PPE should be used. ▪ Provide training on appropriate use of PPE to avoid the spread of contamination. ▪ Provide adequate and available supplies necessary for adherence to proper personal protective equipment (PPE) use.	standards of practice (OSHA, CDC, APIC), must: ▪ Outline in policies and procedures the circumstances in which PPE must be worn, including but not limited to, Standards and Transmission Based Precautions such as Contact, Droplet, and Airborne precautions to be followed to prevent spread of infections; which includes selection and use of PPE (e.g., indications, donning/doffing procedures) and specifies the clinical conditions for which specific PPE should be used (e.g., *C. difficile,* influenza). ▪ Provide training on appropriate use of PPE to avoid the spread of contamination ▪ Provide adequate supplies necessary for adherence to proper PPE use (e.g., donning/doffing gloves, gowns, masks). These supplies are to be readily accessible in-patient care areas (i.e., nursing units, therapy rooms, and patient rooms). Necessary elements are to include providing adequate respiratory protection such as medical evaluations, fit testing, and training. The policies and procedures address direct and indirect care for infectious patients and include, at a minimum: ▪ Patient care equipment and instruments ▪ Patient placement ▪ Environmental measures ▪ Transport of patients ▪ Textiles and laundry ▪ Waste disposal ▪ Dishware and eating utensils ▪ Adjunctive measures such as post-exposure chemoprophylaxis ▪ Management of visitors ▪ Monitored use of PPE	▪ Training for PPE occurs in orientation and periodically thereafter. ▪ Monitoring occurs for proper use of PPE.

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07.02.05 Hand-washing guidelines The hospital adopts nationally recognized guidelines that are identified as effective in improving patient safety through the prevention of person-to-person transmission of infections.	☐ Compliant ☐ Not Compliant The Centers for Disease Control and Prevention (CDC) "Guideline for Hand Hygiene in Health-Care Settings" recommendations are the standards of practice that serve as the template for development of organizational standards of practice. APIC and SHEA may also be referenced for developing policies on nationally recognized guidelines. Written policies and procedures regarding hand decontamination and the prevention of infections are implemented and address at the least the following: 1. Use of alcohol-based hand rubs (ABHR). 2. Surgical hand antisepsis. 3. Elimination of the use of artificial nails for ALL staff working in intensive care units and operating rooms. 4. Natural nail tips limited to ¼ inch in length. 5. Required glove use and glove changing requirements. There are adequate handwashing facilities, including readily available ABHR dispensers. Each hand-washing sink has a soap dispenser and a method for hand drying.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify the facility has taken actions to prevent infection by implementing evidence-based hand hygiene practices, preferably those established by the Centers for Disease Control and Prevention. ▪ Review the organizational policies on hand hygiene to ensure they include, at a minimum, elements 1-5. ▪ Observe hand hygiene technique throughout the organization in all areas where patient care is delivered to determine if organization policies are being followed.
07.02.06 Reduce risk of Legionella in water systems The infection control plan includes processes to reduce the risk of growth and spread of legionella and other opportunistic pathogens in building water systems. **The infection control leader collaborates**	☐ Compliant ☐ Not Compliant Legionnaire's disease, a severe sometimes fatal pneumonia, can occur in persons who inhale aerosolized droplets of water contaminated with the bacterium legionella. The infection control coordinator collaborates with the facilities manager to reduce the risk of growth and spread of legionella and other opportunistic pathogens in the water systems. Outbreaks generally are linked to	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The hospital implements a water management program that considers the ASHRAE industry standard and the CDC

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with a multi-disciplinary team to reduce the risk of growth and spread of legionella and other opportunistic pathogens in the water systems. §482.42	environmental reservoirs in large or complex water systems, including those found in healthcare facilities such as hospitals and long-term care facilities. Legionella can grow in parts of building water systems that are continually wet, and certain devices can spread contaminated water droplets via aerosolization. Examples of these system components and devices include: ▪ hot- and cold-water storage tanks. ▪ water heaters. ▪ water-hammer arrestors. ▪ pipes, valves, and fittings. ▪ expansion tanks. ▪ water filters. ▪ electronic and manual faucets. ▪ Aerators. ▪ faucet flow restrictors. ▪ showerheads and hoses. ▪ centrally-installed misters, atomizers, air washers, and humidifiers. ▪ non-steam aerosol-generating humidifiers. ▪ eyewash stations. ▪ ice machines. ▪ hot tubs/saunas. ▪ decorative fountains. ▪ cooling towers. ▪ medical devices (e.g., CPAP machines, hydrotherapy equipment, bronchoscopes, heater-cooler units). **The hospital must implement a Water Management Program that considers the ASHRAE industry standard and the CDC toolkit, and includes control**	toolkit, and includes control measures such as physical controls, temperature management, disinfectant level control, visual inspections, and environmental testing for pathogens. ▪ **A water management multi-disciplinary team has been identified and roles developed.** ▪ **A description of the building water system is available in text and diagram formats.** ▪ **A risk assessment has been completed that identifies patient risks, and water sources that are opportunistic to pathogen growth.** ▪ **Control points have been identified with measures and monitoring procedures have been implemented.** ▪ **Outbreak and contingency plans have been developed and implemented.** ▪ **A communication plan is developed and provided to hospital staff as per the hospital policy.** ▪ **The infection control plan addresses a water management program.**

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	measures such as physical controls, temperature management, disinfectant level control, visual inspections, and environmental testing for pathogens. **The Infection Control Committee (function):** ▪ **Verifies the Water Management Program has been implemented as designed.** ▪ **Reviews and approves the hospital risk assessment to identify where legionella and other opportunist waterborne pathogens could grow and spread.** ▪ **Reviews and approves the Water Management Program, including actions taken to reduce the growth and spread of legionella and other opportunist water pathogens.** ▪ **Validates conditions and outcomes to ensure the Water Management Program is effective. This validation must be completed and documented annually.** **Procedures for measuring and monitoring the water system are implemented and testing is conducted based on the hospital risk assessment and in accordance with hospital policy and nationally recognized standards of practice.** **Once the Water Management Program has been implemented, a communication plan is developed and shared with the staff on a routine basis as established by the hospital policy.**	
07.02.07 <u>Prevention of infections: Central venous catheters</u> The organization adopts nationally recognized clinical practice standards that are identified as effective in improving patient safety through the prevention of	☐ Compliant ☐ Not Compliant Vascular catheter-related infections are the leading cause of hospital-associated blood stream infections and are associated with significant morbidity in critically ill patients. Most central venous catheter-related infections are considered preventable.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Verify the facility has taken actions to prevent central line-associated bloodstream infection by implementing

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infection: ▪ The prevention of central venous catheter-related infections The organization adheres to effective methods of preventing central venous catheter-related blood stream infections. Organizational policies and procedures reflect evidence-based strategies for infection reduction and processes to monitor compliance and infection rates.	Evidence shows that most central venous catheter-related infections are caused by organisms that colonize the skin at the insertion site and migrate down the extra luminal surface of the catheter through the transcutaneous tract created at the time of insertion. **IMPLEMENTATION APPROACHES** ▪ "Before insertion" practices, include: □ Use of aseptic technique during central line insertion. □ Disinfecting skin with an appropriate antiseptic before catheter insertion and at the time of dressing changes in accordance with evidence-based guidelines. ▪ After insertion practices, include: □ Disinfection of catheter hubs and injection ports before accessing the ports. □ The prompt removal of the catheter as soon as it is no longer essential.	evidence-based practices. ▪ Review the policy for central catheter insertion and care. It must reflect: □ Evidence-based strategies for infection reduction, and □ Define a process to monitor compliance and infection rates. ▪ Review patient records to determine compliance with the policy.
07.02.08 <u>Surgical site infections (SSI)</u> The organization adopts nationally recognized clinical practice guidelines that are identified as effective in improving patient safety through the reduction of surgical site infections.	☐ Compliant ☐ Not Compliant The organization ensures the evaluation of each preoperative patient in light of his or her planned surgical procedure for the risk of SSI and implements appropriate antibiotic prophylaxis and other preventive measures based on that evaluation. Organizational policies and procedures are in place regarding the prevention of SSI's, including selection, timing, and discontinuation of antibiotics. Antibiotic prophylaxis should be given according to nationally recognized guidelines. Feedback to the surgical team and OR staff of surgical infection rates is important for ongoing infection-reduction efforts. Infection trends are monitored and corrective actions are taken when appropriate.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Verify the facility has taken actions to prevent surgical-site infection by implementing evidence-based practices. ▪ Review the organizational policies on prevention of surgical site infections for content. The policies should, at minimum, address the elements below. □ Evidence-based strategies for infection reduction □ Define a process to monitor

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		compliance and infection rates. ▪ Review inpatient and outpatient surgical records to determine if: □ The risk assessment for SSI was completed. □ The appropriate plan of care and intervention was documented as completed.
07.02.09 Recall process There is a process for the recall and disposal or reprocessing of outdated or contaminated patient care supplies/ equipment.	☐ Compliant ☐ Not Compliant If products are recalled due to ineffective sterilization, a process exists: ▪ To notify the physician(s) of patients for whom these supplies may have been used. ▪ To remove the products from patient care.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review policies related to the product recall mechanism to verify they address: □ The provision for physician notification. □ The removal of products from patient care.
07.03.01 Staff orientation and training There is a hospital-wide plan for staff orientation and ongoing training in infection prevention and control.	☐ Compliant ☐ Not Compliant The infection preventionist(s)/infection control officer(s) is responsible for competency-based training and education of hospital personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the hospital, on the practical applications of infection prevention and control guidelines, policies and procedures. Ongoing education is provided appropriate to the topic and when identified through analysis of trends.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ As infection control content is mandatory for clinical caregivers and highly encouraged for support staff, this content is to be noted in the orientation and reorientation curricula. ▪ Interview staff to verify content is

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		covered in orientation and during annual education events.
07.03.02 Employee health policies The Infection Control Committee shall establish and evaluate employee health policies.	☐ Compliant ☐ Not Compliant The employee health plan identifies the reports to be collected and submitted quarterly for review by the Medical Staff and the Infection Control Committee(function). These employee health reports include: ▪ workdays lost. ▪ immunization rate. ▪ employee screening, etc. A process is in place to: 1. Record employee injuries and illnesses using the OSHA-mandated Form 300 "Log of Work-Related Injuries and Illnesses." 2. Complete and post the annual OSHA Form 300A "Summary of Work-Related Injuries and Illnesses report," per OSHA instructions. 3. Complete OSHA Form 301 "Injury and Illness Incident Report."	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the Infection Control Committee minutes or the medical staff minutes when it acts as a committee-of-the-whole to verify the facility has an employee health policy, approved annually by the Infection Control Committee (function).
07.03.03 Employee health: Vaccines for healthcare workers Vaccinations are made available to all healthcare workers **in accordance with state and federal law**. The vaccination status of all employees is maintained. **There is a process in place for ensuring all**	☐ Compliant ☐ Not Compliant **Healthcare workers (HCWs) are at risk for exposure to serious, and sometimes deadly, diseases. HCWs who work directly with patients or handle material that could spread infection, get appropriate vaccines to reduce the chance that they will get or spread vaccine-preventable diseases.**	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The hospital has taken actions to prevent diseases by implementing evidence-based practices, preferably those established by

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employees are vaccinated as required by hospital policy or have been granted an exemption.	**Recommended vaccines for HCWs include:** ▪ **Hepatitis B: Serologic evidence of immunity or complete Hep B vaccine series** ▪ **Flu (Influenza): One dose annually** ▪ **MMR (Measles, Mumps, & Rubella): Serologic evidence of immunity or MMR vaccine** ▪ **Varicella (Chickenpox): Serologic evidence of immunity or prior vaccine** ▪ **Tdap (Tetanus, Diphtheria, Pertussis): Tdap and booster every 10 years. Pregnant HCWs should have Tdap during pregnancy.** ▪ **COVID-19** Employee health policies addressing influenza vaccinations are made available to employees. Such policies are based on national guidelines, such as the CDC (https://www.cdc.gov/flu/professionals/healthcareworkers.htm).	the Centers for Disease Control and Prevention (CDC). ▪ Employee health policies and procedures include: □ Vaccinations are made available to all healthcare workers. □ **A process for ensuring all employees are vaccinated or have been granted an exemption.** □ All employees have been offered the **recommended** vaccinations. □ The vaccination status of all employees is maintained. □ Employee **exemption from** vaccination is documented.

07.03.04 Employee health: COVID-19 Vaccination of Hospital Staff

The hospital must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Note: This standard was added by addendum in 2021.

All hospitals are required to achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the hospital and/or its patients or determine an individual is exempt from the COVID–19 vaccination requirements under existing federal law.

STAFF SUBJECT TO COVID–19 VACCINATION REQUIREMENTS

- "Staff" refers to individuals who provide any care, treatment, or other services for the hospital and/or its patients, including employees, licensed practitioners, adult students, trainees, volunteers, and individuals who

INTERVIEW AND DOCUMENT REVIEW

Verify:

- Policies and procedures address each required element.
- A list of all staff and their vaccine status is maintained. If any concerns are identified with the staff vaccine status list, verify the percentage of vaccinated staff.
- Documentation by selecting a sample of staff (vaccinated and unvaccinated direct

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a multi-dose vaccine.

1. *Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following hospital staff, who provide any care, treatment, or other services for the hospital and/or its patients:*
   - *i. Hospital employees;*
   - *ii. Licensed practitioners;*
   - *iii. Students, trainees, and volunteers; and*
   - *iv. Individuals who provide care, treatment, or other services for the hospital and/or its patients, under contract or by other arrangement.*
2. *The policies and procedures of this section do not apply to the following hospital staff:*
   - *i. Staff who exclusively provide telehealth or telemedicine services outside of the hospital setting and who do not have any direct contact with patients and other staff specified in paragraph 1 above; and*
   - *ii. Staff who provide support services for the hospital that are performed exclusively outside of the hospital setting and who do not have any direct contact with patients and*

provide care, treatment, or other services for the hospital and/or its patients, under contract or by other arrangement (e.g., clinical staff, administrative staff, leadership, fiduciary board members, housekeeping staff, food service staff, etc., individuals under contract or arrangement with the hospital, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers).

- The vaccination is required for all staff that interact with other staff and patients in any location, beyond those that physically enter facilities, clinics, homes, or other sites of care. Staff would not include anyone who provides only telemedicine services or support services outside of the hospital and who does not have any direct contact with patients and other staff specified in §482.42(g)(1) (that is, 100% of their time is remote from sites of patient care, and remote from staff who do work at sites of care).
- There may be many infrequent services and tasks performed in or for a hospital that is conducted by "one-off" vendors, volunteers, and professionals. Hospitals are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), or services that are performed exclusively off-site, not at or adjacent to any site of patient care (such as accounting services), but they may choose to extend COVID-19 vaccination requirements to them if feasible. Hospitals should consider the frequency of presence, services provided, and proximity to patients and staff. For example, a plumber who makes an emergency repair in an empty restroom or service area and correctly wears a mask for the entirety of the visit may not be an appropriate candidate for mandatory vaccination. On the other hand, a crew working on a construction project whose members use shared facilities (restrooms, cafeteria, break rooms) would be subject to these requirements due to the fact that they are using common areas also used by staff, patients, and visitors.

VACCINATION DEFINITIONS

care staff, contracted staff, and staff with an exemption). For each individual identified by the hospital as:

- ☐ Vaccinated: Review hospital records to verify vaccination status.
- ☐ Unvaccinated: Review hospital records to determine if they have been educated and offered vaccination. Review documentation of the medical contraindication, as applicable, to verify it is signed and dated by physician or advanced practice provider, states the specific vaccine that is contraindicated and the recognized clinical reason for the contraindication with a statement recommending exemption.

Observe:

- Staff providing care to determine compliance with current standards of practice with infection control and prevention.

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other staff specified in paragraph 1 above.

3. *The policies and procedures must include, at a minimum, the following components:*

   i. A process for ensuring all staff specified in paragraph 1 above (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine, prior to staff providing any care, treatment, or other services for the hospital and/or its patients;

   ii. A process for ensuring that all staff specified in paragraph 1 above are fully vaccinated, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily

- "Primary Vaccination Series" refers to staff who have received a single-dose vaccine or all required doses of a multi-dose vaccine for COVID-19.
- "Fully vaccinated" refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.
- "Booster," per CDC, refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have weakened over time.

VACCINE EXEMPTIONS

While nothing precludes an employer from requiring employees to be fully vaccinated, there may be some individuals eligible for exemptions from the COVID–19 vaccination requirements under existing federal law. Accordingly, hospitals must establish and implement a process by which staff may request an exemption from COVID–19 vaccination requirements based on an applicable federal law. Certain allergies, recognized medical conditions, or religious beliefs, observances, or practices, may provide grounds for exemption. Hospitals must have a process for collecting and evaluating such requests, including the tracking and secure documentation of information provided by those staff who have requested exemption, the facility's decision on the request, and any accommodations that are provided.

- Employers must follow federal laws protecting employees from retaliation for requesting an exemption on account of religious belief or disability status.
- "Clinical contraindication" refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States. For staff members who request a medical exemption from vaccination, all documentation confirming recognized clinical contraindications to COVID–19 vaccines which support the staff member's request must be signed and dated by a licensed practitioner who is not the

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delayed, as recommended by the CDC, due to clinical precautions and considerations;

iii. A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

iv. A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph 1 above;

v. A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

vi. A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable federal law;

vii. A process for tracking and securely documenting information provided by those staff who have requested, and for whom the center has granted, an exemption from the staff COVID-19 vaccination requirements;

viii. A process for ensuring that all

individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable state and local laws. Such documentation must contain all information specifying which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member and the recognized clinical reason(s) for the contraindications; and a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID–19 vaccination requirements based on these recognized clinical contraindications.

- "Temporarily delayed vaccination" refers to vaccination that must be temporarily postponed, as recommended by CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment in the last 90 days.

POLICY & PROCEDURE REQUIREMENTS

The hospital policy and procedure must meet all required elements, including a process for:

- Ensuring all required staff have received, at a minimum, the first dose of a multi-dose COVID-19 vaccine, or a one-dose COVID-19 vaccine, before staff provide any care, treatment, or other services for the hospital and/or its patients;
- Ensuring all required staff are fully vaccinated; and the hospital continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the hospital, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
- Tracking and securely documenting the COVID-19 vaccination status for all required staff;
- Tracking and documenting staff who have received any recommended

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documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable state and local laws, and for further ensuring that such documentation contains:

A. All information specifying which of the authorized or licensed COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

B. A statement by the authenticating practitioner recommending that the staff member be exempted from the center's COVID-19 vaccination requirements based on the recognized clinical contraindications;

ix. A process for ensuring the tracking

booster doses, or recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;

- How staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable federal laws, such as religious beliefs or other accommodations;
- Tracking and securely documenting information confirming recognized clinical contraindications to COVID-19 vaccines provided by those staff who have requested and have been granted a medical exemption to vaccination;
- All documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:
  - □ All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and
  - □ A statement by the authenticating practitioner recommending that the staff member be exempted from the hospital's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
- Ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

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and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and *x. Contingency plans for staff who are not fully vaccinated for COVID-19.* §482.42(g)(1) §482.42(g)(1)(i-iv) §482.42(g)(2) §482.42(g)(2)(i-ii) §482.42(g)(3) §482.42(g)(3)(i-viii) §482.42(g)(3)(viii)(A-B), §482.42(g)(3)(viii)(B)(ix-x)	▪ Contingency plans for staff that are not yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (g)(3)(x)), including deadlines for staff to be vaccinated. ▪ All staff are offered and provided education on the COVID-19 vaccination. Education should be documented. **VACCINATION LIST** The hospital must provide a list of all staff and their vaccination status at the time of survey, including: ▪ The percentage of unvaccinated staff, excluding those staff that have approved exemptions. ▪ Identification of any staff member remaining unvaccinated because of medical contraindication or religious exemption. ▪ Identification of newly hired staff (hired in the last 60 days). ▪ The position or role of each staff member. **DOCUMENTATION OF STAFF VACCINATION** Hospitals must track and securely document the vaccination status of each staff member, including those for whom there is a temporary delay in vaccination, such as recent recipients of monoclonal antibodies or convalescent plasma. Vaccine exemption requests and outcomes also must be documented. This documentation will be an ongoing process as new staff are onboarded. While hospital staff may not have personal medical records on file with their employer, all staff COVID–19 vaccines must be appropriately documented by the hospital. Examples of acceptable forms of proof of vaccination include: ▪ CDC COVID–19 vaccination record card (or a legible photo of the card). ▪ Documentation of vaccination from a health care provider or electronic health record.	

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- State immunization information system record.
- If vaccinated outside of the U.S., a reasonable equivalent of any of the previous examples.

CONTINGENCY PLANNING

Hospitals must make contingency plans in consideration of staff that are not fully vaccinated to ensure that they will soon be vaccinated and will not provide care, treatment, or other services for patients until such time as such the primary vaccination series for COVID–19 is complete and the individual is considered fully vaccinated, or, at a minimum, has received a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine.

This planning should also address the safe provision of services by individuals who have requested an exemption from vaccination while their request is being considered and by those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations.

Contingency planning may extend beyond the specific requirements of this rule to address topics such as staffing agencies that can supply vaccinated staff if some of the facility's staff are unable to work. Contingency plans might also address special precautions to be taken when, for example, there is a regional or local emergency declaration, such as for a hurricane or flooding, which necessitates the temporary use of unvaccinated staff in order to ensure the safety of patients. For example, expedient evacuation of a flooding facility may require assistance from local community members of unknown vaccination status. Facilities may have contingency plans that meet the requirements in their existing Emergency Preparedness policies and procedures.

Infection Control Measures/Accommodations of Unvaccinated Staff:

Staff who are not yet fully vaccinated, or who have been granted an exemption or accommodation as authorized by law, or who have a temporary

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delay, must adhere to additional precautions that are intended to mitigate the spread of COVID-19. There are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission including, but not limited to:

- Reassigning staff who have not completed their primary vaccination series to non-patient care areas, to duties that can be performed remotely (i.e., telework), or to duties which limit exposure to those most at risk (e.g., assign to patients who are not immunocompromised, unvaccinated);
- Requiring staff who have not completed their primary vaccination series to follow additional, CDC-recommended precautions, such as adhering to universal source control and physical distancing measures in areas that are restricted from patient access (e.g., staff meeting rooms, kitchen), even if the facility or service site is located in a county with low to moderate community transmission.
- Requiring at least weekly testing for exempted staff and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community transmission, in addition to following CDC recommendations for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients
- Facilities may also consult with their local health departments to identify other actions that can potentially reduce the risk of COVID-19 transmission from unvaccinated staff.

07.04.01 **Decontamination and**	☐ Compliant	☐ Not Compliant	This standard is not met as evidenced by:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
sterilization policies There are written policies and procedures based on manufacturer's instructions and nationally recognized guidelines for the decontamination and sterilization techniques performed in any location of the facility approved by the Infection Control Committee (function).	Policies and procedures are written for all types of activities relating to decontamination of supplies and equipment and protect the staff and visitors. The Infection Control Committee/function periodically approves these policies. A policy identifies when sterilization, low-level, high-level disinfection, or chemical disinfection is acceptable and delineates the steps of each disinfection processes used in the hospital. The policies address the equipment used for manual and automated processes. **The policies are based on the manufacturer's instructions for use and nationally recognized organizational guidelines such as AST and IAHCSMM. Policies and procedures are** easily accessible to personnel. **After use, instruments are properly cleaned and sterilized.** **The hospital provides appropriate education, training, and competence to staff handling, cleaning, sterilizing, and storing instrumentation and assesses competency with these tasks.** **Hinged instruments should be opened as wide as possible for proper cleaning. The use of decontamination stringers may be helpful in keeping hinged instruments open throughout the cleaning process.** **To protect sharp and delicate instruments, approved instrument protectors should be used. Heavy items should be placed below lighter, more delicate items. Every effort should be made to evenly distribute the weight within the tray to facilitate sterilant contact, as well as even heating and drying in steam sterilization processes**. **When peel packaging items for sterilization, care should be taken to keep hinged instruments opened and ensure there is adequate space in the package for the sterilant to contact all parts of the instrumentation. Care should also be taken to help ensure excess stress is not placed on the sides or seals of the peel pack.**	**DOCUMENT REVIEW** Verify: ▪ **Policies and procedures address disinfection and sterilization.** ▪ **Documentation** that the Infection Control Committee has reviewed and approved all departmental policies regarding decontamination and sterilization. ▪ **Practices** are consistent with CDC guidelines, OSHA, **evidence-based guidelines**, and state and local laws. ▪ **Through observation and interview that staff are familiar with policies and procedures and follow them.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.04.02 Decontamination of reusable items and reuse of single-use devices If reuse is approved within the organization, the FDA Reuse of Single Use Devices Guidelines must be followed. There are approved policies for the collecting, receiving, decontaminating, cleaning, disinfecting, and sterilizing of reusable instruments.	☐ Compliant ☐ Not Compliant Sterilization may be provided via a contracted vendor. Reuse of single use devices must be in compliance with the FDA *Reuse of Single Use Devices Guidelines*. If the hospital decides to reuse single use items, its policies and practices should identify and document how it ensures: 1. The device can be adequately cleaned and sterilized. 2. The physical characteristics or quality of the device will not be adversely affected by reprocessing. 3. The device will remain safe and effective for its intended use.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ Policies and procedures for the collection, receipt, and sterilization of reusable instruments are enforced. ▪ Policies demonstrate and document consideration of all three processes consistent with FDA guidelines regarding reuse of single use items, if applicable. ▪ Through observation and discussion with staff that the reuse policy is implemented.
07.04.03 High level disinfection/sterilization and processing of endoscopes **Reusable flexible endoscopes are visually inspected and evaluated for cleanliness, missing parts, clarity of lenses, integrity of seals and gaskets, moisture, damage, and function after disinfection/sterilization and again before use. Flexible endoscopes and endoscope accessories are stored to minimize contamination and protect the device or item from damage.**	☐ Compliant ☐ Not Compliant **The hospital has policies and procedures consistent with nationally accepted guidelines for processing and high-level disinfection/sterilization of endoscopes that address:** ▪ **Precleaning of flexible endoscopes** ▪ **Transport of endoscope to ensure compliance with infection control practices and to maintain integrity of the scope** ▪ **Leak testing** ▪ **Manual cleaning** ▪ **Mechanical processing**	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** **Verify:** ▪ **The policy on processing endoscopes includes precleaning, leak testing, manual cleaning including appropriate rinsing, inspection of scopes, mechanical cleaning, transport, and storage (including the length of time scopes may be stored before recleaning is required).**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	After processing is complete, endoscopes are stored according to manufacturer recommendation and hospital policy in an appropriate cabinet. **The hospital maintains records of endoscope processing including date, time, scope details, method, verification, identity of mechanical processor if indicated, lot numbers of solutions, and identity of the individual performing processing.** **A multidisciplinary team that includes infection preventionists, endoscopists, endoscopy processing personnel, and other identified individuals may evaluate the need to implement a surveillance program for endoscopes through the QAPI Program to ensure appropriate handling and storage of chemicals used during sterilization.** **The hospital follows recommendations of nationally recognized practices from CDC, APIC, AAMI, etc.**	▪ **Cleaning and sterilization of endoscopes for adherence to policy and manufacturer's IFU.** ▪ **Expiration dates and loads and lot number validation for chemicals and test strips used for cleaning and disinfection/sterilization and appropriate storage of each.** ▪ **Through interview that there is a process used to ensure effective processing and sterilization of endoscopes.** ▪ **Determine if incorporated into QAPI program.**
07.04.04 <u>Immediate use steam sterilization (IUSS) in surgical settings</u> Immediate use sterilization (IUSS) practices are based on current nationally recognized infection control guidelines and standards of practice.	☐ Compliant ☐ Not Compliant **Note:** This standard was previously numbered 07.04.03. Surgical disinfection and sterilization procedures are expected to be consistent with accepted national guidelines to prevent the transmission of infectious disease and protect the health and safety of patients. IUSS was formerly known as "flash sterilization." The term IUSS is used to describe the process for steam sterilizing an instrument that is needed immediately, not intended to be stored for later use, and which allows for minimal or no drying after the sterilization cycle. The availability of IUSS is not considered an appropriate substitute for maintaining a sufficient inventory of instruments. **PHYSICAL MONITORS USED WITH IUSS CYCLES**	This standard is not met as evidenced by: **<u>OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW</u>** ▪ Review the Infection Control Plan to verify that the infection prevention and control program is consistent with the national standards of practice. **Note:** If the answer to any of the following questions is "no," a citation under the appropriate infection control Standard is warranted. ▪ Is IUSS reserved for immediate use needs (e.g., used only emergently), when a

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Policies are designed based on device manufacturer's written instructions for reprocessing any reusable device must be followed. The cycle parameters required to achieve sterilization are determined by the design of an instrument, the characteristics of the load, the sterilizer capabilities, and the packaging.

The facility adopts policies regarding the parameters required to achieve sterilization including the physical monitoring of each IUSS cycle, including;

1. Adherence to manufacturer's instructions for sterilization.
1. Identification of devices that are NOT compatible with IUSS.
2. The facility identifies for each IUSS cycle, the appropriate PHYSICAL MONITORS (time, temperature, pressure).
3. The policy identifies:
   - the indications for use of a Chemical Indicator (CI)
   - the indications for use of a Biological Indicator (BI).
   - the sterilization procedure.
   - use of labels.
   - frequency for testing.

needed instrument has been contaminated and there is no sterile replacement available, or for a patient care item that cannot be packaged, sterilized, and stored before use)?

- Is there a process in place to ensure IUSS is not used for implants (in most circumstances, as described above); instruments used on patients with known or suspected CJD or similar disorders; devices or loads not validated with the specific cycle; and single-use devices?
- Are instrument(s) to undergo IUSS first cleaned and disinfected following the manufacturer's IFU?
- Verify that all personnel who perform IUSS:
  - □ Have the necessary time, equipment, supplies and facilities readily available.
  - □ Have been trained and are able to correctly follow the manufacturer's IFU(s) regarding IUSS with respect to each instrument, , sterilizer(s), and container(s) and cleaning supplies they are using for IUSS.
  - □ Have had their competency initially verified before they undertake IUSS, and periodically thereafter.
  - □ Can personnel provide evidence that

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		the sterilizer cycle being used for IUSS is indicated in the device manufacturer's IFU? □ Are physical monitors used documented to record that cycle parameters are met for each load? □ Is there evidence that the sterilizer is being maintained as required by the manufacturer's IFU? □ Is the rigid sterilization container/ packaging or tray used in a particular cycle consistent with how it is labeled by the manufacturer? □ Is the rigid sterilization container being used for the load consistent with its manufacturer's recommendations for IUSS (e.g., load weight, configuration of instruments)?
07.04.05 <u>Sterilization and decontamination devices</u> Policies and/or procedures describe the use of devices used to monitor sterilization or decontamination results in compliance with manufacturer's instructions.	☐ Compliant ☐ Not Compliant **Note:** This standard was previously numbered **07.04.04.** Policies and procedures are developed consistent with manufacturer's instructions and national guidelines such as CDC, CDC-HICPAC, AORN, AAMI, etc. Practice reflects implementation of the policies. Testing is accomplished, whether or not a load is processed, to document unit capacity.	This standard is not met as evidenced by: **<u>OBSERVATION AND DOCUMENT REVIEW</u>** Verify: ▪ Policies are in place. ▪ Logs are maintained for each type of quality control mechanism. □ Review the logs to assure that frequencies are within the guidelines.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Chemical indicators can be any of several types to demonstrate the product has gone through a sterilization process. Vendor contracts specify the quality controls used. Policies and/or procedures govern the use of monitoring devices, including the following: 1. Bacteriologic spore tests are used at least weekly in all steam sterilizers. 2. Bacteriologic spore tests are used in every load of any type of pressurized gas or liquid sterilization process. 3. Use of chemical indicators with each package that has gone through a sterilizer cycle 4. Testing is accomplished, whether or not a load is processed, to document unit capacity. The FDA provides guidance on sterilization: https://www.fda.gov/medical-devices/general-hospital-devices-and-supplies/ethylene-oxide-sterilization-medical-devices.	
07.04.06 Sterilization data requirements Appropriate documentation, including temperature and pressure readings, is recorded and maintained for every sterilized load.	☐ Compliant ☐ Not Compliant **Note:** This standard was previously numbered **07.04.05**. A policy requires that for each sterilizer load (e.g., low temperature sterilization devices, such as equipment for cleaning endoscopes and reprocessing equipment), readings are maintained and specifies how long the documentation is retained. The readings may be automatically printed values or handwritten, and include the person's name or initials, time and date. The load control numbers documentation includes identification of the equipment used, the sterilization cycle, and date for each sterilized item.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Observe the load control mechanism to verify: ▪ Policy addresses requirements. ▪ Implementation via the quality control logs.
07.04.07 Preparing, assembling,	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
wrapping, storage and distribution of sterile equipment and supplies There are approved policies for the preparing, assembly, wrapping, storage, and distribution of sterile equipment and supplies.	**Note:** This standard was previously numbered **07.04.06**. The policies address each step of the process in detail. The distribution of sterile equipment policies would address the process for obtaining supplies after normal working hours.	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify that: ▪ Policies are in place describing all five processes. ▪ Policies are enforced.
07.04.08 Shelf life of sterilized products There is identification of the shelf life for each type of sterilized product used on or around any hospital patient or in or around any product or equipment that is used for patient care.	☐ Compliant ☐ Not Compliant **Note:** This standard was previously numbered **07.04.07**. Time-related or event-related dates do not have to exist but some form of declaration shall be made for employees to understand the hospital's decision for whether the instruments are sterile for a limited amount of time or until the package/barrier is compromised.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ The policy describes how long each type of package is considered sterile. It addresses commercially prepared products as well as products sterilized in the hospital. ▪ Observe for compliance in all patient care areas.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.04.09 Environmental requirements in decontamination rooms The physical environment for areas used for final decontaminating, cleaning, and/or sterilizing equipment or supplies provides for the following: ▪ Adequate space. ▪ A double sink. ▪ Air flow in the direction from the clean area toward the dirty area. ▪ An air exchange rate of at least six in the clean area and at least ten in the dirty area.	☐ Compliant ☐ Not Compliant **Note:** This standard was previously numbered **07.04.08**. The facilities provided for the functions of conducting normal sterile processing activities shall not pose an undue risk to adequacy of the process or generate harm to staff or patients.	This standard is not met as evidenced by: **OBSERVATION** Verify: ▪ Traffic patterns, space allocation, air patterns and exchanges. ▪ Safety monitors and protections for staff.
07.05.01 Housekeeping There are policies and procedures approved by the Infection Control Committee relating to the description of the scope and practices of Housekeeping, Linen Services and the hospital's environment.	☐ Compliant ☐ Not Compliant The current approved practices are available to the staff. Housekeeping polices are reviewed and approved through the Infection Prevention and Control leadership at least every three years. The policies include, but are not limited, to: 1. High Risk Cleaning Procedures 2. Air Supply and Return Grilles 3. Maintenance of Ceilings 4. Maintenance of Housekeeping and Laundry Equipment 5. Waste Disposal	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ Policies meet current accepted practices of the industry and have been approved by the infection control committee. ▪ Housekeeping policies have been approved by the Infection Control Committee (function) at least every three years.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.05.02 High-risk cleaning procedures	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
There are policies and procedures for the cleaning of areas in the hospital deemed as high risk due to their special functions. These would include, but are not limited to: 1. Surgery 2. Labor and Delivery 3. Cardiac Catheterization Lab 4. Bone Marrow Rooms 5. Central Sterile Processing 6. Newborn Nursery 7. Linen processing, etc.	Policies are accessible to staff for the proper tasks, cleaning solutions, frequencies, and tools sufficient to disinfect and reduce the spread of microbes and communicable diseases.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Review policies and observe operations to determine if acceptable techniques are being used. ▪ Verify that high-risk cleaning policies have been approved by the Infection Control Committee (function) at least every three years.
07.05.03 Air supply and return grilles	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Air supply and return grilles are clean.	The HVAC grilles do not have a buildup of dust or debris.	**OBSERVATION** ▪ Observe all areas of the facility to determine if adequate cleaning is being accomplished to prevent the buildup of dust/debris on the grilles. (Take special care to observe the ICU, OR, Delivery Room, food preparation areas, etc.)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.05.04 Maintenance of ceilings	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Ceilings do not have openings to areas which cannot be cleaned regularly. Ceiling tiles do not have moisture stains/mildew.	Care is taken to reduce the potential that dust and other contaminants may fall from ceiling spaces into food service or patient care areas. Ceiling tiles are exchanged when they are moistened to minimize the potential for bacterial growth.	**OBSERVATION** ▪ In the sensitive areas noted above, determine the risk of contamination from the ceilings. □ Verify that ceiling tiles are clean with no evidence of dust or other contaminates. □ Ceiling tiles are not stained.
07.05.05 Maintenance of housekeeping and laundry equipment	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Policies and procedures govern the care and cleaning of housekeeping and laundry equipment.	There are written procedures describing processes for decontaminating cleaning equipment. These include, but are not limited to: 1. The frequency with which the equipment is cleaned. 2. The cleaning products used on each type of equipment. 3. Where and how the equipment is to be stored to reduce re-contamination.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Review policies and observe practice to determine whether the hospital is following current accepted practices of the industry.
07.05.06 Waste disposal	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Policies and procedures govern the proper storage and disposal of waste including biomedical and infectious.	There are written procedures which describe methods of holding, handling, transporting, storage, and disposal of all types of waste.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Review policies and observe practice to determine if acceptable methods are being used for trash storage and disposal.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.06.01 Soiled linen management	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Contaminated linen is placed and stored in hampers or other holding devices which reduce the potential for particles becoming airborne and/or liquids from dripping from or absorption into the holding device. Contaminated linen collection bags or containers will be labeled and/or color coded to communicate that the contents contain infectious materials. Soiled linen containers will not be used for storage or transport of clean linen. The dirty portion of the laundry has negative pressure to prevent airborne contamination, in accordance with state and federal guidelines for healthcare laundry facilities.	Soiled linen is appropriately stored in nonabsorbent, covered containers in non-patient care areas. Measures are taken which reduce the potential for particles becoming airborne and/or liquids dripping from, or absorption into, the holding devices. Staff are trained on the use of laundry products and processes. When laundering occurs in the facility, the cycles consist of flush, main wash, bleaching, rinsing, and souring and the procedures are based on national guidelines (e.g., CDC, OSHA, Association for Linen Management, Association for Professionals in Infection Control and Epidemiology (APIC)). When hot water is used, it is maintained at an appropriate temperature for the appropriate length of time. Low water temperatures are appropriately matched with chlorine bleach or other laundry additives for cleaning and decontamination.	**DOCUMENT REVIEW AND OBSERVATION** ▪ Hospital policies address each element of the standard and are approved by the infection control committee. ▪ Observe operations to determine whether approved methods are consistently used for handling and storage of contaminated linen. □ Contaminated containers are sanitized before use to transport clean linen.
07.06.02 Clean linen storage	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Clean linen is stored in the hospital in a manner which reduces the potential for airborne or surface contamination.	Linen transported is appropriately contained and covered. Clean linens are packaged prior to transport to prevent inadvertent contamination from dust and dirt during loading, delivery, and unloading. Clean inventory is transported in a manner to prevent the spread of dust and soil onto clean linen from transport carts and/or wheels. The lowest shelf of the clean linen storage and transportation carts is enclosed and not open to the spread of dust and other potential	**OBSERVATION AND INTERVIEW** ▪ Observe for the storage and transport of clean linen. Verify: ▪ Transport carts are enclosed. ▪ Clean linen storage shelves and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	contaminants.	transportation carts do not have open grating as the lowest shelf.
07.07.01 Extermination program There is a pest extermination plan to control the presence and reproduction of pests. The pest control program must be safe for use around patients and staff.	☐ Compliant ☐ Not Compliant There is an ongoing pest extermination process within the hospital. This can be by provided by hospital employees or by a contracted outside service. Pest control addresses the external and interior of the building(s). Measures are taken to reduce the opportunities for insects and other pests to have access into the facilities. Outside doors have self-closing devices. Windows are permanently closed or have sufficient screening. Air intakes are sufficiently filtered. Exhaust air ducts have controlled air current. All openings to the outside of the physical hospital are protected to effectively reduce the potential of the entrance of pests into the hospital. Use of poisons is not considered appropriate due to the potential of exposure to decomposing carcasses as well as the poison. Traps must not present a hazard to patients or staff.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review records of pest control. ▪ Observe the availability of MDSD precautions for any chemicals. ▪ Observe for exposure of patients and staff to hazardous conditions. ▪ Observe whether sufficient measures have been taken to prevent pest entry.

08

MATERIALS MANAGEMENT

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
08.00.01 Inventory	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
An appropriate inventory of non-expired supplies is provided to support the services offered to the patients. A process is in place to assure that outdated/expired supplies are not used.	The purchasing service orders and stocks supplies to reduce the potential of inventory outage or backorder for essential commodities. The use of outdated/expired supplies should not occur.	**OBSERVATION AND INTERVIEW** ▪ Observe supply carts, cabinets, and storeroom(s) and interview staff. □ Are there outdated/expired supplies present? □ Are there shortages, frequent back orders, or inappropriate substitutions of essential supplies?
08.00.02 Supplies for patient care	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The commodities supplied to the patient care and support services meet the needs of each group.	The supplies are of the sizes and quantities needed to accommodate the requirements of the procedures/tasks to be performed.	**OBSERVATION AND INTERVIEW** ▪ Observe supply carts, cabinets, and storeroom(s) and interview staff. □ Verify the availability of the necessary variety of supplies.
08.00.03 Safe storage of supplies	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The commodities supplied to patient care and support services are stored so as to protect them from damage or loss from moisture, thermal change, rodents, vermin, or theft.	Supplies are stored above floor surfaces **in accordance with nationally recognized standards of practice. For example, the FDA requires at least 6 inches of floor clearance for non-sterile supplies and food items. AAMI requires 8 inches of floor clearance for sterile supplies**. **The lowest shelf has a solid surface/barrier to ensure supplies are kept**	**OBSERVATION** Verify: ▪ Supplies are stored off the floor **based on nationally-recognized guidelines**.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	clean. Supplies are grouped/segregated by type. Hazardous chemicals are not stored with food products, dressings, or medications. Supplies requiring special temperature ranges are identified and stored accordingly.	▪ **Supplies and supply carts, cabinets, and storerooms meet the requirements**.
08.00.04 Policies on supply availability A policy and procedure is in place that specifies the type of supply products to be purchased or to be kept in stock.	☐ Compliant ☐ Not Compliant The policies and procedures are approved by administration and represent sound practices for the acquisition, storage and delivery of materials to the facility. Emergency and contingency plans are formally documented and known by both material management personnel and supervisory staff.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review policies and procedures to verify they address materials including: □ Acquisition □ Delivery □ Storage □ Emergency acquisition
08.00.05 For future use		
08.00.06 Product recall Policies and procedures are in place to provide for an effective product recall system that includes: 1. Receipt and distribution of recall	☐ Compliant ☐ Not Compliant **A recall log is maintained to verify all elements of the process are completed.**	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ A policy covers **each standard**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
notices. 2. Identification of product availability within the hospital. 3. Notification of recalls to appropriate departments/staff. 4. Verification of recall of all available products.		**requirement**. ▪ The policy has been implemented. ▪ **Staff are aware of the process for notification and recall of products**. ▪ **The recall log is maintained.**

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09

EMERGENCY MANAGEMENT

INTRODUCTION

ACHC Emergency Management Standards establish emergency preparedness requirements to ensure adequate planning for both natural and man-made disasters. Acute Care Hospitals must coordinate compliance with these Standards with other regulatory agency requirements that the hospital is required to follow.

ACHC believes it is important for hospitals to consider mitigation, recovery, and business continuity while planning for emergencies, but the scope and focus of the Emergency Management Standards is the continuity of operations during and immediately after the emergency.

The Emergency Preparedness Program (also known as the Emergency Management Program) consists of many different policies, plans, and components. Some of these are to be shared with the hospital's community emergency response agency, such as:

- Hazard Vulnerability Analysis (HVA)
- Emergency Operations Plan (EOP)
- Evacuation Plan

The Standards in this chapter are based on Conditions of Participation (CoP) requirements from the Centers for Medicare & Medicaid Services (CMS); the 2012 edition of the NFPA 101 Life Safety Code; and the 2010 edition of NFPA 110 Standard for Emergency and Standby Power Systems. There are three essential requirements for maintaining access to healthcare services during an emergency:

1. Safeguarding human resources.
2. Maintaining business operations.
3. Protecting physical resources.

There are four core elements that are central to a successful Emergency Preparedness Program:

1. Risk Assessment and Emergency Planning

   ACHC requires all facilities to perform a risk assessment that uses an all-hazards approach prior to establishing an emergency operations plan (EOP). This risk assessment is often referred to as a Hazard Vulnerability Analysis (HVA).

2. Policies and Procedures

   ACHC requires the facility to develop and implement policies and procedures that support execution of the EOP. These policies and procedures may be part of the EOP or they may be maintained separately. If they are separate from the EOP, the EOP must reference where they are located to facilitate access.

3. Communication Plan

   ACHC requires the facility to develop and maintain an emergency preparedness communication plan. The communication plan may be part of the EOP, or it may be maintained separately. If the communication plan is separate from the EOP, the EOP must reference the location of the plan to facilitate access.

4. Training and Testing

   ACHC requires the facility to develop and maintain an emergency preparedness training and testing plan. All staff must be trained as to their role in the event of an emergency, and this training must be conducted annually and documented. The facility must conduct drills or exercises to test the EOP to identify gaps and areas for improvement.

CHAPTER 09 TABLE OF CONTENTS

CLARIFICATIONS AND DEFINITIONS*

*Provided for reference. **Note**: Some definitions appeared in the previous edition of this manual at Standard 09.00.08. **Bold copy** indicates new or revised content.

ALL-HAZARDS APPROACH

An all-hazards approach is an integrated approach to emergency preparedness planning that focuses on capacities and capabilities that are critical to preparedness for a full spectrum of emergencies or disasters. An all-hazards approach to emergency planning does not exclude or limit a response to any specific type of an emergency event.

AT-RISK PERSONS

At-risk persons are individuals with access and functional limitations that may interfere with their ability to access or receive medical care before, during, or after a disaster or emergency. The 2013 Pandemic and All-Hazards Preparedness Reauthorization Act defines at-risk individuals as children, older adults, pregnant women, and individuals who may need additional response assistance. Examples of these populations may include but are not limited to individuals with disabilities, individuals from diverse cultures, individuals who have limited English proficiency or are non-English speaking, individuals who are transportation disadvantaged, individuals who have chronic medical disorders, and individuals who have pharmacological dependency. **At-risk populations, in the event of emerging infectious diseases (EID) and communicable diseases, may also include older adults and people of any age with underlying medical conditions or who are immunocompromised, for whom exposure may place them at higher risk for severe illnesses.**

BUILDING CLASSIFICATION: HEALTHCARE OCCUPANCY

An occupancy used to provide medical or other treatment or care simultaneously to one or more patients on an inpatient basis, where such patients are mostly incapable of self-preservation due to age, physical or mental disability, or because of security measures not under the occupants' control.

The health care facilities regulated by this occupancy type are those that provide sleeping accommodations for their occupants.

Examples of Healthcare Occupancies:

- Acute Care Hospitals
- Critical Access Hospitals
- Psychiatric Hospitals
- Specialty Hospitals
- Inpatient hospices
- Nursing homes
- Skilled nursing facilities

- Long term care facilities
- Inpatient substance abuse facilities

COMMUNITY PARTNERS

For full-scale and community-based exercises, community partners are any emergency management officials (fire, police, emergency medical services, etc.). The category can also include those that may assist in an emergency, such as surrounding providers and suppliers.

DOCUMENTATION REQUIREMENT

Providers and suppliers are encouraged to keep documentation and their written emergency preparedness program for a period of at least two years.

EMERGENCY (OR DISASTER)

An event that can affect the facility internally as well as the overall target population or the community at large. Emergencies can be internal, man-made, or natural events, and can be small or large events.

EMERGENCY OPERATIONS PLAN (EOP)

Whether it is called the emergency operations plan, the emergency response plan, the emergency management plan, or simply the Plan, it must include key elements of emergency planning. The plan is part of the overall Emergency Preparedness Program and is based on the top risks determined by the risk assessment (i.e., HVA). All policies and procedures that support emergency preparedness and execution of the EOP are considered part of the EOP and must meet applicable EOP requirements as outlined in the ACHC Standards.

EMERGENCY PREPAREDNESS PROGRAM

The Emergency Preparedness Program is the over-all coordination of emergency management policies, procedures, and activities. Whether it is called emergency preparedness or emergency management, it encompasses all activities to provide a comprehensive approach to potential or actual emergencies.

RISK ASSESSMENT

The risk assessment is conducted prior to establishment of the EOP and identifies the essential components of the EOP. This approach is specific to the location of the provider and considers the particular types of hazards most likely to occur in their area. These may include, but are not limited to, care-related emergencies; equipment and power failures; interruptions in communications, including cyber-attacks; loss of a portion or all of a facility; and interruptions in the normal supply of essentials, such as water and food. This 'all-hazards' approach to a risk assessment is often referred to as a Hazard Vulnerability Analysis (HVA).

STAFF

The term 'staff' includes employees, individuals providing services under arrangement (contract), volunteers, students, chaplains, and physicians. Guests, visitors, sales representatives, and service contractors who are supervised are not considered 'staff.'

TRAINING AND TESTING TYPES

Note: ACHC definitions are aligned with the Homeland Security Exercise and Evaluation Program (HSEEP) guidelines.

Full-Scale Exercise (FSE)

A full-scale exercise is an operations-based simulation that typically involves multiple agencies, jurisdictions, and disciplines performing functional activities (for example, joint field office, emergency operation centers, etc.) and integrating operational elements involved in the response to a disaster event, i.e., "boots on the ground" response activities (for example, hospital staff treating mock patients). Though there is no specific number of entities required to participate in a full-scale community-based exercise, it is recommended that it be a collaborative exercise which involves, at a minimum, local or state emergency officials to develop community-based responses to potential threats.

Functional Exercise (FE)

A functional exercise is an operations-based simulation that is designed to validate and evaluate capabilities, multiple functions and/or sub-functions, or interdependent groups of functions. FEs are typically focused on exercising plans, policies, procedures, and staff members involved in management, direction, command, and control functions.

Mock Disaster Drill

A mock disaster drill is a coordinated, supervised activity usually employed to validate a specific function or capability in a single agency or organization. Mock disaster drill are commonly used to provide training on new equipment, validate procedures, or practice and maintain current skills. For example, mock exercises may be appropriate for establishing a community-designated receiving center or shelter. Mock disaster drill also can be used to determine if plans can be executed as designed, to assess whether more training is required, or to reinforce best practices. A mock disaster drill is useful as a stand-alone tool, but a series of drills can be used to prepare several organizations to collaborate in an FSE.

Tabletop Exercise (TTX)

A tabletop exercise involves key personnel discussing simulated scenarios in an informal setting. Tabletop exercises can be used to assess plans, policies, and procedures. It is a discussion-based activity that involves senior staff, elected or appointed officials, and other decision-making personnel in a group discussion centered on a hypothetical scenario. Tabletop exercises can be used to assess plans, policies, and procedures without deploying resources.

Workshop

A workshop, for the purposes of this CMS guidance, is a planning meeting, seminar, or practice session that establishes the strategy and structure for an exercise program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

PLANNING

09.00.01 CONDITION OF PARTICIPATION: Emergency Preparedness

The hospital must comply with all applicable Federal, State, and local emergency preparedness requirements.

The hospital must develop and maintain a comprehensive emergency preparedness program **that meets the requirements of this chapter**, *utilizing an all-hazards approach.*

The requirements established by this Chapter apply to all facilities owned, rented, leased or used by the hospital that provides patient care and treatment services. This applies regardless of the NFPA "occupancy" designation of the facility. The hospital may have off-site facilities that are only used as physician exam offices, but all the requirements of this chapter must apply.

§482.15

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must have an emergency preparedness program that includes:

1. Planning
2. Procedures
3. Communication
4. Training & Testing

Emergency preparedness requirements focus on continuity of operations, not recovery of operations, hazard mitigation, or business continuity. Facilities may choose to include planning for recovery of operations, hazard mitigation, and business continuity in their emergency preparedness plan, but these items are not a requirement.

The emergency preparedness program must describe a facility's comprehensive approach to meeting the health, safety, and security needs of the staff and patient population during an emergency situation. The program must also address how the facility will coordinate with other healthcare facilities, as well as the whole community during an emergency situation.

The term "comprehensive" in this requirement is to ensure that facilities do not choose only one potential emergency that may occur in their area, but rather demonstrate that they have considered multiple events during development of the Program. As emerging infectious disease outbreaks may affect any facility in any location across the country, a comprehensive Emergency Preparedness Program should include emerging infectious diseases and pandemics during a public health emergency (PHE). The Program's plan for emerging infectious disease should encompass how facilities will plan, coordinate and respond to a localized and widespread pandemic, similar to the 2019 Novel Coronavirus (COVID-19) PHE. Facilities

INTERVIEW AND DOCUMENT REVIEW

Verify:

The Emergency Preparedness Program is documented in writing.

- The Emergency Preparedness Program includes the four key elements described.
  - ☐ Is the Program reviewed **every two years (biennially)**?
  - ☐ Is Program documentation retained for at least two years?
- Facility leadership can describe the facility's Emergency Preparedness Program.
- The Program was developed based on an all-hazards approach.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	should ensure their Emergency Preparedness Programs are aligned with their state and local emergency plans/pandemic plans. The Emergency Preparedness Program must be reviewed **every two years (biennially)**.	
09.00.02 Hazard Vulnerability Analysis (HVA) ***The hospital must develop and maintain an emergency preparedness plan that must be reviewed and updated at least every two years. The plan must:*** ***(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.*** §482.15(a) §482.15(a)(1) The hospital conducts a risk assessment (i.e., Hazard Vulnerability Analysis) to ascertain conceivable threats and disasters that could affect the ability to operate the facilities of the organization, or to provide services to their patients, and the probability of those events occurring. The hospital's Hazard Vulnerability Analysis (HVA) must be shared with the community's emergency response agencies. The hospital must identify likely	☐ Compliant ☐ Not Compliant Prior to establishing an Emergency Operations Plan, the hospital must perform a risk assessment (i.e., Hazard Vulnerability Assessment) based on using an all-hazards approach. All-hazards planning does not specifically address every possible threat but ensures hospitals evaluates its capacity and capability to address a broad range of related emergencies. The hospital may choose to create a single Hazard Vulnerability Analysis (HVA) that applies to all the sites of the hospital, or an individual Hazard Vulnerability Analysis (HVA) for each of their locations. The hospital may rely on a community-based assessment (i.e., HVA) developed by other entities, such as their public health agencies, emergency management agencies, and regional healthcare coalitions or in conjunction with conducting its own facility-based assessment. It is expected that the hospital will have a copy of this risk assessment and to work with that entity that developed it to ensure that the hospital emergency plan is in alignment. All facilities where patient care and treatment is provided are required to have an assessment conducted for hazards, including facilities which the hospital may not own but where they provide treatment for their patients. Some remote locations may have different hazards and therefore a separate Hazard Vulnerability Analysis (HVA) would be appropriate. Hospitals must prioritize the potential hazards to their organization, and these priorities are documented in the Hazard Vulnerability Analysis (HVA). The hospital shares their HVA with their community partners to help set	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The Hazard Vulnerability Analysis (HVA) is reviewed by the organization and updated every two years (biennially) by the Emergency Management Committee. ▪ The hospital has shared or attempted to share their HVA with one or more community partners.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

hazards for their community service area (e.g., natural disaster, bioterrorism threats, disruption of utilities such as water, sewer, electrical communications, fuel, nuclear accidents, industrial accidents, and other likely mass casualties, unforeseen widespread communicable diseases, etc.) and develop appropriate responses that will assure the safety and wellbeing of patients.

The HVA is documented and reviewed by the oversight committee on emergency management for relevancy and accuracy at least every two years.

priorities with the Hazard Vulnerability Analysis (HVA).

Community partners may include:

- The department of public health
- The department of public safety
- The department of public works
- Local municipality representatives
- Other government agencies
- Community organizations
- Vendors
- Other health care organizations

The all-hazards risk assessment (HVA) must be consistent with the concepts outlined in the National Preparedness Systems, published by the US Department of Homeland Security, as well as guidance by the Agency for Healthcare Research and Quality (AHRQ).

When meeting the requirements for the all-hazards risk assessment (HVA), hospitals must consider the following:

1. Identification of all business functions essential to the hospitals' operations that should be considered during an emergency.
2. Identification of all risks or emergencies that the hospital may reasonably expect to confront.
3. Identification of all contingencies for which the hospital should plan.
4. Consideration of the hospital's location, including all locations where the hospital delivers patient care or services, or has business operations.
5. Assessment of the extent to which natural or man-made emergencies may cause the hospital to cease or limit operations.
6. Determination of what arrangements with other hospitals, other

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

healthcare providers or suppliers, or other entities might be needed to ensure that essential services could be provided during an emergency.

7. **For public health emergencies, such as emerging infectious diseases (EID) or pandemics: Facilities should consider risk assessments to include the needs of the patient population they serve in relation to a communicable or EID outbreak. Planning should include a process to evaluate the facility's needs based on the specific characteristics of an EID that includes, but is not limited to:**
   - □ **Increased need for PPE.**
   - □ **Considerations for screening patients and visitors; which may also include testing considerations for staff, visitors, and patients for infectious diseases.**
   - □ **Transfers and discharges of patients.**
   - □ **Home-based healthcare settings.**
   - □ **Physical environment, including but not limited to changes needed to achieve distancing, isolation, or capacity/surge.**

09.00.03 Emergency Operations Plan

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

A written Emergency Operations Plan (EOP) is developed, maintained, and available to the staff for crisis preparation and response.

The Emergency Operations *Plan must be based on and include* ***strategies for addressing emergency events identified by the risk assessment.***

§482.15(a)(2)

The written emergency operations plan (EOP) and associated procedures address situations for each department and/or service within the hospital and for each building used for patient treatment and/or housing. The organization may choose to have one EOP that is inclusive for all their facilities where patients are treated and housed, or they may choose to have individual EOPs for each location.

The hospital shares the details of the EOP with the community's emergency response agencies. The hospital assesses the community's abilities to meet the needs of the hospital during an emergency event. This involvement with the community and the assessment of the community's abilities is

INTERVIEW AND DOCUMENT REVIEW

- Review the Emergency Operations Plan to determine its applicability with the potential emergencies identified in the Hazard Vulnerability Analysis (HVA).
  - □ Was the EOP reviewed with local authorities per the policy of the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

The EOP is based on the priorities established in the current Hazard Vulnerability Analysis (HVA). The EOP is reviewed with the community's emergency response agencies to synchronize responses to common emergency events.

The hospital develops or makes revisions to its emergency preparedness plan that considers EIDs as potential threats that can impact operations and continuity of care within the healthcare setting.

The EOP is reviewed every two years (*biennially*) by the Emergency Management Committee to ensure relevancy and accuracy. Adjustments are documented and changes made based on lessons learned during actual emergency events and during planned exercises.

The hospital uses it annual Hazard Vulnerability Analysis (HVA) as a foundation for the Emergency Operations Plan to determine the strategies and activities designed to reduce the risk associated with emergency events.

documented.

The written EOP includes a plan for the possibility of a widespread infection outbreak or pandemic.

The Emergency Operations Plan must be integrated into the facility-wide Quality Assurance Performance Improvement (QAPI) plan.

An emergency plan is one part of a facility's emergency preparedness program. The plan provides the framework, which includes conducting facility-based and community-based risk assessments that will assist a facility in addressing the needs of their patient populations, along with identifying the continuity of business operations which will provide support during an actual emergency. In addition, the emergency plan supports, guides, and ensures a facility's ability to collaborate with local emergency preparedness officials. This approach is specific to the location of the facility and considers particular hazards most likely to occur in the surrounding area. These include, but are not limited to:

- Natural disasters.
- Man-made disasters.
- Facility-based disasters that include but are not limited to:
  - □ Care-related emergencies.
  - □ Equipment and utility failures, including but not limited to power, water, gas, etc.
  - □ Interruptions in communication, including cyber-attacks.
  - □ Loss of all or portion of a facility; and
  - □ Interruptions to the normal supply of essential resources, such as water, food, fuel (heating, cooking, and generators), and in some cases, medications and medical supplies (including medical gases, if applicable).
  - □ **Emerging infectious diseases (EIDs) such as Influenza, Ebola, Zika**

hospital?

- □ Does the hospital share their plans and abilities with the local authority in community emergency preparedness during the planning phase as well as the implementation phase?

Verify:

- Emergency Management is integrated into the facility-wide QAPI Plan.
- Emergency Management related data is collected and utilized to improve the quality of patient care and patient safety. Improvements are monitored to insure improvement in outcomes/results.
- **Does the EOP provide for the influx of patients during an emergency?**
- Documentation reflects that the EOP was shared with local authorities per the policy of the hospital and reviewed with the community emergency preparedness and response plan.
- Facility leadership can identify the hazards (e.g., natural, man-made, facility, geographic, **EIDs,** etc.) that were identified in the facility's risk assessment and how the risk assessment was conducted.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Virus, COVID-19 or SARS-CoV-2 and others.

Note: These EIDs may require modifications to facility protocols to protect the health and safety of patients, such as location and personal protective equipment (PPE) measures.

Emerging Infectious Diseases (EIDs)

The type of infectious diseases to consider or the care-related emergencies that are a result of infectious diseases are not specified. Adding EIDs within a facility's risk assessment ensures that facilities consider having infection prevention personnel involved in the planning, development, and revisions to the EOP, as these individuals would likely be coordinating activities within the facility during a potential surge of patients. Some examples of EIDs may include but are not limited to:

- **Potentially infectious bio-hazardous waste.**
- **Bioterrorism.**
- **Pandemic influenza.**
- **Highly communicable diseases (such as Ebola, Zika Virus, SARS, or novel COVID-19 or SARS-CoV-2)**
  EID's may be localized to a certain community or be widespread (as seen with the COVID-19 PHE) and therefore plans for coordination with local, state, and federal officials are essential. Facilities should engage and coordinate with their local healthcare systems and healthcare coalitions, and their state and local health departments when deciding on ways to meet surge needs in their community.

The EOP includes a plan for the influx or a surge of patients and must be reviewed by the community's emergency response agency.

Surge Planning

Hospitals must have policies and procedures which include emergency staffing strategies and plan for emergencies resulting in a surge of patients.

- **The EOP addresses widespread infection control outbreak or pandemic.**
- The plan is reviewed and updated every two years (*biennially*) by looking for documentation of the date of the review and updates that were made to the plan based on the review.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

These strategies encompass procedures to preserve the healthcare system while continuing to provide care for all patients at an appropriate level (e.g., home-based care, outpatient, urgent care, emergency room, or hospitalization). Facilities must have policies which address their ability to respond to a surge in patients. As required, these policies and procedures must be aligned with a facility's risk assessment and should include planning for EIDs. Concentrated efforts will be required to mobilize all aspects of the healthcare system to reduce transmission of disease, direct people to the right level of care, and decrease the burden on the healthcare system.

<u>Surge Planning During Natural Disasters</u>

In most circumstances, staffing strategies and surge planning for natural disasters are event-specific and focus on evacuations, transfers, and staffing assistance from areas that are not impacted by the emergency.

<u>Surge Planning for Infectious Diseases/Pandemics:</u>

Infectious diseases may rise to the level of pandemic, causing severe impact to response and staffing strategies within the healthcare system. The primary goals in planning for infectious disease pandemics are to:

- **Reduce morbidity and mortality.**
- **Minimize disease transmission.**
- **Protect healthcare personnel.**
- **Preserving hospital/system functioning**

Facilities are encouraged to consider developing policies and procedures that could be implemented during an emergency to reduce non-essential healthcare visits and slow surge within the facility, such as:

- **Instructing patients to use available telehealth options, advice lines, patient portals, and/or on-line self-assessment tools.**
- **Call options to speak to an office/clinic staff member and identification of staff to conduct phone interactions with patients.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ **Development of protocols for rapid triage and assessment.** ▪ **Algorithms to identify which patients can be managed by telephone and advised to stay home, and which patients will need to be sent for emergency care or come to the facility.**	
09.00.04 Patient population *The Emergency* Operations *Plan* (EOP) *must address patient population, including but not limited to persons at-risk.* §482.15(a)(3)	☐ Compliant ☐ Not Compliant When creating the EOP, emergency response considerations should be given to at-risk populations within the hospital, which include individuals with disabilities, are from diverse cultures, have limited English proficiency or are non-English speaking, lack transportation, have chronic medical disorders, or have pharmacological dependency. 'At-risk' individuals also mean children, pregnant women, senior-citizens, and other individuals who have special needs in the event of an emergency. Mobility is an important part in effective and timely evacuations, and therefore facilities are expected to properly plan to identify patients who would require additional assistance, ensure that means for transport are accessible and available and that those involved in transport, as well as the patients and residents are made aware of the procedures to evacuate. For outpatient facilities, the emergency plan is required to ensure that patients with limited mobility are addressed within the plan.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify ▪ The addresses specific patient populations. □ The EOP identifies a plan for at-risk groups according to their needs.
09.00.05 Services *The Emergency* Operations *Plan* (EOP) *must address the type of services the hospital has the ability to provide in an emergency.*	☐ Compliant ☐ Not Compliant When creating the EOP, the type of services that the hospital can provide during an emergency must be identified and addressed. The EOP includes a plan for the continuation of these services during the facility's response to the emergency event. If specific equipment is required for services listed, as in radiological diagnostic services as an example, the	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The EOP identifies the type of services that the hospital has the ability to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.15(a)(3) **The EOP also addresses services needed that cannot be provided by the facility during an emergency as part of assessing continuity of operations and services.**	plan must state how equipment will be made available under emergency power.	provide during an emergency. ▪ The EOP addresses **services needed that cannot be provided during an emergency.** ▪ Services to be provided. If specific equipment is required for service, validate the provisions to keep the specific equipment available for use. In general, equipment that can be plugged into red emergency outlets is presumed to be available for the continuation of services during an emergency.

09.00.06 Continuity of operations

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The Emergency Operations *Plan* (EOP) *must address the continuity of operations, including delegations of authority and succession plans.*

§482.15(a)(3)

When creating the EOP, consideration should be given to:

- how the hospital will continue to operate the facility during the emergency event, and
- who is delegated as the authority during the emergency event, and
- how the succession of that authority is provided.

An Incident Command System (ICS) as described by the US Department of Homeland Security, Federal Emergency Management Agency (FEMA) is an effective means to provide for the continuity of operations.

The Incident Command System (ICS) is a management system designed to enable effective and efficient incident management by integrating a combination of facilities, equipment, personnel, procedures, and communications operating within a common organizational structure across

INTERVIEW AND DOCUMENT REVIEW

- Review the Emergency Operations Plan to verify that it provides for the continuity of operations.
  - □ Does the EOP address the delegation of authority during the emergency event, and the succession of that authority?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	multiple entities. The emergency plan must identify which staff would assume specific roles in another's absence through succession planning and delegations of authority. Succession planning is a process for identifying and developing internal people with the potential to fill key positions in the hospital. Succession planning increases the availability of experienced and capable employees that are prepared to assume these roles as they become available. During times of emergency, facilities must have employees who are capable of assuming various critical roles in the event that current staff and leadership are not available. At a minimum, there should be a qualified person who "is authorized in writing to act in the absence of the administrator or person legally responsible for the operations of the facility."	
09.00.07 <u>Collaboration</u>	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The Emergency Operations *Plan* (EOP) *must include a process for cooperation and collaboration with local, tribal, regional, State, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.* §482.15(a)(4)	Planning with officials in advance of an emergency to determine how such collaborative and cooperative efforts would achieve and foster a smoother, more effective, and more efficient response in the event of a disaster. The EOP addresses how the hospital will cooperate with external authorities during the emergency management planning process, in order to maintain an integrated response during the emergency. While the responsibility for ensuring a coordinated disaster preparedness response lies upon the state and local emergency planning authorities, the facility must include this integrated response process in its emergency plan. Facilities are encouraged to participate in a healthcare coalition as it may provide assistance in planning and addressing broader community needs that may also be supported by local health department and emergency management resources. In order to facilitate planning, facilities must share their plan with any	**<u>INTERVIEW AND DOCUMENT REVIEW</u>** Verify: ▪ The EOP provides for collaboration with relevant authorities during the planning process for emergency management. ▪ Copies of the EOP have been forwarded to listed collaborative authorities for their use and reference. **Note:** Evidence of communication beyond making the EOP available to these entities is not required.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

collaborators and/or authorities listed within the plan.

PROCEDURES

09.01.01 Policies & Procedures

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must develop and implement emergency preparedness policies and procedures. These policies and procedures must be based on the Emergency Operations Plan (EOP), the Hazard Vulnerability Analysis, and the Communication plan.

These Policies and procedures must be reviewed and updated every two years (*biennially*) by the Emergency Management Committee.

Written agreements with vendors and/or suppliers are updated annually if their goods or services are required as part of the EOP.

The staff roster is updated at least semi-annually.

§482.15(b)

The format of the EOP and the policies and procedures that a facility uses are at their discretion. ACHC does not prescribe or specify that the EOP must include the content of the policies and procedures. However, the facility must address all the requirements for the EOP and all the requirements for the policies and procedures.

If policies and procedures are not included in the EOP, then the EOP must reference where they are located. All referenced policies and procedures must meet all requirements for review and documentation as if included in the EOP directly.

Contracts are to be renewed annually or when vendors/suppliers are changed.

Real-time electronic tracking systems of staff members are deemed to meet the requirement for semi-annual updates to the call-back roster.

Facilities should also consider updates to their emergency preparedness policies and procedures during the course of a disaster, including planning for an emergency event with a duration longer than expected (for instance, during public health emergencies such as pandemics, the Centers for Disease Control and Prevention (CDC) and other public health agencies may issue periodic, on-going, event-specific guidance and recommendations to healthcare workers).

Facilities should ensure their programs have policies in place to update or provide additional emergency preparedness procedures to staff. This may include a policy delegating an individual to monitor guidance by public

INTERVIEW AND DOCUMENT REVIEW

Verify:

- Policies and procedures described in standards 09.01.02 through 09.01.14 are established.
- If the relevant P&P are separate from the EOP, they must be referenced in the EOP with locations noted.
- Relevant P&P have been reviewed and updated every two years per 09.01.01. Score timeline issues under both this Standard and the ACHC Standard requiring the specific component of emergency preparedness.
- Written agreements with vendors and/or suppliers have been updated annually.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	health agencies and issuing directives and recommendations to staff such as use of PPE when entering the building; isolation of patients under investigation (PUIs); and any other applicable guidance in a public health emergency.	
09.01.02 Nutritional Services *The policies and procedures for food, water* and nutritional services *must address the provision of subsistence needs for staff and patients whether they evacuate or shelter in place.* *These policies and procedures must be reviewed and updated* per ACHC Standard 09.01.01 by the Emergency Management Committee. §482.15(b)(1)(i)	☐ Compliant ☐ Not Compliant The policy and procedure (P&P) for nutritional services describes the strategies for ensuring nutritional needs are met during situations in which hospital services or utilities are disrupted. The P&P outline methods for meeting the nutritional needs of patients, visitors, and staff while sheltered in place, or evacuated to other locations. During an emergency event, the facility may experience a disruption in one or multiple services, such as: 1. Loss of water, gas, fuel, or electricity. 2. Equipment failure, e.g., dishwashing machines, pumps, refrigeration, cooking appliances. 3. Disruption with the delivery and grocery and food preparation items. Nutritional Services P&P anticipate possible disruptions and prepare strategies for ensuring continuity of services, including: 1. Alternative methods for heating foods and water used for cooking. 2. Written agreements with food suppliers for priority grocery delivery in the event of a disruption with the supply of food products. The written agreements are updated per ACHC Standard 09.01.01. The hospital calculates the volume of food, drinking water, paper products, and utensils needed to feed the patients, staff, and visitors for at least three days. The calculation parameters used are documented. The hospital stores a three-day inventory of:	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ P&P for nutritional services address methods for ensuring the nutritional needs of patients and personnel are met during emergencies, including major facilities disruption. ▪ Policies and procedures have been reviewed and updated per 09.01.01. ▪ The plan and calculations used to determine the quantity of drinking water and food meets the needs of all the staff and inpatients during an emergency event. ▪ Written agreements with vendors and/or suppliers to determine that they have been updated annually.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

1. Fresh and frozen foods.
2. Dairy products.
3. Drinking water.
4. Paper products.
5. Special dietary requirements, e.g., diabetic, Kosher, and vegetarian diets.

09.01.03 Supplies

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The policies and procedures for medical supplies, pharmaceutical supplies, and general equipment *must address the provision of subsistence needs for staff and patients that are sheltered in place.*

The policy and procedure provides for how the hospital will replenish the supplies and equipment after the emergency event begins.

All medical supplies, pharmaceutical supplies, and general equipment designated for emergency response are inventoried, documented, and reviewed and updated semi-annually.

These policies and procedures must be reviewed and updated per ACHC Standard 09.01.01 by the Emergency Management Committee.

The hospital identifies in written policies and procedures the medical supplies, pharmaceutical supplies, and general equipment it will need to meet the potential needs of staff and patients in an emergency while sheltered in place.

The Office of the Assistant Secretary for Preparedness and Response (ASPR) states that organizations should be prepared to "stand on their own" for at least 72 hours before an organized Federal response can effectively relieve the situation. That benchmark must be considered when identifying the medical supplies, pharmaceutical supplies, or general equipment that are required.

The amount and type of emergency supplies and equipment is left to the individual facility to determine but must be based on the reality of their EOP.

Emergency supplies and equipment must be maintained to ensure an acceptable response at the beginning of an event. This would require the supplies and equipment are stored in such a manner to ensure their safety (protection against theft or damage, contamination, or deterioration) and availability when needed.

The hospital makes provisions to ensure the availability of those supplies

INTERVIEW AND DOCUMENT REVIEW

Verify:

- Through interview of the person in charge of Emergency Management that there are medical supplies, pharmaceutical supplies and general equipment inventoried and stored for immediate response in an emergency.
- The organization has reviewed and updated the inventory of emergency response supplies on a semi-annual basis.
- P&P provide for the supplies and equipment needed in the initial phase of an emergency event.
- Policies and procedures have been reviewed and updated per 09.01.01.
- **Verify the organization has a policy that includes the anticipation of**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.15(b)(1)(i)	when needed. The hospital must have a plan to protect these limited emergency supplies and must have a plan for prioritizing their use until replacement supplies are available. The plan must also address the events of a disruption in the supply chain for these emergency utilities, such as a disaster involving the entire surrounding community. Once patients have been evacuated to other facilities, it would be the responsibility of the receiving facility to provide for the patient's subsistence needs. This standard does not require the facility to be responsible for subsistence needs of individuals in the community. The provision of subsistence needs only applies to staff and patients. **ANTICIPATE SUPPLY SHORTAGES** **Hospital policies identify:** ▪ **Actions to take when the organization experiences shortages of medications or supplies.** ▪ **Strategies recommended by state and federal health agencies including how to access the national stockpile of medications and supplies.** ▪ **Medications and doses used to treat the communicable disease.** ▪ **Pharmaceutical sources and suppliers of the medications.** ▪ **Suppliers of the emergency equipment and supplies, and when possible, back-up suppliers.** **In advance of a communicable disease outbreak or pandemic, the hospital determines the types and quantities of equipment, supplies, and medications needed for continuity of patient care. While stockpiling is not required, the hospital determines the quantities of supplies needed for a one-month period of time:** ▪ **Beds**	**supply shortages and contingencies in the event of a communicable disease outbreak or pandemic.** ▪ Review written agreements with vendors and/or suppliers to verify that they have been updated annually. ▪ **Verify the organization has a process for providing updates to the Incident Command Center regarding availability of equipment/supplies.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- **Ventilators PPE: Facemasks, gowns, gloves**
- **Hand sanitizer**
- **Cleaning supplies**
- **Paper products, such as toilet paper, paper towels**
- **Others**

PERPETUAL INVENTORY

During a widespread communicable disease outbreak or pandemic, a shortage of supplies should be anticipated.

The hospital has a process to update the Incident Command Center regarding available equipment/supplies, such as:

- **beds**
- **ICU beds**
- **ventilators**
- **gloves, facemasks, gowns**
- **IV infusion pumps**
- **Quantities of medications used to treat the communicable disease.**

The organization considers an electronic report of the current availability of supplies to post on the facility's intranet. Facilities have flexibility to identify appropriate tools for tracking of inventory, however facilities may consider electronic tracking tools consistent with state recommendations and guidelines.

09.01.04 Utilities

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The policies and procedures for alternate sources of energy must address the

The hospital must ensure the continuation of operation of strategic utilities during an emergency event, including:

INTERVIEW AND DOCUMENT REVIEW

Verify:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

provision of subsistence needs for staff and patients whether they evacuate or shelter in place.

The alternate sources of energy must maintain:

- *Temperatures to protect patient health and safety, and for the safe and sanitary storage of provisions.*
- *Emergency lighting.*
- *Fire detection, extinguishing, and alarm systems.*
- *Sewage and waste disposal.*

The policies and procedures for alternate sources of energy provides for the continuation of utilities such as emergency power, fuel, medical air, gas, and vacuum, during an emergency event.

These policies and procedures must be reviewed and updated per ACHC Standard 09.01.01 by the Emergency Management Committee.

§482.15(b)(1)(ii)(A-D)
§482.41(a)(2)

- emergency power.
- fuel for generators and boilers.
- medical air, gas and vacuum.
- sewage and waste disposal.

The hospital needs to document what areas of the facility are served by emergency power, and what areas are not. This standard does not specify what HVAC units (if any) are to be connected to emergency power generators; however, emergency power generators must maintain temperatures to protect patient health and safety, and to protect the safe storage of provisions. The hospital's policies and procedures need to address how the hospital determined which HVAC units (if any) are connected to emergency power.

The hospital must have written agreements which are updated annually with vendors, suppliers, or others to provide for the following utilities during an emergency event:

- Service and repairs for the generators
- Replenishment of fuel for generators and boilers
- Portable cylinders of medical air and medical gas
- Portable vacuum
- Non-potable water for processing

The hospital shall determine the quantity of fuel supply to have on hand for the emergency generators and boilers. This quantity is based on the circumstances of the hospital and the availability of replacement fuel.

At a minimum, the quantity of fuel maintained for the emergency generators must be calculated to include all these elements per the specifics under NFPA 72, 2010 edition, sections 10.5.6.3 and 10.5.10.6:

- At least a 24-hour supply to maintain the fire alarm system under

- P&P are in place regarding the provision for alternate sources of energy to maintain temperature; emergency lighting; fire detection; fire extinguishing; fire alarm systems; and sewage and waste disposal.
- P&P have been reviewed and updated per 09.01.01.
- Utility supplies for emergency power, fuel, medical air, gas, and vacuum, and non-potable water is appropriate for the size of the hospital operations, the services provided and the number of staff and inpatients.
- Review the hospital's risk assessment of the facilities sewage and wastewater disposal systems and their plans to maintain the necessary services during an emergency.
- Written agreements with vendors and/or suppliers have been updated annually.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

non-alarm conditions.

- An additional amount of fuel for continuance under alarm operation for five minutes.
- An additional amount for six months of generator testing.

For installations in seismic areas, compliance for maintenance of fuel supply for generators must comply with NFPA 110 (2010 edition).

Whatever quantity of fuel is maintained; consideration must be given to its capability to replenish the fuel supply before it is exhausted. The hospital shall maintain documentation of its fuel supply needs and its procedures for fuel replenishment in times of emergency. If the hospital uses the same fuel supply for multiple uses, (heating, hot water, generator, etc.) the hospital must maintain fuel supplies to address its total needs and to address periods where re-supply may be limited (i.e., snow, flooding, transportation disruption, etc.).

Hospitals must develop policies and procedures to address the provisions of sewage and waste disposal including solid waste, recyclables, chemical, biomedical waste, and wastewater.

Facilities must identify and assess their sewage and wastewater disposal systems as part of their facility-based risk assessment and make necessary plans to maintain these services. This standard does not require the onsite treatment of sewage, but the facility must make provisions for maintaining necessary services.

If used, portable generators are connected to a facility's electrical circuits via a power transfer system, as recommended by the generators' manufacturer. A power transfer system typically consists of a transfer switch, generator power cord and power inlet box in accordance with manufacturer instructions and NFPA 70, Article 400.8.

Extension cords or other temporary wiring devices may not be used to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	connect electrical equipment in the facility to a portable and mobile generator.	
09.01.05 Patient and staff tracking	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The policies and procedures must address a system to track the location of on-duty staff and sheltered patients in the hospital's care during an emergency. *If on-duty staff and sheltered patients are relocated during an emergency, the hospital must document the specific name and location of the receiving facility or other location.* *These policies and procedures must be reviewed and updated* per ACHC Standard 09.01.01 by the Emergency Management Committee. §482.15(b)(2)	Hospitals must have policies and procedures in place regarding a system to track the location of staff and patients in the hospital's care during an emergency. Tracking patients after an emergency is not a requirement of this standard.	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Written P&P are in place regarding the tracking of on-duty staff and sheltered patients in the hospital's care during an emergency. ▪ P&P have been reviewed and updated per 09.01.01. ▪ Written agreements with vendors and/or suppliers are updated annually.
09.01.06 Evacuation	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The policies and procedures must address the safe evacuation from the hospital, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of	The evacuation plan may be part of the Emergency Operations Plan (EOP) or it may be separate. If separate, the EOP must reference where to find the evacuation plan. Hospitals must consider multiple transportation options for patient evacuation and collaborate with healthcare coalitions to better inform and assist in planning activities for the efficient and effective use of limited	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ P&P provide for the Emergency Evacuation Plan. ▪ The Emergency Evacuation Plan

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
communication with external sources of assistance. The policies and procedures provide for a written Emergency Evacuation Plan which identifies when and how patients will be evacuated from the facility. The Emergency Evacuation Plan is reviewed by the community emergency response agency. *These policies and procedures must be reviewed and updated* per ACHC Standard 09.01.01 by the Emergency Management Committee. §482.15(b)(3)	resources. A written Emergency Evacuation Plan must be created which identifies when and how the hospital will evacuate patients from the hospital when it is no longer safe to provide patient care and treatment services at the facility. The written Emergency Evacuation Plan must be reviewed with the local community emergency response agency. Additional evacuation procedures for specialty patient care units must be developed and incorporated into the Emergency Evacuation Plan. **Patient safety is the priority and any existing guidance on patient rights and safe setting (e.g., §482.13(c)(2) for hospitals) should be continued. Facilities should consider how they would address a situation where a patient/resident refuses to evacuate; leaving a patient in an unsafe environment is not acceptable.**	was reviewed by the local community emergency response agency. ▪ P&P consider multiple transportation options for patient evacuation needs. □ **How would staff handle a situation in which a patient refused to evacuate?** ▪ P&P have been reviewed and updated per 09.01.01.
09.01.07 Shelter in Place *The policies and procedures must address the means to shelter in place for patients, staff, and volunteers who remain in the facility during an emergency event.* *These Policies and procedures must be reviewed and updated* per ACHC Standard 09.01.01 by the Emergency Management Committee. §482.15(b)(4)	☐ Compliant ☐ Not Compliant The hospital must have policies and procedures in place that address a means to shelter in place for patients, staff and volunteers who remain in the facility during an emergency event. The policy must include criteria for selecting patients and staff that would be sheltered in place and a description of how they would ensure their safety. Hospitals must make plans to shelter all patients in the event that an evacuation cannot be executed.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ P&P address a means to provide shelter for patients, staff and volunteers who remain in the facility during an emergency. ▪ P&P have been reviewed and updated per 09.01.01.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.01.08 Medical Documentation *Policies and procedures must address a system of medical documentation that preserves patient information, protects confidentiality of patient information, and secures and maintains the availability of records.* *These policies and procedures must be reviewed and updated* per ACHC Standard 09.01.01 by the Emergency Management Committee. §482.15(b)(5)	☐ Compliant ☐ Not Compliant Hospital policies are in compliance with HIPAA rules which protect the privacy and security of an individual's protected health information. This Standard does not require any particular type or style of medical documentation system and does not require the hospital to have the same system as other healthcare providers in their region.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ P&P address a system of medical documentation to be used in the event of an emergency. ▪ The medical documentation system preserves patient information and protects the confidentiality of patient information. □ Are patient medical records available during the emergency event? ▪ P&P have been reviewed and updated every two years per 09.01.01.
09.01.09 Volunteers *The policies and procedures must address the use of volunteers in an emergency, and must address other emergency staffing strategies, including the process and role for integration of State and Federally designated healthcare professionals to address surge needs during an emergency.* The Policies and procedures provide for a volunteer management plan that assigns and supervises volunteers during an	☐ Compliant ☐ Not Compliant **If the hospital uses volunteers as part of their emergency staffing strategy, policies and procedures clearly outline what type(s) of volunteers would be accepted during an emergency and what role(s) these volunteers might play.** The volunteer management plan may be part of the Emergency Operations Plan (EOP) or it may be separate. If separate, the EOP must reference where to find the volunteer management plan. The facility must have a plan to verify each volunteer's identity, license, credentials, certifications, malpractice insurance, and hospital privileges,	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ P&P include a volunteer management program, **if volunteers are used**. □ **Through interview with hospital leadership, the staffing strategy. If no volunteers are used, does the facility have other emergency staffing strategies?**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
emergency event. *These policies and procedures must be reviewed and updated* per ACHC Standard 09.01.01 by the Emergency Management Committee. §482.15(b)(6)	within 72 hours of activating the Incident Command Center, when possible. The volunteer's identity and evidence of state professional license will be verified prior to providing patient care. Federal, local, or state-based systems shall be utilized to verify the identity and credentials of health professionals, when possible. Any special issues, such as spontaneous non-medical volunteers, stress management for volunteers, and legal issues, such as workers' compensation, insurance, and safety are addressed in advance and included in the policies and procedures.	▪ **There is a P&P that addresses surge needs during an emergency.** ▪ P&P have been reviewed and updated every two years per 09.01.01**.**
09.01.10 Continuity of services *The policies and procedures must address the development of arrangements with other hospitals and other providers to receive patients in the event of limitations or cessation of operations to maintain the continuity of services to patients.* *These Policies and procedures must be reviewed and updated* per ACHC Standard 09.01.01 by the Emergency Management Committee. §482.15(b)(7)	☐ Compliant ☐ Not Compliant A transfer agreement must be signed with other hospitals in the region whereby patients may be expected to evacuate to or from. **When developing transfer agreements, facilities account for the patient population and the ability for the receiving facility to provide continuity of services.** The purpose of these transfer agreements is: ▪ to assist physicians and facilities in the treatment of trauma patients. ▪ to facilitate the timely transfer of patients and information necessary in the care and treatment of patients. ▪ the continuity of the care and treatment appropriate to the needs of the trauma patients. ▪ the utilization of knowledge and other resources of both facilities in a coordinated manner to improve the professional health care of trauma patients.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the P&P to determine if it identifies the local hospitals with whom they have transfer agreements. □ Verify that the transfer agreements are completed and signed by representatives from each organization. ▪ Review P&P to ensure they have been reviewed and updated every two years per 09.01.01.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.01.11 Invoking the 1135 Waiver	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The policies and procedures must address the role of the hospital under a waiver declared by the Secretary of Health and Human Services*, in accordance with section 1135 of the* Social Security *Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.* **Waivers issued under section 1135 are time-limited, and waive only federal requirements, not state requirements for licensure, or conditions of participation, and are meant to ensure sufficient health care items and services are available to meet the needs of individuals in such areas.** *These policies and procedures must be reviewed and updated* per ACHC Standard 09.01.01 by the Emergency Management Committee. §482.15(b)(8)	When the President of the United States declares a disaster and the HHS Secretary declares a public health emergency, the Secretary is authorized under section 1135 to take certain actions to waive or modify certain Medicare, Medicaid, or Children's Health Insurance Program requirements to ensure that sufficient health care items and services are available to meet the needs of individuals enrolled in the Social Security Act programs in the emergency areas. This will allow hospitals who provide such services in good faith to be reimbursed and exempted from sanctions (absent any determination of fraud or abuse). Once an 1135 Waiver is authorized, health care providers can submit requests to operate under that authority or for other relief that may be possible outside the authority, to the CMS Location (Regional Office) with a copy to ACHC. CMS has stated that they expect the state or local emergency management officials would designate alternate care sites and would plan jointly with local facilities on issues related to staffing, equipment, and supplies at such alternate sites. This requirement encourages providers to collaborate with their local emergency officials in proactive planning to allow an organized and systematic response to assure continuity of care even when services at their facilities have been severely disrupted.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Review P&P to verify it includes the role the hospital has under an 1135 Waiver. ▪ Verify that P&P identify the alternate care site identified by the state or local emergency management officials. ▪ Review P&P to ensure they have been reviewed and updated every two years per 09.01.01**.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

09.01.12 Security

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The policies and procedures must address a comprehensive process to provide for the security of the patients, staff and visitors during an emergency event.

These policies and procedures must be reviewed and updated per ACHC Standard 09.01.01 by the Emergency Management Committee.

During an emergency event, patients, visitors, and staff must be protected from threats concerning security. Policies, procedures, and systems must be developed to monitor and reduce adverse outcomes. The organization identifies and implements a process on how supplemental security resources are obtained in the event of a disaster.

The policies and procedures must address:

1. The differing needs of each location where the hospital operates.
2. The special needs of patient populations treated at the hospital (e.g., patients with psychiatric diagnoses, patients on special diets, newborns, etc.).
3. Security of patients and walk-in patients.
4. Security of supplies from misappropriation.
5. Identification of personnel that are needed to implement and carry out the hospital's emergency plans.

INTERVIEW AND DOCUMENT REVIEW

Verify:

- P&P reflect a comprehensive plan to ensure that the security and well-being of patients are assured during emergency situations.
- How supplemental security forces are obtained in the event of a disaster.
- Policies, procedures, and systems are in place to provide emergency security services.
- P&P have been reviewed and updated per 09.01.01.

09.01.13 Decontamination

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The policies and procedures must address how the hospital arranges for the chemical, biological and radioactive decontamination.

These policies and procedures must be reviewed and updated per ACHC Standard 09.01.01 by the Emergency Management Committee.

Decontamination procedures must be in place for internal and external accidents. The hospital designates teams to respond to emergency events and initiate the decontamination procedures. A plan describing the decontamination procedures can be integrated into a single plan or multiple plans.

During an emergency, aspects of the physical environment must contain, neutralize, or destroy potentially harmful materials and wastes.

The procedures for the cleanup of spills and accidents must include the

DOCUMENT REVIEW

Verify:

- P&P address decontamination activities.
- P&P have been reviewed and updated every two years per 09.01.01.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	notification of the appropriate authorities based on the size and severity of the spill and hospital resources available.	
09.01.14 Incident Command Center	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The policies and procedures must address the identification where the hospital's incident command center will be located. The policies ensure essential equipment and support is intact and maintained for use in directing and controlling response and recovery operations. The policy provides for a process for activation of the incident command center, and how it is operated. These policies and procedures must be reviewed and updated per ACHC Standard 09.01.01 by the Emergency Management Committee.	There is a reference in the policies and procedures to the location of the command center for directing and controlling hospital emergency response functions. The policies and procedures also include or reference: ▪ a list of facility equipment (e.g., telephones, displays, fax machines, computers), to be used in the Incident Command Center. ▪ a layout diagram identifying where the equipment is to be set up in the Incident Command Center. ▪ the locations of emergency power that is available in the Incident Command Center.	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ P&P: □ Identify the location of the command center. □ include a setup process for the Incident Command Center with drawings. □ Have been reviewed and updated per 09.01.01. ▪ **There is a process for providing updates to the ICC regarding availability of equipment/supplies.**
COMMUNICATION		
09.02.01 Communication plan	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital must develop and maintain an emergency communication plan that complies with Federal, State, and local laws, and must be reviewed and updated	The communication plan may be part of the EOP or it may be separate. If separate, the EOP must reference where to find the communication plan. All hospital units and departments must have a process in place to initiate the call back of staff on each unit. Staff must be able to make external	**DOCUMENT REVIEW** Verify: ▪ The staff call-back roster has been updated semi-annually.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
per ACHC Standard 09.01.01. The communication plan must include a tiered rapid process for alert and notification of staff in an emergency. This includes staff mobilization and communications call-back processes used at the beginning of an emergency event. The communication plan provides for the dispensing of information by hospital designated spokespersons to the media. §482.15(c)	notifications and demonstrate the capability to share information with the incident commander and necessary external partners. The communication plan must include a process for the notification of key personnel who are either at the hospital or away from the hospital whenever the Incident Command System is activated. The staff call-back roster is dated and is updated per Standard 009.01.01. The communication plan identifies the location where the media will be briefed.	▪ **Through interviews with leadership or the designee responsible for the Emergency Preparedness Program that collaboration takes place with federal, state, and local officials to ensure the communication plan complies with requirements.** ▪ P&P have been reviewed and updated every two years per 09.01.01.

09.02.02 Contact information

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The communication plan must include the names and contact information for:

- *Staff*
- *Entities providing services under arrangement*
- *Patient's physicians*
- *Other hospitals and CAHs*
- *Volunteers*
- *Federal, State, tribal, regional, and local emergency preparedness staff*
- *Other sources of assistance.*

§482.15(c)(1)

Emergency preparedness officials may include, but are not limited to, emergency management agencies which may be local to the community as well as local officials who support the Incident Command System depending on the nature of the disaster (e.g., fire, police, public health, etc.).

Additionally, emergency management officials also include the state public health departments and federal emergency preparedness officials (FEMA, ASPR, DHS, CMS, etc.) and tribal emergency officials, as applicable.

Facilities have discretion in the formatting of this information but it should be readily available and accessible to leadership and staff during an emergency event. Facilities that use electronic data storage should be able to provide evidence of data back-up with hard copies or demonstrate capability to reproduce contact lists or access this data during emergencies. Contact information contained in the communication plan must be accurate

DOCUMENT REVIEW

- Review the emergency communications plan to verify it contains the names and contact information of the individuals noted.
- **Verify that the facility has contact information for the State Survey Agency and/or public health departments.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.15(c)(1)(i-v) §482.15(c)(2) §482.15(c)(2)(i-ii)	**and current. Any changes to information for entities on the contact list are updated in the Contact Information when changes are discovered and at a minimum as follows (reference 009.01.01):** ▪ **Staff rosters must be updated on a semi-annual basis. Facilities must update contact information for incoming new staff and departing staff throughout the year. Real-time electronic tracking systems of staff members meet the requirement for semi-annual updates to the call-back roster.** **Entities providing services under arrangement must be updated annually.**	
09.02.03 Primary and alternate means of communication *The communication plan must include primary and alternate means for communication with the following:* ▪ *The hospital's staff* ▪ *Federal, State, tribal, regional, and local emergency management agencies.* §482.15(c)(3) §482.15(c)(3)(i-ii)	☐ Compliant ☐ Not Compliant Reliable communication must be maintained by the hospital during an emergency event. Backup technology must be considered and utilized with the consideration that traditional methods of communication may not be available. Alternative methods must be explored and planned for in the written procedure. Primary and alternate means of communication include: ▪ Land-line telephones ▪ Pagers ▪ Internet provided by satellite or non-telephone cable systems ▪ Cellular telephones ▪ Radio transceivers (walkie-talkies) ▪ Various other radio devices, such as NOAA weather radio and amateur radio (HAM) ▪ Satellite telephone communication systems The communication plan provides for written procedures and methods on	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the emergency communications plan and determine that it meets the requirement for primary and alternate communication means with staff and outside agencies.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	how the hospital communicates with staff and outside agencies that have a functional role with the hospital's response and recovery phases during an emergency event.	
09.02.04 Information sharing *The communication plan must include a method for sharing information and medical documentation for patients under the hospital's care, as necessary, with other health care providers to maintain the continuity of care.* §482.15(c)(4)	☐ Compliant ☐ Not Compliant Sharing patient information with other healthcare providers is critical during an emergency, especially when patient transfer and evacuation is conducted. The hospital must have a method that allows this sharing of information in a timely and efficient manner. Facilities are required to develop a method for sharing information and medical documentation for patients under the facility's care, as necessary, with other health care providers to maintain continuity of care. Such a system must ensure that information necessary to provide patient care is sent with an evacuated patient to the next care provider and would also be readily available for patients being sheltered in place. While the regulation does not specify timelines for delivering patient care information, facilities are expected to provide patient care information to receiving facilities during an evacuation, within a timeframe that allows for effective patient treatment and continuity of care. Facilities should not delay patient transfers during an emergency to assemble all patient reports, tests, etc. to send with the patient. Facilities should send all necessary patient information that is readily available and should include at least, patient name, age, DOB, allergies, current medications, medical diagnoses, current reason for admission (if inpatient), blood type, advance directives and next of kin/emergency contacts. There is no specified means (such as paper or electronic) for how facilities are to share the required information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the emergency communications plan to determine it addresses the hospital's plan on sharing patient information with other healthcare providers.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.02.05 Release of information *The communication plan must include a means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).* *The communication plan must include a means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).* §482.15(c)(5) §482.15(c)(6)	☐ Compliant ☐ Not Compliant A covered entity may use or disclose protected health information to notify or assist in the notification of (including identifying or locating), a family member, a personal representative of the individual, or another person responsible for the care of the individual of the individual's location, general condition, or death. Any such use or disclosure of protected health information for such notification purposes must be in accordance with paragraphs (b)(2), (b)(3), (b)(4), or (b)(5) of section 45 CFR 164.510, as applicable. A covered entity may use or disclose protected health information to a public or private entity authorized by law or by its charter to assist in disaster relief efforts, for the purpose of coordinating with such entities the uses or disclosures permitted by paragraph (b)(1)(ii) of section 45 CFR 164.510. The requirements in paragraphs (b)(2), (b)(3), or (b)(5) of section 45 CFR 164.510 apply to such uses and disclosures to the extent that the covered entity, in the exercise of professional judgment, determines that the requirements do not interfere with the ability to respond to the emergency circumstances.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the emergency communications plan to verify it includes the necessary means to provide patient information to family members, personal representative, or other individuals responsible for the care of the patient.
09.02.06 Hospital information *The communication plan must include a means of providing information about the hospital's occupancy, needs, and its ability to provide assistance, to the authorities having jurisdiction, the Incident Command Center, or designee.* §482.15(c)(7)	☐ Compliant ☐ Not Compliant Communicating critical information to the authorities having jurisdiction regarding the hospital during an emergency is vital to a well-organized response to an emergency. The hospital may have multiple authorities having jurisdiction they need to communicate their capabilities with during an emergency: Local, regional, tribal, and or State authorities.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the emergency communications plan to verify that it addresses how the hospital will communicate its abilities during an emergency to the appropriate authorities.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

REPORTING A FACILITY'S NEEDS

Generally, in small community emergency disasters, reporting the facility's needs will be coordinated through established processes to report directly to local and state emergency officials. Reporting needs may include but are not limited to shortages in PPE; need to evacuate or transfer patients; requests for assistance in transport; temporarily loss of part or all facility function; and staffing shortages.

In large scale emergency disasters or pandemics, reporting of needs specific to a facility may be altered by local, state, and federal public health and emergency management officials due to the potential volume of requests. Some emergency management officials at all levels of governance may require facilities to report specific data or slow reporting to manage volume.

REPORTING A FACILITY'S ABILITY TO PROVIDE ASSISTANCE

During widespread disasters, reporting a facility's ability to provide assistance is critical within a community. Pre-planning and collaborating with emergency officials before an emergency to determine what assistance may be necessary directly supports surge planning within a community.

During widespread disasters, facilities may be required to report the following to local officials:

- **Ability to care for patients requiring transfer from different healthcare settings;**
- **Availability of PPE;**
- **Availability of staff who may be able to assist in a mass casualty incident;**
- **Availability of electricity-dependent medical and assistive equipment, such as ventilators and other oxygen equipment (BiPAP, CPAP, etc.), renal replacement therapy machines (e.g., home and facility-based hemodialysis, peritoneal dialysis, continuous renal replacement therapy and other machines, etc.),**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

and wheelchairs and beds.

TRAINING AND TESTING

09.03.01 Emergency Training

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must develop and maintain a training program that is based on the Emergency Operations Plan (EOP), the Hazard Vulnerability Assessment (HVA), the policies and procedures, and the communication plan.

The hospital must do all of the following:

- *Provide initial training in emergency management policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected role.*
- *Provide emergency management training when the emergency plan is significantly updated and at least biennially or every two years.*
- *Maintain documentation of all emergency management training.*
- *Demonstrate staff knowledge of emergency procedures.*
- *The training program must be reviewed and updated biennially or*

A well organized, effective training program must include initial training for new and existing staff in emergency preparedness policies and procedures as well as refresher trainings every two years.

The hospital must provide initial training in emergency preparedness policies and procedures to all staff, including individuals providing services under arrangement, volunteers, and physicians, consistent with their expected role.

The hospital must provide ongoing emergency preparedness training to all staff at least every two years. The hospital must maintain documentation of the training. The hospital must be able to demonstrate staff knowledge of emergency procedures.

While facilities are required to provide training to all staff every two years, it is up to the facility to decide what level of training each staff member will be required to complete based on an individual's involvement or expected role during an emergency. There may be core topics that apply to all staff, while certain staff may require additional topics.

The training provided by the facility must be based on the facility's risk assessment policies and procedures as well as the communication plan. The intent is that new and existing staff, volunteers and individuals providing services at the facility are familiar and trained on the facility's processes for responding to an emergency. Training should include individual-based response activities in the event of a natural disaster, such as what the process is for staff in the event of a forecasted hurricane. It should also include the policies and procedures on how to shelter-in-place or evacuate. Training should include how the facility manages the continuity of care to its

DOCUMENT REVIEW

- Review the training program to ensure all staff are educated on the emergency preparedness program.
  - ☐ **Refer back to the facility's risk assessment to determine if the training and testing program is reflecting risks and hazards identified within the facility's program.**
- Are staff (including contract workers and physicians) receiving training on emergency preparedness every two years?
- **Verify documentation is available and accurate for training and testing.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
every two years. §482.15(d) §482.15(d)(1)(i-v)	**patient population, such as triage processes and transfer/discharge during mass casualty or surge events. Furthermore, the facility must train staff based on the facility's risk assessment. Training for staff should mirror the facility's emergency plan and should include training staff on procedures that are relevant to the hazards identified. For example, for EID's this may include proper use of PPE, assessing needs of patients and how to screen patients and provide care based on the facility's capacity and capabilities and communications regarding reporting and providing information on patient status with caregiver and family members.** **Facilities must also be able to demonstrate additional training when the emergency plan is significantly updated. Hospitals that have changed their EOP should plan to conduct initial training to all staff on the new or revised sections of the plan. If a facility determines the need to add additional policies and procedures based on a new risk identified in the facility's risk assessment, the facility must train all staff on the new policies and procedures and the staff responsibilities. Facilities are not required to retrain staff on the entire emergency plan but can choose to train staff on the new or revised element of the emergency preparedness program. For example, a facility identifies during an influenza outbreak that additional policies and procedures and adjustments to the risk assessment are needed to address a significant influx of patients/clients/residents. The facility identifies clinical locations in which contagious patients can be triaged in a manner to minimize exposure to non-infected individuals. The training for this new or revised policy can be done without needing to re-train staff on the entire program.**	

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

09.03.02 Emergency exercises

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must develop and maintain a testing program (exercises) *that is based on the Emergency* Operations *Plan* (EOP), the Hazard Vulnerability Assessment (HVA), *the policies and procedures, and the communication plan*.

The training and testing programs must be reviewed and updated ***at least every two years****.*

Hospitals and free-standing ambulatory health care occupancy facilities that are part of the hospital system must participate in two emergency exercises to test the EOP per calendar year.

Each exercise is to be planned by the oversight committee on emergency management and implemented to build competencies in staff.

The hospital must conduct two exercises per year*, to test the emergency plan:*

1. *The hospital must participate in a full-scale exercise that is community-based, or when a community-based exercise is not accessible, an individual facility-based exercise. If the hospital experiences an actual natural or man-made emergency that requires activation of the emergency*

The purpose of the emergency exercises is to demonstrate the effectiveness of the hospital's emergency plan and to use the results of the exercises to improve the hospital's EOP.

The testing program may be part of the EOP or it may be separate. If separate, the EOP must reference where to find the testing program.

Each implementation exercise (either an actual emergency or a simulation) is analyzed and evaluated and all documentation of the analysis and evaluations (after-action report/critique) must be maintained. The emergency management committee uses this information to improve the hospital's capability to respond to emergencies, and to make improvements to the Emergency Operations Plan. The emergency committee submits reports to hospital leadership, and as appropriate, state, and federal entities.

The scenario for tabletop exercises cannot be related topics that have been used for other tabletop exercises within a two-year timeframe from the date of the last such exercise.

Buildings classified as "business occupancies" that provide patient care are required to perform one emergency exercise per calendar year. Every other year, these providers must participate in either a community-based full-scale exercise (if available) or conduct an individual facility-based functional exercise. In the opposite years, these providers must conduct a testing exercise of their choice, which includes either a community-based full-scale exercise (if available); an individual, facility-based functional exercise; a drill; or a tabletop exercise or workshop that includes a group discussion led by a facilitator. The facilitator must have specialty experience or education in Emergency Preparedness operations for the latter.

DOCUMENT REVIEW

- Review the evaluation records of the emergency exercises.
- Assure that all after-action plan items have been documented in the oversight committee on emergency management meeting minutes and the Quality Assurance Performance Improvements (QAPI) minutes.
- Ensure that each exercise is based on one of the identified Hazard Vulnerability Analysis (HVA) hazards.
- Ensure that buildings classified as healthcare occupancy or ambulatory healthcare occupancy each receives at least two emergency exercises within the past calendar year.
- Ensure that buildings classified as business occupancies and provide patient care activities each receives at least one emergency exercise within the past calendar year.

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*plan, the hospital is exempt from engaging in **its next required full-scale** or individual facility-based full-scale exercise for 1-year following the onset of the actual event.*

2. *The hospital must participate in a second exercise(s) of their choice:*
   a. *A full- scale exercise that is community-based or an individual facility-based functional exercise;*

   or

   b. a ***mock disaster*** drill

   or

   c. a tabletop exercise or ***workshop that is led by a facilitator and includes a group discussion, using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.***

The hospital completes an after-action report.

The hospital must *analyze the hospital's response to and maintain documentation of all drills, tabletop exercises, and emergency events, and revise the hospital's emergency plan, as needed.*

§482.15(d)
§482.15(d)(2)(i-iii)

PARTICIPATION

Regulations do not specify a minimum number of staff, or the roles of staff in the exercises, but it is strongly encouraged that facility leadership and department heads participate. If an exercise is conducted at the individual facility-based level and is testing a particular clinical area, staff who work in this clinical area should participate in the exercise for a clear understanding of their roles and responsibilities. Facilities can review which members of staff participated in the previous exercise to ensure participation in subsequent exercises. A sign-in roster for the exercise is acceptable to substantiate staff participation. A sufficient number of staff should participate in the exercise to thoroughly assess the risk, policy, procedure, or plan being tested.

EXEMPTION BASED ON ACTUAL EMERGENCY

An actual emergency event or response of sufficient magnitude that requires activation of the relevant emergency plans meets the full-scale exercise requirement and exempts the facility from engaging in their next required full-scale exercise (community- or facility-based) following the actual event. The hospital must be able to demonstrate this through written documentation. Documentation may include but is not limited to a section 1135 waiver issued to the facility (time limited and event-specific); documentation alerting staff of the emergency; documentation of facility closures; meeting minutes which addressed the time and event-specific information. The hospital must also complete an after-action report of the actual emergency and identify corrective actions integrated into the emergency preparedness program.

- **Example: If a hospital completed the full-scale exercise in January 2020 and is scheduled to conduct an exercise of choice in November 2020 but experiences an actual emergency in March 2020 which required activation of its emergency plan, the hospital is exempt from the next required full-scale exercise in January 2021 but must complete the exercise of choice. If the hospital**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

conducted an exercise of choice prior to the actual emergency and had a full-scale exercise scheduled for November 2020, then the hospital would be exempt from that full-scale exercise.

OPERATIONAL REQUIREMENTS

09.04.01 Emergency power

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must implement emergency power systems based on the Emergency Operations *Plan (*EOP) in the 'Planning' section (see standard 09.00.01), *and the Policies and procedures* in the 'Procedures' section (see standard 009.01.01).

The emergency power generator must be located to minimize the damage from flooding in accordance with the location requirements found in NFPA 99-2012 Health Care Facilities Code (and TIAs 12-2 to 12-6), NFPA 101-2012 Life Safety Code (and TIAs 12-1 to 12-4), and NFPA 110-2010 Standard for Emergency and Standby Power Systems, when a new structure is built or when an existing structure or building is renovated.

The hospital must implement the emergency power inspection, testing, and maintenance requirements found in NFPA 99-2012, NFPA 101-2012, and NFPA 110-2010.

NFPA 99 covers emergency power requirements for lighting, fire detection systems, extinguishing systems, and alarm systems. NFPA 99 does not specify emergency power requirements for maintaining supplies and its facility temperature requirements are limited to heating equipment for operating, delivery, labor, recovery, intensive care, coronary care, nursery, infection/isolation rooms, emergency treatment spaces, and general patient/resident rooms. NFPA 99 does not require heating in general patient rooms during the disruption of normal power where the outside design temperature is higher than 20 degrees Fahrenheit or where a selected room(s) is provided for the needs of all patients (where patients would be internally relocated), then only that room(s) needs to be heated.

Therefore, Essential Electrical Systems (EES) in hospitals should include/accommodate any additional electrical loads the facility determines necessary to meet all subsistence needs required by emergency preparedness plans, policies, and procedures, unless the facility's emergency plans, policies and procedures determine that the hospital will relocate patients internally or evacuate in the event of an emergency.

Additional load testing of the generator, other than what is required by NFPA 110-2010 is not required by this standard.

INTERVIEW AND DOCUMENT REVIEW

Note: Generator inspection and testing requirements are scored in the Life Safety chapter.

Verify:

- The hospital's plan to keep the generator operational during the emergency.
- Generators installed since July 5, 2016, have been located in an area to minimize the damage from flooding. Ask for the installation date of existing generators if they appear to be new; alternately, the date can be verified on testing documentation for the annual or 3-yr/4-hr generator load testing.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

The hospital must maintain an onsite fuel source to power emergency generators and must have a plan on how it will keep emergency power systems operational during the emergency unless the hospital decides to evacuate.

§482.15(e)(1-3)

09.04.02 Integrated Healthcare Systems

☐ Compliant ☐ Not Compliant ☐ N/A

This standard is not met as evidenced by:

If a hospital is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the hospital may choose to participate in the healthcare system's coordinated emergency preparedness program.

If elected, the unified and integrated emergency preparedness program must:

1. *Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.*
2. *Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and*

Large health systems may develop an integrated emergency preparedness program for all of their facilities, which would include an integrated training program. Therefore, to offset some of the financial burden, facilities that are part of a large health system may opt to participate in their health system's universal training program.

DOCUMENT REVIEW

- If elected, review the hospital's plan on how it will provide a unified and integrated approach to emergency preparedness to all separately certified healthcare facilities.

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services offered.

3. *Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance with the program.*
4. *Include a unified and integrated Emergency Operations Plan that meets the requirements of the Planning section of this chapter. The unified and integrated EOP must also be based on and include the following:*
    a. *A documented community-based risk assessment, utilizing an all-hazards approach.*
    b. *A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.*
5. *Include integrated policies and procedures that meet the requirements set forth in the Procedures section of this chapter; a coordinated communication plan that meets the requirements set forth in the Communication section of this chapter; and training and testing program that meets the requirements set forth on the Testing & Training section of this*

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

chapter.

§482.15(f)(1-4)
§482.15(f)(4)(i-ii)
§482.15(f)(5)

09.04.03 Transplant hospitals

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

If a hospital has one or more transplant programs (as defined in §482.70), then a representative from each transplant program must be included in the development and maintenance of the hospital's emergency preparedness program, and the hospital must develop and maintain mutually agreed-upon protocols that address the duties and responsibilities of the hospital, each transplant program, and the Organ Procurement Organization (OPO) for the Donation Service Area (DSA) where the hospital is situated, unless the hospital has been granted a waiver to work with another OPO, during an emergency.

§482.15(g)
§482.15(g)(1-2)

No additional information.

INTERVIEW AND DOCUMENT REVIEW

- Did a representative from each transplant program participate in the development of the hospital's emergency preparedness program?
- Have mutually agreed upon protocols that address the duties and responsibilities of the hospital and each transplant program been developed?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

COMPLIANCE RESOURCES

09.05.01 CMS Resources

The CMS standards stated herein are enforceable as if reproduced in their entirety within this standard and are incorporated by reference as approved by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA).

§482.15(h)(1)(i-xii)

Not Scored at this Standard

For information on the availability of this material at NARA, call 202.741.6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html

If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

National Fire Protection Association,
1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011;

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(xii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

10

MEDICAL RECORDS

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

10.00.00 CONDITION OF PARTICIPATION: Medical record services

The hospital must have a medical record service that has administrative responsibility for medical records.

A medical record must be maintained for every individual evaluated or treated in the hospital.

The texting of patient orders is prohibited regardless of the platform utilized.

In order to be compliant with the CoPs, all providers must utilize and maintain systems/platforms that are secure, encrypted, and minimize the risks to patient privacy and confidentiality as per HIPAA regulations and the hospital and CAH CoPs.

It is expected that providers will implement procedures/processes that routinely assess the security and integrity of the texting systems/platforms that are being utilized, in order to avoid negative outcomes that could compromise the care of patients.

§482.24

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The facility should have an organizational plan, which shows the responsible person for medical records (health information) of every individual treated at the facility.

The term "hospital" includes all locations of the hospital.

The hospital must have one unified medical record service that has administrative responsibility for all medical records, both inpatient and outpatient records.

The hospital must create and maintain a medical record for every individual, both inpatient and outpatient, evaluated or treated in the hospital.

The term "medical records" includes at least written documents, computerized electronic information, radiology film and scans, laboratory reports and pathology slides, videos, audio recordings, and other forms of information regarding the condition of a patient.

TEXTING

CMS does not permit the texting of orders by physicians or other health care providers. The practice of texting orders from a provider to a member of the care team is not in compliance with the Conditions of Participation (CoPs).

The texting of patient information among members of the health care team is permissible if accomplished through a secure platform.

INTERVIEW AND DOCUMENT REVIEW

- Review the organizational structure and policy statements.
- Interview the person responsible for the medical record (health information) service to determine that it is structured appropriately to meet the needs of the facility and the patients.
- Verify the facility does not permit the texting of orders by physicians or other health care providers.
- Review a sample of active and closed medical records for completeness and accuracy in accordance with Federal and State laws and regulations and hospital policy.

Note: The sample should be 10 percent of the average daily census and be no fewer than 30 records.

- Additionally, select a sample of outpatient records to verify compliance in outpatient departments, services, and locations.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

10.00.01 For future use

10.00.02 Organization and staffing

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The organization of the medical record service must be appropriate to the scope and complexity of the service performed.

The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records.

§482.24(a)

The medical records service must be organized, equipped, and staffed in accordance with the scope and complexity of the hospital's services and in such a manner as to comply with the requirements of this regulation and other Federal and State laws and regulations.

There must be an established medical record system that is organized and employs adequate personnel to ensure prompt:

- Completion of medical records.
- Filing of medical records.
- Retrieval of medical records.

The term "employs adequate personnel" means:

- That medical record personnel are employees of the hospital.
- That the hospital employs an adequate *number* of medical record personnel, employs adequate *types* of medical record personnel, and employs personnel who possess *adequate education, skills, qualifications, and experience* to ensure the hospital complies with requirements of this regulation and other Federal and State laws and regulations.

INTERVIEW AND DOCUMENT REVIEW

- Determine that there is an established system in place that addresses the following activities of the medical record service:
  - □ timely processing of records.
  - □ coding/indexing of records.
  - □ record retrieval.
  - □ protecting confidentiality of medical information.
  - □ retrieval and compilation of data of quality assurance activities.
- Verify that the system is reviewed and revised as needed.
- Review written job descriptions and staffing schedules to determine if staff is carrying out all designated responsibilities.
  - □ Interview staff, as needed.
- Verify that the hospital employs adequate medical record personnel as previously described.
  - □ Are medical records promptly

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		completed in accordance with State law and hospital policy? ▪ Select a sample of past patients of the hospital (inpatient and/or outpatient). Request those patients' medical records. □ Can the hospital promptly retrieve those records?
10.00.03 Retention of medical records *The hospital must maintain a medical record for each inpatient and outpatient.* *Medical records must be accurately written, promptly completed, properly filed and retained, and accessible.* *The hospital must use a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries*. §482.24(b)	☐ Compliant ☐ Not Compliant The hospital must maintain a medical record for each inpatient and outpatient evaluated or treated in any part or location of the hospital. All medical records must be accurately written. The hospital must ensure that all medical records accurately and completely document all orders, test results, evaluations, care plans, treatments, interventions, care provided and the patient's response to those treatments, interventions, and care. All medical records must be promptly completed. Every medical record must be complete with: ▪ All documentation of orders, diagnosis, evaluations, treatments. ▪ Test results. ▪ Care plans. ▪ Discharge plans. ▪ Consents. ▪ Interventions. ▪ Discharge Summary.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Identify the location(s) where medical records are maintained. ▪ Verify that a medical record is maintained for each person treated or receiving care. The hospital may have a separate record for inpatients and outpatients. However, when two different systems are used, they must be appropriately cross referenced and accessible. ▪ Verify that procedures ensure the integrity of authentication and protect the security of patient records. ▪ Verify that medical records are stored and maintained in locations where the records are secure, that protects them

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Clinical evaluation information obtained from post-discharge follow-up telephone calls (excluding patient satisfaction calls).
- Care provided along with the patient's response to those treatments and interventions.

The record must be completed promptly after discharge in accordance with State law and hospital policy but no later than 30 days after discharge.

The medical record must be properly filed and retained.

The hospital must have a medical record system that ensures the prompt retrieval of any medical record, of any patient evaluated or treated at any location of the hospital within the past 5 years.

Note: Standard 10.00.04 (§482.24(b)(1)) addresses the 5-year medical record retention requirement.

The medical record must be accessible.

The hospital must have a medical record system that allows the medical record of any patient, inpatient, or outpatient, evaluated and/or treated at any location of the hospital within the past 5 years to be accessible by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed.

Medical records must be properly stored in secure locations where they are protected from fire, water damage and other threats.

Medical information such as consultations, orders, practitioner notes, x-ray interpretations, lab test results, diagnostic test results, patient assessments and other patient information must be accurately written, promptly completed and properly filed in the patients' medical record, and accessible to the physicians or other care providers when needed for use in making assessments of the patient's condition, decisions on the provision of care to the patient, and in planning the patient's care. This requirement applies to the medical records of current inpatients and outpatients of the hospital.

from damage, flood, fire, etc.; access is limited to only authorized individuals.

- Verify that records are accurate, completed promptly, easily retrieved and readily accessible, as needed, in all locations where medical records are maintained.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The hospital must have a system of author identification and record maintenance that ensures the integrity of the authentication and protects the security of all record entries. The medical record system must correctly identify the author of every medical record entry and must protect the security of all medical record entries. The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. Locations where medical records are stored or maintained must ensure the integrity, security, and protection of the records. These requirements apply to both manual and electronic medical record systems.	
10.00.04 Record security and retention requirements *Medical records must be retained in their original or legally reproduced form for a period of at least 5 years.* §482.24(b)(1)	☐ Compliant ☐ Not Compliant All medical records are retained in their original or legally reproduced form in hard copy, microfilm, computer memory banks, or other electronic storage media. The hospital must be able to promptly retrieve the complete medical record of every individual evaluated or treated in any part or location of the hospital within the last five years. In accordance with federal and state law and regulations, certain medical records may have retention requirements that exceed five years (for example: FDA, OSHA, EPA).	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Verify that medical records are retained for at least five years, or more, as required by state or local laws. ▪ Verify that medical records are stored in a secured manner. ▪ Select a sample of patients, both inpatient and outpatient who were patients of the hospital within the previous 48-60 months. Request their medical record. Include both hospital campus and off campus locations. Is the medical record: □ Promptly retrievable?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		□ Complete? □ In original or in a legally reproduced form?
10.00.05 Coding and indexing *The hospital must have a system of coding and indexing medical records. The system must allow for timely retrieval by diagnosis and procedure, in order to support medical care evaluation studies.* §482.24(b)(2)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the facility uses a coding and indexing system that permits timely retrieval of medical records by diagnosis procedure.
10.00.06 Security of medical information *The hospital must have a procedure for ensuring the confidentiality of patient records.* *Information from or copies of records may be released only to authorized individuals, and the hospital must ensure that unauthorized individuals cannot gain access to or alter patient records.* *Original medical records must be released by the hospital only in accordance with Federal or State laws, court orders, or subpoenas.* *The texting of patient orders is prohibited*	☐ Compliant ☐ Not Compliant **RELEASE OF INFORMATION OR COPIES OF RECORDS** The hospital must have a procedure to ensure the confidentiality of each patient's medical record, whether it is in paper or electronic format, or a combination of the two, from unauthorized disclosure. Confidentiality applies wherever the record or portions thereof are stored, including but not limited to central records, patient care locations, radiology, laboratories, record storage areas, etc. A hospital is permitted to disclose medical record information, without a patient's authorization, in order to provide patient care and perform related administrative functions, such as payment and other hospital operations. 1. Payment operations include hospital activities to obtain payment or be reimbursed for the provision of health care to an individual.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Verify that policies are in place that limit access to and disclosure of medical records to authorized users and uses, and that require written authorization for other disclosures. □ Are the policies consistent with the regulatory requirements? ▪ Observe whether patient records are secured from unauthorized access at all times and in all locations.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

regardless of the platform utilized.

The texting of patient information among members of the health care team is permissible if accomplished through a secure platform.

§482.24(b)(3)

2. Health care operations are administrative, financial, legal, and quality improvement activities of a hospital that are necessary to conduct business and to support the core functions of treatment and payment. These activities include, but are not limited to:
   - Quality assessment and improvement activities.
   - Case management and care coordination.
   - Competency assurance activities, conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs.
   - Business planning, development, management, and administration and certain hospital-specific fundraising activities.

POLICIES AND PROCEDURES

The hospital must develop policies and procedures that reasonably limit disclosures of information contained in the patient's medical record to the minimum disclosure necessary, except when the disclosure is for treatment or payment purposes, or as otherwise required by State or Federal law.

When the minimum necessary standard is applied, a hospital may not disclose the entire medical record for a particular purpose, unless it can specifically justify that the whole record is the disclosure amount reasonably required for the purpose.

A hospital may disclose information from the medical record electronically and may also share an electronic medical record system with other health care facilities, physicians, and practitioners, so long as the system is designed and operated with safeguards that ensure that only authorized disclosures are made.

The hospital must obtain written authorization from the patient or the patient's representative for any other disclosure of medical record information.

- Ask the hospital to demonstrate precautions taken to prevent physical or electronic altering of content previously entered into a patient record, or to prevent unauthorized disposal of patient records.
- Verify that patient medical record information is released only as permitted under the hospital's policies and procedures.
- Conduct observations and interview staff to determine what safeguards are in place or precautions are taken to prevent unauthorized persons from gaining physical access or electronic access to information in patient records.
- If the hospital uses electronic patient records, is access to patient records controlled through standard measures, such as business rules defining permitted access, passwords, etc.?
- Do the hospital's policies and procedures provide that "original" medical records are retained, unless their release is mandated under Federal or State law, court order or subpoena? Interview staff responsible for medical records to determine if they are aware of the limitations on release of "original" medical records.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

PREVENTING UNAUTHORIZED ACCESS

The hospital must ensure that unauthorized individuals cannot gain access to patient records. This applies to records in electronic as well as hard copy formats.

Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients in the hospital and outpatients in outpatient clinics.

- For hard copy records, locked cabinets or file rooms and limiting access to keys or pass codes may be employed.
- For electronic records technical safeguards, such as business rules that limit access based on need to know, passwords, or other control mechanisms, must be in place.

When disposing of copies of medical records, physical safeguards might include shredding documents containing confidential information, taking appropriate steps to erase information from media used to store electronic records, etc.

RELEASE OF ORIGINAL RECORDS

The hospital must not release the original of a medical record that exists in a hard copy, paper version only, unless it is required to do so in response to a court order, a subpoena, or Federal or State laws.

For electronic records, the hospital must ensure that the media or other mechanism by which the records are stored electronically are not removed in such a way that all or part of the record is deleted from the hospital's medical record system.

The hospital must have policies and procedures that address how it assures that it retains its "original" medical records unless their release is mandated by law/court order/subpoena.

Policies are in place that address the organization of the medical records service including:

- Observe the hospital's security practices for patient records. Are patient records left unsecured or unattended? Are patient records unsecured or unattended in hallways, patient rooms, nurse's stations, or on counters where unauthorized persons could gain access to patient records?
- Verify that there is an established system in place that addresses protecting the confidentiality of medical information.
- Verify that the facility does not permit the texting of orders by physicians or other healthcare providers.
- Verify that the security and integrity of the texting systems/platforms used are routinely assessed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Confidentiality. ▪ Release of information. ▪ Retention. ▪ Storage. ▪ Security of medical records in all areas of the inpatient and outpatient areas of the organization. **SECURE SYSTEMS/PLATFORMS** To be compliant with the CoPs, all providers must use and maintain systems/platforms that are secure, encrypted, and minimize the risks to patient privacy and confidentiality as per HIPAA regulations and the hospital CoPs. It is expected that providers will implement procedures/processes that routinely assess the security and integrity of the texting systems/platforms that are being used, to avoid negative outcomes that could compromise the care of patients.	
10.01.01 Content of the record *The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services.* §482.24(c) The Medical Records Committee shall recommend policies for medical record maintenance and supervise medical	☐ Compliant ☐ Not Compliant The medical record must contain complete information/documentation regarding evaluations, interventions, care provided, services, care plans, discharge plans, and the patient's response to those activities. Patient medical record information, such as laboratory reports, test results, consults, assessments, radiology reports, dictated notes, etc., must be promptly filed in the patient's medical record in order to be available to the physician and other care providers to use in making assessments of the patient's condition, to: ▪ justify admission.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of open (active) and closed medical records for completeness and accuracy in accordance with facility policy. ▪ Select charts of patients admitted or housed in the hospital as observation status; exclude ED patients and other outpatients.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
records to ensure proper recording of sufficient data to evaluate patient care.	▪ justify continued hospitalization. ▪ support the diagnosis. ▪ describe the patient's progress. ▪ describe the patient's response to medications. ▪ describe the patient's response to services such as interventions, care, treatments, etc. ▪ support planning the patient's care.	▪ Verify each record contains information to: □ Justify admission and continued hospitalization. □ Support the diagnosis. □ Describe patient's progress. □ Describe response to medications and services. ▪ Verify that medical record documentation issues are identified, reported and action taken to correct deficiencies in a timely manner for all disciplines documenting in the medical record.
10.01.02 Medical record policies	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The medical record department has written policies that address: 1. Required content of the medical record. 2. Medical record maintenance. 3. The parts of the medical record that are the responsibility of the physician must be authenticated by the physician. 4. Those portions of the medical record, if any, that may be delegated to a	Medical staff policy, consistent with state law, defines: The portions of the medical record that may be delegated to non-physician practitioners, such as: ▪ Medical History ▪ Physical Examination ▪ Progress Notes ▪ Operative Report ▪ Discharge Summary The requirements for co-signature and/or authentication, consistent with state law for non-physician practitioners, especially:	**DOCUMENT REVIEW** ▪ Verify that medical staff policies and/or rules and regulations indicate what, if any, portions of the medical history, physical examination, progress notes, operative report or discharge summary may be delegated. ▪ Verify that the medical staff rules and regulations or policies define those entries in the medical record entered by house staff or non-physicians that

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
non-physician practitioner.	▪ Nurse Practitioners (NP) ▪ Physician Assistants (PA) ▪ Certified Registered Nurse Anesthetists (CRNA) ▪ Certified Nurse Midwives (CNM) When non-physician practitioners are approved by the medical staff to performing medical histories or physical examinations and documentation of findings, such information must be reviewed and authenticated by the responsible physician within the time frame noted by medical staff policies or rules and regulations, consistent with state law.	require counter signature by supervisory or attending medical staff. **Note**: H&P requires co-signature in all circumstances when not completed by a DO/MD. ▪ Verify that all records/entries requiring authentication have been authenticated.
10.01.03 <u>Legible and complete</u> *All patient medical record entries must be legible, complete, dated, timed, and authenticated in written or electronic form by the person responsible for providing or evaluating the service provided, consistent with hospital policies and procedures.* §482.24(c)(1)	☐ Compliant ☐ Not Compliant Entries in the medical record may be made only by individuals as specified in the hospital and medical staff policies. All entries in the medical record must be legible. Orders, progress notes, nursing notes, or other entries in the medical record that are not legible may be misread or misinterpreted and may lead to medical errors or other adverse patient events. All entries in the medical record must be complete. A medical record is considered complete if it contains sufficient information to: ▪ identify the patient. ▪ support the diagnosis/condition. ▪ justify the care, treatment, and services. ▪ document the course and results of care, treatment, and services. ▪ promote continuity of care among providers. With these criteria in mind, an individual entry into the medical record must	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review a sample of open and closed medical records to determine whether all medical record entries are legible. □ Are they clearly written in such a way that they are not likely to be misread or misinterpreted? ▪ Determine whether orders, progress notes, nursing notes, or other entries in the medical record are complete. ▪ Does the medical record contain sufficient information to: □ identify the patient? □ Support the diagnosis/condition? □ Justify the care, treatment, and

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contain sufficient information on the matter that is the subject of the entry to permit the medical record to satisfy the completeness standard.

All entries in the medical record must be dated, timed, and authenticated, in written or electronic form, by the person responsible for providing or evaluating the service provided.

1. The time and date of each entry (orders, reports, notes, etc.) must be accurately documented.

   Timing establishes when an order was given, when an activity happened or when an activity is to take place. Timing and dating entries is necessary for patient safety and quality of care.

   Timing and dating of entries establish a baseline for future actions or assessments and establishes a timeline of events. Many patient interventions or assessments are based on time intervals or timelines of various signs, symptoms, or events. (71 FR §68687)
2. The hospital must have a method to establish the identity of the author of each entry. This would include verification of the author of faxed orders/entries or computer entries.
3. The hospital must have a method to require that each author takes a specific action to verify that the entry being authenticated is his/her entry or that he/she is responsible for the entry, and that the entry is accurate.

The requirements for dating and timing do not apply to orders or prescriptions that are generated outside of the hospital until they are presented to the hospital at the time of service. Once the hospital begins processing such an order or prescription, it is responsible for ensuring that the implementation of the order or prescription by the hospital is promptly dated and timed in the patient's medical record.

PRE-PRINTED ORDER SETS

When a practitioner is using a preprinted order set, the ordering practitioner

services?

- □ Document the course and results of care treatment, and services?
- □ Promote continuity of care among providers?

- Determine whether medical record entries are dated, timed, and appropriately authenticated by the person who is responsible for ordering, providing, or evaluating the service provided.
- Determine whether all orders, including verbal orders, are written in the medical record and signed by the practitioner who is caring for the patient and authorized by hospital policy (and in accordance with State law) to write orders.
- Determine whether the hospital has a means for verifying signatures, written and electronic, written initials, codes, and stamps when these are used for authorship identification.
  - □ For electronic medical records, ask for demonstration of security features that maintain the integrity of entries and verification of e-signature and authorizations.
  - □ Examine policies and procedures for using the system and verify whether

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may be in compliance with the requirement at §482.24(c)(1) to date, time, and authenticate an order if the practitioner accomplishes the following:

1. Last page:
   Sign, date, and time the last page of the orders, with the last page also identifying the total number of pages in the order set.
2. Pages with Internal Selections:
   Sign or initial any other (internal) pages of the order set where selections or changes have been made.

- The practitioner should initial/sign the top or bottom of the pertinent page(s).
- The practitioner should also initial each place in the preprinted order set where changes, such as additions, deletions, or strike-outs of components that do not apply, have been made.
- It is not necessary to initial every preprinted box that is checked to indicate selection of an order option, so long as there are no changes made to the option(s) selected.

PRE-ESTABLISHED ELECTRONIC ORDER SET

In the case of a pre-established electronic order set, the same principles apply; the practitioner would date, time, and authenticate the final order that resulted from the electronic selection/annotation process, with the exception that pages with internal changes would not need to be initialed or signed if they are part of an integrated single electronic document.

1. Authentication of medical record entries may include written signatures, initials, computer key, or other code.
2. For authentication, in written or electronic form, a method must be established to identify the author.
3. When rubber stamps or electronic authorizations are used for authentication, the hospital must have policies and procedures to ensure that such stamps or authorizations are used only by the individuals

documents are being authenticated after they are created.

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whose signature they represent. There shall be no delegation of stamps or authentication codes to another individual.
Note: Some insurers and other payers may have a policy prohibiting the use of rubber stamps as a means of authenticating the medical records that support a claim for payment. Medicare payment policy, for example, no longer permits such use of rubber stamps. Thus, while the use of a rubber stamp for signature authentication is not prohibited under the CoPs and analysis of the rubber stamp method per se is not an element of the survey process, hospitals may wish to eliminate their usage to avoid denial of claims for payment.

ELECTRONIC MEDICAL RECORD
Where an electronic medical record is in use, the hospital must demonstrate how it prevents alterations of record entries after they have been authenticated. Information needed to review an electronic medical record, including pertinent codes and security features, must be readily available to surveyors to permit their review of sampled medical records while onsite.

COUNTERSIGNATURE
When State law and/or hospital policy requires that entries in the medical record made by residents or non-physicians be countersigned by supervisory or attending medical staff members, then the medical staff rules and regulations must address counter-signature requirements and processes.

AUTO-AUTHENTICATION
A system of auto-authentication in which a physician or other practitioner authenticates an entry that he or she cannot review, e.g., because it has not yet been transcribed, or the electronic entry cannot be displayed, is not consistent with these requirements.

- There must be a method of determining that the practitioner did, in fact, authenticate the entry after it was created.
- In addition, failure to disapprove an entry within a specific time period is not acceptable as authentication.

The practitioner must separately date and time his/her signature

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authenticating an entry, even though there may already be a date and time on the document since the latter may not reflect when the entry was authenticated.

For certain electronically generated documents, where the date and time that the physician reviewed the electronic transcription is automatically printed on the document, the requirements of this section would be satisfied. However, if the electronically-generated document only prints the date and time that an event occurred (e.g., EKG printouts, lab results, etc.) and does not print the date and time that the practitioner actually reviewed the document, then the practitioner must either authenticate, date, and time this document itself or incorporate an acknowledgment that the document was reviewed into another document (such as the H&P, a progress note, etc.), which would then be authenticated, dated, and timed by the practitioner.

Computerized Provider Order Entry (CPOE) is the preferred method of order entry by a provider.

An order entered via CPOE, with an immediate download into the provider's electronic health records (EHR), is permitted as the order would be dated, timed, authenticated, and promptly placed in the medical record.

10.01.04 <u>Dating, timing, and authentication of orders</u>

All orders, including verbal orders, must be dated, timed, and authenticated promptly by the ordering practitioner or by another practitioner who is responsible for the care of the patient only if such a practitioner is acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

PROMPTLY AUTHENTICATE ORDERS

The hospital must ensure that all orders, including verbal orders, are dated, timed, and authenticated <u>promptly</u>. This regulation provides that, if State law is silent regarding a specific timeframe for authentication of verbal orders, then the facility is responsible to define in policy the timeframe for the authentication of verbal orders.

"Prompt" is defined as performed readily or immediately.

Verbal orders are orders for medications, treatments, interventions, or other

<u>DOCUMENT REVIEW</u>

- Does the hospital have policies and procedures requiring prompt authentication of all orders, including verbal orders, by the ordering practitioner or, if permitted under State law, hospital policy and medical staff bylaws, rules and regulations,

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and regulations.

§482.24(c)(2)

patient care that are transmitted as oral, spoken communications between senders and receivers, delivered either face-to-face or via telephone.

The receiver of a verbal order must date, time, and sign the verbal order in accordance with hospital policy.

Hospital policies and procedures for verbal orders include a read-back and verification process.

The prescribing practitioner must verify, sign, date, and time the order as soon as possible after issuing the order, in accordance with hospital policy, and State and Federal requirements.

Authentication of a verbal order may be written, electronic, or faxed.

- The hospital must have a method for establishing the identity of the practitioner who has given a verbal order, including verification of the author of faxed verbal orders or computer entries.

In some instances, the ordering practitioner may not be able to authenticate his or her order, including a verbal order (e.g., the ordering practitioner gives a verbal order which is written and transcribed, and then is "off duty" for the weekend or an extended period of time). In such cases it is acceptable for another practitioner who is responsible for the patient's care to authenticate the order, including a verbal order, of the ordering practitioner, as long as it is permitted under State law, hospital policies and medical staff bylaws, rules, and regulations.

Hospitals may choose in their policies to restrict which practitioners it would authorize to authenticate another practitioner's orders. For example, a hospital could choose to restrict authentication of orders for pediatric patients to practitioners who are privileged to provide pediatric care. (77 FR 29053, May 16, 2012)

- All practitioners responsible for the patient's care are expected to have knowledge of the patient's hospital course, medical plan of care,

another practitioner responsible for the care of the patient?

- Do the hospital's policies and procedures for verbal orders include a "read back and verify" process where the receiver of the order reads back the order to the ordering practitioner to verify its accuracy?
- Determine whether there is a State law that defines the authentication of verbal orders. If the State is silent, the hospital must have a policy and procedure that defines the time frame for authentication of verbal orders.
- Review orders, including verbal orders, in a sample of medical records.
  - □ Have orders been dated, timed, and authenticated promptly by the ordering practitioner or, if permitted under State law, hospital policy and medical staff bylaws, rules and regulations, another practitioner who is responsible for the care of the patient?
  - □ Has the receiver of a verbal order, dated, timed, and signed the order according to hospital policy?

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condition, and current status.

- When a practitioner other than the ordering practitioner authenticates an order, that practitioner assumes responsibility for the order as being complete, accurate and final.
- A qualified non-physician practitioner, such as a physician assistant (PA) or nurse practitioner (NP), who is responsible for the care of the patient may authenticate a physician's or other qualified non-physician practitioner's order only if the order is within his/her scope of practice.

If state law requires that the ordering practitioner authenticate his/her own orders, or his/her own verbal orders, then a practitioner other than the prescribing practitioner would not be permitted to authenticate the verbal order in that State. (71 FR 68682 and 77 FR 29053, May 16, 2012)

NOTE CONCERNING VERBAL ORDERS FOR LABORATORY TESTS

The requirement to authenticate promptly a verbal order applies to verbal orders associated with both inpatients and outpatients.

It is possible that a hospital verbal order for a laboratory test could be authenticated in compliance with the Clinical Laboratory Improvement Amendment (CLIA) regulatory standard of authentication, i.e., within 30 days, but nonetheless be out of compliance with the hospital Medical Records Services requirement for prompt authentication of all orders, including verbal orders.

Because CLIA laboratories – even if physically situated in a hospital – are surveyed for compliance only with CLIA regulations, the laboratory would not be cited for a deficiency by a CLIA survey team. However, hospital surveyors conducting a survey would cite the hospital's inpatient or outpatient recordkeeping for deficiencies under the Medical Record Services CoP if the lab order originated for a patient during a hospital inpatient stay or hospital outpatient clinic visit, and the order was not authenticated promptly.

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10.01.05 Pre-printed orders, order sets, and protocols

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Hospitals may use pre-printed and electronic standing orders, order sets, and protocols for patient orders only if the hospital:

(i) *Establishes that such orders and protocols have been reviewed and approved by the medical staff and the hospital's nursing and pharmacy leadership;*

(ii) *Demonstrates that such orders and protocols are consistent with nationally recognized and evidence-based guidelines;*

(iii) *Ensures that the periodic and regular review of such orders and protocols is conducted by the medical staff and the hospital's nursing and pharmacy leadership to determine the continuing usefulness and safety of the orders and protocols; and*

(iv) *Ensures that such orders and protocols are dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient only if such a practitioner is acting in accordance*

WHAT IS COVERED BY THIS REGULATION?

There is no standard definition of a "standing order" in the hospital community at large, but the terms "pre-printed standing orders," "electronic standing orders," "order sets," and "protocols for patient orders" are various ways in which the term "standing orders" has been applied.

ACHC generally uses the term "standing order(s)" to refer interchangeably to pre-printed and electronic standing orders, order sets, and protocols.

- The lack of a standard definition for these terms and their interchangeable and indistinct use by hospitals and health care professionals may result in confusion regarding what is or is not subject to the requirements of 42 CFR §482.24(c)(3), particularly with respect to "order sets."

NOT CONSIDERED TO BE A STANDING ORDER

Not all pre-printed and electronic order sets are considered a type of "standing order" covered by this regulation.

Where the order sets consist solely of menus of treatment or care options designed to facilitate the creation of a patient-specific set of orders by a physician or other qualified practitioner authorized to write orders, and none of the treatment choices and actions can be initiated by non-practitioner clinical staff before the physician or other qualified practitioner actually creates the patient-specific order(s), such menus would not be considered "standing orders" covered by this regulation. In such cases the menus provide a convenient and efficient method for the physician/practitioner to create an order, but the availability of such menu options does not create an "order set" that is a "standing order" subject to the requirements of this regulation.

The physician/practitioner may, based on his/her professional judgment, choose to:

INTERVIEW AND DOCUMENT REVIEW

- Ask the hospital's medical staff and its nursing and pharmacy leadership whether standing orders are used. If yes, ask them to describe how a standing order is developed and monitored, and their role in the process.
- Ask to see an example of one or more standing orders, including documentation on the development of the order, including:
  - ☐ Reference to the evidence-based national guidelines that support it.
  - ☐ Participation of medical staff and nursing and pharmacy leadership in review and approval of the standing order.
  - ☐ Description of the protocol to be followed when initiating execution of the order, including description of the roles and responsibilities of various types of staff.
  - ☐ Description of the process for authenticating the order's initiation by the practitioner responsible for the care of the patient, or another authorized practitioner.

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with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules, and regulations. §482.24(c)(3) §482.24(c)(3)(i-iv)	1. use the available menu options to create an order. 2. not use the menu options and instead create an order from scratch. 3. modify the available menu options to create the order. In each case the physician/practitioner exercises his/her privileges to prescribe specific diagnosis and/or treatment activities that are to be implemented for a patient. In cases where hospital policy permits treatment to be initiated by a nurse, for example, *without a prior specific order from the treating physician/practitioner,* this policy and practice must meet the requirements of this regulation for review of standing orders, regardless of whether it is called a standing order, a protocol, an order set, or something else. ▪ Such treatment is typically initiated when a patient's condition meets certain pre-defined clinical criteria. For example, standing orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen where it is not practical for a nurse to obtain either a written, authenticated order or a verbal order from a physician or other qualified practitioner prior to the provision of care. **Hybrids**, where a component for non-practitioner-initiated treatment is embedded within a menu of options for the physician or other qualified practitioner, still require compliance with the requirements for a standing order for that component. ▪ For example, if an order set includes a protocol for nurse-initiated potassium replacement, that protocol must be reviewed under the requirements of this regulation before it may become part of a menu from which a physician or other qualified practitioner would select treatments for a particular patient. **REQUIREMENTS FOR "STANDING ORDERS"** Hospitals have the flexibility to use standing orders to expedite the delivery of patient care in well-defined clinical scenarios for which there is evidence	□ Evidence of training of personnel on the order protocol. □ Evidence of periodic evaluation and, if needed, modification of the standing order, including whether the order remains consistent with current evidence-based national guidelines, staff adherence to the protocol for initiation and execution, and whether there have been any preventable adverse events associated with the order. ▪ Ask staff providing clinical services in areas of the hospital where standing orders might be typically used, including but not limited to, the emergency department, labor and delivery units, and inpatient units, whether standing orders are used. If yes, ask them: □ To describe a typical scenario where a standing order would be used, and what they would do in that case. □ For a copy of the protocol for that standing order. Does their description conform to the protocol? ▪ Review a sample of medical records of patients where a nurse-initiated standing order was used and verify that the order was documented and authenticated by a practitioner

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	supporting the application of standardized treatments or interventions. Appropriate use of standing orders can contribute to patient safety and quality of care by promoting consistency of care, based on objective evidence, when orders may be initiated as part of an emergency response or as part of an evidence-based treatment regimen. where it is not practicable for a nurse or other non-practitioner to obtain a verbal or authenticated written order from a physician or other practitioner responsible for the care of the patient prior to the provision of care. In all cases, implementation of a standing order must be medically appropriate for the patient to whom the order is applied. Much of the evidence on the effectiveness of standing orders in hospitals has been narrowly focused on aspects of their use by Rapid Response Teams addressing inpatient emergencies. However, standing orders may also be appropriate in other clinical circumstances, including, but not limited to: ▪ Protocols for triaging and initiating required screening examinations and stabilizing treatment for emergency department patients presenting with symptoms suggestive of acute asthma, myocardial infarction, stroke, etc. (This does not relieve a hospital of its obligations under the Emergency Medical Treatment and Labor Act (EMTALA) to have qualified medical personnel complete required screening and, when applicable, stabilizing treatment in a timely manner.) ▪ Post-operative recovery areas. ▪ Timely provision of immunizations, such as certain immunizations for newborns, for which there are clearly established and nationally recognized guidelines. Standing orders may not be used in clinical situations where they are specifically prohibited under federal or state law. ▪ For example, the hospital patient's rights regulation at 42 CFR §482.13(e)(6) specifically prohibits the use of standing orders for restraint	responsible for the care of the patient.

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or seclusion of hospital patients.

When deciding whether to use standing orders, hospitals should also be aware that, although use of standing orders is permitted under the hospital Conditions of Participation, some insurers, including Medicare, may not pay for the services provided because of the use of standing orders.

MINIMUM REQUIREMENTS FOR STANDING ORDERS

Hospitals may employ standing orders only if the following requirements are met for each standing order for a well-defined clinical scenario:

1. Each standing order must be reviewed and approved by the hospital's medical staff and nursing and pharmacy leadership before it may be used in the clinical setting. The regulation requires a multi-disciplinary collaborative effort in establishing the protocols associated with each standing order.
2. The hospital's policies and procedures for standing orders must address:
   - □ the process by which a standing order is developed.
   - □ approved.
   - □ monitored.
   - □ initiated by authorized staff.
   - □ subsequently authenticated by physicians or other practitioners responsible for the care of the patient.
3. For each approved standing order, there must be specific criteria identified in the protocol for the order for nurse or other authorized personnel to initiate execution, for example, the specific clinical situations, patient conditions, or diagnoses by which initiation of the order would be justified. Under no circumstances may a hospital use standing orders that require any staff not authorized to write patient orders to make clinical decisions outside of their scope of practice in order to initiate such orders.

   Since residents are physicians, this regulation does not require specific

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criteria for a resident to initiate the execution of a standing order. However, there may be state laws governing the practice of residents in hospitals that are more restrictive; if so, the hospital is expected to comply with the state law.

Likewise, the hospital may choose through its policies and medical staff bylaws, rules, and regulations to restrict the role of residents with respect to standing orders.

4. Policies and procedures should also address the instructions that the medical, nursing, and other applicable professional staff receive on the conditions and criteria for using standing orders as well as any individual staff responsibilities associated with the initiation and execution of standing orders. An order that has been initiated for a specific patient must be added to the patient's medical record at the time of initiation, or as soon as possible thereafter.

   □ Standing order policies and procedures must specify the process whereby the physician or other practitioner responsible for care of the patient acknowledges and authenticates the initiation of all standing orders after the fact, with the exception of influenza and pneumococcal vaccines, which do not require such authentication in accordance with § 482.23(c)(2).

   □ The hospital must be able to document that the standing order is consistent with nationally recognized and evidence-based guidelines. This does not mean that there must be a template standing order available in national guidelines which the hospital copies, but rather that the content of each standing order in the hospital must be consistent with nationally recognized, evidence-based guidelines for providing care. The burden of proof is on the hospital to show that there is a sound basis for the standing order.

5. Each standing order must be subject to regular, periodic review by the medical staff and the hospital's nursing and pharmacy leadership, to determine the continuing usefulness and safety of the orders and

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protocols.

□ At a minimum, an annual review of each standing order would satisfy this requirement.

□ However, the hospital's policies and procedures must also address a process for the identification and timely completion of any requisite updates, corrections, modifications, or revisions based on changes in nationally recognized, evidence-based guidelines. The review may be prepared by the hospital's QAPI program, so long as the medical staff and nursing and pharmacy leadership read, review, and, as applicable, act upon the final report.

Among other things, reviews are expected to consider:

- Whether the standing order's protocol continues to be consistent with the latest standards of practice reflected in nationally recognized, evidence-based guidelines.
- Whether there have been any preventable adverse patient events resulting from the use of the standing order, and if so, whether changes in the order would reduce the likelihood of future similar adverse events. Note that the review would not be expected to address adverse events that are a likely outcome of the course of patient's disease or injury, even if the order was applied to that patient, unless there is concern that use of the standing order exacerbated the patient's condition.
- Whether a standing order has been initiated and executed in a manner consistent with the order's protocol, and if not, whether the protocol needs revision and/or staff need more training in the correct procedures.

6. An order that has been initiated for a specific patient must be added to the patient's medical record at the time of initiation, or as soon as possible thereafter.

□ The hospital must ensure each standing order that has been executed

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is dated, timed, and authenticated promptly in the patient's medical record by the ordering practitioner or another practitioner responsible for the care of the patient.

□ Another practitioner who is responsible for the care of the patient may date, time, and authenticate the standing order instead of the ordering practitioner, but only if the other practitioner is acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.

7. Further, the responsible practitioner must be able to modify, cancel, void or decline to authenticate orders that were not medically necessary in a particular situation. The medical record must reflect the physician's actions to modify, cancel, void or refusal to authenticate a standing order that the physician determined was not medically necessary.

10.01.06 Abbreviations and symbols

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Abbreviations and symbols are used sparingly. The following have been developed by the organization:

1. A list of standardized abbreviations, symbols, and dose designations.
2. A list of abbreviations, symbols, and dose designation that should never be used.
3. Explicit organizational policies and procedures regarding the use of only standardized abbreviations and dose designations.

A current abbreviations and symbols list,

The use of non-standardized abbreviations and dose designations is a demonstrated cause of medication errors.

Although the use of abbreviations and dose designations is reputed to save time and make order writing more efficient, illegible handwriting and the use of abbreviations or dose designations that are unfamiliar or that have multiple meanings may lead to confusion and errors.

- For example, the use of "U" for "units" is especially problematic because when handwritten, "U" often looks like a zero. Numerous case reports document that errors related to insulin dosage have occurred because of this.
- Using handwritten trailing zeros or a leading decimal point without a leading zero are dangerous order writing practices because the decimal point is sometimes not seen, and misinterpretation of such orders can lead

INTERVIEW AND DOCUMENT REVIEW

- Review the organizational policies and procedures regarding the use of standardized abbreviations and dose designations.
- Review the facility's approved list of:
  - □ Abbreviations, symbols, and dose designations.
  - □ Abbreviations and dose designations that should never be used.
- Verify compliance by sampling the last 30 discharges.

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with a legend of their meaning is maintained in the facility for all persons who document in patient medical records. These lists are approved by the professional Medical Staff. All staff entering data into the medical record will be educated on use of abbreviations. Policy compliance will be monitored.	to as much as a 10-fold dosing error. Experiential data show that using standardized abbreviations and symbols and standardized phraseology reduces medication and treatment errors.	▪ Interview staff to verify awareness of the approved and do not use lists.
10.01.07 History and physical (H&P) requirements *All records must document (as appropriate) **e**vidence of –* ▪ *A medical history and physical examination completed and documented no more than 30 days before or 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services and except as provided under standard 10.01.08. The medical history and physical examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.* §482.24(c)(4) §482.24(c)(4)(i)	☐ Compliant ☐ Not Compliant The purpose of an H&P is to determine whether there is anything in the patient's overall condition that would affect the planned course of the patient's treatment, such as an allergy to a medication that must be avoided, or a co-morbidity that requires certain additional interventions to reduce risk to the patient. The H&P documentation must be placed in the medical record within 24 hours of admission or registration, but in all cases prior to surgery or a procedure requiring anesthesia services, including all inpatient, outpatient, or same-day surgeries or procedures. The H&P may be handwritten or transcribed. An H&P that is completed within 24 hours of the patient's admission or registration, but after surgery or a procedure requiring anesthesia would not be in compliance.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of inpatient medical records for various types of patients and outpatient medical records for patients having same day surgery or a procedure requiring anesthesia to verify □ There is an H&P that was done no more than 30 days before or 24 hours after admission or registration, but for all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure. □ The H&P documentation was placed in the medical record within 24 hours after admission or registration, but for all cases involving surgery or

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.24(c)(4)(i)(A)		a procedure requiring anesthesia services, prior to the surgery or procedure.
10.01.08 History and physical (H&P) update requirements *All records must document (as appropriate) evidence of –* ▪ *An updated examination of the patient, including any changes in the patient's condition, when the medical history and physical examination are completed within 30 days before admission or registration and except as provided in standard 10.01.09. Documentation of the updated examination must be placed in the patient's medical record within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia services.* §482.24(c)(4)(i)(B)	☐ Compliant ☐ Not Compliant When an H&P is completed within the 30 days before admission or registration, the hospital must ensure that an updated medical record entry documenting an examination for any changes in the patient's condition is placed in the patient's medical record within 24 hours after admission or registration, but in all cases involving surgery or a procedure requiring anesthesia services, prior to the surgery or procedure. **REQUIREMENTS FOR THE UPDATE EXAMINATION** The examination must be conducted by a practitioner who is credentialed and privileged by the hospital's medical staff to perform an H&P. The update note must document an examination for any changes in the patient's condition since the time that the patient's H&P was performed that might be significant for the planned course of treatment. ▪ The physician, oromaxillofacial surgeon, or qualified licensed individual uses his/her clinical judgment, based upon his/her assessment of the patient's condition and co-morbidities, if any, in relation to the patient's planned course of treatment to decide the extent of the update assessment needed as well as the information to be included in the update note in the patient's medical record. ▪ If, upon examination, the licensed practitioner finds no change in the patient's condition since the H&P was completed, he/she may indicate in the patient's medical record that the H&P was reviewed, the patient was examined, and that "no change" has occurred in the patient's condition since the H&P was completed. Such statements in the medical record	This standard is not met as evidenced by: **DOCUMENT REVIEW** In the sample of medical records selected for review, look for cases where the medical history and physical examination was completed within 30 days before admission or registration. 1. Determine whether an updated medical record entry documenting an examination for changes in the patient's condition was completed and documented in the patient's medical record within 24 hours after admission or registration. 2. Determine whether, in all cases involving surgery or a procedure requiring anesthesia services, the update was completed and documented prior to the surgery or procedure.

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would meet the requirement for documenting the H&P update.

- Any changes in the patient's condition must be documented by the practitioner in the update note and placed in the patient's medical record within 24 hours of admission or registration, but prior to surgery or a procedure requirement anesthesia services.

Additionally, if the practitioner finds that the H&P done before admission is incomplete, inaccurate, or otherwise unacceptable, the practitioner reviewing the H&P, examining the patient, and completing the update may disregard the existing H&P, and conduct and document in the medical record a new H&P within 24 hours after admission or registration, but prior to surgery or a procedure requiring anesthesia.

10.01.09 Exception for outpatient surgical procedures

An assessment of the patient (in lieu of the requirements of standard 10.01.07) *is completed and documented after registration,* and immediately *prior to surgery or a procedure requiring anesthesia services, when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.*

§482.24(c)(4)(i)(C)

☐ Compliant ☐ Not Compliant ☐ NA

In lieu of the comprehensive history and physical and update to the history and physical (Standards 10.01.07 and 10.01.08), the hospital and its medical staff may have established a policy for selected patients that would require a modified or less comprehensive presurgical or pre-procedural assessment of the patient.

In accordance with the medical staff policy:

- A history and physical is required within 30 days of the procedure
- The update to the history and physical would be replaced with a patient assessment.

The medical staff policy defines the elements of the patient assessment to be completed immediately prior to the outpatient surgery. At a minimum, this brief physical examination includes an assessment of the airway, lungs, and heart. The pertinent history must be verified with the patient.

Based on the assessment, a statement of verification signed by a physician is

This standard is not met as evidenced by:

DOCUMENT REVIEW

- In the sample of medical records selected for review, look for cases in which the outpatient surgery policy option was selected.
- Verify the patient's planned procedure is in accordance with the medical staff policy.
- Verify the medical record includes:
  - ☐ a history and physical completed at least 30 days prior to the procedure.
  - ☐ the patient assessment is completed and documented after registration, and immediately prior to surgery or a procedure requiring anesthesia

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	required indicating that there have been no interval changes. For patient safety, even for healthy patients undergoing "low risk" surgery, a medical history is critical to plan the appropriate anesthesia and/or to react to adverse events that might occur during surgery and anesthesia. It is the responsibility of the healthcare organization to, at a minimum, provide pertinent information to the anesthesia provider for the appropriate assessment of the severity of medical condition of the patient and invasiveness of the proposed surgical procedure well in advance of the anticipated day of procedure for all elective patients.	services, in accordance with policy.
10.01.10 Admitting diagnosis *All records must document the admitting diagnosis.* §482.24(c)(4)(ii)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify in a sample of medical records that the patient's admitting diagnosis is documented.
10.01.11 Consultative reports *All records must document (as appropriate):* ▪ *Results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient.* §482.24(c)(4)(iii)	☐ Compliant ☐ Not Compliant All patient records, both inpatient and outpatient, must contain the results of all consultative evaluations of the patient and appropriate findings by clinical and other staff involved in the care of the patient. This information must be promptly filed in the patient's medical record in order to be available to the physician or other care providers: ▪ to use in making assessments of the patient's condition. ▪ to justify treatment or continued hospitalization. ▪ to support or revise the patient's diagnosis.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of medical records of patients who have orders for consultative evaluations. □ Are the results/reports and other clinical findings of those consultative evaluations included in the patient's medical record, consistent with Medical staff policy?

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	▪ to support or revise the plan of care. ▪ to describe the patient's progress. ▪ to describe the patient's response to medications, treatments, and services.	
10.01.12 Consultation requirements	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Requests for diagnostic testing, which require professional interpretation (psychometrics, pathology, imaging, etc.) and consultations include sufficient detail to facilitate the interpreter's review.	The professional staff that evaluate the diagnostic tests, and/or provide patient assessment consultations, should logically come to their own conclusions; however, these professionals should not have to search for readily available data, which may enhance their review and findings.	**DOCUMENT REVIEW** ▪ Verify that policies and medical staff rules and regulations address the need to provide sufficient information with requested consultations or evaluations. ▪ Review charts to determine orders for consultation include sufficient information and consultative testing and reports are available within appropriate timeframes.
10.01.13 For future use		
10.01.14 For future use		
10.01.15 Documentation of complications	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
All records must document (as appropriate): ▪ *Complications, hospital acquired*	Documentation must be included in the medical record for both inpatients and outpatients.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Through observations, interviews, and review of hospital reports and

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infections, and unfavorable reactions to drugs and anesthesia. §482.24(c)(4)(iv)		documentation, determine if patient complications, hospital-acquired infections, and unfavorable reactions to drugs/anesthesia have been documented in the applicable patient's medical record.
10.01.16 Informed consent *All records must document (as appropriate):* ▪ *Properly executed informed consent forms for procedures and treatments specified by the medical staff, or by Federal or State law if applicable, to require written patient consent.* §482.24(c)(4)(v)	☐ Compliant ☐ Not Compliant Informed consent is discussed in three locations in the CMS Hospital CoPs. See also standard 15.01.11 [42 CFR §482.13(b)(2)] pertaining to patients' rights and standard 30.00.11 [42 CFR §482.51(b)(2)], pertaining to surgical services. Medical staff policies should address which procedures and treatments require written informed consent. **POLICY** Hospitals must assure that the practitioner(s) responsible for the surgery obtains informed consent from patients in a manner consistent with hospital policy. The hospital has a policy that describes the informed consent process including: 1. Who may obtain the patient's informed consent. 2. Which procedures require informed consent. 3. The circumstances under which surgery is considered an emergency and may be undertaken without an informed consent. 4. The circumstances when a patient's legal representative, rather that the patient, may give informed consent for surgery. 5. The content of the informed consent form and instructions for	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the hospital's medical staff has specified which procedures and treatments require written patient consent. ▪ Verify that the hospital's informed consent form contains the elements listed as the minimum elements of a properly executed informed consent. ▪ Compare the hospital's informed consent form to the policies on informed consent, to verify consistency. If there is applicable state law, verify that the form is also consistent with the requirements of that law. ▪ Review a minimum of six random medical records of patients who have, are undergoing, or are about to undergo a procedure or treatment that requires informed consent.

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completing it.

6. The process used to obtain informed consent, including how informed consent is to be documented in the medical record.
7. Mechanisms that ensure that the informed consent form is properly executed and is in the patient's medical record prior to the surgery (except in an emergency).
8. If the informed consent process and informed consent form are obtained outside the hospital, how the properly executed informed consent form is incorporated into the patient's medical record prior to the surgery.

Informed consents are written in simple sentences (4th grade comprehension level) and in the primary language of the patient.

Interpreter services will be provided as need is identified.

After the informed consent discussion has occurred, the patient or legal representative will be asked to recount what he or she has been told.

The medical record must contain a document recording the patient's informed consent for those procedures and treatments that have been specified as requiring informed consent.

There may also be applicable federal or state law requiring informed consent. The informed consent form contained in the medical record should provide evidence that it was properly executed.

INFORMED CONSENT FORMS

A properly executed informed consent form should reflect the patient consent process. Except as specified for emergency situations in the hospital's informed consent policies, all inpatient and outpatient medical records must contain a properly executed informed consent form prior to conducting any procedure or other type of treatment that requires informed consent.

An informed consent form, in order to be properly executed, must be consistent with hospital policies as well as applicable State and Federal law or

- □ Verify that each medical record contains informed consent forms.
- □ Verify that each completed informed consent form contains the information for each of the elements listed above as the minimum elements of a properly executed informed consent, as well as any additional elements required by state law and/or the hospital's policy.

regulation.

A properly executed informed consent form contains the following minimum elements:

1. Name of the hospital at which the procedure or other type of medical treatment is to take place.
2. Name of the specific procedure, or other type of medical treatment for which consent is being given.
3. Name of the responsible practitioner who is performing the procedure or administering the medical treatment.
4. Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient or the patient's legal representative. (Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity. Hospitals are free to delegate to the responsible practitioner, who uses the available clinical evidence as informed by his/her professional judgment, the determination of which material risks, benefits and alternatives will be discussed with the patient.)
5. Signature of the patient or the patient's legal representative.
6. Date and time the informed consent form is signed by the patient or the patient's legal representative.

If there is applicable state law governing the content of the informed consent form, then the hospital's form must comply with those requirements.

A well-designed informed consent form might also include the following additional information:

7. Name of the practitioner who conducted the informed consent discussion with the patient or the patient's representative.
8. Date, time, and signature of the person witnessing the patient or the

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patient's legal representative signing the consent form.

9. Indication or listing of the material risks of the procedure or treatment that were discussed with the patient or the patient's representative.
10. Statement, if applicable, that physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies and, in the case of residents, based on their skill set and under the supervision of the responsible practitioner.
11. Statement, if applicable, that qualified medical practitioners who are not physicians who will perform important parts of the surgery or administration of anesthesia will be performing only tasks that are within their scope of practice, as determined under State law and regulation, and for which they have been granted privileges by the hospital.

10.01.17 Adequacy of available information

All records must document (as appropriate):

- *All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition.*

§482.24(c)(4)(vi)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The requirement means that the stated information is necessary to monitor the patient's condition and that this and other necessary information must be in the patient's medical record.

For necessary information to be used, it must be promptly filed in the medical record so that health care staff involved in the patient's care can access/retrieve it to monitor the patient's condition and provide appropriate care.

The medical record must contain:

- All practitioner's orders (properly authenticated).
- All nursing notes (including nursing care plans).
- All reports of treatment (including complications and hospital-acquired infections).

DOCUMENT REVIEW

Review inpatient records to verify:

- The records contain appropriate documentation of practitioners' orders, interventions, findings, assessments, records, notes, reports, and other information necessary to monitor the patient's condition.
  - ☐ Is the information included in patient records in a prompt manner so that health care staff involved in the care of the patient has access to the information necessary to monitor

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	▪ All medication records (including unfavorable reactions to drugs). ▪ All radiology reports. ▪ All laboratory reports. ▪ All vital signs. ▪ All other information necessary to monitor the patient's condition.	the patient's condition?
10.01.18 Discharge summary *The records must document (as appropriate):* • *Discharge summary with outcome of hospitalization, disposition of case and provisions for follow-up care.* §482.24(c)(4)(vii)	☐ Compliant ☐ Not Compliant All patient medical records must contain a discharge summary. A discharge summary discusses the outcome of the hospitalization, the disposition of the patient, and provisions for follow-up care. Follow-up care provisions include any post-hospital appointments, how post-hospital patient care needs are to be met, and any plans for post-hospital care by providers such as home health, hospice, nursing homes, or assisted living. The MD/DO or other qualified practitioner who admitted the patient, is responsible for the patient during the patient's stay in the hospital. This responsibility would include developing and entering the discharge summary. Other MDs/DOs who work with the patient's MD/DO, are covering for the patient's MD/DO, and who are knowledgeable about the patient's condition, the patient's care during the hospitalization, and the patient's discharge plans may write the discharge summary at the responsible MD/DO's request. In accordance with hospital policy, and 42 CFR §482.12(c)(1)(i) the MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and MD/DO assistants to the extent recognized under State law or a State's regulatory mechanism. Whether delegated or non-delegated, we would expect the person who	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ A discharge summary is included to ensure proper continuity of care. ▪ A final diagnosis is included in the discharge summary. **Note:** For patient stays under 48 hours, the final progress notes may serve as the discharge summary and must contain the outcome of hospitalization, the case disposition, and any provisions for follow-up care.

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	writes the discharge summary to authenticate, date, and time their entry. For delegated discharge summaries, we would expect the MD/DO responsible for the patient during his/her hospital stay to co-authenticate and date the discharge summary to verify its content. The discharge summary requirement would include outpatient records. For example: ▪ The outcome of the treatment, procedures, or surgery. ▪ The disposition of the case. ▪ Provisions for follow-up care for an outpatient surgery patient or an emergency department patient who was not admitted or transferred to another hospital.	
10.01.19 Discharge summary timeline A concise discharge summary must be completed on each patient within seven days of patient discharge.	☐ Compliant ☐ Not Compliant To facilitate the transition of care between providers, it is essential that the discharge summary document is available to the next provider, at a minimum, by the time of the patient's next appointment. Future care of the patient may depend upon findings/events incurred during the inpatient stay. All tests/diagnostics pending at the time of discharge may be noted as such in the discharge summary. As new results are obtained, relating to the inpatient stay, the document may be amended by the discharging practitioner.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Observe the discharge process for compliance with standard. ▪ Review the patient record for inclusion and completion of the discharge summary within the designated time frame.
10.01.20 Medical record delinquency *All records must document (as appropriate):* ▪ *Final diagnosis with completion of*	☐ Compliant ☐ Not Compliant All medical records must contain a final diagnosis. All medical records must be complete within 30 days of discharge or	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the medical records of a sample of patients who have been discharged

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medical records within 30 days following discharge. §482.24(c)(4)(viii)	outpatient care.	for more than 30 days. □ Are those records complete? □ Does each record have the patient's final diagnosis?

10.01.21 Electronic patient event notifications

☐ Compliant ☐ Not Compliant ☐ NA (hospital does not have EMR or EMR does not have notification capability)

This standard is not met as evidenced by:

If the hospital utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard at 45 CFR 170.205(d)(2), then the hospital must demonstrate that—

1. *The system's notification capacity is fully operational and the hospital uses it in accordance with all State and Federal statutes and regulations applicable to the hospital's exchange of patient health information.*
2. *The system sends notifications that must include at least patient name, treating practitioner name, and sending institution name.*
3. *To the extent permissible under applicable federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange*

This requirement gives a patient's primary care physician and/or post-acute providers secure electronic access to the patient's health information to facilitate continuity of care.

This requirement is limited to those hospitals using an electronic medical record (EMR) system with the technical capacity to generate information for electronic patient event notifications at the time of survey and/or implemented during a term of accreditation.

ESTABLISHED CARE RELATIONSHIP

A patient's established primary care practitioner or established primary care practice group or entity, is a care relationship that the patient recognizes as primary or one that is evidenced by documentation of the relationship in the patient's medical record. Hospitals are to send notifications to those practitioners or providers that have an established care relationship with the patient.

NOTIFICATION POLICY

The hospital has a written policy that defines its processes, including:

- The information to be sent as part of the electronic notification including, at least, patient name, treating practitioner name, and name of the sending institution. Note: Hospitals are not prohibited from sending more detailed information, if consistent with all State and Federal statutes and regulations.

INTERVIEW AND DOCUMENT REVIEW

- Interview hospital leadership or staff to verify the organization has methods to send patient event notifications to patients' physician or intermediary regarding ED registrations, inpatient admissions, and discharges/transfers.
- Verify the organization has a written patient event notifications policy.
- Review medical records to verify patient event notifications containing the minimum required information have been sent, in accordance with federal and state laws and regulations and hospital policy.
- Verify the organization has made reasonable efforts to send electronic notifications to post-acute care practitioners/providers.

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of health information, at the time of:

(i) The patient's registration in the hospital's emergency department (if applicable).

(ii) The patient's admission to the hospital's inpatient services (if applicable).

4. *To the extent permissible under applicable federal and state law and regulations and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately prior to, or at the time of:*

(i) The patient's discharge or transfer from the hospital's emergency department (if applicable).

(ii) The patient's discharge or transfer from the hospital's inpatient services (if applicable).

5. *The hospital has made a reasonable effort to ensure that the system sends the notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners and entities,*

- Identification of the patient's practitioner(s), provider group, or post-acute care entity to receive notifications.
- Methods for sending notifications to the patient's practitioner(s)/provider(s) at time of ED registration and/or patient admission.
- Methods for sending notification at time of discharge from the ED and upon discharge/transfer from inpatient services.
- Documenting the successful or unsuccessful transmission of notifications and reasons when unsuccessful.
- Documentation and reporting of HIPAA privacy breaches, i.e., notifications sent to incorrect recipient. (See Standard 10.00.06.)

A hospital is not prevented from:

- Sending patient event notifications to other practitioners, in accordance with all applicable laws, who may be relevant to a patient's post-discharge care and would benefit from receiving patient event notifications.
- Seeking to identify these other practitioners.

EXEMPTIONS

A hospital would not be expected to send an electronic patient event notification when:

- The receiving provider lacks the technological capabilities to receive this patient notification information.
- The hospital is not able to identify a primary care practitioner for a patient.
- The patient has not identified a provider to whom they would like information about their care to be sent.
- There is no applicable post-acute care (PAC) provider or supplier identified.

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which need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:

(i) The patient's established primary care practitioner;

(ii) The patient's established primary care practice group or entity; or

(iii) Other practitioner, or other practice group or entity, identified by the patient as the practitioner, or practice group or entity, primarily responsible for his or her care.

§482.24(d)
§482.24(d)(1-3)
§482.24(d)(3)(i-ii)
§482.24(d)(4)
§482.24(d)(4)(i-ii)
§482.24(d)(5)
§482.24(d)(5)(i-iii)

10.01.22 For future use

10.01.23 For future use

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10.01.24 Initial assessments

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

An initial assessment is documented by each discipline rendering services to a patient.

This assessment is documented within time frames determined by hospital/service policies and incorporates/findings from other sources while keeping duplication of data to a minimum.

The assessment is inclusive of physical, emotional, educational, and social findings appropriate to the service setting (inpatient, outpatient, and ambulatory care) and the age and presenting problems of the patient.

Initial patient assessments provide a baseline for the patient at the time of admission. From these assessments, the needs of the patient are identified, and the plan of care is developed.

Direct care providers, such as nursing, nutrition, rehabilitation specialists, respiratory care, social service, etc., have established policies delineating the data collection process. These policies identify the time frames for beginning and completing the initial assessment, the basic structure (components), and identify who can perform the assessment.

Policies are in place describing the scope and content of the initial assessment for:

- Medical staff.
- Nursing, general.
- Nursing: ambulatory care, ambulatory surgery, special care units, obstetrics, emergency department, pediatrics, and other subspecialties.
- Nutrition Services: Screens and full assessment.
- Pharmacy, clinical intervention.
- Rehabilitation: Physical Therapy, Occupational Therapy, Speech Language Pathology, and other rehabilitation.
- Behavioral health.
- Respiratory care.
- Social services.
- Pediatrics and other clinical services provided.

DOCUMENT REVIEW

- Review hospital policies that address initial patient assessments. Verify that:
  - ☐ Policies describe the initial patient assessment requirements for each listed discipline.
  - ☐ The elements and timelines of the initial assessment are identified.
- Review a minimum of five inpatient and five outpatient records to verify initial assessments by all disciplines are appropriate, complete, and timely.
  - ☐ Verify that initial assessments are completed and within the timelines as established by policy.

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10.01.25 Progress notes	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
All records shall document reassessments and findings by clinical and other staff involved in the care of patients. Reassessments are entered as progress notes into the clinical record by each discipline providing care to the patient, at the time of the reassessment and at frequencies established within discipline specific standard(s) of practice. Reassessments are documented whenever there is: 1. A significant change in the patient's condition or status. 2. A significant response (desired or undesired) to a procedure/ intervention. 3. At specified time intervals. Progress notes are dated, timed, and signed by the author. Minimally, progress notes are authored by: 1. Physicians, at least daily. 2. Nurses, with a change of shift or care giver. 3. Other support staff with each observation or, at intervals no less	Hospital policy describes expectations for providing progress notes. Progress notes may be facilitated by the use of "flow" sheets or other checklist forms of documentation.	**DOCUMENT REVIEW** ▪ Verify that discipline-specific standards of practice have been established and address the three required criteria for reassessment. ▪ Review medical records to verify: □ Appropriate assessments and reassessments are completed, timed, dated, and authenticated. □ Practitioners prepare progress notes at the defined frequency.

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than every five visits or weekly, whichever comes first.

4. For behavioral medicine patients, at least weekly for inpatients and monthly for outpatients.

10.01.26 Multidisciplinary plan of care: Assessment and reassessment

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Each patient will have a comprehensive, integrated, multidisciplinary plan of care, which is developed from the initial patient assessment. This care plan will include, at a minimum, physician, and nursing components.

The plan of care is initiated within time frames established by the hospital.

The plan is updated whenever there are significant changes in the list of patient problems, needs and diagnoses. The plans of care focus on:

- Immediate needs.
- The patient's needs for education regarding the diagnosis, treatment, and continuing management of health care problems and the maintenance of health.
- Discharge planning.

When patient reassessment dictates the need to change the treatment plan, the

Individual plans of care are developed at the time of the initial assessment. Coordinated plans of care may include:

- Clinical or Critical Pathways, which are matched to the patient as soon as the principle diagnoses are known.
- A Master Treatment Plan (MTP), which is coordinated as soon as at least two disciplines have completed their assessments (except for behavioral medicine in which all disciplines shall complete initial assessments to develop the MTP by the fifth day.)

Individual care providers are knowledgeable of the comprehensive plan of care. Each discipline involved with the care of a patient is responsible to contribute to the plan of care.

Staff are expected to review the plan of care at the start of each shift; documentation of this review is not required.

Modifications to the plan of care are dated, timed, and signed by the author.

Updates to the plan of care occur:

- Whenever there is a significant change in the patient's condition or status.
- At specified time intervals.

DOCUMENT REVIEW

- Review inpatient and outpatient records. The plan of care should be consistent with the observations in the progress notes.
- Verify that:
  - ☐ A plan of care is initiated within the established timeframe.
  - ☐ The plan of care is updated whenever there are significant changes in the list of patient problems, needs and diagnosis.

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plan of care is modified.

10.01.27 Outpatient problem list

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

If the hospital provides ongoing ambulatory care to a patient for the same problem(s), the list of problems, needs and diagnoses is developed and included in the medical record by at least the third visit.

Whether this is in freestanding clinics, or via mechanisms in the acute care hospital, the coordination of services for patients with repeating ambulatory care is based upon a common problem list.

This list also includes known allergies and all medications (legend and non-legend) taken by the patient to assess for potential interactions, interferences and incompatibilities.

DOCUMENT REVIEW

- Does the hospital provide ongoing ambulatory care (oncology, transfusion, mental health, physical rehabilitation, dialysis, etc.)?
  - □ If so, verify that hospital policy requires the establishment of a multidisciplinary problem list for each patient within the required time frame.
  - □ Review outpatient records to verify that a problem list has been initiated by at least the third visit for patients returning for the same problem and has been appropriately updated.

10.01.28 Obstetric patients

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Hospital policy describes the expectations relative to forwarding prenatal records and diagnostic test results **as well as the contents of the prenatal record.**

The prenatal record may include information regarding the findings from ultrasounds, laboratory data such as CBC, blood group - RH screen for irregular antibodies, rubella screen (titer), RPR, sexually transmitted diseases, genetic testing, and most recent PAP Smear; UA, and any other testing performed.

DOCUMENT REVIEW

Verify:

- **When the prenatal record is forwarded to the hospital in advance of admission, it is updated by the physician or non-physician practitioner, upon admission.**

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		▪ Obstetric prenatal records include all assessments **required by the hospital.**
10.01.29 Newborn care Requirements for initial assessment, interventions, and reassessment are clearly defined, approved by the medical staff and implemented in the hospital.	☐ Compliant ☐ Not Compliant A newborn record, which is separate from that of the mother, is initiated and maintained. **Nursing and medical data sheets can include state mandated protocols and evidence-based care practices and all relevant maternal medical information defined by hospital policy and consistent with standards of care.** This record reflects almost continuous observations during the first hours of transition, from **birth** until **physiological** stabilization has occurred **including all treatment provided and response to treatment. A physician physical assessment is documented for newborns at the frequency defined by hospital policy and consistent with standards of practice, and state and local law.** Initial data are recorded by nursing including legal identification processes.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Policies appropriately identify required content of newborn care records. ▪ Patient records reflect documentation of complete assessments**.** **Note:** Adult medical/surgical facilities without OB must meet these requirements, as there may be precipitous deliveries in the hospital.
10.01.30 Pediatric/adolescent patients The medical record of pediatric and adolescent patients includes documentation of the achievement of physical, emotional, and social developmental markers.	☐ Compliant ☐ Not Compliant Hospital policy describes the physical, emotional, and social development criteria to be assessed and documented for pediatric and adolescent patients. Due to the broad range of growth markers, there may be multiple flowcharts or other mechanisms to facilitate pediatric assessment. Each such assessment should have sufficient content to indicate that there has been an assessment of the developmental processes and nurturing (to screen out abuse/neglect). Immunization history is an expected datapoint.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that Medical Staff and hospital policies appropriately identify required developmental markers and nurturing as key data points in pediatric records. ▪ Examine pediatric/adolescent medical records to verify: □ The completion of age-appropriate

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Considerations, in addition to height and weight, may include head circumference and neuromuscular sensory markers in the very young. 1. In toddlers, the factors indicating communication, social and dexterity skills may be key. 2. Social values begin to appear in the preschool child and may be altered in the child living in a dysfunctional setting. 3. Peer relationships and competitiveness emerge as strong factors in the early school age child (progress and "getting along" in school). The development of secondary sexual characteristics may be key in ascertaining behavioral issue concerns.	physical, emotional, and social development assessments.

11

PHYSICAL ENVIRONMENT

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

GENERAL REQUIREMENTS

11.00.01 CONDITION OF PARTICIPATION: Physical environment

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment, and for special hospital services appropriate to the needs of the community.

§482.41

This standard applies to all locations of the hospital, all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations, regardless of occupancy designation.

The hospital's Facility Maintenance and hospital departments or services responsible for the hospital's buildings and equipment (both facility equipment and patient care equipment) must be incorporated into the hospital's QAPI program and be in compliance with the QAPI requirements.

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

Note: Score this Condition after review of all standards with a focus on the list of systems identified in 11.00.02 below.

One surveyor should conduct survey of the Physical Environment; however, each surveyor, as he/she conducts his/her survey assignments, should assess the hospital's compliance with this standard.

11.00.02 Required plans and performance standards

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital shall maintain written plans for the following areas:
01: Building Safety
02: Building Security
03: Hazardous Materials and Waste
04: Fire Safety Control
05: Medical Equipment Management
06: Utility Systems Management

Plans are reviewed and approved at least once every 12 months by the organization's committee that oversees safety in the environment.

The hospital shall maintain written plans for each of the six areas identified. Performance improvement goals or indicators are included for each area.

The hospital designates an individual/individuals as responsible for each of the six areas **of the physical environment**.

The qualifications of the **responsible individual(s) are documented**.

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

- Review the hospital written plans for managing each of the six areas identified.
- Do written procedures exist instructing staff on the proper action to take for each of the six areas?
- Do performance improvement goals and objectives exist for each area?
- Is there an identifiable person or

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

The annual review is documented.

department or team responsible for each area to facilitate corrections or improvements as necessary?

- Is there evidence of active monitoring and follow-up for each area?

BUILDING SAFETY

11.01.01 Periodic monitoring for safety issues

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The physical environment of each facility used for treating or housing patients shall be inspected once every six months in patient care areas, and once every 12 months in non-patient care areas to identify safety related concerns and issues.

The environmental risk assessment strategy for patient care in a safe setting shall be performed at least once every six-months.

Inspections must be documented with date, initials or signatures of individuals participating in the inspection, and all deficiencies are **denoted** with the action item **for resolution**.

§482.13(c)(2)

Special care is given to ensure compliance with applicable codes, standards and regulations related to the physical environment during inspections of patient care and non-patient care areas of the hospital.

The environmental risk assessment strategy for **a safe setting takes** a unit-specific approach and is based on nationally recognized standards. The risk assessment tool used is approved through the Safety Committee.

Interior and exterior walking surfaces are inspected for tripping or slipping hazards. Electrical hazards, ergonomics, corridor clutter, fluid leaks, signage, egress lighting and paths of egress are of particular **focus.**

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

- Verify that records have been maintained demonstrating safety inspections were conducted once every six months in patient care areas and once every 12 months for non-patient care areas.
- Verify the specific environmental risk assessment tool for a patient-safe care setting has been approved by the Safety Committee and contains a list of elements the hospital has identified are ligature risks, hazardous, or that provide accessible means for a patient to harm themselves or others.
- Additional facilities associated with the hospital, either owned or leased must also be monitored for safety. Records demonstrating correction of actions

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

should be reviewed. All items identified in the report should be reviewed for corrective action.

11.01.02 Building safety

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients, visitors, and staff are assured.

The hospital identifies hazards specific to weather on both interior and exterior locations.

The hospital must ensure that all buildings at all locations of the certified hospital meet state and federal accessibility standards (e.g., Office of Civil Rights requirements).

The patient has the right to receive care in a safe setting. The hospital must implement environmental risk assessment strategies appropriate to the specific care environment and patient population served.

The risk assessment strategy shall address age, psychiatric, diminished capacity, and any other patient related factors the hospital identifies as applicable.

Review of the environment includes elements that would allow at-risk patients to cause intentional harm to self or others, including ligature risk, unattended hazardous items, windows that can be opened or broken, unprotected lighting fixtures, other unsecured objects considered dangerous, or other conditions identified by the hospital to be dangerous.

Hospitals are expected to address hazards and risk for age-related factors. Healthcare provided to neonatal, pediatric, and geriatric patients must be in accordance with nationally recognized standards.

Accessibility requirements apply to the interior and exterior of all buildings. This standard enacts additional assurance that individuals with physical challenges are not prevented from access.

OBSERVATION AND DOCUMENT REVIEW

- Verify that the condition of the hospital is maintained in a manner to assure the safety and well-being of patients (e.g., condition of ceilings, walls, and floors, presence of patient hazards, etc.). Review the interior and exterior for hazards related to weather conditions.
- **Provide findings for accessibility observations in the standards related to the individual element which is not in compliance with accessibility requirements.**
- Observe patient care environments for unattended items such as utility or housekeeping carts that contain hazardous items that may pose a safety risk to patients, visitors and staff. Examples of these items could include cleaning agents, disinfectant solutions, mops, brooms, tools, etc.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

§482.41(a)
§482.13(c)(2)

11.01.03 Safety committee

There is a Safety Committee that is developed to identify the opportunities to improve all issues related to safety existing within the hospital.

Multi-disciplinary membership shall consist of individuals who have knowledge and authority of the operations within their own area/service.

☐ Compliant ☐ Not Compliant

Safety Committee membership includes representation from administration, clinical, and support services. This team is responsible for all safety-related policies, procedures, and processes in the hospital.

The Safety Committee meets periodically, to review reports, analyze trends, discuss safety related issues in the physical environment, and identify opportunities to resolve physical environment safety issues.

The Safety Committee reports appropriate results of monitoring and committee actions and recommendations to leadership, Quality Assessment Performance Improvement (QAPI), and department managers.

ACHC does not specify the frequency of Safety Committee meetings, but meeting held less than once every two months require a risk assessment to indicate the effectiveness of less frequent meetings.

This standard is not met as evidenced by:

DOCUMENT REVIEW

- Review:
  - □ The appointment process, composition of, and duties of the Safety Committee and their performance.
  - □ Minutes of committee meetings. Determine if recommendations for action were made for specific safety issues.
  - □ Reports of the Safety Committee to the governing body to determine effectiveness of the committee to make recommendations on physical environment issues.
- Evaluate the frequency of the Safety Committee meetings. If less frequent than once every two months, then review risk assessment indicating the effectiveness of the less-frequent meetings.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.01.04 Safety Committee chairperson	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The chief executive officer (CEO) of the hospital shall appoint the chairperson of the Safety Committee. The appointment must be documented.	The role of the chairperson is to assure that concerns that are identified by the Safety Committee can receive timely administrative attention. Appointment of the chairperson to a one-year term to allow a change in leadership is recommended. While this is not a requirement, rotation the chairperson's role prevents domination by one individual.	**INTERVIEW** ▪ Verify the appointment.
11.01.05 Safety officer	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
An individual is appointed by the chief executive officer to serve as the organization's Safety Officer with responsibilities to intervene whenever conditions in the environment present a threat to the life and health of the occupants or threaten damage to the physical environment. This appointment must be documented.	The CEO annually appoints an individual possessing knowledge of safety requirements. This position is responsible for all safety issues not specifically assigned to another member or to a safety committee. Authority to take any action needed relating to situations that pose immediate threat to life, health, and/or property shall be included in the appointment document.	**DOCUMENT REVIEW** ▪ Review the appointment process and content of the appointment document. ▪ Verify the appointment has been reaffirmed annually.
11.01.06 For future use		
11.01.07 For future use		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.01.08 Review of safety policies and procedures The Safety Committee reviews safety policies and procedures at least every 36 months **or more frequently as conditions change.** §482.13(c)(2)	☐ Compliant ☐ Not Compliant People, processes, and characteristics change; therefore, all safety policies and procedures shall be reviewed at least once every 36 months and approved for appropriateness by the Safety Committee. The chairperson of the Safety Committee shall sign and date the policies **to document the periodic review.**	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ **Policy and procedures address what the hospital does to curtail contaminated materials and unsafe items that pose a safety risk to patents and staff**. ▪ An appraisal has been documented at least once in the past 36 months within the Safety Committee minutes ▪ Policies are current.
11.01.09 Smoking/tobacco products policy The hospital has and enforces a facility-wide policy prohibiting the use and sale of tobacco products within the buildings used for treating or housing patients.	☐ Compliant ☐ Not Compliant Smoking and the use of lighting material for smoking is also a fire hazard. Smoke in a hospital contaminates air in the central air system. Smoking is dangerous around oxygen. The hospital must actively promote a tobacco free environment. The policy on smoking must address the requirements found in chapter 18/19.7.4 of the 2012 Life Safety Code, including: ▪ Prohibited areas ▪ Signage ▪ Ashtray construction ▪ Metal containers with lids for ash disposal	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify policy and observe practice.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The policy shall prohibit smoking by patients unless authorized to smoke by the attending physician. If permitted, smoking must be out of doors and away from entrances or air intakes. If permitted indoors, it must be confined to controlled smoking areas which prevent exposure to non-smokers, must not contaminate the central air system, and the smoke from the controlled area must be exhausted to the out of doors. Other patients and staff must be protected from exposure.	
11.01.10 Eyewash stations and emergency showers Where the eyes or body of any person may be exposed to injurious corrosive materials, ASNI Z358.1-2014 approved eyewash stations and/or emergency showers shall be provided within the work area for immediate emergency use.	☐ Compliant ☐ Not Compliant Where injurious corrosive materials exist, organizations must conduct a risk assessment to determine the need for ANSI Z358.1-2014 approved eyewash stations and/or emergency showers. ANSI Z358.1-2014 is the standard for the proper design, installation and maintenance of emergency eyewash and shower equipment. **Note:** To purchase your own copy of the ANSI Z358.1-2014 standard, follow this link: http://webstore.ansi.org/	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ In areas where injurious corrosive materials are observed, review the organization's risk assessment to determine the need for emergency eyewash or shower equipment. ▪ Check logs to ensure plumbed emergency eyewash and shower equipment are activated weekly to verify operation and to ensure the flushing fluid is available. ▪ Examine emergency eyewash and shower equipment to ensure it complies with ANSI Z358.1-2014 standards for installation and operation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

BUILDING SECURITY

11.02.01 Building security

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The organization shall have policies and other measures to identify and minimize security risks to patients, visitors, and staff.

The organization's security features are based on nationally recognized standards to ensure the safety of vulnerable patients.

Access to non-clinical rooms identified as hazardous locations must be secured to prevent patient and visitor entry.

§482.41(a)

Policies, procedures, and systems shall be developed to monitor and reduce **security concerns**. Examples of security issues include theft of personal or commercial items, abduction, and assaults of individuals in and outside the facilities.

Security risks **include locations in which hazardous materials are located. Examples of such locations include, but are not limited to, boiler and fuel-fired heater rooms, electrical rooms, clean and dirty storage rooms.**

INTERVIEW AND DOCUMENT REVIEW

- Verify that policies and procedures are in place. Review documents to determine if the security program is effective or if there are security concerns.
- Interview staff to determine if security and safety is an issue.
- Review:
  - □ Security risk assessments for frequency and thoroughness of assessments, and follow-through on recommended actions.
  - □ Policy and procedures on what the hospital does to curtail unwanted visitors that pose a safety or security risk to patents and staff.
  - □ The hospital's security efforts to protect vulnerable patients including newborns, children, and patients at risk of suicide or intentional harm to self or others. Security mechanisms must note references to nationally recognized standards of practice.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.02.02 Security management	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
An individual or department shall be assigned responsibility for monitoring and addressing security concerns.	Smaller facilities may have full time or part time security staff that reports to an administrative staff person. Larger facilities may have their own security department and security officers. Consideration should be given how to process supplemental security resources in the event of a disaster. This may be accomplished with Memorandums of Understanding (MOU). The hospital has established a relationship with the local police department to facilitate timely response if external police assistance is required. External support for security is available on a timely basis from the local police department.	**INTERVIEW** ▪ Interview various hospital employees to determine if they can identify the person or department responsible for security issues. ▪ Does adequate staff and supervision exist? ▪ Review security reports for occurrences of security problems. □ Are security issues handled quickly and thoroughly? □ Is follow-up appropriate?
11.02.03 For future use		
11.02.04 Security sensitive areas	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital identifies areas that they believe to be security sensitive and have control systems in place to protect the areas and contents. These security sensitive areas are documented.	There are many different types of areas in a hospital that can be considered security sensitive, such as nurseries, pharmacies, cashiers box, medical records, etc. The organization must first identify these areas and then have systems in place to control and protect these areas. Note: Control systems can be physical locks on doors, observation systems, as well as special response plans. Any locks on doors must comply with the Life Safety Code, 2012 edition. The hospital reviews the list of security sensitive areas on an annual basis, to	**INTERVIEW AND DOCUMENT REVIEW** ▪ Review the list of security sensitive areas. Determine if all sensitive areas are included. ▪ Determine through interview if the security control system is sufficient to protect identified areas.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	determine accuracy and whether additional locations need to be added.	
11.02.05 Security incident procedures	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital has written procedures to follow in the event of a security incident.	Security incidents may include an infant abduction, VIP visit, civil disobedience, bomb threat, or unruly patient or guest. The hospital must have written procedures that their security staff must follow in the event of a security incident.	**DOCUMENT REVIEW** ▪ Review list of written procedures for security incidents. Evaluate if the list adequately covers procedures for staff to follow in the event of an incident. ▪ Interview staff to verify whether they received training on security incident procedures.
HAZARDOUS MATERIALS AND WASTE		
11.03.01 Hazardous materials and waste plan	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
There shall be a system to identify, handle, process, and dispose of hazardous materials and wastes. Each service area within the hospital shall develop and maintain a list of the hazardous materials and wastes housed in the area and/or used by staff.	A hazardous material is defined as any substance or material that could adversely affect the safety of the public, handlers or carriers during use, transportation, storage, or disposal. Aspects of the physical environment are designed and maintained to contain, neutralize, or destroy potentially harmful materials and wastes. Examples of hazardous waste include but are not limited to chemotherapy waste, chemical waste, infectious waste, waste gas, and radioactive waste. The hospital designates in writing an individual responsible for the coordination of activities to ensure procedures are written, approved (by the appropriate committee), and implemented for response to spills, accidents, and emergency in-house decontamination for patients of the emergency department.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Review the procedures for the processes used in using, storage, transporting and disposal of these materials and wastes are written and updated once every three years. ▪ Observe for appropriate handling storage, processing and disposal of hazardous materials and wastes. ▪ Interview staff to determine the effectiveness of hazardous spill training.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.03.02 Storage and disposal of trash	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital must have procedures for the proper routine storage and prompt disposal of trash. §482.41(b)(4)	"Trash" refers to common garbage as well as bio-hazardous waste. The storage and disposal of trash must be in accordance with federal, state, and local laws and regulations (i.e., EPA, OSHA, CDC, State environmental, health and safety regulations). The procedures for proper routine storage and disposal of trash must be written and reviewed by the Safety Committee once every three years.	**OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ The hospital has developed and implemented policies for the proper storage and disposal of trash. ▪ Staff adhere to these policies and that the hospital has signage, as appropriate. ▪ The hospital has trained individuals to sign the EPA manifest.
11.03.03 Program minimizes exposure	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hazardous materials and waste plan is organized in a manner that minimizes potential exposure to patients, visitors, staff, and the surrounding community.	Policies and procedures should address the prevention and response to spills, slips, falls, and accidents.	**OBSERVATION AND DOCUMENT REVIEW** Review hazardous waste plans for various waste products. Verify compliance.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.03.04 Labels, inventory, and safety data sheets (SDS) The hospital identifies and documents all hazardous materials and waste used, stored, or generated throughout the hospital, and ensures that they are properly labeled.	☐ Compliant ☐ Not Compliant Hazardous products are appropriately labeled according to regulations and NFPA standards. Safety Data Sheets (SDS) are maintained (or are available within 10 minutes) and always available to the staff for every hazardous material with which they may come in contact. Hazardous materials that must be included on the inventory are those whose storage, use or handling are regulated by standards or laws. The inventory is updated annually. SDS information may be stored electronically or obtained through the internet or a fax-back service. However, paper copies of the SDS of all hazardous products must be maintained on the premise of the facility, in the event the electronic copies are not available. Copies of the SDS may be maintained on flash-drives in lieu of paper copies, provided a battery-operated computer is available to display them.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review the hazardous materials and waste management plan. ▪ Check hazardous materials during building tour looking for proper labeling, use, disposal, and storage. ▪ Ask staff to provide you a Safety Data Sheet for random selected materials. ▪ Confirm paper copies of the Safety Data Sheets are available to the hospital staff, or copies in CDs or flash-drives provided a battery-operated computer is available to display them. ▪ Review inventory of hazardous materials and confirm that it is updated annually.
11.03.05 Personal protective equipment (PPE) Appropriate Personal Protective Equipment (PPE) is provided to staff, as necessary, to protect against possible exposure to hazardous materials and wastes.	☐ Compliant ☐ Not Compliant Personal protective equipment must be readily available to the staff to prevent exposure to harmful substances per the Occupational Safety and Health Administration (OSHA). The types of protective equipment can range from gloves to a self-contained breathing apparatus. The types of protective devices needed for handling chemicals are listed on the warning label accompanying a product or on the relevant SDS.	This standard is not met as evidenced by: **OBSERVATION** ▪ Review the hazardous materials and waste plan for exposure to risk content. □ Look for evidence of use of PPE. □ Is PPE available?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.03.06 Hazardous materials: Routine monitoring	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Hazardous materials and wastes are monitored to reduce the exposure potential to harmful agents.	Routine inspections of the occupied areas of the hospital occur to observe and record how hazardous substances are stored, handled, separated, and organized. Environmental tests are performed for substances that produce harmful vapors to ensure that engineering controls are adequate to provide a safe environment. Policies and procedures have been developed to comply with these federal (OSHA) regulations.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Review documented routine monitoring of hazardous materials. ▪ Observations will be made of the storage containers (which may range from labeling the container to the use of explosion proof cabinets), the availability and use of personal protective equipment, and staff knowledge of the hazardous materials and waste management plan.

FIRE SAFETY CONTROL

11.04.01 Written fire control plans	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital must have written fire control plans that contain provisions for: ▪ *Prompt reporting of fires* ▪ *Extinguishing fires* ▪ *Protection for patients, personnel and guests* ▪ *Evacuation* ▪ *Cooperation with fire-fighting authorities* §482.41(b)(5)	The fire control plans must describe the roles expected of staff at the area or location of the fire, and in areas and locations away from the fire. Plans include how and when to activate the alarm, the proper method to contain smoke and fire, the correct method for when and how to use a fire extinguisher, and when and where to evacuate patients. The fire control plan must meet the requirements of chapter 18/19.7.1.21 of the 2012 Life Safety Code, including but not limited to: ▪ Plan must be made available to all personnel ▪ Plan must be available at the telephone operator position(s) or the continuously manned security center	**INTERVIEW AND DOCUMENT REVIEW** ▪ Review the hospital's written fire control plans to verify they contain the provisions identified. ▪ Verify that hospital staff reported all fires as required. ▪ Interview staff throughout the hospital to verify their knowledge of their responsibilities during a fire.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Provide instruction in fire-safety procedures and devices to all staff The plan must also include instructions on how to evacuate the building when instructed to do so by a person of authority. The term 'staff' includes all individuals, whether employees, volunteers, students, or contract workers who are performing their job requirements within the facility.	
11.04.02 Fire drills - quarterly Fire drills shall be conducted at least quarterly on all shifts in all buildings classified as healthcare occupancy or ambulatory healthcare occupancy. For buildings classified as business occupancy (or other occupancies), fire drills are conducted annually on all shifts. **The transmission of a fire alarm signal shall be tested quarterly during fire drills from the alarm panel in the protected premise, to the emergency response force.** All fire drills are documented.	☐ Compliant ☐ Not Compliant The fire plan is practiced without prior warning to the occupants of the building(s). Observers document actual reactions to the event. Fire drills **expectations include:** ▪ Simulation of emergency fire conditions. ▪ A coded announcement is permitted between 9:00 pm and 6:00 am in lieu of activating the audible notification devices on the fire alarm system, but the fire alarm system still needs to be activated for each drill. ▪ **Actual patients** are not required to be moved during drills. ▪ Evacuation of simulated patients to the nearest smoke compartment barrier door. ▪ Non-customary shifts such as 12-hour shifts and weekend staffing patterns. ▪ Staff participation in the drills inasmuch as the hospital's fire response plan requires their response to fire alarms. ▪ **Quarterly, the transmission of the fire alarm signal and simulation of fire conditions must be tested during fire drills per NFPA 101 *Life Safety Code* (2012 edition), 18/19.7.1.4.**	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Participation is based upon staff's role in accordance with the Fire Control Plan, which may be at the point of alarm and away from the point of alarm. ▪ Review logs to ensure: □ Each healthcare occupancy and each ambulatory healthcare occupancy had one drill per shift per quarter. □ Off-site business occupancies have had annual fire drills on each shift. □ **Fire drill records indicate the fire alarm system signal is transmitted quarterly from the fire alarm panel to the emergency response force when fire drills are conducted. Note: A deficiency in transmitting the signal during a fire drill is cited at 13.02.03.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ **For Fire alarm systems – transmitting signal, see standard 13.02.03.**	
11.04.03 Fire drill critique Each fire drill shall be evaluated by observers located in strategic areas to record the responses of the staff and the processes being followed. Each fire drill critique is documented.	☐ Compliant ☐ Not Compliant Detailed documentation of critiquing of the drills shall be maintained. A proper critique must include; ▪ the staff's response to the alarm; ▪ the building's response to the alarm; and ▪ the fire alarm response. This information is to be used by the Safety Committee/team to improve hospital fire response systems. Actual fire alarms (non-drills) may be used in lieu of planned fire drills provided all areas of response are properly critiqued.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review: ▪ Records of the analysis of the fire drill implementations. ▪ Safety Team/Committee minutes to determine if they evaluate fire drills to improve the hospital's fire response.
11.04.04 Approval by state and local fire agencies *The hospital must maintain written evidence of regular inspection and approval by state or local fire control agencies.* §482.41(b)(6)	☐ Compliant ☐ Not Compliant The frequency of inspections by state or local authorities on fire safety should be at minimum, once per calendar year. Inspection frequencies greater than one per year will be considered if the hospital has historical evidence proving longer frequencies between inspections does not present an unsafe environment for the hospital. Evidence substantiating a safe environment would be consecutive reports indicating no findings or minimal findings. Where state and local fire control authorities refuse to provide inspections, the hospital must have written documents from the state and local fire control authorities indicating their decision not to provide inspections.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Examine: ▪ Copies of inspection and approval reports from state and local fire control agencies to verify evidence of inspections and correction of any deficiencies. ▪ Documentation from state or local fire control authorities where they refuse to provide inspections.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.04.05 Minimize the risk of danger from fire The hospital shall minimize the risk of danger from fire, smoke, and the harmful products of combustion.	☐ Compliant ☐ Not Compliant The hospital must take a proactive approach to reduce the risk of harm and danger to the occupants of the facility. This standard does not require the hospital to install fire safety features that are not required by any applicable code, standard or regulation.	This standard is not met as evidenced by: **OBSERVATION** ▪ During the building tour, identify situations that exist which may present a danger to the occupants from the harmful effects of fire, smoke, and the products of combustion.
11.04.06 Fire response: Staff training All staff members, including volunteers, students, physicians, and chaplains in the hospital must be trained and have knowledge on the proper procedure to respond to fire situations, both at the point of the alarm and away from the point of the alarm.	☐ Compliant ☐ Not Compliant **All employees shall be periodically instructed and kept informed with respect to their duties under the fire response plan.**	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review training records to ensure staff receives fire response training.
MEDICAL EQUIPMENT MANAGEMENT		
11.05.01 Medical equipment and systems: Maintenance There is an established, scheduled Preventive Maintenance Program for medical equipment relating directly or indirectly to patient care, which shall be maintained and tested periodically in	☐ Compliant ☐ Not Compliant 'Medical equipment' is defined as a device intended to be used for diagnostic, therapeutic, or monitoring of care to a patient in a hospital. All medical equipment (electrical and non-electrical) shall be included in the process for preventive maintenance. Written testing criteria for each type of equipment included in the preventive maintenance system is required. For	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review records and/or equipment for evidence of routine inspections and documentation of the hospital's

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

accordance with the manufacturer's recommendations.

Hospitals may choose to employ alternative maintenance activities and/or schedules provided they develop, implement, and maintain a documented Alternate Equipment Management (AEM) Program, to minimize risks to patients and others in the hospital associated with the use of medical equipment.

hospitals that elect to perform equipment maintenance in accordance with the manufacturer's requirements, documentation of the manufacturer's recommendations and the hospital's maintenance activities are maintained.

The organization may use an alternative method of communication to staff on medical equipment inspections, in lieu of stickers applied to medical equipment identifying the next inspection due date**.**

ALTERNATE EQUIPMENT MANAGEMENT (AEM) PROGRAM

A hospital may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer, provided the activities and frequencies do not reduce the safety of the equipment. Hospitals that choose to employ alternate maintenance activities and/or schedules use a documented AEM Program to minimize risks associated with the use of medical equipment to patients and others in the hospital. The AEM Program must be based on generally accepted standards of practice for medical equipment maintenance, such as ANSI/AAMI EQ 56:1999/(R) 2008, *Recommended Practice for a Medical Equipment Management Program*.

The determination of whether it is safe to perform medical equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are hospital employees or contractors. In the case of medical equipment, a clinical or biomedical technician or engineer would be considered qualified.

The hospital must maintain records of the qualifications of hospital personnel who make decisions on placing equipment in an AEM Program and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.

In determining whether or not to include equipment in an AEM Program, and which maintenance strategies to use in developing maintenance activities and frequencies for particular equipment, the hospital must take into account the biomedical preventive maintenance program.

- □ Are inspections conducted in a timely manner? Are past-due inspections common or rare?
- □ Can the staff recognize whether the equipment they are using has been inspected or is due for inspection? While stickers applied to the medical equipment identifying the next inspection due date are not a requirement of this standard, there must be some form of effective communication to the staff on the current preventive maintenance of that equipment
- □ Is the preventive maintenance process one that alerts the staff to potentially unsafe equipment?

- If the hospital is using an AEM program for inspection, testing, and maintenance activities, then the following activities need to be reviewed:
  - □ Documentation for the AEM program. Determine if it addresses the requirements for equipment to have maintenance activities and frequencies less than the manufacturer's recommendations.
  - □ Is the determination of the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

typical health and safety risks associated with the equipment's use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the hospital where it is used.

A hospital is expected to identify any equipment in its AEM Program that is "critical equipment," for which there is a risk of serious injury or death to a patient or staff person should the equipment fail.

Different types of equipment present different combinations of severity of potential harm and likelihood of failure. The hospital is expected to be able to demonstrate to a surveyor the factors it considered in its risk assessment for equipment placed in its AEM Program.

Some equipment may not be eligible for placement in the AEM Program:

- Federal or state laws that may require the hospital to inspect, test and maintain their equipment strictly in accordance with the manufacturer's recommendation.
- Other CMS Conditions of Participation require adherence to manufacturer's recommendations which preclude their inclusion in the AEM program.
- Imaging and radiologic equipment, whether used for diagnostic or therapeutic purposes, must be maintained in accordance with the manufacturer's recommendations.
- Medical laser devices are not eligible.
- New equipment for which sufficient maintenance history—either based on the hospital's own or its contractor's records, or available publicly from nationally recognized sources—is not available to support a risk-based determination, must not be immediately included.

The hospital may use one or more maintenance strategies for its AEM Program in order to determine the appropriate inspection, testing and maintenance activities and frequencies, based upon the nature of the equipment and the level of risk it presents to patient or staff health and alternative maintenance activities and frequencies being performed by qualified individuals?

- □ Verify that the hospital has documented maintenance activities and frequencies for all equipment included in the AEM program.
- □ Verify the hospital is evaluating the safety and effectiveness of the AEM program on an annual basis.
- □ If the hospital has identified equipment as having such a very low level of risk that it has determined it can use a broad interval range or departmental 'sweeps', ask the hospital for the evidence used to make this determination, and determine if it is reasonable.
- □ Of the critical equipment that is included in the AEM program, ask the hospital to explain how the decision was made to place this critical equipment in the program.
- □ Of the equipment that is included in the AEM program, ask the hospital to describe the methodology for applying maintenance strategies and determining alternative maintenance activities and/or frequencies.
- □ If the hospital is utilizing the AEM

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

safety. The risk to patient health and safety that is considered in developing alternative maintenance strategies must be explained and documented in the AEM Program.

In developing AEM maintenance strategies, hospitals may rely upon information from a variety of sources, including, but not limited to:

- Manufacturer's recommendations.
- Nationally recognized expert associations.
- The hospital's own experience.
- The contractor's own experience.
- Other materials.

For each type of equipment subject to the AEM Program, there must be documentation indicating:

- The types and level of risks to patients or staff health and safety.
- Alternative maintenance activities and the differences from the manufacturer's recommendations when they are known.
- The date when AEM Program maintenance activities were performed and what actions, if any, were taken.
- Documentation of equipment failures and identifying if any harm resulted to an individual.

The AEM Program must be compliant with these requirements at all times and must have written policies and procedures that address the effectiveness of the program. The hospital must have a written annual evaluation of the AEM Program that addresses the following factors:

- How equipment is evaluated to ensure there is no degradation of performance.
- How incidents of equipment malfunctioning are investigated, including whether or not the malfunction could have been prevented; what steps

program, review the annual evaluation to determine they address:

- How the equipment is evaluated.
- How incidents of equipment malfunction are investigated.
- The use of performance data.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	will be taken to prevent future malfunctions; and how a determination is made whether or not the malfunction resulted from the use of an AEM strategy. ▪ The process for the removal of equipment from service determined to be unsafe or no longer suitable for its intended application. ▪ The use of performance data to determine if modifications in the AEM Program procedures are required.	
11.05.02 Medical equipment inventory The hospital maintains a written inventory of all medical equipment available for use.	☐ Compliant ☐ Not Compliant The inventory shall include all medical equipment used directly or indirectly for patient treatment and care. All equipment must be inspected, tested, and maintained to ensure safety, availability, and reliability. In addition, all equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained in accordance with manufacturer recommendations or is in an AEM Program, is listed in an inventory which includes a record of maintenance activities. If the hospital is using an AEM Program, the equipment managed through that program must be separately identified on the equipment inventory from that equipment which is managed though the manufacturer's recommendation program. Critical equipment, whether in an AEM Program or not, must also be readily identified as such. To facilitate effective management, a well-designed equipment inventory contains the following information for all equipment included. However, hospitals have the flexibility to demonstrate how alternative means they use are effective in enabling them to manage their equipment. ▪ A unique identification number. ▪ The equipment manufacturer.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review inventory list. Compare with field observed equipment to ensure all medical equipment is included. ▪ If the hospital utilizes the AEM program, does the inventory for the AEM program contain any equipment which is not eligible for the AEM?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ The equipment model number. ▪ The equipment serial number. ▪ A description of the equipment. ▪ The location of the equipment. ▪ The identity of the department considered to "own" the equipment. ▪ Identification of the service provider. ▪ The acceptance date. ▪ Additional identification deemed useful.	
11.05.03 Patient Call System The hospital maintains a means by which patients can summon help.	☐ Compliant ☐ Not Compliant The hospital maintains a patient call system so patients can summon assistance. A backup system should be available to cover this need during power outages. Patient call systems are not required in psychiatric nursing units, or psychiatric hospitals that do not serve acute-care patients.	This standard is not met as evidenced by: **OBSERVATION AND INTERVIEW** ▪ Observe patient care areas to verify that such a system is in place and operational. ▪ Verify that there is a backup plan in place for periods of power outage.
11.05.04 Safe Medical Device Act (SMDA) The hospital has taken actions to comply with the Safe Medical Device Act (SMDA).	☐ Compliant ☐ Not Compliant Facilities shall demonstrate through the development and implementation of policies and procedures that they have addressed the issues and spirit of this act.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review organization policies and procedures, tracking systems, and their ability to demonstrate compliance.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.05.05 Medical equipment procurement The hospital obtains information and opinions when acquiring new medical equipment from the individuals who operate and service the equipment.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review organization policies and procedures, tracking systems, and the ability to demonstrate compliance.
UTILITY SYSTEMS MANAGEMENT		
11.06.01 Emergency power and lighting *There must be emergency power and lighting in at least the operating, recovery, intensive care, emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights shall be available*. §482.41(a)(1)	☐ Compliant ☐ Not Compliant The hospital must comply with the applicable provisions of the NFPA 101 *Life Safety Code* (2012 Edition) and applicable references, such as NFPA 99 *Health Care Facilities* (2012 edition), and NFPA 110 *Standard for Emergency and Standby Power Systems* (2010 edition) for emergency lighting and emergency power. This provision requires emergency lighting for a period of 1½ hours in health care facilities, enabling those inside to move about safely in an emergency. Facilities are free to expand the coverage of emergency power and lighting based on the size, complexity, and patient care services offered.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the emergency power and lighting cover at least the minimum required areas. Identify how the hospital monitors the readiness of these systems. ▪ Areas of the hospital that are not serviced by the emergency supply source are equipped with battery lamps and flashlights.
11.06.02 Emergency power electrical system Hospitals must have a Type I essential electrical system power source powered by a generator set equipped with a	☐ Compliant ☐ Not Compliant NFPA 99, 2012 edition specifies Type I essential electrical system power source to be classified as Type 10, Class X, Level 1 generator set per NFPA 110 *Standard for Emergency and Standby Power System*, 2010 edition.	This standard is not met as evidenced by: **INTERVIEW AND OBSERVATION** Verify that: ▪ The hospital has a Type I Essential

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
transfer switch, in accordance with NFPA 99, (2012 edition). For all essential electrical systems constructed, modernized, or renovated since 1983, the functions of patient care depending on lighting or appliances that are permitted to be connected to the emergency system are divided into two mandatory branches, the life safety branch and the critical branch, and must comply with NFPA 99.	The emergency power system is a separate electrical system that is divided into two major systems: 1. the emergency system 2. the equipment system. The emergency system is subdivided into the two branches in accordance with NFPA 99, 2012 edition: 1. The life safety branch. 2. The critical branch. Consideration should be given to generator failure solutions, processes for repair, and how to connect external resources during an emergency.	Electrical System powered by generator with an automatic transfer switch ▪ There is an emergency power system in place that is subdivided into two branches, the life safety branch and the critical branch for systems installed or modified since January 1, 1984.
11.06.03 Water management plan	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Monitoring of water quality and temperatures are identified as control points in the Water Management Program. Potable water is tested annually and treated as necessary.	Reports for water testing quality monitoring will be reported to the water management team and Safety Committee. The facility leader will attend the scheduled water management team meetings with reports for water testing and monitoring. For specific water management program compliance activities, refer to Infection Prevention and Control standard 07.02.06. Precautions are taken to assure compliance with state and local standards related to domestic hot water temperature to protect patients against scalding or burning.	Verify: ▪ Water reports and annual testing are submitted to the water management team and Safety Committee. ▪ Through interview with the maintenance director, that domestic hot water temperature is maintained based on state and local standards and talk with risk manager to assess any incidents or patient safety incident-related reports.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

11.06.04 **For future use**

11.06.05 **For future use**

11.06.06 **For future use**

11.06.07 **For future use**

11.06.08 **Plant equipment and systems: Maintenance**

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

There is an established, scheduled Preventive Maintenance Program for plant equipment and systems that shall be maintained and tested periodically in accordance with the manufacturers' recommendations.

As an alternative approach, hospitals may choose to employ alternative maintenance activities and/or schedules provided they develop, implement, and maintain a documented Alternate Equipment Management AEM) Program, to minimize risks to patients and others in the hospital associated with the use of facility equipment.

Plant equipment is defined as devices intended to support the physical environment of the hospital. Such equipment includes, but is not limited to, boilers, natural gas, HVAC system and related vents and filters, electrical power/equipment, and fans, plumbing and the potable water supply. Plant equipment is not limited to utilities only.

For hospitals that elect to perform equipment maintenance in accordance with the manufacturer's requirements, the hospital must maintain documentation of the manufacturer's recommendations as well as the hospital's maintenance activities.

All equipment (electrical and non-electrical) that is used to support the physical environment shall be included in the process for preventive maintenance. There shall be written testing criteria for each type of equipment included in the preventive maintenance system.

ALTERNATE EQUIPMENT MANAGEMENT (AEM) PROGRAM

A hospital may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer, provided the activities and frequencies do not reduce the safety of the equipment. Hospitals that choose to employ alternate

DOCUMENT REVIEW

- Verify that there is an established Preventive Maintenance Program of the plant equipment and whether a routine schedule is established and operational.
- Review records and/or equipment for evidence of routine inspections and documentation of the hospital's plant equipment Preventive Maintenance Program.
  - □ Are inspections conducted in a timely manner? Are past-due inspections common or rare?
- If the hospital is using an AEM Program for inspection, testing, and maintenance activities, then the following activities need to be reviewed:
  - □ Review the documentation for the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

maintenance activities and/or schedules must develop, implement, and maintain a documented AEM Program to minimize risks to patients and others in the hospital associated with the use of facility equipment. The AEM Program must be based on generally accepted standards of practice for facility equipment maintenance, such as ASHE 2009, *Maintenance Management for Health Care Facilities*.

The determination of whether it is safe to perform facility equipment maintenance without following the equipment manufacturer recommendations must be made by qualified personnel, regardless of whether they are hospital employees or contractors. In the case of facility equipment, a facilities management professional would be considered qualified.

The hospital must maintain records of the qualifications of hospital personnel who make decisions on placing equipment in an AEM Program and must be able to demonstrate how they assure contracted personnel making such decisions are qualified.

In determining whether or not to include equipment in an AEM Program, and which maintenance strategies to use in developing maintenance activities and frequencies for particular equipment, the hospital must take into account the typical health and safety risks associated with the equipment's use. Note that the risk may vary for the same type of equipment, depending on the patient care setting within the hospital where it is used.

A hospital is expected to identify any equipment in its AEM Program which is "critical equipment," for which there is a risk of serious injury or death to a patient or staff person should the equipment fail.

Multiple factors must be considered since different types of equipment present different combinations of severity of potential harm and likelihood of failure. The hospital is expected to be able to demonstrate to a surveyor the factors it considered in its risk assessment for equipment placed in its AEM Program.

AEM Program. Determine if it addresses the requirements for equipment to have maintenance activities and frequencies less than the manufacturer's recommendations.

- □ Is the determination of alternative maintenance activities and frequencies being performed by qualified individuals?
- □ Verify that the hospital has documented maintenance activities and frequencies for all equipment included in the AEM Program.
- □ Verify the hospital is evaluating the safety and effectiveness of the AEM Program on an annual basis.
- □ If the hospital has identified equipment as having such a very low level of risk that it has determined it can use a broad interval range or departmental 'sweeps', ask the hospital for the evidence used to make this determination, and determine if it is reasonable.
- □ Of the critical equipment that is included in the AEM Program, ask the hospital to explain how the decision was made to place this critical equipment in the program.
- □ Of the equipment that is included in

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Some equipment may not be eligible for placement in the AEM Program, for one or more of the following reasons: ▪ Federal or state laws may require the hospital to inspect, test, and maintain their equipment strictly in accordance with the manufacturer's recommendation. ▪ CMS Conditions of Participation or NFPA codes and standards which identify specific intervals or require adherence to manufacturer's recommendations which preclude inclusion in the AEM Program. ▪ New equipment may lack sufficient maintenance history, either based on the hospital's own or its contractor's records, or available publicly from nationally recognized sources, to support a risk-based determination, must not be immediately included in the AEM Program. The hospital may use one or more maintenance strategies for its AEM Program to determine the appropriate inspection, testing and maintenance activities and frequencies, based upon the nature of the equipment and the level of risk it presents to patient or staff health and safety. The risk to patient health and safety that is considered in developing alternative maintenance strategies must be explained and documented in the AEM Program. In developing AEM maintenance strategies, hospitals may rely upon information from a variety of sources, including, but not limited to: ▪ Manufacturer's recommendations. ▪ Nationally recognized expert associations. ▪ The hospital's experience. ▪ The contractor's experience. ▪ Other materials. For each type of equipment subject to the AEM Program, there must be documentation indicating:	the AEM Program, ask the hospital to describe the methodology for applying maintenance strategies and determining alternative maintenance activities and/or frequencies.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ The types and level of risks to patients or staff health and safety. ▪ Alternative maintenance activities and the differences from the manufacturer's recommendations when they are known. ▪ The date when AEM Program maintenance activities were performed and what actions, if any, were taken. ▪ Documentation of equipment failures and identifying if any harm resulted to an individual. The AEM Program must be compliant with these requirements at all times and must have written policies and procedures that address the effectiveness of the program. The hospital must have a written annual evaluation of the AEM Program that addresses: ▪ How equipment is evaluated to ensure there is no degradation of performance. ▪ How incidents of equipment malfunctioning are investigated, including whether or not the malfunction could have been prevented; what steps will be taken to prevent future malfunctions; and how a determination is made whether or not the malfunction resulted from the use of an AEM strategy. ▪ The process for the removal of equipment from service when determined to be unsafe or no longer suitable for its intended application. ▪ The use of performance data to determine if modifications in the AEM Program procedures are required.	
11.06.09 Plant equipment inventory	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital maintains a written inventory of all plant equipment available for use.	The inventory shall include all plant equipment used directly or indirectly for the healthcare facility.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Review inventory list. Compare with field observed equipment to ensure all

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

All equipment must be inspected, tested, and maintained to ensure safety, availability, and reliability. In addition, all equipment, regardless of whether it is leased or owned, and regardless of whether it is maintained in accordance with manufacturer recommendations or is in an AEM Program, is listed in an inventory which includes a record of maintenance activities.

If the hospital is using an AEM Program, the equipment managed through that program must be separately identified on the equipment inventory from equipment managed per the manufacturer's recommendation. Critical equipment, whether in an AEM Program or not, must also be readily identified as such.

To facilitate effective management, a well-designed equipment inventory contains the following information. However, hospitals have the flexibility to demonstrate how alternative means they use are effective in enabling them to manage their equipment.

- A unique identification number.
- The equipment manufacturer.
- The equipment model number.
- The equipment serial number.
- A description of the equipment.
- The location of the equipment.
- The identity of the department considered to "own" the equipment.
- Identification of the service provider.
- The acceptance date.
- Additional identification deemed useful.

plant equipment is included.

- If the hospital uses the AEM Program, does the inventory contain any equipment which is not eligible for the AEM?

11.06.10 **For future use**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

DESIGN, CONSTRUCTION, AND MONITORING OF THE ENVIRONMENT

11.07.01 Adequate facilities and supplies

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must maintain adequate facilities for its services.

§482.41(d)

Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

§482.41(d)(2)

The extent and complexity of facilities shall be determined by the services offered.

§482.41(d)(3)

Diagnostic and therapeutic facilities must be located for the safety of patients.

§482.41(d)(1)

Buildings must have an outside window or outside door in every sleeping room, and for any building constructed after July 5, 2016, the sill height must not exceed 36 inches above the floor. Windows in atrium walls are considered outside windows for the purposes of this requirement.

The sill height requirement does not apply

The hospital shall provide facilities adequate to serve the needs of the patients.

Diagnostic and therapeutic facilities must be located in rooms or areas specifically designed for the purpose intended.

Adequate facilities means the hospital has facilities that are:

- Designed and maintained in accordance with federal, state, and local laws, regulations, and guidelines; and
- Designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice.

Facilities must be maintained to ensure an acceptable level of safety and quality.

Supplies are to be stored to ensure their safety (i.e., protection against theft or damage, contamination, or deterioration) and the storage practices do not violate fire codes or otherwise endanger patients (storage of flammables, blocking passageways, storage of contaminated or dangerous materials, safe storage practices for poisons, etc.). Additionally, "supplies must be maintained to ensure an acceptable level of safety" would include that the hospital identifies the supplies it needs to meet its patients' needs for both day-to-day operations and those supplies that are likely to be needed in likely emergency situations such as mass casualty events resulting from natural disasters, mass trauma, disease outbreaks, etc.; and the hospital has plans that ensure the availability of those supplies when needed.

Physical facilities must be large enough, numerous enough, appropriately designed and equipped, and of appropriate complexity to provide the services

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

- Observe the hospital layout and determine if the patient's needs are met. Toilets, sinks, specialized equipment, etc. should be accessible.
- Discuss with members of the medical staff and department heads the adequacy of the facilities to meet the needs of the patients being treated at the hospital.
- Has the hospital identified supplies that are likely to be needed in emergency situations?
- Has the hospital made adequate provisions to ensure the availability of those supplies when needed?
- Verify through observation that the physical facilities are large enough and properly equipped for the scope of services provided and the number of patients served.
- Are facilities appropriate to meet the needs of hospital patients? Discuss with members of the medical executive

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
to newborn nurseries and rooms intended for occupancy for less than 24 hours. *The sill height in special nursing care areas of new occupancies must not exceed 60 inches.* §482.41(b)(9) §482.41(b)(9)(i-ii)	offered in accordance with federal and state laws, regulations and guidelines and accepted standards of practice for that location or service. In each area of diagnostic and/or therapeutic facilities, consideration shall be given to safety and security of equipment, persons, and their personal property.	committee, members of the medical staff (team captain); nursing staff (RN surveyor), and department heads (ADM surveyor) to determine if the needs of patients are being met. ▪ Verify that x-ray, physical therapy, and other specialized services are provided in areas appropriate for the service provided and provide appropriate safety and security for all persons. ▪ Discuss with members of the medical staff and department heads the adequacy of safety in service placement in the hospital.
11.07.02 For future use		
11.07.03 Ventilation, light, and temperature controls *There must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.* §482.41(d)(4)	☐ Compliant ☐ Not Compliant Excessive humidity in the operating room is conducive to bacterial growth and compromises the integrity of wrapped sterile instruments and supplies. Humidity levels in operating rooms must comply with NFPA 99 (2012 edition) which references ASHRAE 170 for HVAC in health care facilities, which allows 20% RH or greater. RH levels must be monitored and timely corrective actions taken when necessary. The lower humidity levels permitted by NFPA 99 and ASHRAE 170 may not be compatible with the Instructions for Use (IFU) for some sterile supplies and electro-mechanical equipment used in operating rooms. **Note:** While manufacturers of supplies and equipment will be expanding the	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Verify: □ All food and medication preparation areas are well lighted. □ The hospital is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving treatments with hazardous

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

lower level of RH range in which their products may function to 20%, the pace of this change is likely to take time. For facilities that continue to use older equipment it could be many years before this older equipment is replaced and all of the equipment they use will function appropriately at lower RH levels. ACHC expects hospitals to follow the current IFUs for supplies and equipment used in their ORs.

Acceptable standards such as from the Association of Operating Room Nurses (AORN) or the Facility Guidelines Institute (FGI) should be incorporated into hospital policy.

Organization staff should obtain and be aware of current Guidelines for Design and Construction of Health Care Facilities from the Facility Guidelines Institute (FGI) and current guidelines from the Center for Disease Control (CDC).

There must be proper ventilation and air-pressure relationships to surrounding areas in at least the following areas:

- Areas using ethylene oxide, nitrous oxide, glutaraldehyde, ethylene, pentamidine, or other potentially hazardous substances.
- Locations where oxygen is transferred from one container to another.
- Isolation rooms and reverse isolation rooms (both must be in compliance with Federal and State laws, regulations, and guidelines such as OSHA, CDC, NIH, etc.).
- Pharmaceutical preparation areas (hoods, cabinets, etc.).
- Laboratory locations.
- Soiled utility rooms.
- Clean utility rooms.
- Sterile processing rooms.
- Operating rooms.

chemical, surgical areas, and other areas where hazardous materials are stored.

□ Food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on nationally-accepted sources such as the United States department of Agriculture, the Food and drug Administration, or other nationally-recognized standard.

□ Pharmaceuticals are stored at temperatures recommended by the product manufacturer.

□ Each operating room has temperature and humidity control mechanisms.

□ The hospital has elected in writing to adopt CMS categorial waiver 13-25.

- Review:

□ monitoring records for temperature to ensure that appropriate levels are maintained.

□ humidity maintenance records for anesthetizing locations to ensure, if monitoring determined humidity levels were not within acceptable parameters, that corrective actions were performed in a timely manner to achieve acceptable levels.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	There must be adequate lighting in all the patient care areas, and food and medication preparation areas. ▪ Temperature, humidity, and airflow in the anesthetizing locations must be maintained within acceptable standards to inhibit microbial growth, reduce risk of infection, control odor, and promote patient comfort. ▪ Each operating room should have separate temperature control. ▪ The hospital must ensure that an appropriate number of refrigerators and/or heating devices are provided and ensure that food and pharmaceuticals are stored properly and in accordance with nationally accepted guidelines (food) and manufacturer's recommendations (pharmaceuticals). ▪ While temperature and humidity tracking logs are not mandatory, the organization needs to have documentation that clearly indicates they are tracking the temperature and humidity settings of critical areas (such as Building Automation Systems) and taking appropriate action when a reading is out of proper range. In lieu of alternative documentation methods, review temperature and humidity tracking log(s) to ensure that appropriate temperature and humidity levels are maintained.	▪ Interview department heads to determine if they feel that their areas have proper and adequate ventilation, light, and temperature control. What guidelines are used in food preparation area? How often is monitoring conducted?
11.07.04 For future use		
11.07.05 For future use		
11.07.06 Assessing risk prior to construction When the hospital plans for renovation and construction, a written assessment is made to reduce the risk to the organization.	☐ Compliant ☐ Not Compliant Prior to demolition, construction, and renovation activities a risk assessment is conducted on utility requirements, air quality requirements, infection control, vibrations, noise, and other hazards that could affect patients, staff,	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ A risk assessment is conducted prior to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	and visitors.	construction activities. ▪ Actions are taken as a result of risk assessments for current renovation activities.
11.07.07 Monitoring the physical environment A process is established by the hospital to continuously monitor the physical environment. Investigations are made and reports are submitted to the appropriate committee for safety on: ▪ Injuries to patients. ▪ Occupational illnesses and staff injuries. ▪ Incidents involving damage to the facility or property of others. ▪ Security incidents involving staff, patients or others within the facility. ▪ Spills and exposures of hazardous materials and waste. ▪ Deficiencies and failures of the fire safety management systems. ▪ Problems, failures, and user errors on medical equipment; laboratory equipment; and utility equipment.	☐ Compliant ☐ Not Compliant The appropriate committee for safety may be different depending on the issue, and patient confidentiality. When legal processes are followed, opportunities to make improvements on care, treatment, and services or to prevent the same or similar incident from occurring, is not lost. Where confidentiality is required, a summary of the incident must be share with the individual(s) designated to coordinate safety management activities. Reports are reviewed and appropriate action recommended by the committee(s) responsible for safety activities. The committee is responsible for follow-up activities to ensure all reported incidents are properly resolved. Offsite patient care areas are inspected semi-annually.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Documentation of hazardous surveillance inspections confirms all areas are properly inspected. ▪ Minutes from the appropriate committee on safety issues indicate that incidents are being investigated and reported, and follow-up activities are being tracked.

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QUALITY ASSESSMENT & PERFORMANCE IMPROVEMENT (QAPI)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.00 CONDITION OF PARTICIPATION: Quality Assessment Performance Improvement *The hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven quality assessment and performance improvement program.* *The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.* *The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.* §482.21	☐ Compliant ☐ Not Compliant The hospital must ensure that the program scope requirements are met.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the hospital's QAPI program to verify that it meets each of the following elements: □ Development □ Implementation □ Maintenance □ Effectiveness □ Ongoing □ Data-driven □ Hospital wide □ Contract services □ Improved outcomes □ Reduction of medical errors **Note:** If non-compliance does not rise to the Condition Level, score at standard 12.00.07.
12.00.01 Data collection and analysis: Program scope ▪ *The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.*	☐ Compliant ☐ Not Compliant The hospital must ensure that the program data requirements are met. The annual QAPI plan identifies: 1. The goal of the quality assurance program to identify and reduce medical errors and improve health outcomes.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The scope of the QAPI Program is to identify and reduce medical errors and improve health outcomes.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

§482.21(a)(1)

- *The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.*

§482.21(a)(2)

- *The program must incorporate quality indicator data including patient care data, and other relevant data such as data submitted to or received from Medicare quality reporting and quality performance programs, including but not limited to data related to hospital readmissions and hospital-acquired conditions.*

§482.21(b)
§482.21(b)(1)

- *The hospital must use the data collected to monitor the effectiveness and safety of services and quality of care.*
- *The frequency and detail of data collection must be specified by the hospital's governing body.*

§482.21(b)(2)
§482.21(b)(2)(i)
§482.21(b)(3)

2. The quality indicators, including adverse patient events, that will be measured, analyzed, and tracked on an ongoing basis.
3. The performance indicators and data collection activities for:
   - □ Every department and service
   - □ Every contracted service
4. Frequency and detail of data collection activities.
5. Methods to monitor the effectiveness and safety of services and quality of care
6. The plan to use data collected to monitor the effectiveness and safety of services.
7. Strategies to be used to identify opportunities for improvement and changes.
8. Approval of the annual Quality Plan by the governing body.

The facility demonstrates the ongoing review and analysis of the quality indicators to identify patterns and trends.

The hospital demonstrates that it uses data to monitor the effectiveness of services and the quality of care provided. **The facility can determine the amount and frequency of reporting for each department and contracted service based on performance and level of risk associated with each service.**

- The focus of the QAPI Program is to identify high-risk opportunities and take action to reduce errors.
- The QAPI **Program is ongoing and includes a plan that is reviewed and revised annually**.
- The annual plan has been approved by the governing body.
- The plan includes the frequency and detail of data collection.
- The hospital has a process for measuring, analyzing, and tracking quality, adverse patient events, and other aspects of performance.
- The data collection activities are appropriate to the scope of the hospital.
- Processes are monitored, including:
  - □ Quality of care provided.
  - □ Effectiveness and safety of services provided.
  - □ Adverse patient events.
- Data collection activities include:
  - □ Every hospital department and service.
  - □ Each **patient care and patient care-associated** contracted service.
- Data is analyzed to identify patterns and trends. Data is used to monitor the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		effectiveness of services provided. ▪ **External** data **is used** to **benchmark** program effectiveness and **identify opportunities** for improve**ment**.
12.00.02 Quality improvement program activities ▪ *The hospital must use the data collected to identify opportunities for improvement and changes that will lead to improvement.* §482.21(b)(2)(ii) ▪ *The hospital must set priorities for its performance improvement activities that:* *(i) Focus on high-risk, high-volume, or problem-prone areas;* *(ii) Consider the incidence, prevalence, and severity of problems in those areas; and* *(iii) Affect health outcomes, patient safety and quality of care.* §482.21(c) §482.21(c)(1) §482.21(c)(1)(i-iii) *The hospital must take actions aimed at performance improvement and, after implementing those actions, the hospital*	☐ Compliant ☐ Not Compliant The facility provides evidence that it has implemented the annual QAPI Plan as approved by the governing body. ▪ Data is collected at the frequency established by the governing body. ▪ The facility demonstrates the ongoing review and analysis of the quality indicators; the facility identifies patterns and trends. ▪ The facility has a process to identify opportunities, prioritize, and select annual performance improvement activities based upon available resources. ▪ The facility considers the incidence, prevalence, and severity of problems. ▪ The facility takes action aimed at improving performance. The facility measures the effectiveness of the implemented actions to ensure improvement is sustained.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Review tracking methodology to verify: ▪ The facility measures the quality indicators identified in the annual QAPI plan. The collected data has been used to: □ Identify opportunities for improvement. □ Implement changes that lead to improvement. ▪ The facility demonstrates an ongoing review and analysis of the quality indicators findings that will improve health outcomes and reduce medical errors. ▪ The facility has a process to establish priorities for performance improvement activities that focus on high-risk, high volume, or problem prone areas. ▪ The facility has taken action(s) to improve performance. ▪ The hospital has measured the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
must measure its success, and track performance to ensure that improvements are sustained. §482.21(c)(3)		effectiveness of the implemented actions to ensure improvement is sustained.
12.00.03 Patient safety, medical errors, and adverse events ▪ *The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.* ▪ *The hospital must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, hospital service and operations.* §482.21(a)(1-2) *Performance improvement activities must:* ▪ *track medical errors and adverse patient events,* ▪ *analyze their causes, and* ▪ *implement preventive actions and mechanisms that include feedback and learning throughout the hospital.* §482.21(c)(2)	☐ Compliant ☐ Not Compliant The hospital must ensure that the program activities requirements are met. Medical errors include but are not limited to such things as medication errors and wrong site of surgery, etc. It is important that each error incident can be an opportunity for education and learning for the individuals and areas involved. The facility measures, analyzes, and tracks the quality indicators consistent with the annual QAPI plan. The facility implements a database for tracking medical errors and adverse patient events by category. Through analysis of these data, the facility determines patterns, implements strategies, and monitors the effectiveness of corrective actions implemented. The review of errors includes the individual(s) directly involved as well as representatives of any involved hospital services. The facility provides measurable evidence of improvement in: ▪ Health outcomes. ▪ Reduction of identified medical errors. The annual QAPI Plan, which clearly establishes expectations for safety, is approved by the governing body.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The hospital has demonstrated an ongoing quality program. ▪ The hospital measures, analyzes, and tracks: □ Quality indicators and other aspects of performance. □ Medical errors. □ Adverse patient events. ▪ The hospital has implemented improvement mechanisms, based on data analysis, to reduce medical errors and adverse patient events. ▪ The governing body has clearly established expectations for safety.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

The hospital's governing body (organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:

- *That clear expectations for safety are established.*

§482.21(e)(3)

12.00.04 Performance improvement projects

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

As part of its quality assessment and performance improvement program, the hospital must conduct performance improvement projects.

(1) *The number and scope of distinct improvement projects conducted annually must be proportional to the scope and complexity of the hospital's services and operations.*

§482.21(d)
§482.21(d)(1)

(2) *A hospital may, as one of its projects, develop and implement an information technology system explicitly designed to improve patient safety and quality of care. This project, in its initial stage of*

Each year, the facility identifies and conducts performance improvement projects. The hospital demonstrates it uses data to identify opportunities for improvement and changes that will lead to improvement.

The number and scope of these distinct performance improvement projects is proportional to the scope and complexity of services provided.

The hospital has a process to documentation each performance project, including:

1. Reason for selecting the performance improvement project.
2. Initial baseline data to support the performance improvement project.
3. Ongoing data that demonstrates progress with improving healthcare for each project.
4. Timelines for each phase of the performance improvement project.
5. Data to support sustained improvement.

The implementation of Information Technology (IT) systems can significantly impact healthcare outcomes and improve patient safety.

DOCUMENT REVIEW

Review QAPI documents with hospital leadership to evaluate:

- Does the annual quality plan identify distinct, data-driven performance improvement projects to be addressed during the current year?
- Does the hospital have evidence that it has conducted annual performance improvement projects?
- Are the number and scope of the distinct performance improvement projects proportional to the scope and complexity of services provided?
- Has the hospital documented the required elements for each distinct performance improvement project?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
development, does not need to demonstrate measurable improvement in indicators related to health outcomes. §482.21(d)(2) (3) *The hospital must document:* ▪ *what quality assessment & performance improvement projects are being conducted,* ▪ *the reasons for conducting these projects, and* ▪ *the measurable progress achieved on these projects.* §482.21(d)(3) (4) *A hospital is not required to participate in a QIO cooperative project but its own projects are required to be of comparable effort*. §482.21(d)(4)	Recognizing this type of project may require capital budget expenditures and span across multiple departments and services, installation of an IT system would be an appropriate hospital-wide quality assurance performance improvement activity. If selected as a hospital wide QAPI activity, documentation of the progress of installation would be expected.	▪ Has the hospital implemented strategies to effect change, improve health outcomes, or reduce medical errors? ▪ Has facility achieved improvement? Has improvement been sustained? ▪ Has the facility implemented an Information Technology (IT) performance improvement project? If yes, why was this a hospital priority? Has the project been monitored to ensure the desired outcome has been achieved? ▪ Is the hospital is working with the QIO or does it have a similar project that meets the requirement?
12.00.05 <u>Executive responsibilities</u> *The hospital's governing body (organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:*	☐ Compliant ☐ Not Compliant The governing body, medical staff and administrative officials must determine priorities regarding which processes to monitor with data collection and the subsequent development of planned improvement efforts, as needed. The hospital's governing body must provide strong, clear, and visible attention to expectations for safety and for allocating adequate resources for measuring, assessing, improving, and sustaining the hospital's performance	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** Review the governing body mission, bylaws, annual report and meeting minutes to determine the requirement was met. **Note**: Lack of appropriate direction from the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(1) *That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained;* (2) *That the hospital-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement actions are evaluated;* (5) *That the determination of the number of distinct improvement projects is conducted annually*. §482.21(e) §482.21(e)(1-2) §482.21(e)(5)	and for reducing risks to patients. The medical staff and administrative officials must be held accountable for the implementation of an effective program consistent with Governing Body direction that demonstrates a sustained improvement in patient outcomes and a reduction in medical errors. The hospital-wide quality assessment and performance improvement activities identify and implement strategic actions to improve the quality of care and patient safety. These strategic actions are periodically evaluated to ensure they have been effective.	board, or appropriate involvement and intervention by medical staff or the administrative officials will be scored here. Determine: 1. How do the governing body, medical staff, and hospital leadership demonstrate responsibility and accountability for ensuring the QAPI program is ongoing, defined, implemented, and maintained? 2. Does the QAPI program include patient safety initiatives, such as reduction of medical errors? 3. What is the evidence that the governing body prioritized the performance improvement projects and data collection activities? 4. What is the evidence that performance improvement actions/strategic actions have been implemented and evaluated to ensure these have been effective with improving the quality of care and patient safety? 5. What is the evidence that the governing body has established clear expectations for safety? 6. What is the evidence that the governing body has determined the number of distinct projects annually?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.06 Adequate resources *The hospital's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the hospital), medical staff, and administrative officials are responsible and accountable for ensuring the following:* ▪ *That adequate resources are allocated for measuring, assessing, improving, and sustaining the hospital's performance and reducing risk to patients.* §482.21(e)(4)	☐ Compliant ☐ Not Compliant **ALLOCATION OF HUMAN RESOURCES** The hospital's governing body is responsible for allocating adequate resources for measuring, assessing, improving, and sustaining the hospital's performance and for reducing risks to patients. The hospital provides staff, trained in the principles of quality assurance/ performance improvement, to perform QAPI activities. **TRAINING** Hospital leadership ensures the allocation of human resources to provide education relating to the quality program and program outcomes throughout the organization. Hospital personnel, senior leadership, middle management, Medical Staff, and the Governing Body periodically receive training in the principles of QAPI. Personnel are knowledgeable about the quality projects, performance indicators, and findings as related to duties and areas of responsibility. **ALLOCATION OF TIME** The hospital leadership ensures sufficient time is devoted to the quality program. Hospital leadership allocates staff hours to attend education sessions as well as to participate in QAPI teams and projects as needed. **QUALITY COMMITTEE/FUNCTION** The hospital has a multi-disciplinary hospital-wide Quality Committee (quality function). The Quality Committee(function) is responsible for the development and implementation of an ongoing program that measures performance, analyzes data, and implements strategies for the purpose of improving health outcomes and reducing risk. Participants in the Quality Committee represent hospital leadership and the	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review QAPI minutes and related documents to determine the requirement was met. ▪ Verify that hospital has staff trained in quality principles to perform QAPI activities. ▪ Verify that adequate time is devoted to the quality program. ▪ Verify that the facility has a multi-disciplinary hospital-wide Quality Committee (function) which include representatives from the Medical Staff and hospital leadership. ▪ Determine that QAPI-related education is periodically provided to staff, hospital leadership, medical staff, and the governing body.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	medical staff. The Quality Committee reviews quality reports from all departments and services, discusses opportunities for improvement, and recommends corrective actions. Minutes of the Quality Committee memorialize the discussions of quality activities and corrective actions.	
12.00.07 STANDARD: Quality Assessment Performance Improvement *The hospital's governing body must ensure that the program reflects the complexity of the hospital's organization and services; involves all hospital departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors.* *The hospital must maintain and demonstrate evidence of its QAPI program for review by CMS.* §482.21	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Note: Identified CMS standard-level deficiencies within the Condition of Participation should be cited here if non-compliance does not rise to the Condition level. Do NOT include ACHC-only standard deficiencies.
12.00.08 Unified and integrated QAPI program for multi-hospital systems *If the hospital is part of a system consisting of multiple separately certified hospitals using a system governing body*	☐ Compliant ☐ Not Compliant ☐ N/A if not a multi-hospital system If a decision is made to use a unified and integrated QAPI program for multi-hospital systems, this does not change the requirement that the QAPI must be well organized and accountable to the system's governing body.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Ask hospital leadership if the hospital is part of a multi-hospital system of

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
that is legally responsible for the conduct of two or more hospitals, the system governing body can elect to have a unified and integrated QAPI program for all of its member hospitals after determining that such a decision is in accordance with all applicable State and local laws. *The system governing body is responsible and accountable for ensuring that each of its separately certified hospitals meets all of the requirements of this section. Each separately certified hospital subject to the system governing body must demonstrate that:* *(1) The unified and integrated QAPI program is established in a manner that takes into account each member hospital's unique circumstances and any significant differences in patient populations and services offered in each hospital; and* *(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified hospitals, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular*	Each separately certified hospital is responsible for independently meeting all requirements in this Condition of Participation. The hospital must maintain documentation of this determination by its governing body.	separately certified hospitals. □ If no, it is not necessary to assess compliance with this regulation. □ If yes, verify: ▪ Each separately certified hospital within the system has written policies that address the unique needs of the patient population served at the location. ▪ The integrated QAPI program has written policies that establish the processes for integrating quality reports. ▪ The integrated QAPI program meeting minutes are memorialized. ▪ QAPI reports are submitted to the governing body for review and approval and activities are memorialized in meeting minutes.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

hospitals are duly considered and addressed.

§482.21(f)
§482.21(f)(1-2)

12.01.01 Quality management position

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

There is an individual, trained in quality principles and appointed by the hospital leadership to be in charge of the Quality Assessment Performance Improvement Program.

Depending on the complexity of the organization, the individual in charge of the quality program may have other assigned duties; however, there shall be sufficient time spent by this individual to support all areas of this program.

This individual has received formal training in principles of quality improvement to prepare him/her for the required duties.

INTERVIEW AND DOCUMENT REVIEW

- Review documentation of training.
- Interview the quality manager to verify:
  - □ that sufficient time is devoted to the quality program.
  - □ that the individual has attended formal quality training programs and has a plan for future training.

12.01.02 Quality committee (function)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

There is a multidisciplinary hospital-wide QAPI committee (function). The committee/function is responsible for the development and implementation of a program for measuring, assessing, and improving outcomes.

Participants are representatives of leadership, the medical staff, and other hospital staff as necessary to fulfill its responsibilities.

The participants in the committee/function include individuals within the organization who have the expertise necessary to review and improve the processes that affect outcomes.

DOCUMENT REVIEW

- Review the QAPI Plan and list of committee (function) participants to verify:
  - □ There is a structured coordinated process for development and implementation of the quality program.
  - □ The committee/function is

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		multidisciplinary and includes medical staff representation.
12.01.03 Meetings and documentation of activities The Quality Assessment and Performance Improvement activity must be conducted at formal meetings.	☐ Compliant ☐ Not Compliant Minutes must be kept in sufficient detail to track the progress of the QAPI program.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review samples of minutes and track sample activities forward through time for evidence of resolution. ▪ Review this activity to determine if systemic corrective action is taken.
12.01.04 Annual quality report There is an annual report based on the annual plan which details improvements made during the year as a result of quality initiatives as well as challenges that are as yet unresolved related to quality. The report shall be submitted to the governing body for review and approval.	☐ Compliant ☐ Not Compliant The annual end-of-year Quality Report serves as the basis for development of the subsequent year's annual Quality Plan.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the last three annual reports to verify that they have been reviewed and approved by the governing body.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.01.05 Education program	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
There is a planned, hospital wide, Quality Assessment and Performance Improvement Education Program. Training includes general quality approaches and appropriate team and individual approaches.	The program design and findings are adequately disseminated. Providers are knowledgeable about their roles in the QAPI Program and about findings that impact their duties and responsibilities. The education program does not have to reach all individuals by the time of the survey but there must be an education plan which details how the hospital will accomplish its education program within one year from the date of the QAPI plan. The education plan includes the executive staff, the governing body, the medical staff, and all non-temporary staff.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Review the education plan and documentation of staff training. Compare names of selected individuals for inclusion on the training documentation lists. ▪ Interview selected individuals about the quality and content of training. Are staff, medical staff and members of the governing body able to articulate quality improvement priorities in the organization?
12.01.06 For future use		
12.01.07 Reporting to the governing body	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Periodically, hospital-wide and department-specific quality reports are prepared and submitted to the governing body. These quality reports include medical errors, hospital-acquired complications, and investigations of adverse events. The quality reports indicate patterns identified and corrective actions taken to	The annual Quality Plan identifies the frequency/schedule for submitting quality reports from each department/service to the governing body. The minutes of the Governing Body memorializes the review and discussions of patterns identified and strategic actions to be implemented.	**DOCUMENT REVIEW** Review minutes of the governing body and related documents to verify: ▪ Each department/service has submitted quality reports to the governing body, consistent with the quality plan. ▪ The minutes of governing body meetings memorialize the discussion of quality reports.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

improve quality of services provided.

12.02.01 Culture of safety

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The organization will **promote a** culture of safety.

Policies and procedures are in place to:

1. Prioritize patient safety events that should be reported.
2. Implement a non-punitive "near miss" reporting system.
3. Define a process for analysis of patient safety events.
4. Implement remedial action and measure effectiveness of such action.
5. **Communicate** patient safety issues present within the organization **to leadership** and continuously involve **leadership** in processes to **ensure** that the issues are appropriately addressed, and that patient safety is improved.
6. Provide oversight and coordination of patient safety activities.
7. Provide feedback to frontline healthcare providers about lessons learned.
8. **Implement proactive risk assessments to identify opportunities and**

Responsibility for risk reduction **is shared throughout the hospital.** Free and open communication and non-punitive reporting of adverse events and patient safety concerns are **promoted. O**rganizational objectives and rewards are clearly aligned with the goal of improving patient safety.

A culture of safety overtly encourages and supports the reporting of any situation or circumstance that threatens or potentially threatens the safety of patients or caregivers and views the occurrence of errors and adverse events as opportunities to make the healthcare system better.

Proactive risk assessment methods enable the hospital to identify potential failures in process and implement strategies that would reduce the potential for medical errors that may result in patient harm before it occurs. A variety of tools and methods may be used including Failure Modes and Effect Analysis (FMEA), and others.

INTERVIEW AND DOCUMENT REVIEW

Verify:

- Policies and procedures on safety include all required elements.
- Safety reports and event analysis reports **reflect that actual process is** as defined in policy.
- Meeting minutes include discussion of safety.
- **Documentation of proactive risk assessment(s) confirm that at least one risk assessment is performed.**
- Interview staff members regarding the organization's focus on safety.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

implement measures that reduce the potential for patient harm to occur.

12.02.02 Adverse event review process

Upon discovery of an adverse event, the healthcare organization is required to conduct a Root Cause Analysis (RCA) and prepare an action plan in a manner that ensures compliance with all applicable federal, state, and local requirements.

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Adverse events are injuries resulting from medical care, as opposed to adverse outcomes arising from underlying disease.

The hospital adopts a nationally recognized tool such as the CMS "Hospital-Acquired Conditions" and the National Quality Forum's "Serious Reportable Events" (SRE) to identify events requiring RCA.

A review of **the nationally recognized tool for alignment with hospital policy is completed annually.** The organization retains its RCA for review by surveyors.

Note: Due to the confidential nature of information in the RCA, it is NOT to be submitted to ACHC.

DOCUMENT REVIEW

- Review the hospital's QAPI program to determine it meets the requirement for adverse event reporting.
- Verify that the facility has conducted a root cause analysis (RCA) to investigate the events contributing to the adverse event. The facility demonstrates it has used the information to implement strategic actions to improve patient care and related processes.
- Review the RCA during the onsite survey to verify that the facility is using information to improve processes.

12.02.03 Communication to the patient of an adverse event

The occurrence of an adverse outcome must be communicated to the patient as soon as it is recognized, and the patient is ready physically and psychologically to receive the information. This should occur within 24 hours after the event is discovered.

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Initial explanations should focus on what happened and how it will affect the patient, including immediate effects and the prognosis.

Accurate documentation of the event is important both to facilitate transparent communication with the patient and family as well as to serve as a solid foundation for patient safety improvement initiatives that follow an event.

DOCUMENT REVIEW

- Review patient records for adverse event documentation.
- Verify documentation in medical record of patient and/or family notification of the adverse event.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	If not possible to communicate with the patient, the initial communications should begin with those members of the family or healthcare proxy who will be representing the patient in further discussions.	
12.02.04 Support of caregivers The healthcare organization must have a program designed to provide support to their staff that are experiencing normal stress after experiencing a highly abnormal event.	☐ Compliant ☐ Not Compliant Because caregivers' needs vary, the support system should incorporate a variety of offerings to meet different needs. The objective is to help the staff manage the stress of the adverse events so that they can better care for their patients, so healing can occur, and so the caregiver can comfortably return to the work environment with normal productivity.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documentation of an event that has occurred. ▪ Review policies and procedures for staff debriefing following an event. ▪ Verify debriefing occurred by and with appropriate staff. ▪ Verify staff participation in Root Cause Analysis.

13

LIFE SAFETY

INTRODUCTION

The standards in this chapter are based on Conditions of Participation (CoP) requirements from the Centers for Medicare & Medicaid Services (CMS), the 2012 edition of the NFPA 101 *Life Safety Code* and the 2012 edition of the NFPA 99 *Health Care Facilities Code*. Compliance with the Life Safety Code is based on the different occupancy chapters within the code. All hospitals must include healthcare occupancy designations; however, hospitals may choose to include other occupancy designations if they comply with the respective occupancy chapter provisions.

The occupancy designations may include, but are not limited to:

- Healthcare Occupancy
- Ambulatory Health Care Occupancy
- Business Occupancy

DEFINITION OF HEALTHCARE OCCUPANCY

An occupancy used to provide medical or other treatment or care simultaneously to four or more patients on an inpatient basis, where such patients are mostly incapable of self-preservation due to age, physical or mental disability, or because of security measures not under the occupants' control. The health care facilities regulated by this occupancy chapter are those that provide sleeping accommodations for their occupants.

The requirements established by this chapter apply to all hospitals, nursing homes, and limited care facilities.

Examples of Healthcare Occupancies:

- Hospitals
- Psychiatric hospitals
- Specialty hospitals
- Inpatient hospices
- Nursing homes
- Skilled nursing facilities
- Long term care facilities
- Inpatient substance abuse facilities
- Emergency Departments - CMS has determined that all emergency departments (free-standing or contiguous to a hospital) shall

comply with healthcare occupancy requirements since patients routinely reside in EDs for more than 24-hours.

DEFINITION OF AMBULATORY HEALTH CARE OCCUPANCY

An occupancy used to provide services or treatment simultaneously to four or more patients that provides, on an outpatient basis, one or more of the following:

- treatment for patients that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others;
- anesthesia that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others;
- emergency or urgent care for patients who, due to the nature of their injury or illness, are incapable of taking action for self-preservation under emergency conditions without the assistance of others.

Examples of Ambulatory Health Care Occupancies include:

- Physical rehab outpatient centers
- Ambulatory surgery centers - CMS has determined that all ambulatory surgical centers shall comply with ambulatory health care occupancy requirements regardless how many patients are incapable of self-preservation.
- Diagnostic centers

DEFINITION OF BUSINESS OCCUPANCY

An occupancy used for the transaction of business other than mercantile.

Examples of Business Occupancies include:

- Administrative offices
- Physician's offices
- Support service centers (i.e., maintenance, laundry, sterile processing, boiler rooms, etc.)

To simplify, this chapter will use the term 'hospital' and refer to all occupancies that are included within the facility that houses the healthcare occupancy. It is expected that the hospital is compliant with the Life Safety Code at all times. However, there may be times during construction, repairs, or emergencies that compliance with the Life Safety Code is not possible. At those times, the organization must either immediately resolve the deficiency or assess the non-compliant issues for Alternative Life Safety Measures, based on the organization's policy.

WAIVERS

Requests for waivers are permitted but only after the Life Safety Code deficiency has been cited during an ACHC survey. As part of the organization's Plan of Correction, a waiver request may be presented to ACHC, which will consider the request and pass it on to the respective CMS Location (Regional Office) for approval. The waiver must explain the unreasonable hardship the healthcare organization has in meeting the Life Safety Code requirement and that non-compliance does not present a safety risk to the patient or staff.

When making a waiver request, the hospital should identify the deficiency, how the hospital deviates from the code, and steps taken by the hospital to ensure an equivalent level of safety. The hospital has the option of requesting a time-limited waiver if the intent is to 'bridge' a period of time until a feature of safety is installed or modified, such as the installation of sprinklers. Waivers approved by CMS are only valid until the next survey cycle. §482.41(b)(2)

EQUIVALENCIES

After consideration of survey findings, the CMS may approve a Fire Safety Evaluation System (FSES) equivalency request for specific provisions of the Life Safety Code, which if rigidly applied, would result in unreasonable hardship for the hospital, but only if the equivalency does not adversely affect the health and safety of patients.

Submission of a FSES equivalency request may be made by the hospital after the deficiency has been cited during a survey. The organization's Plan of Correction will identify that the hospital plans to submit a FSES equivalency request as the proposed correction for that particular deficiency.

The FSES equivalency request will be submitted to ACHC after the Plan of Correction has been submitted. Once received, ACHC will review the FSES equivalency request and may forward it with a recommendation to the CMS Location for consideration and action. Only the CMS Location office may approve FSES equivalency requests for Medicare or Medicaid-participating hospitals.

When making a FSES equivalency request, the hospital should follow the provisions of NFPA 101A *Guide on Alternative Approaches to Life Safety,* 2013 edition. FSES equivalencies approved by CMS are valid until the next survey, or until major renovation or remodeling is conducted in the area where the deficiency is identified, whichever comes first.

The main difference between a waiver request and an equivalency request is that a waiver is seeking permission to not comply with a particular Life Safety Code requirement without any engineering analysis to support that claim. An equivalency request is based on an engineering analysis that demonstrates the hospital has an acceptable level of safety based on other features of fire safety, even though the hospital has not resolved the Life Safety Code deficiency.

INSTRUCTIONS FOR SUBMITTING A WAIVER OR EQUIVALENCY REQUEST

Contact your Account Advisor.

DEFINITION OF NEW CONSTRUCTION VS. EXISTING CONDITIONS

New construction is defined as those areas for which construction documents were approved by state and local governmental agencies after July 5, 2016. Existing conditions is defined as those areas whose construction documents were approved on or before July 5, 2016.

Features of Life Safety installed under new construction requirements, must be maintained to those new construction requirements even after they later qualify as existing conditions.

DEFINITION OF TIME

Please be aware that ACHC standard 13.00.06 defines the intervals between testing and inspection activities identified in this chapter. Since NFPA standards and codes are written by different technical committees, often they do not agree on the definition of what a period of time means, such as 'quarterly' or 'annually.' HFAP has reviewed all of the NFPA standards and developed a standard that everyone can follow, and still meet the intent of the respective NFPA technical committee.

For instance, where one technical committee may consider an 'annual' activity to occur anytime during a calendar year, another technical committee may want the activity to occur close to the anniversary date of the last activity. Therefore, HFAP has decided to change some of the definitions of time to no longer allow a period of time that goes beyond the intent of the NFPA technical committee. As an example, for activities that are required 'every 12 months' or 'annually,' the standard now says the completion of the activity is performed during the 12th month of the annual period, but not beyond.

DOCUMENTATION REQUIREMENTS

Standard 13.00.07 has specific requirements concerning documentation of evidence of compliance for standards in this chapter. Please be fully aware of these requirements as they apply to all testing and inspection documents, whether the hospital creates their own documents or relies on those provided by contractors.

FACILITY DEMOGRAPHIC REPORT (FDR)

A Facility Demographic Report (FDR) is a document that requests basic information concerning the facility and is required to be maintained at all times and updated annually. The FDR form is found in the Appendix and it will be reviewed during a survey.

Since the FDR is a document that requests specific, detailed, engineering data about the facility, it must be completed by an individual who has a working knowledge of the applicable NFPA codes and standards and has experience with the facility. This individual may be one who is employed by the hospital, or it may be one who is contracted by the hospital to complete the document. Failing to properly answer each question on the FDR will result in a citation.

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GENERAL REQUIREMENTS

13.00.01 Life Safety Code compliance

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Except as otherwise provided in this section—

The hospital must meet the applicable provisions and must proceed in accordance with the Life Safety Code (NFPA 101 and Tentative Interim Amendments TIA 12-1, TIA 12-2, TIA 12-3, and TIA 12-4.) Outpatient surgical departments must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served.

§482.41(b)(1)(i)

Notwithstanding paragraph (b)(1)(i) of this section, corridor doors and doors to rooms containing flammable or combustible materials must be provided with positive latching hardware. Roller latches are prohibited on such doors.

§482.41(b)(1)(ii)

The provisions of the Life Safety Code do not apply in a State where CMS finds that a fire and safety code imposed by State law adequately protects patients in hospitals.

§482.41(b)(3)

All hospitals, regardless of size or number of beds, must comply with the NFPA 101 *Life Safety Code* (2012 edition) requirements for all locations. All buildings and spaces owned, leased, or rented which are used for hospital business must comply with the Life Safety Code.

The organization is responsible for developing a systematic process for assessing compliance with the Life Safety Code of each building under its control.

Roller latches may not be used on corridor doors, with the exception of corridor doors that are not required to latch, such as doors to toilet rooms, bathrooms, shower rooms, sink closets and similar spaces that do not contain flammable or combustible materials.

OBSERVATION AND DOCUMENT REVIEW

Verify:

- Through observation, that buildings are in compliance with the applicable occupancy chapters of the Life Safety Code and other applicable codes.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.00.02 Alternative life safety measures policy The hospital must have a written policy on alternative life safety measures (ALSM) whenever situations where a deficiency to the Life Safety Code cannot be immediately resolved, including construction, repair, and improvement operations. All deficiencies to features of Life Safety must be assessed and documented for additional measures the same day they are discovered. The need to implement compensation measures for the life safety deficiency is based on the criteria in the hospital's ALSM policy. The ALSM policy must identify when implementation of a particular compensating measure is required and to what extent that measure is implemented. §482.41(a)	☐ Compliant ☐ Not Compliant Features of life safety may be compromised or impaired during periods of construction, maintenance, or emergency repairs. During these periods, the hospital must perform a documented risk assessment of the deficiency and implement compensating measures based on the criteria of its ALSM policy. Not all deficiencies to life safety may require compensation, but the ALSM policy must clearly distinguish when and to what extent such measures are implemented.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The hospital's ALSM policy clearly identifies that it applies to all conditions when impairments to features of life safety exist, including during periods of construction, maintenance, and emergency repairs. ▪ The ALSM policy clearly identifies what compensating measures will be taken when certain deficiencies are discovered.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.00.03 Alternative life safety measures (ALSM) implementation When a Life Safety Code deficiency cannot be corrected the same day it is discovered, the hospital conducts an assessment and implements appropriate measures to compensate for impairments to the Life Safety Code, based on their ALSM policy. §482.41(a)	☐ Compliant ☐ Not Compliant When conditions exist that compromises a feature of life safety, the organization must conduct an assessment to determine what ALSM, if any, to implement based on their ALSM policy. When alternative measures are implemented, they must be continued until such time the deficiency is resolved. The assessment is documented.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ ALSM documentation reflects that the organization has conducted ALSM assessment for known life safety deficiencies. ▪ Implementation of ALSM is documented for areas in the hospital where a feature of life safety may be compromised, such as construction areas and areas undergoing maintenance.
13.00.04 Notification of emergency response forces The hospital notifies the local emergency response force (fire department) when: ▪ a fire alarm system, or parts thereof are out of service more than four hours in a 24-hour period, and either evacuates the building or portions of the building affected by the outage or implements a fire watch in all affected areas. ▪ an automatic *sprinkler system,* or	☐ Compliant ☐ Not Compliant The phrase 'or parts thereof' refers to circuits or branches of the systems, not a single device. Refer to standard 13.00.09 on the proper method and procedure to conduct a fire watch.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ Documentation of the notification of local fire departments.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

parts thereof *are out of service for more than ten hours* in a 24-hour period, and either evacuates the building or portions of the building affected by the outage or implements a fire watch in all affected areas.

The fire watch and the notification of the local emergency response force are documented.

§482.41(b)(8)
§482.41(b)(8)(i-ii)

13.00.05 Facility Demographic Report (FDR)

The hospital designates an individual to assess the facility's compliance with NFPA 101 *Life Safety Code* (2012 edition), complete and maintain the Facility Demographic Report (FDR) and manage all deficiencies.

The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. The FDR is used as a guide for how the organization provides compliance.

Qualifications and the designation of the responsible individual are documented.

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

ACHC does not set qualifications for the designated individual. However, since the FDR is technical in manner, a person with technical knowledge must be designated.

The hospital must complete the Facility Demographic Report on at least an annual basis, or more often as needed, **for example, when construction or renovations are completed for areas comprising more than 50% of a smoke compartment or 4500 square feet. An FDR must be completed** and maintained as currently accurate for each **individual** facility identified as a healthcare occupancy or an ambulatory healthcare occupancy. Business occupancies are not required to have an FDR.

Note: The FDR template is found at the end of this chapter.

OBSERVATION AND DOCUMENTATION

- Review the documentation in the FDR that designates the responsible individual, and assess the qualifications listed.
- Review the FDR to determine if it has been updated within the past 12 months and is current and maintained.
  - ☐ Has the FDR been updated because of renovations or construction?
- Review the FDR to ensure the organization completed the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
Each facility in the organization identified as a healthcare occupancy or an ambulatory healthcare occupancy has an individual FDR report completed. These FDR reports are available for review by the surveyor. §482.41(a) §482.41(b)(1)		assessment and maintains the accuracy of the information. Verify that each question was answered accurately.
13.00.06 Testing and Inspection - Definitions of time Unless otherwise stated, the periods of time for testing, inspection, and maintenance activities specified within this chapter are: Weekly or 'every 7 days': ▪ The completion of the activity is performed anytime during the calendar week. Monthly or 'every 30 days': ▪ The completion of the activity is performed anytime during the calendar month. Quarterly or 'every 3 months': ▪ The completion of the activity is performed quarterly, during the third month of the quarterly period.	☐ Compliant ☐ Not Compliant Testing and inspection activity cannot exceed the allowable amount of time permitted by the applicable standard or regulation. The completion of the weekly and monthly activities is to be performed during the designated calendar period. The completion of the quarterly, semi-annually, annually, 3-year, 5-year, and 6-year activities is to be performed during the last calendar month of that period.	This standard is not met as evidenced by: **DOCUMENTATION** ▪ When reviewing documentation, make sure testing, inspection or maintenance activity is performed within the limits of this standard. **Note:** If the testing/inspection activity was not conducted within the specified time frame then score non-compliance with the respective standard that requires the testing/inspection activity.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Semi-annually or 'every 6 months':

- The completion of the activity is performed semi-annually, during the 6th month of the semi-annual period.

Annually or 'every 12 months':

- The completion of the activity is performed annually, during the 12th month of the annual period.

3-years:

- The completion of the activity is performed once every 3 years, during the 36th month of the 3-year period.

5-years:

- The completion of the activity is performed once every 5 years, during the 60th month of the 5-year period.

6-years:

- The completion of the activity is performed once every 6 years, during the 72nd month of the 6-year period.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.00.07 Testing and Inspection - documentation Unless otherwise stated, testing, inspection, and maintenance documentation must include, at least, the following information: 1. Name of individual performing the activity 2. Affiliation of the individual performing the activity 3. The signature of the individual performing the activity 4. Activity name 5. Date(s) (month/day/year) that activity was performed 6. The frequency that is required of the activity 7. The NFPA code or standard which requires the activity to be performed, as applicable. 8. The results of the activity, such as 'Pass' or 'Fail.'	☐ Compliant ☐ Not Compliant ☐ Not Applicable All documentation of testing, inspection and maintenance activities must include this basic information. If a component of safety is found to fail its test, then the component must be repaired or replaced immediately or alternative life safety measures must be implemented according to the organization's policy. (See standard 13.00.03) This requirement for documentation does not apply to the inspection and maintenance tags located on portable fire extinguishers. The date the inspection or maintenance activity was performed and the initials of the person performing the activity must be recorded.	This standard is not met as evidenced by: **DOCUMENTATION** ▪ When reviewing documentation, make sure testing, inspection or maintenance results are documented in accordance with this standard. **Note:** If the testing/inspection documentation does not meet the requirements of this standard, then score a finding under the respective standard that required the test or inspection.
13.00.08 Interior finish The interior finish on existing walls and ceilings must be Class A or Class B, except rooms protected with sprinklers	☐ Compliant ☐ Not Compliant Class A interior wall and ceiling finishes have a flame spread rating of 0 – 25, and a smoke development rating of 0 - 450.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENTATION** ▪ Review the flame spread rating of

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
are permitted to be Class C provided the room is separated from the exit access corridor. The interior finish on new construction walls and ceilings must be Class A or Class B, except rooms having a capacity not exceeding four persons are permitted to be Class C; and interior finish on new construction corridor walls not exceeding 4 feet in height that is restricted to the lower half of the wall is permitted to have Class A, Class B, or Class C finish. §482.41(b)(1)	Class B interior wall and ceiling finishes have a flame spread rating of 26 - 75, and a smoke development rating of 0 - 450. Class C interior wall and ceiling finishes have a flame spread rating of 76 - 200, and a smoke development rating of 0 - 450.	selected interior finishes to determine if it meets the proper classification rating. **Note:** Plywood used as interior finish in utility or equipment rooms would be permitted provided it met the required flame spread for that classification.
13.00.09 Fire watch A fire watch consists of dedicated, trained individual(s) with no other concurrent duties constantly circulating throughout the portion of the facility affected by the deficiency or impairment looking for a fire, fire hazards, or hazardous conditions that may affect the fire safety of the facility. §482.41(b)(8)(ii)	☐ Compliant ☐ Not Compliant 'Constantly circulating' the affected areas of the facility means continuously, without interruption. If breaks are desired, then a replacement individual is needed. Only individuals with fire-response training may conduct a fire watch and may not perform any other duty during the fire watch. They are to ensure there is no fire and confirm that other fire protection features of the building such as egress routes, suppression systems, and alarm systems are available and functioning. The individuals must have ready access to fire extinguishers, and the ability to promptly notify the fire department in the event of a fire. If it requires one individual more than 30 minutes to complete one round of the affected area, then additional individuals must be assigned to fire watch duty.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENTATION** ▪ Review documentation of the fire watch. ▪ Check to see that fire watches are performed continuously, without interruption. ▪ Verify that the individual(s) performing the fire watch have received fire-response training.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Fire watches must be documented indicating the start date and time, and the end date and time. The documentation must record all individuals who conduct the fire watch, with their individual start and end times. For guidance on Fire Watches see NFPA 25 *Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems*, 2011 edition, section A.15.5.2 (4)(b).	

MEANS OF EGRESS

13.01.01 Doors	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Corridor doors and doors to hazardous rooms shall be provided with positive latching hardware. Roller latches are not permitted on corridor doors that are required to latch. Corridor doors shall be capable of resisting the passage of smoke. Doors in the path of egress must be side-hinged or pivot-swing type. §482.41(b)(1) §482.41(b)(1)(ii)	Latching devices are necessary to keep patient room doors securely closed in the event of the fire. Positive latching devices are required on all corridor doors. The use of roller latches will not be allowed on corridor doors in hospitals where corridor doors are required to latch (see standard 13.00.01). Corridor doors cannot be restrained in such a way to prevent the door from closing. Doors in the path of egress are required to be side-hinged or pivoted-swinging type and are required to swing in the direction of egress when serving a room or area with an occupant load of 50 or more persons. Doors must open to a minimum of 90 degrees from its closed position and extend no more than seven inches into the corridor when opened to its fullest extent. Horizontal sliding doors are required to be side-hinged and capable of 'breaking away,' unless the door serves a room with an occupant load less than 10 and complies with all of the provisions in 19.2.2.2.10.2 of the 2012 Life Safety Code. A level landing surface is required and shall be maintained on each side of	**OBSERVATION AND DOCUMENT REVIEW** ▪ Examine corridor doors during building tour for compliance. ▪ During the building tour, examine corridor doors to ensure they can close and latch. NOTE: Self-closing is not required. ▪ Examine horizontal sliding doors: Ensure they are also side-hinged and capable of 'breaking away' and swing from the side hinges unless the door serves a room with an occupant load of less than 10 persons. ▪ Ensure doors in the path of egress open to at least 90 degrees and extend no more than seven inches into the corridor when fully opened.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

the door threshold. The depth of the landing is to be at least equal to the width of the widest door leaf.

13.01.02 Door Locks

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Doors in the means of egress must be operable with not more than one releasing operation.

Doors within the means of egress must not be equipped with a latch or lock that requires the use of a tool or key from the egress side, with the exception where the clinical needs of the patients require specialized security measures for their safety.

Doors in the means of egress are permitted to be equipped with delayed egress locks provided the entire facility is protected with automatic sprinklers, or fully detected with smoke detectors.

Doors in the means of egress are permitted to be equipped with access-control locks.

Doors separating elevator lobbies from exit access corridors are permitted to be locked with electrical locks provided all of the provisions of 7.2.1.6.3 of the 2012 Life Safety Code are met.

Doors in the means of egress are permitted to be equipped with locks where the

Occupants accessing doors in the path of egress are not permitted to operate more than one device to open the door.

A door is not permitted to have a lock separate from the latching mechanism (such as a dead-bolt lock) which would require the occupant to operate two devices to open the door. (Note: Pulling on a handle or pushing on the door is not considered an operation.) However, two releasing operations are permitted for existing hardware on a door leaf serving an area having an occupant load not exceeding three, provided that releasing does not require simultaneous operations.

Normally, doors in the path of egress in a healthcare occupancy are not permitted to be locked. However, the Life Safety Code permits five types of locks on doors in the path of egress.

1. Clinical needs locks are those used in psychiatric and behavioral health units. However, staff must be able to unlock the doors at all times (see 18/19.2.2.2.5.1 of the 2012 edition of the Life Safety Code).
2. Clinical needs locks are not permitted to be used for infant or pediatric security. However, door locking arrangement are permitted where patient special needs require specialized protective measures for their safety, provided that all of the provisions of 18/19.2.2.2.5.2 are met.
3. Delayed egress locks must comply with section 7.2.1.6.1 of the 2012 edition of the Life Safety Code and access-control locks must comply with section 7.2.1.6.2 of the same document.
4. Elevator lobbies are permitted to be locked provided they meet all the

OBSERVATION AND DOCUMENT REVIEW

- During the building tour, observe how doors are locked and if they comply with the provisions listed.
- Observe delayed egress locks to ensure that they are only installed in fully sprinklered or fully detected buildings.
- Observe access-control locks to determine they have motion sensors mounted on the egress side to automatically unlock the door when someone approaches; and a 'Push to Exit' button mounted on the egress side within five feet of the door, that unlocks the door when depressed.
- Observe Clinical Needs locks and ensure they are only installed in Psychiatric, Alzheimer's, dementia, and substance abuse units.
- Observe elevator lobby locks and ensure the elevator lobby is smoke detected and the entire building is sprinklered.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
patient's special needs require specialized protective measures for their safety, in accordance with section 18/19.2.2.2.5.2 of the 2012 Life Safety Code. §482.41(b)(1)	requirements in 7.2.1.6.3 of the 2012 Life Safety Code. 5. Doors in the means of egress from nurseries, mother/baby units, ICUs, and ERs are permitted to be locked provided they are equipped with locks in accordance with section 18/19.2.2.2.5.2 of the 2012 Life Safety Code.	▪ Observe special arrangement locks where the needs of the patient require special protective measure locks (i.e., nurseries, mother/baby units, ICUs, ERs), to ensure the entire locked area is smoke detected and the entire building is sprinklered.
13.01.03 Corridor Clutter The exit access corridor must be maintained to the full required width. §482.41(b)(1)	☐ Compliant ☐ Not Compliant Minimum width of exit access corridors for new construction in an acute-care hospital is 8 feet. Minimum width of exit access corridors for new construction in a psychiatric care hospital is 6 feet. Minimum width of exit access corridors for new construction in adjunct areas not intended for use by inpatients is 44 inches. Minimum width of exit access corridors for existing construction is 4 feet. Minimum width of exit access corridors in adjunct areas not intended for use by inpatients is 44 inches. Alterations of the existing width of corridors cannot be reduced to less than that which is required for new construction. Items left unattended in the exit access corridors for more than 30 minutes are not permitted, with the exception of emergency crash carts, and patient isolation supply carts, provided the carts are mounted on wheels, and the organization has a plan to remove the carts from the corridor during a fire emergency. Projections into the required width of the corridor are permitted for certain	This standard is not met as evidenced by: **OBSERVATION** ▪ During the building tour, observe corridors for clutter and unattended items left more than 30 minutes. Ask staff how long carts and equipment are left in corridors. ▪ Observe if the corridor width in existing conditions has been reduced to less than what is required for new construction. ▪ Review the organization's plan to remove the authorized carts and equipment from the corridor during a fire emergency.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	wheeled equipment, such as equipment in use; medical emergency equipment not in use; and patient lift and transport equipment, provided it meets the provisions of 18/19.2.3.4(4) of the 2012 Life Safety Code. Projections into the required width of the corridor are permitted for fixed furniture provided it meets the provisions of 18/19.2.3.4(5) of the 2012 Life Safety Code.	
13.01.04 Suites Suites containing patient sleeping rooms are limited in area to the following: ▪ 5,000 square feet in non-sprinklered buildings. ▪ 7,500 square feet in smoke compartments protected with standard response sprinklers and smoke detectors, or in smoke compartments protected with quick response sprinklers. ▪ 10,000 square feet where direct supervision of the patient sleeping rooms is arranged from a normally attended location in the suite, the suite is fully smoke detected, and the suite is fully protected with quick response sprinklers. Suites containing non-sleeping room suites are limited to 10,000 square feet. §482.41(b)(1)	☐ Compliant ☐ Not Compliant Sleeping room suites exceeding 1,000 square feet are required to have two exit access doors, one of which may be to an exit stairwell, direct exit, horizontal exit, or directly to an adjoining suite, provided the separation between the suites complies with the corridor requirements. Non-sleeping room suites exceeding 2,500 square feet are required to have two exit access doors, one of which may be to an exit stairwell, direct exit, horizontal exit, or directly to an adjoining suite, provided the separation between the suites complies with the corridor requirements. Sleeping suites must be provided with constant staff supervision within the suite. Sleeping suites must be arranged to allow direct supervision of all patient sleeping rooms from a normally attended location, or the entire suite must be provided with total smoke detection coverage. All doors located in the boundary wall of the suite enclosure, including entrance doors, must positively latch. Travel distance between any point in a suite and an exit access door from the suite must not exceed 100 feet.	This standard is not met as evidenced by: **OBSERVATION** ▪ During the building tour, observe the size of the suites to determine if they are within the limits listed. ▪ Check suite entrance doors to ensure they positively latch. ▪ Check sleeping suites to ensure they are staffed continuously. ▪ Check sleeping suite to ensure they have direct supervision of patients from a normally attended location, or the entire suite must be protected with smoke detectors

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.01.05 Signage	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Exits shall be marked by an approved sign readily visible from any direction of exit access and be illuminated. Illuminated signs must be legible in both the normal and emergency lighting mode. Access to exits shall be marked by approved signs in all cases where the way to reach the exit is not readily apparent to the occupants. Exit signs shall be visually inspected monthly for operation of the illumination sources. This inspection is documented. §482.41(b)(1)	All exits must be marked with an approved 'EXIT' sign, with the exception of exterior exit doors which clearly are identifiable as exits. This standard does not necessarily require an exit sign to be visible at every location in an exit access corridor. If the path of egress is apparent, then an exit sign is not required. Monthly inspections of exit signs are required to insure they are still illuminated. Doors that do not lead to exits but could be confused as an exit must have a sign that reads "NO EXIT," with the word "NO" 2-inches tall, and the word "EXIT" 1-inch tall. Enclosed stairwell identification signage is required to be provided in compliance with section 7.2.2.5.4 of the 2012 Life Safety Code for new stairways serving three or more stories and existing stairways serving five or more stories.	**OBSERVATION AND DOCUMENT REVIEW** ▪ During the building tour, observe all exit signs to insure they are properly illuminated. ▪ If the path of egress is not marked, and the way to the exit is not readily apparent, then the organization is non-compliant with this standard. ▪ During the document review session, review the monthly exit sign inspection log to insure all exit signs were inspected.
13.01.06 Exit Discharge	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The walking surface on the exit discharge must be level, having no more than ¼ inch of abrupt change in elevation, and be free from snow and ice accumulation and other weather-related hazards. The exit discharge shall be illuminated under both the normal and emergency lighting mode, all the way to the public way.	The exit discharge is the portion of means of egress from the exit door to the public way. The walking surface must be level and free of cracks and abrupt changes in elevation exceeding ¼ inch. Steps are permitted. The exit discharge must be maintained free from ice and snow and other weather-related hazards. An exit discharge across an unimproved area, such as a lawn, is not considered to be in compliance with this standard due to the uneven walking	**OBSERVATION** ▪ During the building tour, observe all exit discharges to ensure they have level walking surfaces and illumination all the way to the public way.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.41(a) §482.41(b)(1)	surface. Illumination of the exit discharge must be by lighting fixtures with more than one lamp, or multiple lighting fixtures to ensure path is illuminated if one lamp fails.	
13.01.07 Corridor	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Items attached to the wall of the corridor cannot project more than 4 inches into the corridor, may not exceed 36 inches in length; are separated from other wall-mounted projections by at least 48 inches; and are located at least 40 inches above the floor. Corridors must provide access to two approved exits without passing through intervening rooms or spaces, other than other corridors or lobbies. Dead-end corridors are limited to 30 feet. Existing dead-end corridors are permitted to remain if determined to be impractical and unfeasible to alter them to allow two paths of egress. §482.41(b)(1)	Wall mounted items in the corridor are not permitted to project more than 4 inches into the corridor. This includes drinking fountains, flip-down desks for wall charting stations, evacuation chairs, hand-rub dispensers, and any other item attached to the wall surface. This applies to new and existing conditions, regardless how long they have been installed. The path of egress is not permitted from a corridor into a room or suite to reach an exit. Dead-end corridors are created by doors that are locked in the path of egress.	**OBSERVATION** ▪ During the building tour, examine wall-mounted items in the corridor to ensure they do not project more than 4 inches. ▪ During the building tour, observe dead-end corridors, remembering locked doors in the path of egress may create an unexpected dead-end corridor. Do they exceed 30 feet in length? □ If more than 30 feet, are dead-end corridors existing? If existing, would it be impractical or unfeasible to resolve?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.01.08 Path of egress obstructions	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The path of egress must be free and clear of all obstructions or impediments all the way to the public way. §482.41(b)(1)	This standard applies to items and objects that would impede travel along the path of egress, including stairwells, passageways and exit discharges, all the way to the public way. For corridor clutter, see standard 13.01.03.	**OBSERVATION** ▪ During the building tour, examine each path of egress all the way to the public way to ensure there are no objects that would impede access.
13.01.09 Travel distance to exits	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The maximum travel distance between any point in a room and the exit shall not exceed 150 feet for buildings not fully protected with automatic sprinklers. For buildings that are fully protected with automatic sprinklers, the maximum travel distance from any point in a room to an exit is 200 feet. §482.41(b)(1)	The travel distance to an exit is measured along the normal walking path, around objects in rooms, and no closer than 12 inches to corridor walls. The travel distance between any point in a healthcare sleeping room (other than suites) and the exit access door in that room must not exceed 50 feet.	**OBSERVATION** ▪ During the building tour, examine selected travel distances to exits to ensure they are within the allowable amount.
13.01.10 Exit enclosures	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Stairwells and exit passageways must have the required fire resistive rating separation for the number of stories it serves. Stairwells and exit passageways must be	Openings in exit enclosures are limited to those necessary for access from normally occupied spaces and corridors. Existing openings to mechanical equipment spaces protected by fire rated door assemblies are permitted, provided:	**OBSERVATION** ▪ During the building tour, examine exit enclosures to ensure they do not have openings to unoccupied rooms.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
constructed and maintained in accordance with section 7.1 of the 2012 Life Safety Code. §482.41(b)(1)	▪ The space is used solely for non-fuel-fired mechanical equipment. ▪ The space contains no storage of combustibles materials. ▪ The building is protected throughout by an automatic sprinkler system. Penetrations into and openings through an exit enclosure are limited to existing penetrations that are protected with fire-rated materials. New construction exit enclosures are prohibited from penetrations, with the exception of: ▪ Electrical conduit serving the exit enclosure; ▪ Required exit doors; ▪ Ductwork and equipment necessary for independent stair pressurization; ▪ Water or steam piping necessary for heating or cooling of the exit enclosure; ▪ Sprinkler piping; ▪ Standpipes; ▪ Penetrations for fire alarm circuits where the circuits are installed in metal conduit. Items are not permitted to be stored in exit enclosures that have the potential to interfere with its use as an exit. Minimum headroom in exit enclosures must be at least 7 feet 6 inches unless existing conditions which is permitted 7 feet 0 inches. Stairs and ramps that continue more than on-half story beyond the level of exit discharge must be provided with an interruption gate to prevent occupants from traveling past the level of exit discharge during building evacuation.	▪ If existing mechanical spaces open directly to exit enclosure, ensure the space is not used for fuel-fired equipment, the space contains no storage of combustibles, and the building is fully sprinklered. ▪ While stairwells are not to be used as general storage areas, it is permissible to store safety-related items (i.e., evacuation chairs) in stairwells where they will not interfere with the use as an exit.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

FIRE DETECTION SYSTEMS

13.02.01 Fire alarm system - Installation and maintenance

A fire alarm system required for life safety shall be installed and maintained in accordance with sections 18/19.3.4 of the Life Safety Code (2012 edition), and in accordance with NFPA 72, 2010 edition.

§482.41(b)(1)

☐ Compliant ☐ Not Compliant

Basic installation requirements are defined in section 18/19.3.4 in the Life Safety Code (2012 edition).

Specific installation details of the fire alarm system components are defined in NFPA 72 (2010 edition) National Fire Alarm Code.

Once installed, fire alarm systems must be maintained to the original installation requirements.

This standard is not met as evidenced by:

OBSERVATION

Verify:

- Components of the fire alarm system are installed according to the codes and standards identified.
- The fire alarm system is maintained in accordance with the original installation requirements.

13.02.02 Fire alarm system - Testing

Fire alarm systems, and all their components, shall be tested according to NFPA 72 National Fire Alarm Code (2010 edition), Table 14.4.2.2 Test Methods, and Table 14.4.5 Testing Frequencies.

All testing results are documented.

§482.41(b)(1)

☐ Compliant ☐ Not Compliant

Reliability of the hospital's fire alarm system is critical for the safety of the facilities occupants.

This standard does not require the hospital to have all of the components identified in NFPA 72 (2010 edition), Tables 14.4.2.2 and 14.4.5, but if installed, they must be maintained and tested according to the methods and frequencies identified.

The over-all fire alarm system consists of multiple connected and inter-connected components and systems that together create a detection and notification system.

Basic components include power supplies, control panels, initiating devices, notification devices and interface devices, which require specific testing procedures at specified frequencies.

This standard is not met as evidenced by:

DOCUMENT REVIEW

- Documentation demonstrating compliance with NFPA 72 (2010 edition) Tables 14.4.2.2 and 14.4.5 must be maintained for a minimum of three years.
- Documentation must demonstrate that each and every device connected to the fire alarm system is inventoried and accounted for and passed (or failed) its test.
- Verify that the fire alarm test report fully complies with the frequencies

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Secondary components that are controlled by the fire alarm system such as air-handlers, smoke dampers, smoke or fire doors held open, and access-control, or delayed egress locks must be tested through their normal range of control when activated (or de-activated) by the fire alarm system	identified in Table 14.4.5 of NFPA 72 (2010 edition). Each individual fire alarm device that is tested must be identified as to its location, and whether it passed or failed its test. ▪ During the document review session, make sure the hospital annually tests the interface devices (relays) between the fire alarm systems and the locks used on the delayed egress and access-control locks. ▪ Interview staff to determine if the test methods used on the fire alarm system components are consistent with Table 14.4.2.2 of NFPA 72 (2010 edition).
13.02.03 Fire alarm systems - transmitting signal The fire alarm system shall transmit an appropriate signal to an offsite monitoring station, or directly to the emergency response force. This signal shall be tested annually from the alarm panel in the protected premise, to the emergency response force. **The transmission of a fire alarm signal shall be tested quarterly during fire drills from the alarm panel in the protected**	☐ Compliant ☐ Not Compliant This standard does not require the fire alarm system to transmit all three signals, but when the fire alarm system activates an alarm signal, supervisory signal, or a trouble signal, it must be transmitted to an approved location, such as an Auxiliary Fire Alarm System, a Central Station, a Proprietary System, or a Remote Supervising Station. Manual reporting systems and methods are not permitted. Annually, the off-premises monitoring transmission equipment must be tested to ensure the local fire-responding agency received an alarm signal, even if the transmission of that signal is through a third-party entity. Quarterly, the transmission of the fire alarm signal and simulation of fire	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review hospital records to determine whether the fire alarm system signal is transmitted annually from the fire alarm panel to the emergency response force. ▪ **Review hospital fire drill records to determine whether the fire alarm system signal is transmitted quarterly from the fire alarm panel to the**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
premise, to the emergency response force. All results of the tests are documented. §482.41(b)(1)	conditions must be tested during fire drills per NFPA 101 *Life Safety Code* (2012 edition), 18/19.7.1.4. For fire drills, see standard 11.04.02. NFPA 72 (2010 edition) Table 14.4.2.2 (18) (a) through (e), and Table 14.4.5 (22) describes in detail the methods and procedures to follow for each type of system.	**emergency response force when fire drills are conducted.** **Note: If quarterly requirement is found to be deficient, cite at 11.04.02 Fire drills.**
13.02.04 <u>Fire alarm system - Technician qualifications</u> Fire alarm inspection, testing and maintenance personnel shall be qualified and experienced in the testing of fire alarm systems. Documentation identifying the qualification of the individual(s) performing testing, inspecting and maintenance activities on the fire alarm system must be available for review. §482.41(b)(1)	☐ Compliant ☐ Not Compliant Technicians performing inspections, testing and maintenance on fire alarm systems must have proper certification, license, and/or training to do so. Examples of qualified personnel include, but are not limited to individuals with the following qualifications: ▪ Factory trained and certified. ▪ National Institute for Certification in Engineering Technologies (NICET) fire alarm certification. ▪ International Municipal Signal Association (IMSA) fire alarm certification. ▪ Certification by a state or local authority. ▪ Personnel employed, trained, and qualified by an organization listed by a national testing laboratory for the servicing of fire alarm system. The requirement to maintain documentation on the individual providing inspection, testing or maintenance activities on the fire alarm system applies to contracted services as well hospital staff.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Documentation for the individual(s) performing testing, inspection or maintenance of fire alarm system, and their components, must be on file for reviewed. ▪ Review documentation that demonstrates compliance with this standard.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

FIRE SUPPRESSION SYSTEMS

13.03.01 Water-based fire protection system: Installation and maintenance

A water-based fire protection system must be installed and maintained in accordance with section 18.3.5 of the Life Safety Code (2012 edition) in all new construction, remodeled and renovated areas.

A water-based fire protection system must be installed and maintained in accordance with section 19.3.5 of the Life Safety Code (2012 edition) where required in existing construction, or renovated areas.

§482.41(b)(1)

☐ Compliant ☐ Not Compliant

This standard requires the installation of sprinklers in new construction since the adoption of the 1991 edition of the Life Safety Code.

This standard does not require the installation of sprinklers in existing construction prior to the adoption of the 1991 edition of the Life Safety Code, unless the construction type dictates it, or the sprinklers are a measure of equivalency.

All sprinkler systems installed must comply with NFPA 13 *Standard for the Installation of Sprinkler Systems,* (2010 edition), regardless of whether the sprinkler systems are required or not.

Once installed, sprinkler systems must be maintained to the original installation requirements.

This standard is not met as evidenced by:

OBSERVATION AND INTERVIEW

- Interview facility manager to determine what areas qualify as new construction.
- Determine if Construction Type requires sprinklers in existing construction.
- During the building tour, observe if components of the sprinkler system are installed and maintained in accordance with NFPA 13.

13.03.02 Water-based fire protection system: Testing and inspection

If provided water-based fire protection systems and all their components must be tested, inspected and maintained in accordance with NFPA 25 *Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems*, 2011 edition.

All results of testing, inspection and maintenance activities are documented.

☐ Compliant ☐ Not Compliant

Water-based sprinkler systems, including pre-action and dry-pipe systems, are included in this Standard.

This standard does not require a hospital to have automatic sprinkler systems or their components installed, but if present, the sprinkler systems must be tested, inspected, and maintained according to NFPA 25 *Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems* (2011 edition).

Water-based fire protection systems and components, include but are not limited to:

This standard is not met as evidenced by:

DOCUMENT REVIEW

- Documentation demonstrating compliance with NFPA 25 (2011 edition) must be maintained for a minimum of three years.
  - □ Documentation must demonstrate that each and every device connected to the water-based fire protection system is accounted for and passed or failed its test.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.41(b)(1)	▪ Sprinklers ▪ Piping and hangers ▪ Control valves, valve components and trim ▪ Water-flow devices ▪ Standpipe and hoses ▪ Dry-pipe, deluge and pre-action valves ▪ Service mains ▪ Storage tanks Control valves are required to be visually inspected monthly to confirm they are still in their designated position. This inspection must be documented.	▪ Verify that the water-based fire protection system documentation fully complies with the frequencies identified in NFPA 25 (2011 edition). Each individual sprinkler system device that is tested must be identified as to its location, and whether it passed or failed its test. ▪ During the document review session, ensure the sprinkler control valves are inspected monthly.
13.03.03 <u>Water-based fire protection system: Control valves, piping, and hangers</u> If provided, control valves used in water-based fire protection systems must be electronically supervised with tamper switches and connected to the building fire alarm system. Tamper switches must be tested at intervals according to 13.02.02. Sprinkler piping and hangers shall be free of all material, including wire, cable, conduit, HVAC duct, or any other objects, and shall not be used to support any other item or system. §482.41(b)(1)	☐ Compliant ☐ Not Compliant All sprinkler control valves must have tamper switches installed and connected to the building fire alarm system to send electronic supervisory signals. Chains and locks on control valves, while permitted, do not demonstrate compliance with this Standard. Nothing is permitted to be attached to sprinkler piping and hangers, including wire and cable.	This standard is not met as evidenced by: **<u>OBSERVATION</u>** ▪ During the building tour, observe sprinkler control valves to ensure they are electronically monitored. ▪ Examine sprinkler piping and hangers to ensure nothing is suspended or attached to them.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.03.04 Fire pumps: Monthly test If so equipped, electric-motor driven fire pumps must be tested monthly at no-flow conditions in accordance with NFPA 25 *Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems*, 2011 edition. If so equipped, engine-driven fire pumps must be tested weekly at no-flow conditions in accordance with NFPA 25, 2011 edition. The results of all testing activities are documented. §482.41(b)(1)	☐ Compliant ☐ Not Compliant This standard does not require the installation of fire pumps in the facility. If so equipped, the hospital performs monthly fire pump tests at no-flow (or churn) conditions for a minimum of 10 minutes for electric-motor driven pumps and a minimum of 30 minutes for engine-driven pumps. No-flow test must begin by reducing water pressure at the start switch. Suction pressure readings and discharge pressure readings are recorded.	This standard is not met as evidenced by: **DOCUMENTATION** ▪ Review documentation to ensure fire pump is tested in accordance with NFPA 25.
13.03.05 Fire pumps: Annual test If so equipped, fire pumps must be tested annually at specified flow conditions in accordance with NFPA 25 *Standard for the Inspection, Testing and Maintenance of Water-Based Fire Protection Systems*, 2011 edition. The results of all testing activities are documented. §482.41(b)(1)	☐ Compliant ☐ Not Compliant A hospital is not required to have a fire pump installed, but if present, the fire pump must be tested according to the standard. An annual water-flow test is required for all fire pumps, which consists of: 1. A churn test. 2. The pump operated at design flow (100% nameplate capacity). 3. The pump operated at peak flow (150% nameplate capacity). **Note: If available suction supplies do not allow flowing of 150 percent of the rated pump capacity, the fire pump shall be permitted to operate at maximum allowable discharge.**	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documentation to ensure fire pump is tested annually in accordance with NFPA 25 (2011 edition) and this standard.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	4. During peak flow, a power failure is simulated on electric-motor driven pumps equipped with automatic transfer switches to ensure emergency power supply is connected, and confirmation of peak flow continues. 5. After peak flow has been confirmed and documented, normal power is restored to ensure circuit protection devices have not opened. Additional readings and measurements are required during this annual flow test. If peak flow is not attainable due to limitations in water supply, that shall not constitute an unsuccessful test.	
13.03.06 Alternative fire suppression systems: Installation and testing Approved fire suppression systems that are installed, tested and maintained to their respective NFPA standard, are permitted to be an alternative to water-based fire protection systems without the facility being classified as non-sprinklered. All such alternative fire suppression systems shall be connected to the building fire alarm system and initiate an alarm when activated. §482.41(b)(1) The results of all testing activities are documented.	☐ Compliant ☐ Not Compliant Installation of alternative fire suppression systems **is not required**. If so equipped, alternative fire suppression systems **must meet the Standard**. Examples of alternative fire suppression systems are: ▪ Halon systems ▪ FM-200 systems ▪ Inergen systems ▪ CO_2 systems.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview facility manager to determine what areas contain alternative fire suppression systems. ▪ Review documentation to determine if appropriate testing and inspection frequencies are achieved.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.03.07 Water-based standpipes and hoses: Inspection and testing If so equipped, water-based automatic (wet) standpipes, must be tested once every five years at flow conditions equal to original acceptance requirements at the hydraulically most remote location. If so equipped, manual (dry) standpipes must be hydrostatic tested at not less than 200 psi pressure for two hours, or at 50 psi in excess of the maximum pressure, whichever is greater, at least once every five years. If so equipped, occupant-use fire hoses must be un-racked annually, inspecting for abnormal wear conditions. Occupant-use fire hoses must be hydraulically pressure tested in accordance with NFPA 1962, *Standard for the Inspection, Care and Use of Fire Hose, Couplings, and Nozzles and the Service Testing of Fire Hose,* (2008 edition) five years after initial installation and every three years thereafter. The results of all testing and inspection activities are documented. §482.41(b)(1)	☐ Compliant ☐ Not Compliant This standard does not require the installation of standpipes or occupant-use fire hoses. If so equipped, the hospital must perform a 5-year flow test on a wet standpipe in the hydraulically most remote location, usually on the roof, in accordance with NFPA 25. If the hydraulically most-remote location is not attainable, then the local fire AHJ must be consulted for an acceptable alternate location. The water-flow for the test of the standpipe in the hydraulically most remote location must equal the original acceptance requirements. If the original acceptance requirements are not known, then the water-flow must achieve 500 gallons per minute. Dry standpipes, including piping in the fire department connection, must be hydrostatic tested once every five years. This standard does not require the installation of occupant-use fire hoses, but if the hospital is so equipped, then they must be un-racked annually and inspected for abnormal wear, and re-racked without using the same folds. Occupant-use fire hoses must be pressure-tested five years after installation, and every three years thereafter. Organizations that remove occupant-use fire hoses must have the approval of the local or state authority on fire prevention.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify through documentation: ▪ Wet standpipe systems are water-flow tested at least once every five years in accordance with NFPA 25. ▪ Dry standpipe systems, including the piping for the fire department connections, are hydrostatic tested at least once every five years in accordance with NFPA 25. ▪ Annual fire hose inspection and when it was last pressure tested or replaced. ▪ The local or state authority having jurisdiction (AHJ) granted permission to remove occupant-use fire hoses from the facility.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.03.08 Water-based fire department connections If so equipped, Fire Department Connections must be maintained in accordance with NFPA 13 (2010 edition) and inspected quarterly in accordance with NFPA 25 (2011 edition). The results of all inspection activities are documented. §482.41(b)(1)	☐ Compliant ☐ Not Compliant The hospital must inspect the Fire Department Connections (also called Siamese connections) once per quarter. This standard includes those connections where a fire department would hook-up and pump water into the buildings. Fire Department Connections must be properly maintained for immediate use, and not obstructed by vehicles, vegetation, or anything else preventing its view from the street.	This standard is not met as evidenced by: **DOCUMENTATION** ▪ Review documentation to ensure fire department connections are inspected at least once per quarter in accordance with NFPA 25, 2011 edition. ▪ Review documentation of quarterly fire department connections. ▪ Physically observe Fire Department Connections to determine they are not obscured, and they are visible from the street.
13.03.09 Portable fire extinguishers - Installation, inspection, and maintenance Portable fire extinguishers must be installed, inspected and maintained in accordance with *NFPA 10 Standard for Portable Fire Extinguishers*, 2010 edition. Fire extinguishers shall be inspected monthly and maintained annually. The results of all inspection and maintenance activities are documented. §482.41(b)(1)	☐ Compliant ☐ Not Compliant Portable fire extinguishers are not permitted to sit on the floor but are required to be mounted on brackets or placed in cabinets, at least 4 inches above the floor and no higher than 60 inches above the floor. Access to extinguishers must not be obstructed. In large rooms and in certain locations where visual obstructions cannot be completely avoided, means must be provided to indicate the extinguisher location. Fire extinguishers are permitted to be electronically monitored through the building's fire alarm system, provided it meets all the requirements in NFPA 10-2010, chapter 7. The selection of portable fire extinguishers is based on the hazard it is	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review monthly inspection documentation for portable fire extinguisher during building tour. ▪ During the building tour, observe the extinguisher installation to ensure it is at least four inches above the floor and the handle is no more than 60 inches above the floor.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	designated to protect. The travel distance required to get to a fire extinguisher is based on the level of the hazard and the capacity and type of the extinguisher, as identified in NFPA 10. The monthly inspection documentation must identify the date (month/day/year) and signature (or initials) of individual performing the inspection. Electronic documentation is acceptable provided it contains all required data and is retrievable at the time of survey.	
13.03.10 Fire hose valves All fire hose valves must be inspected quarterly. Class I and Class III standpipe hose valves (2½-inch hose valves) must be tested annually. Hose valves on hose stations attached to sprinkler systems, and Class II standpipe hose valves (1½-inch hose valves) must be tested once every three years. Inspections and tests are documented. §482.41(b)(1)	☐ Compliant ☐ Not Compliant If so equipped, fire hose valves must be inspected on a quarterly basis. The inspection ensures the following: ▪ Hose caps are in place and not damaged. ▪ Hose threads are not damaged. ▪ Valve handles are present and not damaged. ▪ Gaskets are inspected for damage or deterioration. ▪ Hose valves are not leaking. ▪ Ensure there are no obstructions to hose valves. ▪ If required, ensure restricting devices are present. Class I and Class III (2½ inch) hose valves must be tested annually by opening and closing the valve. **Note:** Full flow of water is not required. Class II and 1½-inch hose valves must be tested once every three years by opening and closing the valve. **Note:** Full flow of water is not required.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review quarterly inspection documentation to ensure all fire hose valves are inventoried and their location is documented and whether they passed or failed their inspection. ▪ Review annual test of 2½ hose valves and 3-year test of Class II and 1½ hose valves to ensure the valve was opened. ▪ Check test and inspection records to determine if any damaged equipment or failed test/inspection was followed up with appropriate repairs.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.03.11 Internal inspection of piping	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
An internal inspection of water-based fire protection system piping and branch line conditions must be conducted once every five years. §482.41(b)(1)	The internal inspection must be conducted by opening a flushing connection at the end of one main and by removing a sprinkler toward the end of one branch line for the purpose of inspecting for the presence of foreign material. Tubercules or slime, if found, must be tested for indications of Microbiological Influenced Corrosion (MIC). Non-metallic pipe is not required to be inspected internally.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Review inspection documentation to ensure the internal inspection was conducted on the sprinkler piping. ▪ If slime was found, check the documentation for the testing of MIC. ▪ If MIC was determined to be present, check the documentation of corrective actions to eliminate MIC.
13.03.12 Cooking hood fire suppression	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The cooking hood fire suppression system must be inspected monthly and maintained semi-annually. These inspections and maintenance activities are documented. Where cooking hoods are protected in accordance with NFPA 96, *Standard for Ventilation Control and Fire Protection of Commercial Cooking Operations,* 2011 edition, cooking equipment will not cause the room or space housing the cooking equipment to be classified as a hazardous	Cooking hood fire suppression systems must be inspected monthly in accordance with NFPA 17A, *Standard for Wet Chemical Extinguishing Systems,* 2009 edition. The following items need to be verified: ▪ The extinguishing system is in its proper location. ▪ The manual actuators are unobstructed. ▪ The tamper indicators and seals are intact. ▪ The maintenance tag or certificate is in place. ▪ No obvious physical damage or condition exists that might prevent operation.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Review the documentation for the monthly inspection to verify all requirements were met. ▪ Review the documentation for the semi-annual maintenance to ensure all requirements are met. ▪ During the building tour, ensure that kitchens are separated from corridor by appropriate partitions and doors. ▪ During the building tour, examine the kitchen storage rooms to determine

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
area. §482.41(b)(1)	▪ The pressure gauge(s), if provided, shall be inspected physically or electronically to ensure it is in the operable range. ▪ The nozzle blow-off caps, where provided, are intact and undamaged. ▪ Neither the protected equipment nor the hazard has not been replaced, modified, or relocated. At least semiannually, maintenance shall be conducted on all cooking hood fire suppression systems in accordance with the manufacturer's listed installation and maintenance manual. Maintenance shall include: ▪ A check to see that the hazard has not changed ▪ An examination of all detectors, the expellant gas container(s), the agent container(s), releasing devices, piping, hose assemblies, nozzles, signals, all auxiliary equipment, and the liquid level of all non-pressurized wet chemical containers ▪ Verification that the agent distribution piping is not obstructed ▪ Kitchens that have cooking hoods that are equipped with listed, approved fire suppression systems will allow the kitchen to not be considered a hazardous area, even though the kitchen contains heat producing appliances. However, storage rooms greater than 50 square feet containing combustible supplies are still considered hazardous areas and must be protected as such.	compliance with hazardous area requirements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

FIRE SAFETY SYSTEMS

13.04.01 Fire-rated barriers

The hospital shall ensure that fire-rated barriers are properly rated, appropriate for their purpose, free from unsealed penetrations, and have the appropriate fire-rated opening protectives.

§482.41(b)(1)

☐ Compliant ☐ Not Compliant

Not all fire rated barriers are rated the same.

The 2012 edition of the Life Safety Code specifies which fire-rated barrier receives what fire rating.

Opening protectives are fire-rated door assemblies and fire dampers. Not all fire-rated barriers are required to have fire dampers.

Fire-rated barriers are permitted to be combined with smoke compartment barriers, provided all the requirements from each barrier are implemented.

This standard is not met as evidenced by:

OBSERVATION

- During the building tour, refer to the Life Safety Drawings to understand what rating each fire barrier is required to have.
- Examine fire rated barriers above and below the ceiling, looking for unsealed penetrations.
- Examine door assemblies in fire rated barriers to ensure they are properly fire rated, self-closing and positive latching.

13.04.02 Smoke barriers

The hospital shall ensure that smoke compartments are separated by smoke-barrier walls and are properly rated; properly constructed for their purpose; free from unsealed penetrations and have the required opening protectives.

§482.41(b)(1)

☐ Compliant ☐ Not Compliant

The 2012 edition of the Life Safety Code specifies where barriers for smoke compartment**s** are required.

Opening protectives are smoke barrier door assemblies and smoke dampers. Not all smoke barriers are required to have smoke dampers. Smoke barrier doors are not required to be fire-rated or positive latching, however they must self-close.

Although smoke barrier walls are required to have a fire rating, they are not fire-rated barriers. If the smoke barrier does have fire-rated doors, then the fire-rated door assemblies must be maintained properly, including self-

This standard is not met as evidenced by:

OBSERVATION

- During the building tour, examine smoke barriers above and below the ceiling, looking for unsealed penetrations.
- Examine door assemblies in smoke barriers to ensure they are self-closing.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	closing and positive latching. Smoke compartment barriers are permitted to be combined with fire-rated barriers, provided all the requirements from each barrier are implemented.	
13.04.03 Fire and smoke dampers Fire and smoke dampers must be fully tested and operated one year after installation and once every six years thereafter in all healthcare facilities classified as hospitals. In healthcare facilities not classified as hospitals, fire and smoke dampers must be fully tested and operated one year after installation, and once every four years thereafter. The results of all inspection activities are documented. §482.41(b)(1)	☐ Compliant ☐ Not Compliant Fire dampers are required to be installed, maintained, and tested in accordance with NFPA 80 *Standard for Fire Doors and Other Opening Protectives* (2010 edition) and smoke dampers are required to be installed, maintained, and tested in accordance with NFPA 105 *Standard for Smoke Door Assemblies and Other Opening Protectives* (2010 edition). Dampers installed in the facility must be documented identifying the following: ▪ Type of damper ▪ Location of damper (i.e., building, floor, unit, room, area, etc.) ▪ Orientation of damper (i.e., horizontal or vertical) ▪ Date of installation (if known) ▪ Last test date and results (Pass/Fail) **Note**: There are no provisions in the NFPA codes or standards that permit inaccessible dampers to remain inaccessible and untested.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Documentation demonstrating compliance with NFPA 80 (2010 edition) and NFPA 105 (2010 edition) must be maintained for a minimum of six years. ▪ Verify that each fire and smoke damper is documented, and identified as to its location, and whether the damper passed or failed its test.
13.04.04 Overhead rolling/horizontal sliding fire doors If so equipped, overhead rolling and horizontal sliding fire doors are required to be tested once per year for proper operation and closure, in accordance with	☐ Compliant ☐ Not Compliant Hospitals are not required to have overhead rolling or horizontal sliding fire doors, but if present, the doors must be installed, maintained, and tested in accordance with NFPA 80 *Standard for Fire Doors and Fire Windows* (2010	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Documentation demonstrating compliance with NFPA 80 (2010

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
NFPA 80 *Standard for Fire Doors and Fire Windows* (2010 edition). The results of all testing and inspection activities are documented. §482.41(b)(1)	edition) to ensure proper operation. The test of the fire door assembly must be initiated by all devices associated with the control of the door, such as smoke detector and interface, thermal link, etc. Overhead rolling and horizontal sliding fire doors must be tested annually.	edition) must be maintained for a minimum of three years. ▪ Verify that each overhead rolling or horizontal sliding fire door was tested at least annually, and that the test was initiated by the safety device which controls the door.
13.04.05 Construction type The construction type is identified and deemed appropriate for the number of stories in the buildings. The fire-proofing assembly applied to structural steel to meet the requirements of Construction Type must be installed and maintained according to the UL listing and/or manufacturer's recommendation. §482.41(b)(1)	☐ Compliant ☐ Not Compliant Construction Type is determined by the number of stories in the building, as defined in sections 18/19.1.6, of the 2012 Life Safety Code. Construction type must be identified in accordance with NFPA 220, 2012 edition. Construction type must be correctly identified in the ACHC Facility Demographic Report, using NFPA 220 nomenclature. Floor assemblies are designed and maintained in accordance with the required fire resistive rating for the facility's construction type.	This standard is not met as evidenced by: **OBSERVATION** ▪ Examine the Facility Demographic Report to find the facility's Construction Type. ▪ Observe number of stories and sprinkler installation to determine if the Construction Type listed is correct. ▪ Observe the fireproofing material applied to the structural steel to ensure it is installed and maintained correctly.
13.04.06 Separated occupancies When different occupancies are claimed to be separated in the facility, 2-hour fire rated barriers separate healthcare occupancies from all other occupancies,	☐ Compliant ☐ Not Compliant If the organization claims to have separated occupancies in the same building as the healthcare occupancy, then 2-hour fire rated barriers must separate the occupancies. Note that a 2-hour fire rated floor assembly does qualify as an appropriate	This standard is not met as evidenced by: **OBSERVATION** ▪ During the building tour, refer to the Life Safety Drawings to identify barriers that separate occupancies.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
and 1-hour fire rated barriers separate non-healthcare occupancies. §482.41(b)(1)	barrier for occupancy separation but does not qualify as an appropriate building (i.e., construction type) separation.	▪ Examine fire rated barriers to determine if they are free from unsealed penetrations and have appropriately rated doors assemblies.
13.04.07 Fire-rated door assemblies	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Fire door assemblies must meet the provisions of NFPA 80 *Standard for Fire Doors and Fire Windows,* 2010 edition. All fire-rated doors assemblies, whether they are located in a fire rated barrier or not, must be tested and inspected on an annual basis according to NFPA 80, 2010 edition. The test and inspection is documented. §482.41(b)(1)	Doors in fire-rated door assemblies must have a legible label that identifies its fire rating. Frames in fire-rated door assemblies must have a legible label that identifies it as a fire-rated frame. Note that frames are not required to be labeled with an hourly rating, unless the assembly rating is for three or more hours. Fire-rated door assemblies must have self-closing devices, positive latching hardware, gaps between meeting edges of door pairs are no more than one-eighth inch, and the space between the bottom of the door and the floor is no more than three-quarter inch. All after-market hardware installed on fire-rated door assemblies must be listed for use on fire-rated door assemblies. All fire-rated door assemblies throughout the facility must be inventoried, then tested and inspected on an annual basis, including those fire-rated door assemblies that are not located in a fire-rated barrier.	**OBSERVATION** ▪ During the building tour, examine fire door labels to ensure the door is properly rated for the fire barrier designation. If the label is not legible, then the door is not compliant. ▪ Measure the gap between meeting edges of door pairs and the undercut of the door to ensure they are within limits. ▪ Examine after-market hardware installed on fire-rated doors (astragals, coordinators, closers, etc.) to ensure they are listed for use on fire-rated door assemblies. ▪ Review the documentation that demonstrates that each individual fire-rated door assembly is tested and inspected on an annual basis.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.04.08 Hazardous areas	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Hazardous areas, as defined in 18/19.3.2 of the 2012 edition of the Life Safety Code, must be protected with the following: ▪ For new construction and existing areas that are remodeled or renovated, all hazardous areas must be protected with 1-hour fire-rated barriers that extend from the floor to the deck and be equipped with ¾-hour fire-rated door assemblies that self-close and positively latch. The hazardous area must be protected with automatic sprinklers. ▪ For existing construction, hazardous areas must be protected with 1-hour fire rated barriers that extend from the floor to the deck and ¾-hour fire-rated door assemblies that self-close and positively latch if the area is not protected with automatic sprinklers, OR be protected with non-rated smoke resistant barriers that extend from the floor to the ceiling (provided the ceiling also resists the passage of smoke) and equipped with doors that are smoke resistant and self-close if the hazardous area is protected with automatic sprinklers. §482.41(b)(1)	Hazardous areas must be identified on the organization's Life Safety Drawings. The type of barrier for a hazardous area is dependent on whether the area is new or existing construction, and whether or not the area is sprinklered. Review the list of hazardous areas found in sections 18/9.3.2 of the 2012 edition of the Life Safety Code. There are certain exceptions to the requirement that spaces in existing conditions that are repurposed for the storage of combustible supplies have to meet new construction requirements. Under certain conditions, the space may be able to meet hazardous area requirements for existing conditions. Refer to Chapter 43 in the 2012 Life Safety Code for details.	**OBSERVATION** ▪ During the building tour, examine the Life Safety Drawings for hazardous areas. Once found, observe the hazardous area to verify that it meets the requirements listed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.04.09 Ceilings Ceilings which are required to limit the passage of smoke, such as ceilings containing smoke or heat detectors, and sprinklers, and used in conjunction with corridors and hazardous rooms that have smoke resistant barriers, are free from cracks, holes, or missing tiles. §482.41(b)(1)	☐ Compliant ☐ Not Compliant Where ceilings are expected to resist the passage of smoke, they cannot have any missing tiles, or cracks or holes. Gaps or cracks exceeding one-eighth inch constitutes non-compliance with this Standard. Suspended grid and acoustical tile type of ceiling, when properly installed and maintained, can limit the passage of smoke.	This standard is not met as evidenced by: **OBSERVATION** ▪ During the building tour, observe ceilings for missing tiles, cracks, or holes. Especially look for missing escutcheon plates around sprinklers, and communication wires penetrating the ceiling.
13.04.10 Corridor Walls In new construction, corridor walls are permitted to be non-rated and are required to resist the passage of smoke and are permitted to extend from the floor to the ceiling, provided the ceiling also resists the passage of smoke. In existing construction, corridor walls are required to be 30-minute fire-rated, and extend from the floor to the deck, with all penetrations properly sealed in non-sprinklered smoke compartments, and door openings are not required to be fire-rated. In existing construction, corridor walls in fully sprinklered smoke compartments are permitted to be non-rated and are required	☐ Compliant ☐ Not Compliant A 30-minute fire rated wall is defined by NFPA as 3½-inch steel studs with one layer of 5/8-inch gypsum board on one side.	This standard is not met as evidenced by: **OBSERVATION** ▪ During the building tour, examine above the ceilings in corridors in non-sprinklered smoke compartments to determine if corridor walls extend to the deck and are free from unsealed penetrations.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
to resist the passage of smoke and are permitted to extend from the floor to the ceiling, provided the ceiling also resists the passage of smoke. §482.41(b)(1)		
BUILDING SERVICES		
13.05.01 Fireplaces Direct-vent gas fireplaces are permitted inside smoke compartments containing patient sleeping areas, but not inpatient sleeping rooms. §482.41(b)(1)	☐ Compliant ☐ Not Compliant Direct-vent gas fireplaces are permitted inside smoke compartment containing patient sleeping areas, provided the following are met: ▪ All such devices are properly maintained; ▪ No such device is located in a patient sleeping room; ▪ The smoke compartment is fully protected with quick response sprinklers; ▪ The direct-vent fireplace is equipped with a sealed glass front with a wire mesh panel or screen; ▪ The controls for the direct-vent gas fireplace are locked or located in a restricted location; ▪ Electrically supervised carbon monoxide detection is provided in the room where the fireplace is located.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ If a fireplace is observed, verify that is not located in a patient sleeping room.
13.05.02 Elevator recall All elevators, new or existing, that have a travel distance 25 feet or more above or below the level that best serves the needs	☐ Compliant ☐ Not Compliant Elevator recall is designed to capture the control of the car, return it to a previously designated floor, and open its door when a smoke detector located in the elevator lobby, elevator shaft, or elevator mechanical room is	This standard is not met as evidenced by: **DOCUMENT REVIEW** During the document review session,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
of the local emergency fire response force must be equipped with elevator recall, also known as Firefighter's Service, Phase 1. Elevator recall is tested and operated monthly. All results of the test are documented. §482.41(b)(1)	in alarm. Elevator recall is tested monthly in accordance with the Life Safety Code, regardless of what the Elevator Safety Code requires.	review testing documents to ensure the organization is testing recall every month.
13.05.03 Trash and linen chutes	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
All trash and linen chute inlet and discharge door assemblies are properly fire-rated, are self-closing, and positive latching. Chute door assemblies have not been modified in the field. Trash chutes discharge into a collection room that is not used for any other purpose. An approved automatic sprinkler system is installed inside the chute at the top and at the lowest service level, and on alternating floors levels. Trash and linen discharge rooms are separated from the corridor and other areas with 1-hour fire rated barriers. §482.41(b)(1) §482.41(b)(4)	Trash and linen chutes must be maintained with fire-rated doors at each inlet and discharge opening. Field modifications to the doors are not permitted. Sprinklers inside the chutes must be inspected and maintained at the same frequency as other building sprinklers. Existing linen chutes are permitted to discharge into the same room as trash chutes provided the room is protected with automatic sprinklers.	**OBSERVATION** ▪ During the building tour, examine chute doors for field modification, such as welded repairs, after-market latching devices, and add-on locks. If any observed, then chute doors are not compliant with this standard. ▪ Examine sprinklers inside the chute for dust and dirt accumulation. ▪ Examine trash chute discharge room to determine if it used for any other purpose or storage. ▪ Examine trash and linen discharge room to determine if it meets the 1-hour fire separation requirement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.05.04 Generator inspection	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Emergency power generators and all appurtenant components must be inspected weekly. Generators located indoors must be separated from the rest of the facility with 2-hour fire-rated barriers. Batteries used in connection with the generator shall be inspected weekly and maintained in full compliance with the manufacturers' recommendations, and electrolyte specific gravity levels on lead-acid batteries shall be recorded. Sealed lead-acid batteries must have an electrical conductive test performed. Results of inspection shall be documented. §482.41(b)(1) §482.41(c)	Routine inspection must be accomplished in accordance with NFPA 110 (2010 edition). For all emergency power generators located inside the building (regardless of when they were installed), the generator must be installed within a separate room with a minimum of 2-hour fire-rated barriers. If located outside the building, the generator shall be located in an enclosure capable of resisting the entrance of snow and rain. No other equipment except that which serves the space is permitted to be stored in these rooms. Where sealed lead-acid batteries are utilized, electrolyte specific gravity levels are not required to be recorded; however, conductance testing will be required, with the results documented. A fuel quality test shall be performed at least annually using tests approved by ASTM standards. A remote manual stop station must be located outside the room housing the generator, or elsewhere on the premises when the generator is located outside the building.	**OBSERVATION AND INTERVIEW** ▪ Confirm generators located indoors are separated with 2-hour fire-rated barriers, and no other items are stored in the room. ▪ Review weekly inspection log and confirm battery electrolyte specific gravity readings or conductive readings are recorded. ▪ Review annual fuel quality test to ensure it has been conducted.
13.05.05 Generator monthly load test	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Emergency power generators shall be tested 12 times a year with a dynamic load of at least 30% of nameplate rating, with testing intervals not less than 20 days and	Emergency power generator sets shall be tested in accordance with NFPA 110 (2010 edition).	**DOCUMENT REVIEW** ▪ Request records to verify that testing is performed as required. Check monthly test dates to ensure no tests

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
not more than 40 days, for a minimum of 30 minutes. In lieu of meeting 30% nameplate rating during each monthly load test, generator may be operated to meet the manufacturers' recommended prime mover's exhaust gas temperature. If the hospital cannot meet the 30% nameplate rating or the exhaust gas temperature for any of the monthly load tests, then a supplemental annual load test must be conducted with connected loads of 50% of nameplate rating for 30 minutes, followed by 75% of nameplate rating for 60 minutes, for a total of 90 continuous minutes. The monthly load tests must still be conducted at the appropriate intervals even if they do not meet the load requirements. Results of tests shall be documented.		are accomplished sooner than 20 days and no later than 40 days from previous test. ▪ If applicable, examine annual load tests to ensure designated loads are met and test was for at least 90 continuous minutes.
13.05.06 Generator 3-year load test Emergency power generators shall be tested once every 36 months for a minimum of four continuous hours at a connected load of at least 30% nameplate rating or operated to meet the manufacturers' recommended prime	☐ Compliant ☐ Not Compliant Emergency power generator 3-year load test shall be tested in accordance with NFPA 110 (2010 edition).	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Request records to verify that testing is performed as required.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
mover's exhaust gas temperature. Results of tests shall be documented. §482.41(b)(1) §482.41(c)		
13.05.07 Automatic transfer switch test Automatic transfer switches shall be tested 12 times a year, with testing intervals not less than 20 days and not more than 40 days. Results of tests shall be documented. §482.41(b)(1) §482.41(c)	☐ Compliant ☐ Not Compliant All automatic transfer switches must be tested monthly, operating the transfer switch from the standard position to the alternate position and then return to the standard position. Tests shall be in accordance with NFPA 110 (2010 edition).	This standard is not met as evidenced by:
13.05.08 Medical gas shutoff valves Medical gas shutoff valves shall be labeled to reflect the rooms that are controlled by such valves. Medical gas shutoff valves must be accessible from a standing position in the corridor on the floor served by the shut-off valves, and not located behind doors or other building appurtenances. Medical gas shutoff valves must be placed such that a wall intervenes between the	☐ Compliant ☐ Not Compliant Medical gas shutoff valves must be accessible and properly labeled to assist in proper routine adjustment of systems and during emergencies.	This standard is not met as evidenced by: **OBSERVATION** Verify that: ▪ Medical gas shutoff valves are accessible and labeled. ▪ Medical gas shutoff valves are located in the corridor on the same story as the area served. ▪ Medical gas shutoff valves are located outside of the room with outlets/inlets that it controls.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
valve and the outlets/inlets that it controls. The medical gas shutoff valve must not be located in a room with a station outlet/inlet that it controls. Access to medical gas shutoff valves must not be obstructed. §482.41(b)(1) §482.41(c)		
13.05.09 Utility systems Utility systems are properly installed and maintained to a fire-safe condition. §482.41(a)	☐ Compliant ☐ Not Compliant Utility systems must be installed and maintained to a fire-safe condition. Access to electrical control panels must not be obstructed. Circuits in electrical control panels must be properly labeled as to their use. Electrical junction box covers must be properly installed. Electrical wires and cables are not permitted to be tied to conduits.	This standard is not met as evidenced by: **OBSERVATION** Verify that: ▪ Electrical control panels have proper clearance, and all circuits are labeled. ▪ Electrical junction boxes are properly covered. ▪ Electrical conduits are free of attached wires and cables.
13.05.10 Medical gas systems and equipment: Maintenance There is a routine monitoring and maintenance system for oxygen, compressed air, and vacuum systems and equipment. Hospital medical gas systems and equipment must be installed,	☐ Compliant ☐ Not Compliant Storage of compressed medical gas cylinders is limited as follows: ▪ Up to 300 cubic feet per smoke compartment is permitted to be stored outside of a designated room provided the cylinders are properly secured.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Observe hospital's storage areas of compressed medical gas cylinders during building tour.

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inspected, tested and maintained in accordance with NFPA 99 (2012 edition) chapter 5 and chapter 11. Storage of all medical compressed gas cylinders must comply with NFPA 99, *Standard for Health Care Facilities*, 2012 edition. §482.41(c)	▪ For quantities over 300 cubic feet but less than 3,000 cubic feet per smoke compartment, cylinders must be stored outside the facility or within an interior room with limited combustible construction with a door that can be secured against unauthorized entry. ▪ Oxidizing gases must be separated from combustibles a minimum of 20 feet in non-sprinklered areas; or five feet in sprinklered areas; or in an enclosed cabinet of non-combustible construction having a minimum fire protection rating of ½-hour. ▪ For rooms containing gas manifold systems, or storage rooms of compressed gas cylinders in total quantities of 3,000 cubic feet or greater, the room must meet the following conditions: □ Walls having a minimum of one-hour fire resistive rating. □ Door assemblies having a minimum of one-hour fire resistive rating. □ Doors must be self-closing, positive latching and be secured. □ All electrical devices must be protected from physical damage or located a minimum of 60 inches above the floor. □ If heated, must be by indirect means. □ Racks and chains or other fastening devices must be present to secure all cylinders. □ A constant mechanical ventilation system with its inlet no more than 12 inches above the floor, or where natural ventilation is used in lieu of mechanical ventilation, it must consist of two louvered openings, each having a minimum free area of 72 square inches, with one located within 12 inches above the floor and the other located within 12 inches of the ceiling. □ Mechanical ventilation must be at the rate of 1 cfm/5 cubic feet of designed stored gas, but no less than 50 cfm and no more than 500 cfm.	▪ Review hospital's policy on inspection, testing, and maintenance on medical gas systems, including alarm panels. ▪ Examine testing and inspection records for evidence of routine inspections and documentation of the hospital's monitoring and maintenance program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Flammable liquids, gases and vapors are not permitted to be stored with oxidizing gases. ▪ Rooms containing gas manifold systems are not permitted to be used for any other purpose. ▪ The gas content of medical piping systems must be readily identifiable with appropriate labeling with the name of the gas contained. Labels must appear on piping at intervals of not more than 20 feet, and at least once in each room and each story traversed by the piping system. Medical gas systems, including master alarm panels and branch alarm panels must be inspected, tested, and maintained according to the hospital's policy, which is consistent with NFPA 99 (2012 edition) chapter 5. For inspection and testing frequency intervals greater than one year, a risk assessment must demonstrate no adverse implications based on historical evidence.	
13.05.11 Cooking hood cleaning Kitchen cooking exhaust hoods and associated equipment are inspected and cleaned on a semi-annual basis. §482.41(b)(1)	☐ Compliant ☐ Not Compliant Kitchen cooking hoods are designed to capture air-born grease from the foods that are prepared underneath the canopies. The filters, traps, hoods, exhaust duct, and exhaust fans are required to be inspected and cleaned in accordance with NFPA 96 (2011 edition). Fusible links must be removed and replaced with new fusible links during every semi-annual cleaning. Used fusible links must be destroyed so they cannot be used again. Listed hoods containing mechanical or fire-actuated dampers, internal washing components, or other mechanically operated devices shall be inspected and tested by properly trained, qualified, and certified persons every six months or at frequencies recommended by the manufacturer in	This standard is not met as evidenced by: **OBSERVATION** ▪ Review documentation to ensure the organization inspected and cleaned their cooking hood exhaust system(s) on a semi-annual basis.

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accordance with their listings.

13.05.12 Health Care Facilities Code

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Except as otherwise provided in this section, the hospital must meet the applicable provision and must proceed in accordance with the Health Care Facilities Code (NFPA 99-2012 edition, and Tentative Interim Amendments TIA-12-2, TIA 12-3, TIA 12-4, TIA 12-5 and TIA 12-6).

Chapters 7, 8, 12 and 13 of the adopted Health Care Facilities Code do not apply to a hospital.

If application of the Health Care Facilities Code required under this section would result in an unreasonable hardship for the hospital, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of the patients.

§482.41(c)
§482.41(c)(1-2)

NFPA 99, 2012 edition, has standards that apply design and operating conditions for a variety of health care mechanical systems, such as medical gas systems, electrical systems, HVAC systems, electrical equipment, gas equipment, hyperbaric facilities, and additional information useful for the operation of a healthcare facility.

NFPA 99 does apply to all health care facilities, with the exception of home care. Construction and equipment requirements referenced in NFPA 99 do apply to new construction and new equipment, unless otherwise stated in the individual chapters. Existing conditions must comply with either NFPA 99-2012, or the edition of NFPA 99 that was adopted by CMS at the time of the equipment or component installation.

Only the altered, renovated, or modernized portion of an existing system or individual component shall be required to meet the installation and equipment requirements stated in NFPA 99-2012.

An existing system that is not in strict compliance with NFPA 99 shall be permitted to be continued in use, unless the authority having jurisdiction (i.e., CMS or ACHC) has determined that such use constitutes a distinct hazard to life.

Certain building systems in health care facilities must be designed to meet Category 1 through Category 4 requirements as detailed in Chapter 4 of NFPA 99-2012. Each system must be evaluated for its potential impact on both the patients and the caregivers if the system should fail. Based on worst-outcome scenario of a failure's impact, the system is assigned a category. The chapter on that particular building system then describes the requirements for the selected category. The four levels of system categories

OBSERVATION AND DOCUMENT REVIEW

Note: ACHC has specific standards regarding medical gas equipment, medical gas systems, utility systems, and emergency power generators that are also referenced in NFPA 99. Deficiencies with those specific systems and equipment should be scored under those explicit Standards. Other deficiencies observed pertaining to NFPA 99 issues may be scored under this standard.

- Confirm the organization has conducted the necessary risk assessments on the building services listed, to determine the Category designation of the risk of that system to the patient and caregiver.
- Confirm the organization's Safety Committee has reviewed and approved the Category designations for the listed building services.

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as defined by Chapter 4 of NFPA 99-2012 are based on the risks to patients and caregivers in the facility.

Therefore, a risk assessment is required for certain building systems that the organization has, based on a documented defined procedure. HFAP does not prescribe what format the risk assessment must follow, but NFPA 99-2012 recommends the following documents:
ISO/IEC 31010 Risk Management – Risk Assessment Techniques

- NFPA 551 Guide for the Evaluation of Fire Risk Assessments
- SEMI S10-0307E Safety Guidelines for Risk Assessment and Risk Evaluation Process
- Other formal process

The results of the risk assessment procedure must be documented and the records reviewed and approved by the organization's Safety Committee.

All risk assessments must be available for review during a survey.

Only the following building systems are required to be evaluated for categories in a risk assessment:

- Gas and vacuum systems
- Electrical systems
- HVAC systems
- Electrical equipment
- Gas equipment

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OPERATING FEATURES

13.06.01 Decorations

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Combustible decorations are not permitted in the healthcare occupancy unless one of the following criteria is met:

1. They are flame-retardant or are treated with approved fire-retardant coating.
2. The decoration meets the requirements of NFPA 701, *Standard Methods of Fire Tests for Flame Propagation of Textiles and Films,* 2010 edition.
3. The decorations, such as photographs, paintings and other art, are attached directly to the walls and ceiling (but not to the doors) in accordance with the following:
   - □ The decorations do not interfere with the operation of any exit or exit access openings.
   - □ The decorations do not exceed 20 percent of the wall and ceiling area inside any room or space of a smoke compartment that is not protected throughout by automatic sprinklers.
   - □ The decorations do not exceed 30 percent of the wall and ceiling area

Combustible decorations consist of any material that could support flame, and if they are not flame retardant, then they are not permitted unless they meet the provisions of this standard.

Doors, whether they are doors to an exit access or doors to an actual exit may not be covered, obstructed, or otherwise visually obscured with coverings, furnishings, or decorations

OBSERVATION

- During the building tour, observe areas for combustible decorations. If hospital claims they are fire retardant, they must have documentation to demonstrate compliance.
- For combustible decorations that are attached directly to the wall or ceiling, calculate the amount of surface covered by the decorations and compare to the total surface of the wall and ceiling in that area or room.

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inside any room or space of a smoke compartment that is protected throughout by automatic sprinklers.

- □ Decorations do not exceed 50 percent of the wall and ceiling area inside patient sleeping rooms having a capacity not exceeding four persons in a smoke compartment that is protected throughout by automatic sprinklers.

4. The decorations are photographs or paintings in such limited quantities that a hazard of fire development or spread is not present.

Exit access doors and exit doors are free from hangings, mirrors, decorations, or curtains that could obscure or confuse the direction of exit.

§482.41(b)(1)

13.06.02 Trash receptacles

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Trash receptacles and soiled linen hoppers exceeding 32-gallon capacity must be stored in an approved hazardous room.

§482.41(b)(4)

An accumulative total capacity of trash receptacles shall not exceed 32 gallons in any 64 square foot area, outside of a hazardous room.

Containers used solely for recycling clean waste or for patient records awaiting destruction are excluded from meeting this standard provided all the following are met:

- Each container is limited to a maximum capacity of 96 gallons;
- Containers must be labeled and listed as meeting FM Approval

OBSERVATION

- During the building tour, observe if any trash receptacles that exceed 32 gallons are not stored in a hazardous room.
- Where multiple trash receptacles less than 32 gallons each are

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	standard 6921 or equal. ▪ Containers with capacities greater than 96 gallons must be located in a room protected as a hazardous area when not attended.	accumulated, determine whether they exceed 32-gallon capacity in a given 64 square foot area. ▪ For containers containing clean waste or patient records awaiting destruction, confirm the capacity of the container does not exceed 96 gallons, and is labeled as meeting FM Approval 6921, or equal.
13.06.03 Portable heaters Portable heaters with elements that exceed 212°F are not permitted inside a healthcare occupancy. Portable electric heaters with elements that do not exceed 212°F are not permitted in a smoke compartments containing patient sleeping or treatment areas. §482.41(a)	☐ Compliant ☐ Not Compliant No additional information	This standard is not met as evidenced by: **OBSERVATION** ▪ During the building tour, look under work stations, in storage rooms, and patient rooms for portable space heaters.
13.06.04 Life Safety drawings Basic drawings of the facility indicating the following features are required: ▪ Rated walls and barriers, including their fire rating ▪ Exit, exit enclosure, horizontal	☐ Compliant ☐ Not Compliant Basic Life Safety drawings are critical to the maintenance of life safety features in the hospital. Life Safety drawings must include the basic information identified in the standard and may include additional information that is pertinent to the life safety features. However, background clutter such as column lines, furniture	This standard is not met as evidenced by: **OBSERVATION** ▪ Review the Life Safety drawings before starting the building tour. The hospital's representatives must be able to interpret the drawings and be

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exit, and exit discharge

- Suite-of-rooms, their boundaries and total area
- Hazardous rooms
- Smoke barriers separating smoke compartments, the total area of each smoke compartment, and the farthest travel distance to the closest smoke barrier door
- The farthest travel distance to the closest exit
- Areas of the facility that are and are not protected with sprinklers
- Smoke partitions

The condition of the physical plant and the overall hospital environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. The Life Safety Drawings are required as a guide for determination of how the organization provides compliance.

These Life Safety Drawings are available for review by the surveyor.

§482.41(a)
§482.41(b)(1)

and cabinets are not desirable.

Hospital staff must be able to answer all questions concerning the Life Safety drawings.

Smoke partitions are barriers that are required to resist the passage of smoke but are not necessarily required to have a fire resistive rating.

Examples where smoke partitions are located, are:

- Corridor walls and suite enclosure walls in fully sprinklered smoke compartments.
- Hazardous room barriers in existing conditions where the hazardous room is protected with sprinklers.

able to answer questions that may arise.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.06.05 Alcohol based hand-rub dispensers Alcohol based hand-rub (ABHR) dispensers are permitted to be installed in exit access corridors of healthcare occupancies, and ambulatory health care occupancies. §482.41(a) §482.41(b)(7)	☐ Compliant ☐ Not Compliant ABHR dispensers are required to be protected in accordance with 8.7.3.1 of the 2012 Life Safety Code, unless all of the following restrictions for ABHR dispenser in healthcare occupancy corridors, are met: ▪ The corridor must be at least 6 feet wide. ▪ Maximum dispenser quantity is 1.2 liters in rooms, corridors and areas open to corridors. ▪ Maximum dispenser quantity is 2.0 liters in suites of rooms. ▪ ABHR dispensers must be separated by at least 4 feet. ▪ No more than 10 gallons aggregate total of ABHR solution in use per smoke compartment. NOTE: One ABHR dispenser per room or suite is not included in the aggregate total quantity per smoke compartment. ▪ No more than five gallons of ABHR solution per smoke compartment is allowed to be stored outside of a cabinet which meets NFPA 30. ▪ ABHR dispensers shall not be installed over or within one inch (side-to-side) to an ignition source. ▪ In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments. ▪ In corridors of at least six feet in width, maximum corridor projection is four inches. ▪ The ABHR dispensers must be installed in a manner that protects against inappropriate access.	This standard is not met as evidenced by: **OBSERVATION AND INTERVIEW** ▪ During the building tour, observe ABHR dispenser locations for compliance. ▪ Ask facility representative if they know if they have no more than 10 gallons of ABHR solution in dispensers per smoke compartment.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

COMPLIANCE RESOURCES

13.07.01 CMS Resources

The CMS standards stated herein are enforceable as if reproduced in their entirety within this standard and are incorporated by reference as approved by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may inspect a copy at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA).

§482.15(h)

Not scored at this Standard

For information on the availability of this material at NARA, call 202.741.6030, or go to:

http://www.archives.gov/federal_register/code_of_federal_regulations/ibr_locations.html

If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the Federal Register to announce the changes.

National Fire Protection Association,
1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 617.770.3000.

(i) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011;

(ii) TIA 12-2 to NFPA 99, issued August 11, 2011.

(iii) TIA 12-3 to NFPA 99, issued August 9, 2012.

(iv) TIA 12-4 to NFPA 99, issued March 7, 2013.

(v) TIA 12-5 to NFPA 99, issued August 1, 2013.

(vi) TIA 12-6 to NFPA 99, issued March 3, 2014.

(vii) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(viii) TIA 12-1 to NFPA 101, issued August 11, 2011.

(ix) TIA 12-2 to NFPA 101, issued October 30, 2012.

(x) TIA 12-3 to NFPA 101, issued October 22, 2013.

(xi) TIA 12-4 to NFPA 101, issued October 22, 2013.

(xii) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

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14

ORGAN PROCUREMENT

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.00.00 CONDITION OF PARTICIPATION: Organ, tissue, and eye procurement §482.45	☐ Compliant ☐ Not Compliant The hospital must ensure the specific organ, tissue, and eye procurement requirements are met.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify the facility has an effective organ procurement program in place that includes all required elements. ▪ If facility has no Organ Procurement Organization (OPO), Tissue Bank, or Eye Bank agreement, cite as Condition-level non-compliance.
14.00.01 Organ/tissue donation and transplantation *The hospital must have and implement written protocols that:* *Incorporate an agreement with an OPO (Organ Procurement Organization), under 42 CFR 486.322, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the hospital.* ▪ *The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of*	☐ Compliant ☐ Not Compliant The hospital must have a written agreement to address: ▪ The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the hospital. ▪ A definition of "imminent death." ▪ A definition of "timely notification." ▪ The OPO's responsibility to determine medical suitability for organ donation. ▪ How the tissue and/or eye bank will be notified about potential donors using notification protocols developed by the OPO in consultation with the hospital-designated tissue and eye bank(s). ▪ Notification of each individual death in a timely manner to the OPO (or designated third party) in accordance with the terms of the agreement. ▪ The designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The hospital's written agreement with the OPO addresses all required information. ▪ The hospital's governing body has approved the organ procurement policies. ▪ Death records reflect that the hospital has implemented its organ procurement policies. ▪ Through staff interviews awareness of the hospital's policies and procedures for organ, tissue, and eye procurement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose. §482.45(a) §482.45(a)(1)	by the hospital. ▪ The OPO, tissue bank, and eye bank are permitted access to the hospital's death record information according to a designated schedule, e.g., monthly or quarterly. ▪ The hospital is not required to perform credentialing reviews for, or grant privileges to, members of organ recovery teams as long as the OPO sends only "qualified, trained individuals" to perform organ recovery. ▪ Interventions the hospital will use to maintain potential organ donor patients so that the patient organs remain viable. When death is imminent, the hospital must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable. **IMMINENT DEATH** The hospital should have a written policy, developed in coordination with the OPO and approved by the hospital's medical staff and governing body, to define imminent death. The definition for imminent death should strike a balance between the needs of the OPO and the needs of the hospital's care givers to continue treatment of a patient until brain death is declared or the patient's family has made the decision to withdraw supportive measures. Collaboration between OPOs and hospitals will create a partnership that furthers donation, while respecting the perspective of hospital staff. The definition for imminent death might include a patient with severe, acute brain injury who: ▪ Requires mechanical ventilation. ▪ Is in an intensive care unit (ICU) or emergency department AND ▪ Exhibits clinical findings consistent with a Glascow Coma Score that is less than or equal to a mutually-agreed-upon threshold.	▪ The organ, tissue, and eye donation program is integrated into the hospital's QAPI program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- MD/DO are evaluating a diagnosis of brain death.
- MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.

Hospitals and their OPO should develop a definition of imminent death that includes specific triggers for notifying the OPO about an imminent death.

In determining the appropriate threshold for the Glascow Coma Score (GCS), it is important to remember that if the threshold is too low, there may be too many "premature" deaths or situations where there is a loss of organ viability. Standards for appropriate GCS thresholds may be obtained from the hospital's OPO or organizations such as The Association of Organ Procurement Organizations.

Note that a patient with "severe, acute brain injury" is not always a trauma patient. For example, post myocardial infarction resuscitation may result in a patient with a beating heart and no brain activity.

The definition agreed to by the hospital and the OPO may include all of the elements listed above or just some of the elements. The definition should be tailored to fit the circumstances in each hospital.

Hospitals may not use "batch reporting" for deaths by providing the OPO with periodic lists of patient deaths, even if instructed to do so by the OPO. If the patient dies during a transfer from one hospital to another, it is the receiving hospital's responsibility to notify the OPO.

TIMELY NOTIFICATION

"Timely notification" means a hospital must contact the OPO by telephone as soon as possible after an individual has died, has been placed on a ventilator due to a severe brain injury, or who has been declared brain dead (ideally within one hour). That is, a hospital must notify the OPO while a brain dead or severely brain-injured, ventilator-dependent individual is still attached to the ventilator and as soon as possible after the death of any other individual, including a potential non-heart-beating donor.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Even if the hospital does not consider an individual who is not on a ventilator to be a potential donor, the hospital must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a hospital to an OPO is timely if it is made:

- As soon as it is anticipated that a patient will meet the criteria for imminent death agreed to by the OPO and hospital or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the hospital (ideally, within one hour)

AND

- Prior to the withdrawal of any life sustaining therapies (i.e., medical or pharmacological support).

Whenever possible, referral should be made early enough to allow the OPO to assess the patient's suitability for organ donation before brain death is declared and before the option of organ donation is presented to the family of the potential donor.

Timely assessment of the patient's suitability for organ donation increases the likelihood that the patient's organs will be viable for transplantation (assuming there is no disease process identified by the OPO that would cause the organs to be unsuitable), assures that the family is approached only if the patient is medically suitable for organ donation, and assures that an OPO representative is available to collaborate with the hospital staff in discussing donation with the family.

It is the OPO's responsibility to determine medical suitability for organ donation, and, in the absence of alternative arrangements by the hospital, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the hospital for this purpose.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.00.02 OPO waiver requests *A hospital may request and CMS may grant a waiver permitting the hospital to have an agreement with a designated OPO other than the OPO designated for the service area in which the hospital is located.* §486.316(e)	☐ Compliant ☐ Not Compliant A waiver would allow the hospital to have an agreement with an "out-of-the-areas" OPO if it meets the following criteria in the statute (Section 1138(a)(2)(a)(i)(ii)). To qualify for a waiver, the hospital must submit data to CMS establishing that: 1. The waiver is expected to increase organ donations. 2. The waiver will ensure equitable treatment of patients referred for transplants within the service area served by the hospital's designated OPO and within the service area served by the OPO with which the hospital seeks to enter into an agreement.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the waiver agreement from the Secretary of HHS to determine when, and why, it was issued and the period for which it was granted.
14.00.03 Tissue and eye bank agreements *The hospital must have and implement written protocols that:* ▪ *Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage, and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such agreement does not interfere*	☐ Compliant ☐ Not Compliant The OPO may serve as a "gatekeeper" receiving notification about every hospital death and should notify the tissue bank or eye bank chosen by the hospital about potential tissue and eye donors. It is not necessary for a hospital to have a separate agreement with a tissue bank if it has an agreement with its OPO to provide tissue procurement services; nor is it necessary for a hospital to have a separate agreement with an eye bank if its OPO provides eye procurement services. The hospital is not required to use the OPO for tissue or eye procurement but is free to have an agreement with the tissue bank or eye bank of its choice. The tissue banks and eye banks define "usable tissues" and "usable eyes." The requirements of this regulation may be satisfied through a single agreement with an OPO that provides services for organ, tissue, and eye, or by a separate agreement with another tissue and/or eye bank outside the	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the hospital has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all potential tissue and eye donors, or an agreement with an OPO that specifies the tissue bank and eye bank to which referrals will be made. ▪ The agreement should also acknowledge that it is the OPO's responsibility to determine medical suitability for tissue and eye donation

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
with organ procurement. §482.45(a)(2)	OPO, chosen by the hospital. The hospital may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.	unless the hospital has an alternative agreement with a different tissue and/or eye bank.
14.00.04 Informed consent requirements *The hospital must have and implement written protocols that:* ▪ *Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to donate organs, tissues, or eyes, or to decline to donate.* §482.45(a)(3)	☐ Compliant ☐ Not Compliant It is the responsibility of the OPO to screen for medical suitability in order to select potential donors. Once the OPO has selected a potential donor, that person's family must be informed of the family's donation options. Ideally, the OPO and the hospital will decide together how and by whom the family will be approached.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the hospital ensures that the family of each potential donor is informed of its options to donate organs, tissues, or eyes, including the option to decline to donate. ▪ Does the hospital have QAPI mechanisms in place to ensure that the families of all potential donors are informed of their options to donate organs, tissues, or eyes, or to decline to donate?
14.00.05 Designated requestors *The individual designated by the hospital to initiate the request to the family must be an organ procurement representative or a designated requestor.* *A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank*	☐ Compliant ☐ Not Compliant Any individuals involved in a request for organ, tissue, and eye donation must be formally trained in the donation request process. A "designated requestor" is defined as a hospital-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community which addresses methodology for approaching potential donor families. Ideally, the OPO and the hospital will decide together how and by whom the	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review hospital records to establish whether hospital staff request organ donation. □ If so, review training schedules and personnel files to verify that all designated requestors have completed the required training.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
community in the methodology for approaching potential donor families and requesting organ or tissue donation. §482.45(a)(3)	family will be approached. Research has shown that the highest consent rates occur when the OPO and hospital staff approaches the family together. If collaboration is not possible, the hospital decides who approaches the family to provide information, discuss the family's options, and request donation. The hospital may have chosen to have an organ procurement coordinator from the OPO approach the family or may choose to have a "designated requestor" approach the family.	▪ Review employee records to determine if individuals involved in organ/tissue/eye donation have received formal training in the consent process for donation. ▪ How does the hospital ensure that only OPO, tissue bank, or eye bank staff or designated requestors are approaching families to ask them to donate? ▪ Does hospital staff know if there has been an improvement in donations?
14.00.06 Sensitivity training	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital must have and implement written protocols that: ▪ *Encourages discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors.* §482.45(a)(4)	Using discretion does not mean a judgment can be made that certain families should not be approached about donation. Hospitals should approach the family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The hospital staff's perception that a family's grief, race, ethnicity, religion or socioeconomic background would prevent donation should never be used as a reason not to approach a family. All potential donor families must be approached and informed of their donation rights.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Review training plans and ensure they encourage discretion. ▪ Review the designated requestor training program to verify that it addresses the use of discretion. ▪ Review the hospital's complaint file for any relevant complaints. ▪ Verify through staff interviews that there has been sensitivity training regarding the process. ▪ Interview a hospital-designated

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

requestor regarding approaches to donation requests.

14.00.07 OPO responsibilities

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

*The hospital must have and implement written protocol**s** that:*

- *Ensure that the hospital works cooperatively with the designated OPO, tissue bank and eye bank in:*
  - □ *Educating staff on donation issues.*
  - □ *Reviewing death records to improve identification of potential donors.*
  - □ *Maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.*

§482.45(a)(5)

Appropriate hospital staff, including all patient care staff, must be trained on donation issues. The training program must be developed in cooperation with the OPO, tissue bank and eye bank, and should include, at a minimum:

- Consent process.
- Importance of using discretion and sensitivity when approaching families.
- Role of the designated requestor.
- Transplantation and donation, including pediatrics, if appropriate.
- Quality improvement activities.
- Role of the organ procurement organization.

Training should be conducted with new employees annually, whenever there are policy/procedure changes, or when problems are determined through the hospital's QAPI program.

Those hospital staff who may have to contact or work with the OPO, tissue bank and eye bank staff must have appropriate training on donation issues including their duties and roles.

Hospitals must cooperate with the OPOs, tissue banks and eye banks in regularly or periodically reviewing death records. This means that the hospital must develop policies and procedures which permit the OPO, tissue bank, and eye bank access to death record information that will allow the OPO, tissue bank and eye bank to assess the hospital's donor potential, assure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the hospital, OPO, tissue bank and eye bank staff

INTERVIEW AND DOCUMENT REVIEW

- Review staff training schedules and attendance sheets to verify that the hospital ensures that all appropriate staff has attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank.
- Request protocols related to death record review.
  - □ Who reviews the records and how often are reviews done?
- Request recorded examples of maintaining potential donors.
- Verify by review of policies and records that the hospital works with the OPO, tissue bank, and eye bank in reviewing death records.
- Verify that the effectiveness of any protocols and policies is monitored as part of the hospital's quality improvement program.
- Determine how confidentiality is

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	performance might be improved. The policies must address how patient confidentiality will be maintained during the review process. The hospital must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that maintains the viability of their organs. The hospital must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.	ensured. ▪ Determine by review, what policies and procedures are in place to ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe. ▪ Verify that there are policies and procedures in place to ensure the coordination between facility staff and OPO staff in maintaining the potential donor.
14.00.08 Organ transplant facilities *A hospital in which organ transplants are performed must be a member of the Organ Procurement and Transplantation Network (OPTN) established and operated in accordance with section 372 of the Public Health Service (PHS) Act (42 U.S.C. 274) and abide by its rules.* *The term "Rules of the OPTN" means those rules provided for in regulations issued by the Secretary in accordance with section 372 of the PHS Act which are enforceable under 42 CFR 121.10. No hospital is considered to be out of compliance with section 1138(a)(1)(B) of the Act (Social Security Act), or with the requirements of*	☐ Compliant ☐ Not Compliant If you have questions concerning the facility membership in the Organ Procurement and Transplantation Network; you may verify the membership by contacting the CMS regional office or by calling the United Network for Organ sharing (UNOS) at 1-804-330-8500.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the hospital is an active Organ Procurement Organization member of a regional affiliate of an OPTN by reviewing documentation. ▪ Verify that there are current copies of all communications from the OPTN regarding standards and regulations impacting procurement and transplant activities. ▪ Review one year of reports submitted by the facility to the OPTN, the Scientific Registry, the OPOs, and any data submitted to the Department per

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
this paragraph, unless the Secretary has given the OPTN formal notice that he or she approves the decision to exclude the hospital from the OPTN and has notified the hospital in writing. §482.45(b) §482.45(b)(1) *For the purpose of these standards, the term "organ" means a human kidney, liver, heart, lung, or pancreas.* §482.45(b)(2)		request of the Secretary.
14.00.09 Data collection and reporting *If a hospital performs any type of transplants, it must provide organ-transplant-related data, as requested by the OPTN, the Scientific Registry, and the OPOs.* *The hospital must also provide data directly to the Department of Health and Human Services when requested by the Secretary.* §482.45(b)(3)	☐ Compliant ☐ Not Compliant If you have questions concerning the facility membership in the Organ Procurement and Transplantation Network; you may verify the membership by contacting the CMS regional office or by calling the United Network for Organ sharing (UNOS) at 1-804-330-8500.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review one year of reports submitted by the facility to the OPTN, the Scientific Registry, the OPOs, and any data submitted to the Department per request of the Secretary to verify: □ The facility submits reports to the OPTN, the Scientific Registry, and the OPOs. □ The facility submits data, as requested, to CMS.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.00.10 Confidentiality of patient records Hospitals and OPOs *must have procedures for ensuring the confidentiality of patient records.* §482.24(b)(3) §486.306(o)	☐ Compliant ☐ Not Compliant Processes are in place to insure the patient records and information exchanged among the hospitals and OPOs remains confidential and is not accessed by unauthorized individuals. Unauthorized individuals are those individuals not directly involved as employees of the hospital or OPO in facilitating organ donation or transplantation.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review hospital procedures to verify that a process is in place for ensuring confidentiality of patient records exchanged with the OPO. ▪ Interview staff for how information is shared and protected. Check for complaints about any lack of confidentiality.

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PATIENT RIGHTS AND SAFETY

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
15.00.00 CONDITION OF PARTICIPATON: Patients' rights *A hospital must protect and promote each patient's rights.* §482.13	☐ Compliant ☐ Not Compliant Protection of patient's rights is demonstrated through privacy, safety, confidentiality of records, the grievance process, advance directives, participation in the plan of care, and **clinically appropriate** use of restraints or seclusion. These requirements apply to all Medicare or Medicaid participating hospitals including short-term, acute care, surgical, specialty, psychiatric, rehabilitation, long-term, children's and cancer, whether or not they are accredited. This rule does not apply to critical access hospitals. (See Social Security Act (the Act) §1861(e)) These requirements, as well as the other Conditions of Participation in 42 CFR §482, apply to all parts and locations (outpatient services, provider-based entities, inpatient services) of the Medicare participating hospital.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ The hospital protects and promotes each patient's rights throughout the facility. **Note:** This full Condition of Participation (CoP) applies to all 42 CFR §482.13 standards listed within this chapter. Survey of the Patients' Rights (CoP) is coordinated by one surveyor. However, each member of the survey team, as he/she conducts his/her survey assignments, should assess the hospital's compliance with the Patients' Rights CoP.
15.01.00 Notice of patient rights *A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights in advance of furnishing or discontinuing patient care whenever possible.* §482.13(a) §482.13(a)(1)	☐ Compliant ☐ Not Compliant The hospital must establish and implement policies and procedures that effectively ensure that patients and/or their representatives have the information necessary to exercise their rights. Patient's Rights are posted in clear sight for patients and visitors to view throughout the hospital and all outpatient settings. The hospital must ensure the notice of rights requirements is met. The hospital must inform each patient, or when appropriate, the patient's representative as allowed by state law, of the patient's rights.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The hospital has a policy for notifying all patients (inpatient and outpatient) of their rights. ▪ The hospital's policy provides for determining when a patient has a representative and who that

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- Whenever possible, this notice must be provided before providing or stopping care.
- All patients, inpatient or outpatient, must be informed of their rights as hospital patients.
- The patient's rights include all of those discussed in this condition, as well as any other rights for which notice is required under state or federal law or regulations for hospital patients. (See 42 CFR §482.11.)
- The patient's rights should be provided and explained in a language or manner that the patient (or the patient's representative) can understand. This is consistent with the guidance related to Title VI of the Civil Rights Act of 1964 issued by the Department of Health and Human Services- Guidance to Federal Financial Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons‖ (August 8, 2003, 68 FR 47311). In accordance with 42 CFR §482.11, hospitals are expected to comply with Title VI and may use this guidance in ensuring effective communication of patient's rights information. Surveyors do not assess compliance with these requirements on limited English proficiency but may refer concerns about possible noncompliance to the Office for Civil Rights in the applicable Department of Health and Human Services Regional Office.

PATIENT'S REPRESENTATIVE

Hospitals are expected to take reasonable steps to determine the patient's wishes concerning designation of a representative. Unless prohibited by applicable State law:

- When a patient who is not incapacitated has designated, (orally to hospital staff or in writing), another individual to be his/her representative, the hospital must provide the designated individual with the required notice of patients' rights in addition to the patient. The explicit designation of a representative takes precedence over any non-designated relationship representative is, consistent with this guidance and state law.
- Information provided to the patients by the hospital complies with federal and state law.
- Through record review and interviews, that the hospital communicates information about their rights to diverse patients, including individuals who need assistive devices or translation services.
  - □ Are alternative means, such as written materials, signs, or interpreters used to communicate when needed?
- Through record review and interview, how the hospital determines whether the patient has a representative, who that representative is, and whether notice of patients' rights is provided as required to patients' representatives.
  - □ Ask patients to tell you what the hospital has told them about their rights.
- Staff knows what steps to take to inform a patient about their rights, including those with special communication needs.
- Through review of inpatient medical records for Medicare beneficiaries, that records contain a signed and dated IM

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

and continues throughout the patient's inpatient stay or outpatient visit, unless expressly withdrawn, orally or in writing, by the patient.

- In the case of a patient who is incapacitated, when an individual presents the hospital with an advance directive, medical power of attorney or similar document executed by the patient and designating an individual to make medical decisions for the patient when incapacitated, then the hospital must, when presented with the document, provide the required notice of its policies to the designated representative. The explicit designation of a representative takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing.
- When a patient is incapacitated or otherwise unable to communicate his or her wishes, there is no written advance directive on file or presented, and an individual asserts that he or she is the patient's spouse, domestic partner (whether or not formally established and including a same-sex domestic partner), parent (including someone who has stood in loco parentis for the patient who is a minor child), or other family member and thus is the patient's representative, the hospital is expected to accept this assertion, without demanding supporting documentation, and provide the required notice to the individual, unless more than one individual claims to be the patient's representative.
  - □ If more than one individual claims to be the patient's representative or the hospital has reasonable cause to believe that an individual is falsely claiming to be the patient's spouse, domestic partner, parent, or other family member, it would be appropriate for the hospital to ask for documentation supporting the claim.

    Under these circumstances, treating one individual as the patient's representative without requesting supporting documentation could result in the hospital violating State law. State laws, including State regulations, may specify a procedure for determining who may be provided within two days of the admission of the patient.
  - □ For patients whose discharge occurred more than two days after the initial IM notice was issued, did the hospital provide another copy of the IM to the patient prior to discharge?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

considered to be the incapacitated patient's representative, and may specify when documentation is or is not required.

- □ The hospital should make its determination regarding the patient's representative based upon the hospital's determination of who the patient would most want to make decisions on his/her behalf. Examples of documentation a hospital might consider could include, but are not limited to, the following: proof of a legally recognized marriage, domestic partnership, or civil union; proof of a joint household; proof of shared or co-mingled finances; and any other documentation the hospital considers evidence of a special relationship that indicates familiarity with the patient's preferences concerning medical treatment.
- □ Hospitals are expected to adopt policies and procedures that facilitate expeditious and non-discriminatory resolution of disputes about whether an individual is the patient's representative, given the critical role of the representative in exercising the patient's rights.
- □ A refusal by the hospital of an individual's request to be treated as the patient's representative, based on one of the above-specified familial relationships, must be documented in the patient's medical record, along with the specific basis for the refusal.

According to the regulation at 42 CFR §489.27(a), (which cross references the regulation at 42 CFR 405.1205), each Medicare beneficiary who is an inpatient (or his/her representative) must be provided the standardized notice, "An Important Message from Medicare (IM)," within two days of admission.

- Medicare beneficiaries who have not been admitted (e.g., patients in observation status or receiving other care on an outpatient basis) are not required to receive the IM. The IM is a standardized, OMB-approved form and cannot be altered from its original format. The IM is to be signed and dated by the patient to acknowledge receipt.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ 42 CFR §405.1205(c) requires that hospitals present a copy of the signed IM in advance of the patient's discharge, but not more than two calendar days before the patient's discharge. ▪ In the case of short inpatient stays, however, where initial delivery of the IM is within two calendar days of the discharge, the second delivery of the IM is not required.	
15.01.01 For future use		
15.01.02 Notice and promotion of patient rights The Patient's Rights document includes, at a minimum, that the patient has: ▪ *The right to participate in the development and implementation of his or her plan of care.* §482.13(b)(1) ▪ *Or his or her representative (as allowed under state law) has the right to make informed decisions regarding his or her care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or*	☐ Compliant ☐ Not Compliant A posted and promulgated patient's rights document exists and may include additional statements of rights. Rights mandated by state or local jurisdictions, not listed, are included. Other statements may derive from organizational philosophy or be influenced by hospital ownership or affiliation. **EMERGENCY DEPARTMENT PATIENT RIGHTS** **Emergency department patient rights must be posted in a conspicuously place(s) likely to be noticed by all individuals seeking care.** **Section 1866(a)(1)(N)(iii) of the Social Security Act requires the posting of signs which specify the rights of individuals with Emergency Medical Conditions (EMCs) and women in labor.** **Suspicion of EMTALA violations would be reported to the appropriate agency within the Centers for Medicare and Medicaid Services.**	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ Posted and promulgated statements of patient's rights are congruent with these and any other known requirements. **Note**: Facility compliance with the rights listed will be scored individually in the standards following. **Noncompliance is scored at the relevant standard.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

inappropriate.

§482.13(b)(2)

- *The right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives…*

§482.13(b)(3)

- *The right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.*

§482.13(b)(4)

- *The right to personal privacy.*

§482.13(c)(1)

- *The right to receive care in a safe setting.*

§482.13(c)(2)

- *The right to be free from all forms of abuse or harassment.*

§482.13(c)(3)

- *The right to the confidentiality of his or her clinical records.*

§482.13(d)(1)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- *The right to access information contained in his or her clinical records within a reasonable time frame.*

§482.13(d)(2)

- *The right to be free from restraints of any form that are not medically necessary...*

§482.13(e)(1)

- The right to be fully informed of and to consent or refuse to participate in any unusual, experimental or research project without compromising his/her access to services.
- The right to know the professional status of any person providing his/her care/services.
- The right to know the reasons for any proposed change in the professional staff responsible for his/her care.
- The right to know the reasons for his/her transfer either within or outside the hospital.
- The right to know the relationship(s) of the hospital to other persons or organizations participating in the provision of

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

his/her care.

- The right of access to the cost, itemized when possible, of services rendered within a reasonable period of time.
- The right to be informed of the source of the hospital's reimbursement for his/her services, and of any limitations which may be placed upon his/her care.
- The right to have pain treated as effectively as possible.
- The right to receive visitors.
- The patient's family has the right of informed consent for donation of organs and tissues.

A hospital must:

- *Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.*

§482.13(h)(1)

- *Inform each patient of the right, subject to his or her consent, to receive the visitors whom he or she*

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

designates, including, but not limited to, a spouse, a domestic partner (including a same sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

§482.13(h)(2)

- *Not restrict, limit or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.*

§482.13(h)(3)

- *Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.*

§482.13(h)(4)

§489.20(q)

15.01.03 Participation in the plan of care

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The patient has the right to participate in the development and implementation of his or her plan of care.

§482.13(b)(1)

The hospital actively includes the patient in the development, implementation, and revision of his/her plan of care. The hospital plans the patient's care, with patient participation, to meet their psychological and medical needs.

The patient's right includes, at a minimum, the right to:

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

- Does the hospital have policies and procedures to involve the patient or the patient's representative (as appropriate) in the development and implementation

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ participate in the development and implementation of his/her inpatient treatment/care plan. ▪ outpatient treatment/care plan. ▪ participate in the development and implementation of his/her discharge plan ▪ participate in the development and implementation of his/her pain management plan. **Note**: For additional information regarding patients' representatives, see standards 15.01.00.	of his/her inpatient treatment/care plan, outpatient treatment/care plan, discharge plan, and pain management plan? ▪ Review records and interview staff and patients, or patients' representatives (as appropriate), to determine how the hospital involves the patient or their representative in the development and implementation of his/her plan of care? ▪ Does the hospital's policy provide for determining when a patient has a representative who may exercise the patient's right to participate in developing and implementing his/her plan of care? ▪ Is there evidence that the patient or the patient's representative was included or proactively involved in the development and implementation of the patient's plan of care? ▪ Were revisions in the plan of care explained to the patient and/or the patient's representative (when appropriate)?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

15.01.04 Participation in decision making

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her care.

The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment.

This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

§482.13(b)(2)

The right to make informed decisions means that the patient or patient's representative is given the information needed to make informed decisions regarding his/her care.

PATIENT'S REPRESENTATIVE

A patient may wish to delegate his/her right to make informed decisions to another person (as allowed under State law).

Hospitals are expected to take reasonable steps to determine the patient's wishes concerning designation of a representative.

Note: For additional information regarding patients' representatives, see standard 15.01.00.

The right to make informed decisions regarding care presumes that the patient has been provided information about his/her health status, diagnosis, and prognosis.

This right includes the patient's participation in the development of their plan of care, including providing consent to, or refusal of, medical or surgical interventions, and in planning for care after discharge from the hospital. The patient or the patient's representative should receive adequate information, provided in a manner that the patient or their representative can understand, to assure that the patient can effectively exercise the right to make informed decisions.

Note: See standard 30.00.11 [§482.51(b)(2)] pertaining to surgical services informed consent, for standard 10.01.15 [§482.24(c)(2)(v)] pertaining to medical records [and for §482.43(c) pertaining to discharge planning] for further detail.

Hospitals must also establish policies and procedures that assure a patient's

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

Verify:

- Hospital policy addresses the patient's or the patient's representative's (as appropriate) right to make informed decisions?
  - □ Does it articulate how the hospital assures patients' ability to exercise this right?
  - □ Does the policy provide for determining when a patient has a representative who may exercise the right to make informed decisions, and who that representative is, consistent with this guidance and state law?
  - □ Does it address the patient's right to have information on his/her medical status, diagnosis, and prognosis?
- That the hospital routinely complies with its policy.
  - □ Review medical records, interview current patients and/or hospital personnel to determine their understanding of the hospital's informed decision-making policies

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

right to request or refuse treatment. Such policies should indicate how the patient's request will be addressed. However, hospitals are under no obligation to fulfill a patient's request for a treatment or service that the responsible practitioner has deemed medically unnecessary or even inappropriate.

REQUIRED HOSPITAL DISCLOSURES TO PATIENTS

Physician Ownership

Provisions of the Medicare provider agreement rules concerning disclosures that certain hospitals are required to make:

- 42 CFR §489.3 defines a "physician-owned hospital" as any participating hospital in which a physician or physicians have an ownership or investment interest, except for those satisfying exception criteria found at 42 CFR §411.356(a) or (b). Surveyors are not required to make an independent determination regarding whether a hospital meets the Medicare definition of "physician-owned," but they must ask whether the hospital is physician-owned.
- 42 CFR §489.20(u)(1) requires that all physician-owned hospitals provide written notice to their patients at the beginning of each patient's hospital inpatient stay or outpatient visit stating that the hospital is physician-owned, in order to assist the patient in making an informed decision about his/her care, in accordance with requirements of 42 CFR §482.13(b)(2).
- A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or for an outpatient service subject to notice. An unplanned inpatient stay or outpatient visit subject to the notice requirement begins at the earliest point at which the patient presents to the hospital.
- The notice must disclose, in a manner reasonably designed to be understood by all patients, that the hospital is physician-owned and

and how they are implemented.

- □ Determine whether patients/ patient representatives are provided adequate information about the patient's medical status, diagnosis, and prognosis, and then allowed to make informed decisions about their care planning and treatment.

- Review records and interview staff and patients or patients' representatives (as appropriate) to verify the hospital assures the patient or the patient's representative (as appropriate) ability to exercise the right to make informed decisions.

ASSESSING REQUIRED DISCLOSURES

Physician Ownership:

If the hospital indicates that it is physician-owned but is exempt under §489.20(v) from the disclosure requirement of §489.20(u)(2), review the signed attestation that it does not have any referring physicians with an ownership/ investment interest or whose immediate family member has an ownership/investment interest in the hospital.

Note: As with any other on-the-spot correction of a deficiency during a

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

that the list of physician owners or investors is available upon request. If the patient (or someone on behalf of the patient) requests this list, the hospital must provide it at the time of the request.

- However, the notice requirement does not apply to any physician-owned hospital that does not have at least one referring physician (as defined at 42 CFR §411.351) who has an ownership or investment interest in the hospital or who has an immediate family member who has an ownership or investment interest in the hospital. In such cases, the hospital must sign an attestation statement that it has no referring physician with an ownership or investment interest or whose immediate family member has an ownership or investment interest in the hospital. The hospital must maintain this attestation in its records.
- 42 CFR 489.20(u)2) provides that physician-owned hospitals must require each physician owner who is a member of the hospital's medical staff to agree, as a condition of obtaining/retaining medical staff membership or admitting privileges, to disclose in writing to all patients they refer to the hospital their ownership or investment interest in that hospital or that of any immediate family member. The hospital must require that this disclosure be made at the time of the referral and the requirement should be reflected in the hospital's policies and procedures governing privileges for physician owners.
- The hospital may exempt from this disclosure requirement any physician owner who does not refer any patients to the hospital.
- 42 CFR 489.12 permits CMS to refuse to enter into a provider agreement with a physician-owned hospital applicant that does not have procedures in place to notify patients of physician ownership in the hospital as required under §489.20(u).
- 42 CFR 489.53(c) permits CMS to terminate a provider agreement with a physician-owned hospital if the hospital fails to comply with the requirements at §489.20(u).

survey, creation of an attestation at the time of a survey does not mean that there was no deficiency and that the hospital would not be cited.

If the hospital is physician-owned but not exempt from the physician ownership disclosure requirements:

- Verify that appropriate policies and procedures are in place to assure that necessary written notices are provided to all patients at the beginning of an inpatient or outpatient stay.
  - □ Review the notice the hospital issues to each patient to verify that it discloses, in a manner reasonably designed to be understood by all patients, that the hospital meets the Federal definition of "physician-owned," that a list of owners and investors who are physicians or immediate family members of physicians is available upon request, and that such a list is provided to the patient at the time the request is made by or on behalf of the patient.
  - □ Determine through staff interviews, observation, and a review of policies and procedures whether the hospital furnishes its list of physician owners and investors at

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	PHYSICIAN ON-SITE PRESENCE 42 CFR 489.20(w) mandates that if there is no MD or DO present in the hospital 24 hours per day, seven days per week, the hospital must provide written notice of this to all inpatients at the beginning of a planned or unplanned inpatient stay, and to outpatients for certain types of planned or unplanned outpatient visits. The purpose of this requirement is to assist the patient in making an informed decision about his/her care, in accordance with 42 CFR 482.13(b)(2). Hospitals that have an MD/DO on-site 24/7 (including residents who are MDs or DOs) do not need to issue any disclosure notice about emergency services capability. ▪ The notice must be provided to all inpatients and to those outpatients who are under observation or who are having surgery or any other procedure using anesthesia. ▪ The notice must be provided at the beginning of the planned or unplanned inpatient stay, or outpatient visit subject to notice. ▪ A planned inpatient stay or outpatient visit which is subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned hospital admission for inpatient care or for an outpatient service subject to notice. ▪ An unplanned inpatient stay or outpatient visit which is subject to the notice requirement begins at the earliest point at which the patient presents to the hospital. ▪ Individual notices are not required in the hospital's dedicated emergency department (DED) (as that term is defined in 42 CFR 489.24(b)), but the DED must post a notice conspicuously, in a place or places likely to be noticed by all individuals entering the DED. ▪ The posted notice must state that the hospital does not have an MD or	the time a patient or patient's representative requests it. □ Determine through staff interviews and review of policies, procedures, and staff records whether a physician-owned hospital's medical staff membership and admitting privileging requirements include a requirement that, as a condition of continued membership or admitting privileges, physician owners who refer patients to the hospital agree to provide written disclosure of their own or any immediate family member's ownership or investment interest to all patients at the time of the referral to the hospital. **PHYSICIAN ON-SITE PRESENCE** Verify: ▪ An MD/DO is present in the hospital, at each campus or satellite location providing inpatient services 24 hours/day, seven days/week. ▪ For each required location where an MD/DO is not present: □ Are appropriate policies and procedures in place to assure written notices that an MD/DO is not present at all times are provided at the beginning of an inpatient stay or outpatient stay to all inpatients and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

DO present in the hospital 24 hours per day, 7 days per week, and must indicate how the hospital will meet the medical needs of any patient with an emergency medical condition, as defined in 42 CFR 489.24(b) [the EMTALA definition], at a time when there is no MD or DO present in the hospital.

- If an emergency department patient is determined to require admission, then the individual notice requirements of 42 CFR 489.20(w) would apply to that patient.
- Before admitting an inpatient or providing outpatient services requiring notice, the hospital must obtain a signed acknowledgement from the patient stating that he/she understands that an MD or DO may not be present at all times services are furnished to him/her.
- In the event of an unplanned surgery or inpatient admission to treat an emergency medical condition, it may in some cases be necessary in the interest of the patient's safety to proceed with treatment before the required notice can be given and acknowledgement can be obtained. In such circumstances, the hospital must provide notice and obtain acknowledgement as soon as possible after the patient's stay or visit begins.
- For a hospital that participates in Medicare with multiple campuses providing inpatient services (e.g., a main provider campus and separate satellite, remote, and/or provider-based locations) under one CMS Certification Number, a separate determination is made for each campus or satellite location with inpatient services as to whether the disclosure notice is required. For example, if a hospital has a main campus and a satellite location and a physician is present 24/7 on the main campus but not at the satellite location, the hospital is required to provide the disclosure notice only at the satellite location. No notice is required for patients presenting to the main provider campus in this case.

  □ In this same example, if the hospital also has a provider-based, off-to all outpatients receiving observation services, surgery or another procedure requiring anesthesia?

□ Is there signed acknowledgment by patients of such disclosure, obtained by the hospital prior to the patient's admission or before applicable outpatient services were provided?

□ Ask a sample of inpatients and affected outpatients whether they were provided notice about an MD/DO not being present at all times in the hospital.

□ The hospital's emergency department has signage with the appropriate disclosure information.

□ Review the notice the hospital issues to verify that it indicates how the hospital will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present at that hospital, including any remote location or satellite.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	campus ambulatory (i.e., same-day) surgery department, no notice is required at that off-campus surgery site, since the hospital's main campus does have an MD/DO present 24/7. 42 CFR 489.53(c) permits CMS to terminate a provider agreement with a hospital if the hospital fails to comply with the requirements at 42 CFR §489.20(w) when it does not have an MD or DO on-site 24/7.	
15.01.05 Advance directives *The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with:* ▪ 42 CFR §489.100 ("Definition"). ▪ 42 CFR §489.102 ("Requirements for providers"). ▪ 42 CFR §489.104 ("Effective dates"). §482.13(b)(3)	☐ Compliant ☐ Not Compliant An advance directive is defined at 42 CFR §489.100 as "a written instruction, such as a living will or durable power of attorney for health care, recognized under State law (whether statutory or as recognized by the courts of the State), relating to the provision of health care when the individual is incapacitated." The patient (inpatient or outpatient) has the right to formulate advance directives, and to have hospital staff implement and comply with their advance directive. The regulation at 42 CFR §489.102 specifies the rights of a patient (as permitted by State law) to make medical care decisions, including the right to accept or refuse medical or surgical treatment and the right to formulate, at the individual's option, advance directives. In the advance directive, the patient may provide guidance as to his/her wishes concerning provision of care in certain situations; alternatively, the patient may delegate decision-making authority to another individual, as permitted by State law. (In addition, the patient may use the advance directive to designate a support person, as that term is used in 42 CFR §482.13(h), for purposes of exercising the patient's visitation rights.) When a patient who is incapacitated has executed an advance directive designating a particular individual to make medical decisions for him/her when incapacitated, the hospital must, when presented with the document, provide the designated individual the information required to make informed	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The hospital's advance directive notice advises inpatients or applicable outpatients or their representatives of the patient's right to formulate an advance directive and to have hospital staff comply with the advance directive (in accordance with state law)? □ The notice includes a clear, precise, and valid statement of limitation if the hospital cannot implement an advance directive on the basis of conscience? ▪ What mechanism does the hospital use to allow patients to formulate an advance directive or to update their current advance directive? □ The hospital promotes and protects each patient's right to formulate an

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

decisions about the patient's care. (See also the requirements at 42 CFR §482.13(b) (2).)

The hospital must also seek the consent of the patient's representative when informed consent is required for a care decision. The explicit designation of a representative in the patient's advance directive takes precedence over any non-designated relationship and continues throughout the patient's inpatient stay or, as applicable, outpatient visit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing.

§489.102 also requires the hospital to:

- Provide written notice of its policies regarding the implementation of patients' rights to make decisions concerning medical care, such as the right to formulate advance directives. If an individual is incapacitated or otherwise unable to communicate, the hospital may provide the advance directive information required under §489.102 to the individual's "family or surrogate in the same manner that it issues other materials about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with state law. (§489.102(e)) Notice to the patient or the patient's representative of the patient's rights applies to provision of notice concerning the hospital's advance directive policies.
- Although both inpatients and outpatients have the same rights under 42 CFR §482.13(a)(1), §489.102(b)(1) requires that notice of the hospital's advance directive policy be provided at the time an individual is admitted as an inpatient. However, in view of the broader notice requirements at 42 CFR §482.13(a)(1), the hospital should also provide the advance directive notice to outpatients (or their representatives) who are in the emergency department, who are in an observation status, or who are undergoing same-day surgery. The notice should be presented at the time of registration. Notice is not required for other outpatients, given that they are unlikely to become incapacitated.

advance directive.

- The hospital educates its staff regarding advance directives.
  - □ Interview staff to determine their knowledge of the advance directives of the patients in their care.
- The hospital provides education for the patient population (inpatient and outpatient) regarding one's rights under state law to formulate advance directives.
- Review the records of a sample of patients for evidence of hospital compliance with advance directive notice requirements.
  - □ Does every inpatient or applicable outpatient record contain documentation that notice of the hospital's advance directives policy was provided at the time of admission or registration?
  - □ Is there documentation of whether each patient has an advance directive?
  - □ For patients who have reported an advance directive, is a copy in the medical record?
  - □ Determine to what extent the hospital complies, as permitted under State law, with patient

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ The notice must include a clear and precise statement of limitation if the hospital cannot implement an advance directive on the basis of conscience. At a minimum, a statement of limitation should: □ Clarify any differences between institution-wide conscience objections and those that may be raised by individual physicians or other practitioners. □ Identify the state legal authority permitting such an objection. □ Describe the range of medical conditions or procedures affected by the conscience objection. **Note:** This provision allowing for certain conscience objections to implementing an advance directive is narrowly focused on the directive's content related to medical conditions or procedures. This provision would not allow a hospital or individual physician or practitioner to refuse to honor those portions of an advance directive that designate an individual as the patient's representative and/or support person, given that such designation does not concern a medical condition or procedure. Provision of written notice of the hospital's advance directive policies to the patient or the patient's representative must be documented in the patient's medical record. ▪ Document in a prominent part of the patient's medical record whether or not the patient has executed an advance directive. ▪ Do not condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive. ▪ Ensure compliance with requirements of state law concerning advance directives and inform individuals that complaints concerning the advance directive requirements may be filed with the State survey and certification agency. ▪ Provide for the education of staff regarding policies and procedures on advance directives. The right to formulate advance directives includes the	advance directives that delegate decisions about the patient's care to a designated individual.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

right to formulate a psychiatric advance directive (as allowed by State law).

- Provide community education regarding advance directives and the hospital must document its efforts.

PSYCHIATRIC ADVANCE DIRECTIVE

A psychiatric advance directive might be prepared by an individual who is concerned that at some time he or she may be subject to involuntary psychiatric commitment or treatment.

When the patient is, for whatever reason, unable to communicate his/her wishes, the preferences expressed in the psychiatric advance directive can give critical insight to the MD/DO, nurses, and other staff as they develop a plan of care and treatment for the patient.

The psychiatric advance directive may cover a range of subjects and may name another person who is authorized to make decisions for the individual if he or she is determined legally incompetent to make his/her own choices. It may also provide the patient's instructions about hospitalization, alternatives to hospitalization, the use of medications, types of therapies, and the patient's wishes concerning restraint or seclusion. The patient may designate who should be notified upon his/her admission to the hospital, as well as who should not be permitted to visit him or her. State laws regarding the use of psychiatric advance directives vary.

A psychiatric advance directive is accorded the same respect and consideration given to a traditional advance directive for health care. Hospitals should carefully coordinate how the choices of a patient balance with the rights of other patients, staff, and individuals in the event that a dangerous situation arises.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

15.01.06 Admission notification

The patient has the right to have a family member or representative of his or her choice and his or her own physician notified promptly of his or her admission to the hospital.

§482.13(b)(4)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

IDENTIFYING WHO IS TO BE NOTIFIED

For every inpatient admission, the hospital must ask the patient whether the hospital should notify a family member or representative about the admission.

If the patient requests such notice and identifies the family member or representative to be notified, the hospital must provide such notice promptly to the designated individual. The explicit designation of a family member or representative by the patient takes precedence over any non-designated relationship.

The hospital must also ask the patient whether the hospital should notify his/her own physician. If the patient requests notice to and identifies the physician, the hospital must provide such notice promptly to the designated physician, regardless of whether the admission was scheduled in advance or emergent.

When a patient is incapacitated or otherwise unable to communicate and to identify a family member or representative to be notified, the hospital must make reasonable efforts to identify and promptly notify a family member or patient's representative. If an individual who has accompanied the patient to the hospital, or who comes to or contacts the hospital after the patient has been admitted, asserts that he or she is the patient's spouse, domestic partner (whether or not formally established and including a same-sex domestic partner), parent (including someone who has stood in loco parentis for the patient who is a minor child), or other family member, the hospital is expected to accept this assertion, without demanding supporting documentation, and provide this individual information about the patient's admission, unless more than one individual claims to be the patient's family member or representative. See standard 15.01.00 for additional information regarding the identification of a patient's representative.

INTERVIEW AND DOCUMENT REVIEW

- Determine if the hospital has policies that address notification of a patient's family or representative and physician when the patient is admitted as an inpatient.
- Ask who is responsible for providing the required notice.
  - □ Interview person(s) responsible for providing the notice to determine how they identify the persons to be notified and the means of notification.
  - □ What do they do in the case of an incapacitated person to identify a family member/ representative and the patient's physician?
- Review a sample of inpatient medical records to verify:
  - □ Do the medical records provide evidence that the patient was asked about notifying a family member/representative and his/her physician?
  - □ Is there a record of when and how notice was provided? Was notice provided promptly?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

The hospital facilitates expeditious and non-discriminatory resolution of disputes about whether an individual should be notified as the patient's family member or representative, given the critical role of the representative in exercising the patient's rights. The hospital may also choose to provide notice to more than one family member.

When a patient is incapacitated and the hospital is able through reasonable efforts to identify the patient's own physician – e.g., through information obtained from a family member, or from review of prior admissions or outpatient encounters, or through access to the patient's records in a regional system of electronic patient medical records in which the hospital participates – the hospital must promptly notify the patient's physician of the admission.

PROMPT NOTICE

The hospital must provide the required notice promptly. "Promptly" means as soon as possible after the physician's or other qualified practitioner's order to admit the patient has been given.

Notice may be given in person, by telephone, by e-mail or other electronic means, or by other methods that achieve prompt notification.

It is not acceptable for the hospital to send a letter by regular mail.

MEDICAL RECORD DOCUMENTATION

The hospital must document that the patient, unless incapacitated, was asked no later than the time of admission whether he or she wanted a family member/representative notified, the date, time, and method of notification when the patient made such a request or whether the patient declined to have notice provided.

If the patient was incapacitated at the time of admission, the medical record must indicate what steps were taken to identify and provide notice to a family member/representative and to the patient's physician.

- □ Is there a record of the patient declining to have notice provided to a family member/representative and his/her physician?
- □ Is there documentation of whether the patient was incapacitated at the time of admission, and if so, what steps were taken to identify a family member/representative and the patient's physician?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
15.01.07 Privacy and safety: Personal privacy *The patient has the right to personal privacy.* §482.13(c) §482.13(c)(1)	☐ Compliant ☐ Not Compliant The underlying principle of this requirement is the patient's basic right to respect, dignity, and comfort while in the hospital. **PHYSICAL PRIVACY** "Personal privacy" includes, at a minimum, physical privacy to the extent consistent with their care needs during personal hygiene activities (e.g., toileting, bathing, dressing), during medical/nursing treatments, and when requested as appropriate. People not involved in the care of the patient should not be present without consent while he/she is being examined or treated, nor should video or other electronic monitoring/recording methods be used while he/she is being examined without his/her consent. If an individual requires assistance during toileting, bathing, and other personal hygiene activities, staff should assist, giving utmost attention to the individual's need for privacy. Privacy should be afforded when the MD/DO or other staff visits the patient to discuss clinical care issues or conduct any examination or treatment. Audio/video monitoring (does not include recording) of patients in medical-surgical or intensive-care type units would not be considered to violate the patient's privacy, as long as there exists a clinical need, the patient/patient's representative is aware of the monitoring and the monitors or speakers are located so that they are not readily visible or audible to visitors. ▪ Video recording of patients undergoing medical treatment requires the consent of the patient or his/her representative. A patient's right to privacy may also be limited in situations where a person must be continuously observed to ensure his or her safety, such as when a patient is simultaneously restrained and in seclusion to manage violent or self-destructive behavior or when the patient is under suicide precautions.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Conduct observations/interview patients or their representatives to determine if patients are provided reasonable privacy during examinations or treatments, personal hygiene activities and discussions about their health status/care and other appropriate situations. ▪ Review hospital policy and interview staff concerning their understanding of the use of patient information in the facility directory. □ Does the policy address the opportunity for the patient or patient's representative to restrict or prohibit use of patient information in emergent and non-emergent situations? ▪ Review hospital policy and conduct observations/interview staff to determine if reasonable safeguards are used to reduce incidental disclosures of patient information. ▪ If audio and/or visual monitoring is used in the medical/surgical or ICU setting, observe whether monitor screens

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Security cameras in non-patient care areas such as stairwells, public waiting areas, outdoor areas, entrances, etc., are not generally affected by this requirement.

PROTECTING PATIENT PERSONAL INFORMATION
The right to personal privacy also includes limiting the release or disclosure of patient information.

Patient information includes, but is not limited to, the patient's presence or location in the hospital; demographic information such as name, age, address, income; or information on the patient's medical condition.

Such patient information may not be disclosed without informing the patient or the patient's representative in advance of the disclosure and providing the patient or the patient's representative an opportunity to agree to, prohibit, or restrict the disclosure.

Permitted Disclosures
A hospital is permitted to use and disclose patient information, without the patient's authorization, in order to provide patient care and perform related administrative functions, such as payment and other hospital operations.

- Payment operations include hospital activities to obtain payment or be reimbursed for the provision of health care to an individual.
- Hospital operations are administrative, financial, legal, and quality improvement activities of a hospital that are necessary to conduct business and to support the core functions of treatment and payment. These activities include, but are not limited to:
  1. quality assessment and improvement activities.
  2. case management and care coordination.
  3. competency assurance activities, conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs.

and/or speakers are readily visible or audible to visitors or the public.

- Is the hospital promoting and protecting each patient's right to privacy?
  - □ Are patient names posted in public view?
  - □ Is patient information posted in public view?

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4. business planning, development, management, and administration and certain hospital-specific fundraising activities.

Hospitals must develop and implement policies and procedures that restrict access to and use of patient information based on the specific roles of the members of their workforce.

These policies and procedures must identify the persons, or classes of persons, in the workforce who need access to protected health information to carry out their duties and the categories of protected health information to which access is needed.

One example of a permitted disclosure is a Facility Directory. It is common practice in many hospitals to maintain a directory of patient contact information.

- The hospital must inform the patient, or the patient's representative, of the individual information that may be included in a directory and the persons to whom such information may be disclosed. The patient, or the patient's representative, must be given the opportunity to restrict or prohibit any or all uses and disclosures. The hospital may rely on a patient's/representative's individual's informal permission to list in its facility directory the patient's name, general condition, religious affiliation, and location in the provider's facility. The provider may then disclose the patient's condition and location in the facility to anyone asking for the patient by name and may disclose religious affiliation to clergy. If the opportunity to prohibit or restrict uses and disclosures cannot be provided due to the patient's incapacity or emergency treatment circumstance, and there is no patient representative available, the hospital may disclose patient information for the facility's directory if such disclosure is in the patient's best interest.
- The hospital must provide the patient or the patient's representative an opportunity to prohibit or restrict disclosure as soon as it becomes practicable to do so. The hospital may use patient information to notify,

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or assist in the notification of, a family member, a personal representative of the patient, or another person responsible for the care of the patient of their location, general condition, or death.

- The hospital must have procedures in place, in accordance with State law, to provide appropriate information to patient families or others in those situations where the patient is unable to make their wishes known.

INCIDENTAL USES AND DISCLOSURES MAY BE ACCEPTABLE

An incidental use or disclosure is a secondary disclosure of patient information that cannot reasonably be prevented, is limited in nature, and that occurs as a result of another permitted use or disclosure.

For example, a hospital visitor may overhear a health care professional's confidential conversation with another health care professional or the patient or may glimpse a patient's information on a sign-in sheet or nursing station whiteboard. The regulation protecting patient privacy does not impede these customary and essential communications and practices and, thus, a hospital is not required to eliminate all risk of incidental use or disclosure so long as the hospital takes reasonable safeguards and discloses only the minimum amount of personally identifiable information necessary.

For example, hospitals may:

- Use patient care signs (e.g., "falls risk" or "diabetic diet") displayed at the bedside or outside a patient room.
- Display patient names on the outside of patient charts.
- Use "whiteboards" that list the patients present on a unit, in an operating room suite, etc.

Hospitals are expected to review their practices and determine what steps are reasonable to safeguard patient information while not impeding the delivery of safe patient care or incurring undue administrative or financial burden as a result of implementing privacy safeguards.

Reasonable privacy safeguards could include, but are not limited to:

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	▪ Requesting that waiting customers stand a few feet back from a counter used for patient registration. ▪ Use of dividers or curtains in areas where patient and physician or other hospital staff communications routinely occur. ▪ Health care staff speaking quietly when discussing a patient's condition or treatment in a semi-private room. ▪ Using passwords and other security measures on computers maintaining personally identifiable health information. ▪ Limiting access to areas where white boards or x-ray light boards are in use or posting the board on a wall not readily visible to the public, or limiting the information placed on the board.	
15.01.08 Privacy and safety: Safe setting	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The patient has the right to receive care in a safe setting. §482.13(c)(2)	Each patient receives care in an environment that a reasonable person would consider to be safe. Hospital staff follow current standards of practice for patient environmental safety, infection control, and security. The hospital protects vulnerable patients, including newborns and children. Additionally, this standard is intended to provide protection for the patient's emotional health and safety as well as his/her physical safety. Respect, dignity, and comfort would be components of an emotionally safe environment. Although all risks cannot be eliminated, hospitals must identify patients at risk of self-harm or harm to others and steps taken to minimize those risks in accordance with nationally recognized standards and guidelines. The potential risks include but are not limited to those from ligatures, sharps, harmful substances, access to medications, breakable windows, accessible light fixtures, plastic bags (for suffocation), oxygen tubing, bell cords, etc.	**OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** Review: ▪ Patient and staff incident and accident reports to identify incidents or patterns of incidents concerning safety of the environment. ▪ QAPI, Safety, and Infection Control Committee minutes and reports to verify that the hospital is identifying problems, evaluating those problems, and taking steps to ensure a safe patient environment. ▪ Policy and procedures regarding

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RISK MITIGATION

Although all risks cannot be eliminated, hospitals are expected to:

1. Identify patients at risk for intentional harm to self or others.
2. Identify environmental safety risks for such patients.
3. Provide education and training for staff and volunteers.

Non-psychiatric settings

- Patients with psychiatric conditions may be cared for in non-psychiatric settings. For this reason, the hospital must take steps to identify patients at risk for intentional harm to self or others and mitigate environmental safety risks.
- Psychiatric patients requiring medical care in a non-psychiatric setting (medical inpatient units, ED, ICU, etc.) must be protected when demonstrating suicidal ideation or harm to others.

  Examples of protection could include:

  - □ Providing 1:1 monitoring with continuous visual observation.
  - □ Removal of sharp objects from the room/area.
  - □ Removal of equipment that can be used as a weapon.

Psychiatric units of acute care hospitals: Ligature free environment

- Patients at risk of suicide (or other forms of self-harm) or those who exhibit violent behaviors toward others receive healthcare services in both inpatient and outpatient locations of hospitals.
- The focus for a "ligature resistant" or "ligature free" environment is that of psychiatric units of acute care hospitals and psychiatric hospitals.
- A "ligature free" environment does not apply to non-psychiatric units of acute care hospitals that provide care to those at risk of harm to self or others, e.g., emergency departments, intensive care units, medical-surgical units, and other inpatient and outpatient locations.

unwanted visitors or contaminated materials, or unsafe items that pose a safety risk to patients and staff.

- Observe and interview staff at units where infants and children are inpatients. Are appropriate security protections (such as alarms, arm banding systems, etc.) in place? Are they functioning?
- Access the hospital's security efforts to protect vulnerable patients including newborns and children, and patients at risk of suicide or intentional harm to self or others.
  - □ Is the hospital providing appropriate security to protect patients?
  - □ Are appropriate security mechanisms in place and being followed to protect patients?
  - □ Security mechanisms must be based on nationally recognized standards of practice.

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15.01.09 Privacy and safety: Free from abuse *The patient has the right to be free from all forms of abuse or harassment.* §482.13(c)(3)	☐ Compliant ☐ Not Compliant The intent of this requirement is to prohibit all forms of abuse, neglect (as a form of abuse) and harassment whether from staff, other patients, or visitors. **Abuse** is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment, with resulting physical harm, pain, or mental anguish. This includes staff neglect or indifference to infliction of injury or intimidation of one patient by another. **Neglect**, for the purpose of this requirement, is considered a form of abuse and is defined as the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. Protection from abuse may include: ▪ **Prevention**. Adequate staffing, especially during evening, nighttime, weekend, and holiday shifts, to take care of the individual needs of all patients. Adequate staff means that there are the number and types of qualified, trained, and experienced staff present and available to meet the care needs of every patient.) ▪ **Screening**. Persons with a record of abuse or neglect should not be hired or retained as employees. ▪ **Identification**. The hospital creates and maintains a proactive approach to identify events and occurrences that may constitute or contribute to abuse and neglect. ▪ **Training**. At orientation and through an ongoing training program, all employees receive information regarding abuse and neglect, and related reporting requirements, including prevention, intervention, and detection. ▪ **Investigation**. Timely, thorough, objective investigation occurs for all allegations of abuse, neglect, or mistreatment. **Patients are protected**	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Staffing levels across all shifts are sufficient to care for individual patient's needs. ▪ The hospital implemented an abuse protection plan. ▪ The hospital has a written procedure for investigating allegations of abuse and neglect including methods to protect patients from abuse during investigations of an allegation. ▪ Incidents of substantiated abuse and neglect result in appropriate action. ▪ Appropriate agencies are notified in accordance with state and federal laws regarding incidents of substantiated abuse and neglect. ▪ Evidence that allegations of abuse and neglect are thoroughly investigated. ▪ The hospital conducts criminal background checks as allowed by state law for all potential new hires.

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	from abuse during investigation. ▪ **Reporting/Response**. Incidents of abuse, neglect or harassment are reported and analyzed, with appropriate corrective, remedial, or disciplinary action, in accordance with applicable local, state, or federal law.	▪ Is there evidence the hospital employs people with a history of abuse, neglect, or harassment? Review education documents. Verify: ▪ Staff education is provided on the prevention, identification, and reporting of suspected abuse (including sexual assault) or neglect. Review personnel files of clinical personnel to verify: ▪ Staff has received training on the prevention, identification, and reporting of suspected abuse (including sexual assault) and neglect within the past 24 months. ▪ **Staff can identify various forms of abuse or neglect.** ▪ Staff know what to do if they witness abuse and neglect.
15.01.10 Confidentiality of patient records *The patient has the right to the confidentiality of his or her clinical records.* §482.13(d) §482.13(d)(1)	☐ Compliant ☐ Not Compliant The right to confidentiality means the hospital must safeguard the contents of the medical record regardless of format, from unauthorized disclosure. Confidentiality applies wherever the record or portions thereof are stored, including but not limited to central records, patient care locations, radiology, laboratories, record storage areas, data systems, etc. ▪ A hospital may disclose patient information, without a patient's	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Verify that the hospital has policies and procedures addressing the protection of information in patients' medical record from unauthorized disclosures.

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authorization, to provide care and perform related administrative operations.
Payment operations include activities to obtain payment or be reimbursed for the provision of health care to an individual.

- Hospital operations include administrative, financial, legal, and quality improvement activities of a hospital that are necessary to conduct business and to support the core functions. These activities include but are not limited to quality assessment and improvement activities, case management and care coordination; competency assurance activities, conducting or arranging for medical reviews, audits, or legal services, including fraud and abuse detection and compliance programs; business planning, development, management, and administration and certain hospital-specific fundraising activities.

The hospital must develop policies and procedures that limit disclosures of information contained in the patient's medical record to the minimum necessary, even when the disclosure is for treatment or payment purposes, or as otherwise required by state or federal law. When the minimum necessary standard is applied, a hospital may not disclose the entire medical record for a particular purpose, unless it can specifically justify that the whole record reasonably needed for the purpose.

A hospital may make an authorized disclosure of information from the medical record electronically and may also share an electronic medical record system with other health care facilities, physicians, and practitioners, so long as the system is designed and operated with safeguards that ensure that only authorized disclosures are made.

The hospital must obtain the patient's, or the patient's representative's, written authorization for any disclosure of information in the medical record when the disclosure is not for treatment, payment, or health care operations.

- Observe locations where medical records are stored to determine whether appropriate safeguards are in place to protect medical record information.
- Interview staff to determine their understanding of and compliance with the hospital's policies and procedures for protecting medical record information.
- Observe care units.
  - □ Is patient information posted where it can be viewed by visitors or other non-hospital staff?
  - □ Are medical records accessible to people not involved with the patient's care?
  - □ Is it likely that unauthorized persons could read or remove the clinical record?
  - □ Are clinical information/records available and accessible at the bedside or in the patient's room where people not involved in the patient's care could likely read the information?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

15.01.11 Access to medical records

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The patient has the right to access their medical records, including current medical records, upon an oral or written request, in the form and format requested by the individual if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, and within a reasonable time frame.

The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

§482.13(d)(2)

The regulation at 42 CFR §164.524 specifies that patients should be allowed to inspect and obtain a copy of health information about them that is held by providers; and that providers may not withhold information except under limited circumstances which include:

- Psychotherapy notes.
- A correctional institution or a health care provider acting at the direction of a correctional institution may deny an inmate's request for access, if providing such access would jeopardize the health or security of the individual, other inmates, or officers or employees of the correctional institution.
- The information is about another person (other than a health care provider) and the hospital determines that the patient inspection is reasonably likely to cause sufficient harm to that person to warrant withholding.
- A licensed health care professional has determined that the access requested is reasonably likely to endanger the life or physical safety of the individual or another person.
- The information contains data obtained under a promise of confidentiality (from someone other than a health care provider), and inspection could reasonably reveal the source.
- The information is collected in the course of research that includes treatment and the research is in progress, provided that the individual has agreed to the denial of access and the provider informs the individual that his or her right of access will be reinstated when the research is completed.
- The protected health information is subject to the Clinical Laboratory Improvements Amendments of 1988, 42 CFR §263a, to the extent that

DOCUMENT REVIEW

Verify:

- The hospital promotes and protects the patient's right to access information contained in his/her clinical record.
- The hospital has a procedure for providing records to patients within a reasonable time frame.
- The hospital's system does not frustrate the legitimate efforts of individuals to gain access to their own medical record.
- Procedures include the method to identify what documents were not provided and the reason.

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	providing the requested access would be prohibited by law. ▪ The protected health information is exempt from the Clinical Laboratory Improvements Amendments of 1988, pursuant to 42 CFR §493.3(a)(2). ▪ The information is compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding. ▪ The request is made by an individual's personal representative (as allowed under state law) and a licensed health care professional has determined that access is reasonably likely to cause substantial harm to the individual or another person. In general, each patient should be able to see and obtain a copy of his/her records. Record holders may not deny access except to a portion of the record that meets criteria specified above. If the patient is incompetent, the record should be made available to his or her representative (as allowed under State law). Upon the patient's request, other designated individuals may access the patient's records. The cost of duplicating a patient's record must not create a barrier to the individual's receiving his or her medical record. ▪ Reasonable cost-based fees may be imposed only to cover the cost of copying, postage, and/or preparing an explanation or summary of patient health information, as outlined in 42 CFR §164.524(c).	
15.01.12 <u>Visitation rights</u>	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable	Visitation plays an important role in the care of hospital patients. Hospitals that unnecessarily restrict patient visitation often miss an opportunity to gain valuable patient information from those who may know the patient best with respect to the patient's medical history, conditions,	**<u>INTERVIEW AND DOCUMENT REVIEW</u>** Verify: ▪ The hospital has written policies and procedures that address the right of

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

restriction or limitation that the hospital may need to place on such rights and the reasons for the clinical restriction or limitation.

§482.13(h)

medications, and allergies, particularly if the patient has difficulties with recall or articulation. Visitors may act as an intermediary for the patient, helping to communicate the patient's needs to hospital staff.

Although visitation policies are generally considered to relate to visitors of inpatients, visitors also play a role for outpatients who wish to have a support person present during their outpatient visit.

Hospital visitation policies must address both the inpatient and outpatient settings.

Hospitals are required to develop and implement written policies and procedures that address the patient's right to have visitors. If the hospital's policy establishes restrictions or limitations on visitation, such restrictions/limitations must be clinically necessary or reasonable.

- The hospital is not required to delineate each specific clinical reason for policies limiting or restricting visitation but the policy must include the general reasons for any restrictions/limitations. The right of a patient to have visitors may be limited or restricted when visitation would interfere with the care of the patient and/or the care of other patients.
- The regulation permits flexibility for health care professionals to exercise their best clinical judgment when determining when visitation is, and is not, appropriate. Best clinical judgment takes into account all aspects of patient health and safety, including the benefits of visitation on a patient's care as well as potential negative impacts that visitors may have on other patients in the hospital.

Broad examples of circumstances reasonably related to the care of the patient and/or the care of other patients that could provide a basis for a hospital to impose restrictions or limitations on visitors might include, but are not limited to, when:

- there may be infection control issues.

patients to have visitors.

- Limitations or restrictions on visitation include the clinical rationale.
- Documentation indicates how the hospital identifies and trains staff who play a role in facilitating or controlling access of visitors to patients.
- Hospital staff are aware of the visitation policies and procedures.
  - □ Can staff on a given unit correctly describe the hospital's visitation policies for that unit?

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- visitation may interfere with the care of other patients.
- the hospital is aware that there is an existing court order restricting contact.
- visitors engage in disruptive, threatening, or violent behavior of any kind.
- the patient or patient's roommate(s) need rest or privacy.
- an inpatient substance abuse treatment program has protocols limiting visitation.
- the patient is undergoing care interventions. Hospitals should try to accommodate the needs of any patient who requests that at least one visitor be allowed to remain in the room to provide support and comfort at such times.

It may also be reasonable to limit the number of visitors for any one patient during a specific period, as well as to establish minimum age requirements for visitors. However, when a hospital adopts policies that limit or restrict patients' visitation rights, the burden of proof is upon the hospital to demonstrate that the visitation restriction is reasonably necessary to provide safe care.

If visitation policies differ by type of unit, e.g., separate policies for intensive care units, or for newborn nurseries, the hospital policy must address the clinical rationale for this differentiation explicitly.

The hospital's policies and procedures are expected to address how hospital staff who play a role in facilitating or controlling visitor access to patients will be trained to assure appropriate implementation of the policies and procedures and avoid unnecessary restrictions or limitations on visitation rights.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

15.01.13 Notification of visitation rights

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reason for the clinical restriction or limitation. A hospital must:

1. *Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, when he or she is informed of his or her other rights under this section.*
2. *Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.*

§482.13(h)(1-2)

The required visitation rights notice must address any clinically necessary or reasonable limitations or restrictions imposed by hospital policy on visitation rights, providing the clinical reasons for such limitations/restrictions, including how they are aimed at protecting the health and safety of all patients. The information must be sufficiently detailed to allow a patient (or the patient's support person) to determine what the visitation hours are and what restrictions, if any, apply to that patient's visitation rights.

The notice must also inform the patient (or the patient's support person, where appropriate) of the patient's right to:

- Consent to receive visitors he or she has designated, either orally or in writing, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend;
- Receive the visitors he or she has designated, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend; and
- Withdraw or deny his/her consent to receive specific visitors, either orally or in writing.

A patient's "support person" does not have to be the same person as the patient's representative who is legally responsible for making medical decisions on the patient's behalf.

A support person could be a family member, friend, or other individual who supports the patient during the hospital stay. The support person may also exercise a patient's visitation rights on behalf of the patient with respect to other visitors when the patient is unable to do so.

Hospitals must accept a patient's designation, orally or in writing, of an individual as the patient's support person. The requirements mirror those for

INTERVIEW AND DOCUMENT REVIEW

- Determine whether the hospital's visitation policies and procedures require providing notice of the patient's visitation rights to each patient or, if appropriate, to a patient's support person and/or, as applicable, the patient's representative.
- Review the hospital's standard notice of visitation rights. Does it clearly explain:
  - □ The visitation policy, including any limitations or restrictions, such as visiting hours, numbers of visitors, unit-specific restrictions, etc., and the clinical rationale for such limitations or restrictions?
  - □ The right of the patient to have designated visitors, including but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and the right to withdraw or deny consent to visitation?
- Review a sample of medical records to determine if there is documentation that the required notice was provided.

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a patient's representative. See also standard 15.01.00.

When a patient is incapacitated or otherwise unable to communicate his or her wishes and an individual provides an advance directive designating an individual as the patient's support person (it is not necessary for the document to use this exact term), the hospital must accept this designation, provide the required notice of the patient's visitation rights, and allow the individual to exercise the patient's visitation rights on the patient's behalf.

When a patient is incapacitated or otherwise unable to communicate his or her wishes, there is no advance directive designating a representative on file, and no one has presented an advance directive designating himself or herself as the patient's representative, but an individual asserts that he or she, as the patient's spouse, domestic partner (including a same-sex domestic partner), parent or other family member, friend, or otherwise, is the patient's support person, the hospital is expected to accept this assertion, without demanding supporting documentation, provide the required notice of the patient's visitation rights, and allow the individual to exercise the patient's visitation rights on the patient's behalf.

However, if more than one individual claim to be the patient's support person, it would not be inappropriate for the hospital to ask each individual for documentation supporting his/her claim to be the patient's support person.

- Hospitals are expected to adopt policies and procedures that facilitate expeditious and non-discriminatory resolution of disputes about whether an individual is the patient's support person, given the critical role of the support person in exercising the patient's visitation rights.

A refusal by the hospital of an individual's request to be treated as the patient's support person with respect to visitation rights must be documented in the patient's medical record, along with the specific basis for the refusal. Consistent with the patients' rights notice requirements under the regulation at 42 CFR §482.13(a)(1), the required notice of the patient's

- Ask how the required notice is provided.
  - □ Ask staff responsible for providing the notice how they accomplish this.
  - □ Ask the staff if they are familiar with the concept of a patient's support person and what it means.
- Ask a sample of current hospital patients or patients' support persons (where appropriate) whether they were provided notice of their right to have visitors.
  - □ Ask if they were able to have visitors when they wanted to. If not, verify whether the restriction/ limitation on visitors was addressed in the hospital's visitation policies and notice, and does not violate the regulations at standard 15.01.28 [42 CFR §482.13(h)(3) and (4)].

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

visitation rights must be provided, whenever possible, before the hospital provides or stops care.

The notice to the patient, or to the patient's support person, where appropriate, must be in writing.

If the patient also has a representative who is different from the support person, the representative must be provided information on the patient's visitation rights.

In the event that a patient has both a representative and a support person who are not the same individual, and they disagree on who should be allowed to visit the patient, the hospital must defer to the decisions of the patient's representative. As the individual responsible for making decisions on the patient's behalf, the patient's representative has the authority to exercise a patient's right to designate and deny visitors just as the patient would if he or she were capable of doing so.

The designation of, and exercise of authority by, the patient's representative is governed by State law, including statutory and case law. Many State courts have addressed the concept of substituted judgment, whereby the patient's representative is expected to make medical decisions based on the patient's values and interests, rather than the representative's own values and interests. State courts have also developed a body of closely related law around the matter of a representative acting in the patient's best interest. Such case law regarding substituted judgment and best interest may be a resource for hospitals on how to address such conflict situations as they establish visitation policies and procedures. Hospitals may also choose to use their own social work and pastoral counseling resources to resolve such conflicts to assure the patient's well-being.

The medical record must contain documentation that the required notice was provided to the patient or, if appropriate, the patient's support person.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

15.01.14 Visitation rights: Non-discrimination

A hospital must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the hospital may need to place on such rights and the reason for the clinical restriction or limitation.

A hospital must meet the following requirements:

- *Not restrict, limit or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.*
- *Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.*

§482.13(h)(3-4)

☐ Compliant ☐ Not Compliant

The hospital's policies and procedures must ensure that all visitors enjoy full and equal visitation privileges, consistent with the preferences the patient (or, where appropriate, the patient's support person) has expressed concerning visitors. It is permissible for the patient (or the patient's support person, where appropriate) to limit the visiting privileges of his/her visitors, including providing for more limited visiting privileges for some visitors than those for others.

It is not permissible for the hospital, on its own, to differentiate among visitors without any clinically necessary or reasonable basis. This includes visitors designated by the patient who have characteristics not addressed specifically in 42 CFR §482.13(h)(3), when those characteristics do not reasonably relate to a clinically reasonable basis for limiting or denying visitation. For example, it would not be appropriate to prohibit a designated visitor based on that individual's style of dress, unless there was a clinically reasonable basis for doing so.

Hospitals are expected to educate all staff who play a role in facilitating or controlling visitors on the hospital's visitation policies and procedures and are responsible for ensuring that staff implement the hospital's policies correctly. Hospitals are urged to develop culturally competent training programs designed to address the range of patients served by the hospital.

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

- Review the hospital's visitation policies and procedures to determine whether they restrict, limit, or otherwise deny visitation to individuals on a prohibited basis.
- Interview patients to determine if rights regarding visitation have been explained and enforced.
- Ask the hospital how it educates staff to assure that visitation policies are implemented in a non-discriminatory manner.
- Ask hospital staff who play a role in facilitating or controlling visitors to discuss their understanding of the circumstances under which visitors may be subject to restrictions/ limitations.
  - □ Are the restrictions/limitations appropriately based on the hospital's clinically-based policies?
- Ask hospital patients (or patients' support persons, where appropriate) whether the hospital has restricted or limited visitors against their wishes.

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		□ If yes, verify whether the restriction/ limitation on visitors was addressed in the hospital's visitation policies and in the patient notice, and whether it was appropriately based on a clinical rationale rather than impermissible discrimination.
15.01.15 Patient grievance *The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance.* §482.13(a)(2)	☐ Compliant ☐ Not Compliant The patient should have reasonable expectations of care and services and the facility should address those expectations in a timely, reasonable, and consistent manner. Although standards 15.01.05 and 15. 01.06 [482.13(a)(2)(ii) and (iii)] address documentation of facility time frames for a response to a grievance, the expectation is that the facility will have a process to comply with a relatively minor request more quickly than with a grievance requiring a written response. ▪ For example, a change in bedding, housekeeping of a room, and serving preferred food and beverage may be made relatively quickly and would not usually be considered a "grievance" and therefore would not require a written response. The hospital must inform the patient and/or the patient's representative of the internal grievance process, including whom to contact to file a grievance (complaint). ▪ As part of its notification of patient rights, the hospital must provide the patient or the patient's representative a phone number and address for lodging a grievance with the State agency. ▪ The hospital must inform the patient that he/she may lodge a grievance with the State agency (the State agency that has licensure	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Policies and procedures ensure a grievance process that encourages all personnel to alert appropriate staff concerning any patient grievance. ▪ Through patient (or patient representative) interview, that they know how to file a complaint (grievance) and who to contact if they have a complaint (grievance). ▪ The hospital follows its grievance policies and procedures. ▪ The hospital's process ensures that grievances involving situations or practices that place the patient in immediate danger are resolved in a timely manner. ▪ The patient or the patient's

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

survey responsibility for the hospital) directly, regardless of whether he/she has first used the hospital's grievance process.

A "patient grievance" is a formal or informal written or verbal complaint that is made to the hospital by a patient or the patient's representative, regarding the patient's care (when the complaint is not resolved at the time of the complaint by staff present), abuse or neglect, issues related to the hospital's compliance with the CMS Conditions of Participation (CoPs), or a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR §489.

- "Staff present" includes any hospital staff present at the time of the complaint or who can quickly be at the patient's location (i.e., nursing, administration, nursing supervisors, patient advocates, etc.) to resolve the issue.
- If a patient care complaint cannot be resolved at the time of the complaint by staff present, is postponed for later resolution, is referred to other staff for later resolution, requires investigation, and/or requires further actions for resolution, then the complaint is a grievance for the purposes of these requirements. A complaint is considered resolved when the patient is satisfied with the actions taken on their behalf.
- Billing issues are not usually considered grievances for the purposes of these requirements. However, a Medicare beneficiary billing complaint related to rights and limitations provided by 42 CFR §489 is considered a grievance.
- A written complaint is always considered a grievance. This includes written complaints from an inpatient, an outpatient, a released/discharged patient, or a patient's representative regarding the patient care provided, abuse or neglect, or the hospital's compliance with CoPs. For the purposes of this requirement, an email or fax is considered "written."

representative knows that he/she has the right to file a complaint with the state agency as well as or instead of using the hospital's grievance process.

- The hospital provides the telephone number for the state agency to all patients/patient representatives.
- Beneficiaries are aware of their right to seek review by the QIO for quality-of-care issues, coverage decisions, and to appeal a premature discharge.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Information obtained from patient satisfaction surveys usually does not meet the definition of a grievance. If an identified patient writes or attaches a written complaint on the survey and requests resolution, then the complaint meets the definition of a grievance. If an identified patient writes or attaches a complaint to the survey but has not requested resolution, the hospital must treat this as a grievance if the hospital would usually treat such a complaint as a grievance.
- Patient complaints that are considered grievances also include situations where a patient or a patient's representative telephones the hospital with a complaint regarding the patient's care or with an allegation of abuse or neglect, or failure of the hospital to comply with one or more CoPs, or other CMS requirements. Those post-hospital verbal communications regarding patient care that would routinely have been handled by staff present if the communication had occurred during the stay/visit are not required to be defined as a grievance.
- All verbal or written complaints regarding abuse, neglect, patient harm, or hospital compliance with CMS requirements are considered grievances for the purposes of these requirements.
- Whenever the patient or the patient's representative requests that his or her complaint be handled as a formal complaint or grievance or when the patient requests a response from the hospital, the complaint is considered a grievance and all the requirements apply.

Data collected regarding patient grievances, as well as other complaints that are not defined as grievances (as determined by the hospital), must be incorporated in the hospital's Quality Assessment and Performance Improvement (QAPI) program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
15.01.16 Governing body responsibility for the grievance process *The hospital's governing body must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee.* §482.13(a)(2)	☐ Compliant ☐ Not Compliant The hospital's grievance process is approved by the governing body. The governing body is responsible for the effective operation of the grievance process. This includes the hospital's compliance with all the CMS grievance process requirements. A committee is more than one person. The committee membership should have adequate numbers of qualified members to review and resolve the grievances the hospital receives (this includes providing written responses) in a manner that complies with the CMS grievance process requirements.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Confirm that the hospital's governing body approved the grievance process. □ Is the governing body responsible for the operation of the grievance process, or has the governing body delegated the responsibility in writing to a grievance committee? ▪ Effectiveness of grievance process. □ Are patient or patient representative concerns addressed in a timely manner? □ Are patients informed of any resolution to their grievances? □ Does the hospital apply what it learns from the grievance as part of its continuous quality improvement activities? ▪ **Data collected on complaints and grievances is incorporated into** the hospital's QAPI Program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

15.01.17 Timely grievance referrals

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control, Quality Improvement Organization (QIO).

§482.13(a)(2)

Quality Improvement Organizations (QIOs) are CMS contractors charged with reviewing the appropriateness and quality of care rendered to Medicare beneficiaries in the hospital setting. The QIOs are also tasked with reviewing utilization decisions. Part of this duty includes reviewing discontinuation of stay determinations based upon a beneficiary's request.

Regulations state the functions of the QIOs in order to make Medicare beneficiaries aware of the fact that if they have a complaint regarding quality of care, disagree with a coverage decision, or they wish to appeal a premature discharge, they may contact the QIO to lodge a complaint.

The hospital must have procedures for referring Medicare beneficiary concerns to the QIOs and CMS expects coordination between the grievance process and existing grievance referral procedures so that beneficiary complaints are handled efficiently and referred to the QIO at the beneficiary's request.

This regulation requires coordination between the hospital's existing mechanisms for utilization review notice and referral to QIOs for Medicare beneficiary concerns (See 42 CFR §489.27).

This requirement does not mandate that the hospital automatically refer each Medicare beneficiary's grievance to the QIO; however, the hospital must inform all beneficiaries of this right, and comply with his or her request if the beneficiary asks for QIO review.

Note: Medicare patients have the right to appeal a premature discharge. Pursuant to 42 CFR §412.42(c)(3), a hospital must provide a hospital-issued notice of non-coverage (HINN) to any fee-for-service beneficiary that expresses dissatisfaction with an impending hospital discharge. Medicare Advantage (MA) organizations are required to provide enrollees with a notice of non-coverage, known as the Notice of Discharge and Medicare Appeal

INTERVIEW AND DOCUMENT REVIEW

Verify:

- Through review of patient discharge materials that the hospital is in compliance with 42 CFR §489.27?
- The hospital grievance process includes a mechanism for timely referral of Medicare patient concerns to the QIO?
  - □ What time frames are established?
- Through interview of Medicare patients, that they are aware of their right to appeal premature discharge.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Rights (NODMAR), only when a beneficiary disagrees with the discharge decision or when the MA organization (or hospital, if the MA organization has delegated to it the authority to make the discharge decision) is not discharging the enrollee, but no longer intends to cover the inpatient stay.	
15.01.18 Grievance process	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital. §482.13(a)(2)(i)	The patient or patient's representative should be able to clearly understand the hospital's procedure for **submission of written or verbal grievances**.	**INTERVIEW AND DOCUMENT REVIEW** Review: ▪ The hospital's grievance procedure. ▪ The information provided to patients that explains the hospital's grievance procedures. Verify: ▪ The procedure clearly explains how the patient is to submit either a verbal or written grievance? ▪ Through patient/patient representative interview that the grievance process is understood.
15.01.19 Grievance process response time frames	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The grievance process must specify time frames for review of the grievance and the provision of a response. §482.13(a)(2)(ii)	The hospital must review, investigate, and resolve each patient's grievance within a reasonable time frame. Grievances about situations that endanger the patient, such as neglect or abuse, should be reviewed immediately, given the seriousness of the allegations and the potential for harm to the patient.	**DOCUMENT REVIEW** Verify: ▪ Hospital policy and procedure specifies time frames for

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Regardless of the nature of the grievance, the hospital should make sure that it is responding to the substance of each grievance while identifying, investigating, and resolving any deeper, systemic problems indicated by the grievance. Document when a grievance is so complicated that it may require an extensive investigation. Staff scheduling and fluctuations in the numbers and complexity of grievances can affect the timeframes for the resolution of a grievance and the provision of a written response. On average, a time frame of seven days for the provision of the response would be considered appropriate. Not every grievance must be resolved during the specified timeframe although most should be resolved. Standard 15.01.06 [§482.13(a)(2)(iii)] specifies information the hospital must include in its response. If the grievance will not be resolved, or if the investigation is not or will not be completed within seven days, the hospital should inform the patient or the patient's representative that the hospital is still working to resolve the grievance and that the hospital will follow-up with a written response within a stated number of days in accordance with the hospital's grievance policy. The hospital must attempt to resolve all grievances as soon as possible.	responding to grievances. ▪ The hospital responds to grievances within those time frames.
15.01.20 <u>Patient notification of the grievance process</u> *In its resolution of the grievance, the hospital must provide the patient with a written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.*	☐ Compliant ☐ Not Compliant The hospital provides a written response to patient grievances communicated to the patient or the patient's representative in a language and manner the patient or the patient's representative understands. The hospital may use additional tools to resolve a grievance, such as meeting with the patient and his family. Regulatory requirements for the grievance process are minimum standards, and do not inhibit the use of additional approaches in addressing patient grievances.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** Verify: ▪ The policy and procedure for resolution patient grievances meets the requirement. ▪ Grievance response letters include all

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.13(a)(2)(iii)	However, in all cases the hospital must provide a written notice (response) to each patient's grievance(s). 1. The hospital's decision. 2. The name of the hospital contact person. 3. The steps taken on behalf of the patient to investigate the grievance. 4. The date of grievance investigation completion. When a patient communicates a grievance to the hospital via email the hospital may provide its response via email pursuant to hospital policy. When the email response contains the information stated in this requirement, the email meets the requirement for a written response. ▪ The hospital must maintain evidence of its compliance with these requirements. A grievance is considered resolved when the patient is satisfied with the actions taken on their behalf. There may be situations where the hospital has taken appropriate and reasonable actions on the patient's behalf to resolve the patient's grievance and the patient or the patient's representative remains unsatisfied with the hospital's actions. In these situations, the hospital may consider the grievance closed for the purposes of these requirements. The hospital must maintain documentation of its efforts and demonstrate compliance with CMS requirements. In its written response, the hospital is not required to include statements that could be used in a legal action against the hospital, but the hospital must provide adequate information to address each item stated in this requirement. The hospital is not required to provide an exhaustive explanation of every action the hospital has taken to investigate the grievance, resolve the grievance, or other actions taken by the hospital.	required components. ▪ The hospital retains copies of written notices (responses) to patients.

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RESTRAINT AND SECLUSION

15.02.00 Restraint and seclusion

All patients have the right to be free from physical or mental abuse, and corporal punishment.

All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff.

Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

§482.13(e)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The intent of this standard is to eliminate the inappropriate use of restraint or seclusion.

The safety of the patient, staff, or others is the basis for initiating and discontinuing the use of restraint or seclusion.

The use of restraint or seclusion must be discontinued as soon as possible based on an individualized patient assessment and re-evaluation.

A violation of any of these patients' rights constitutes an inappropriate use of restraint or seclusion and would be subject to a condition level deficiency.

The patient protections in this standard apply to all hospital patients when the use of restraint or seclusion becomes necessary, regardless of patient location. The requirements are not specific to any treatment setting within the hospital. They are not targeted only to patients on psychiatric units or those with behavioral/mental health care needs. Instead, the requirements are specific to the patient behavior that the restraint or seclusion intervention is being used to address.

In summary, these restraint and seclusion regulations apply to:

- All hospitals (acute care, long-term care, psychiatric, children's, and cancer);
- All locations within the hospital (including medical /surgical units, critical care units, forensic units, emergency department, psychiatric units, etc.); and
- All hospital patients, regardless of age, who are restrained or secluded (including both inpatients and outpatients).

The decision to use a restraint or seclusion is not driven by diagnosis, but by a

INTERVIEW, OBSERVATION AND DOCUMENT REVIEW

- Review hospital restraint and seclusion policies and procedures to verify that they address, at a minimum:
  - □ Who has the authority to discontinue the use of restraint or seclusion (based on state law and hospital policies).
  - □ Circumstances under which restraint or seclusion should be discontinued. (See also §482.13(e)(3).)
- Review a sample of medical records of patients for whom restraints were used to manage non-violent, non-self-destructive behavior, as well as a sample of medical records of patients for whom restraint or seclusion was used to manage violent or self-destructive behavior.
  Include in the review patients who are currently in restraint or seclusion, as well as those who have been in restraint or seclusion during their hospital stay.
  - □ What evidence is there that hospital

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

comprehensive individual patient assessment.

The comprehensive assessment should include a physical assessment to identify medical problems that may be causing behavior changes in the patient. For example, temperature elevations, hypoxia, hypoglycemia, electrolyte imbalances, drug interactions, and drug side effects may cause confusion, agitation, and combative behaviors. Addressing these medical issues may eliminate or minimize the need for the use of restraints or seclusion. For a given patient at a particular point in time, this comprehensive individualized patient assessment is used to determine whether the use of less restrictive measures poses a greater risk than the risk of using a restraint or seclusion.

Staff must assess and monitor a patient's condition on an ongoing basis to ensure that the patient is released from restraint or seclusion at the earliest possible time. Restraint or seclusion may only be employed while the unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion should be discontinued. The decision to discontinue the intervention should be based on the determination that the need for restraint or seclusion is no longer present, or that the patient's needs can be addressed using less restrictive methods.

Hospital leadership is responsible for creating a culture that supports a patient's right to be free from restraint or seclusion. Leadership must ensure that systems and processes are developed, implemented, and evaluated that support the patients' rights addressed in this standard, and that eliminate the inappropriate use of restraint or seclusion.

Through the QAPI program, hospital leadership should:

- Assess and monitor the use of restraint or seclusion in the facility.
- Implement actions to ensure that restraint or seclusion is used only to ensure the physical safety of the patient, staff, and others.
- Ensure that the hospital complies with the requirements set forth in

staff identified the reason for the restraint or seclusion, and determined that other less restrictive measures would not be effective before applying the restraint?

- Interview staff who work directly with patients to determine their understanding of the restraint and seclusion policies. If any patients are currently in restraint or seclusion, ascertain the rationale for use and when the patient was last monitored and assessed.
- Is the actual use of restraints or seclusion consistent with hospital restraint and seclusion policies and procedures, as well as CMS requirements?
- Review incident and accident reports to determine whether patient injuries occurred proximal to or during a restraint or seclusion intervention. Are incidents and accidents occurring more frequently with restrained or secluded patients?
- If record review indicates that restrained or secluded patients sustained injuries, determine what the hospital did to prevent additional injury. Determine if the hospital investigated

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this standard as well as those set forth by State law and hospital policy when the use of restraint or seclusion is necessary.

The use of restraint is inherently risky. When the use of restraint is necessary, the least restrictive method must be used to ensure a patient's safety. The use of restraint for the management of patient behavior should not be considered a routine part of care.

The use of restraints for the prevention of falls should not be a routine part of a falls prevention program.

For example, a patient who is displaying symptoms of Sundowner's Syndrome, in which a patient's dementia becomes more apparent at the end of the day than at the beginning of the day:

- The patient is not acting out or behaving in a violent or self-destructive manner. However, the patient has an unsteady gait and continues to get out of bed even after staff has tried alternatives to keep the patient from getting out of bed. There is nothing inherently dangerous about a patient being able to walk or wander, even at night. Under the provisions of this regulation, the rationale that the patient should be restrained because he "might" fall does not constitute an adequate basis for using a restraint for the purposes of this regulation.

When assessing a patient's risk for falls and planning care for the patient, staff should consider whether the patient has a medical condition or symptom that indicates a current need for a protective intervention to prevent the patient from walking or getting out of bed.

A history of falling without a current clinical basis for a restraint intervention is inadequate to demonstrate the need for restraint.

An individualized patient assessment is critical. In this example, an assessment should minimally address the following questions:

- Are there safety interventions or precautions (other than restraint) that can be taken to reduce the risk of the patient slipping, tripping, or possible changes to its restraint or seclusion policies.
- **Verify the facility has an accurate process to track patients in restraint and/or seclusion. Review** data on the use of restraint and seclusion for a specified time period (e.g., 3 months) to determine any patterns in their use.
  - □ Does the number of patients who are restrained or secluded increase on weekends, on holidays, at night, on certain shifts; where contract nurses are used; in one unit more than other units? Such patterns of restraint or seclusion use may suggest that the intervention is not based on the patient's need, but on issues such as convenience, inadequate staffing or lack of staff training. Obtain nursing staffing schedules during time periods in question to determine if staffing levels impact the use of restraint or seclusion.
- Interview a random sample of patients who were restrained to manage non-violent, non-self-destructive behavior. Were the reasons for the use of a restraint to manage non-violent, non-self-destructive behavior explained to the patient in understandable terms?

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	falling if the patient gets out of bed? ▪ Is there a way to enable the patient to safely ambulate? ▪ Is there some assistive device that will improve the patient's ability to self-ambulate? ▪ Is a medication or a reversible condition causing the unsteady gait? ▪ Would the patient be content to walk with a staff person? ▪ Could the patient be brought closer to the nurse's station where he or she could be supervised? If an assessment reveals a medical condition or symptom that indicates the need for an intervention to protect the patient from harm, the regulation requires the hospital to use the least restrictive intervention that will effectively protect the patient from harm. Upon making this determination, the hospital may consider the use of a restraint; however, that consideration should weigh the risks of using a restraint (which are widely documented in research) against the risks presented by the patient's behavior. A request from a patient or family member for the application of a restraint, which they consider to be beneficial, is not a sufficient basis for the use of a restraint intervention. ▪ A patient or family member request for a restraint intervention, such as a vest restraint or raising all four side rails, to keep the patient from getting out of bed or falling should prompt a patient and situational assessment to determine whether such an intervention is needed. If a need is confirmed, the practitioner must then determine the type of restraint intervention that will meet the patient's needs with the least risk and most benefit to the patient. If restraint (as defined by the regulation) is used, then the requirements of the regulation must be met. Patient care staff must demonstrate through their documentation in the patient's medical record that the restraint intervention used is the least restrictive intervention that protects the patient's safety, and that the use of	Could the patient articulate his/her understanding?

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restraint is based on individual assessments of the patient. The assessments and documentation of those assessments must be ongoing to demonstrate a continued need for restraint.

Documentation by the physician or other staff once a day may not be adequate to support that the restraint intervention needs to continue and may not comply with the requirement to end the restraint as soon as possible. A patient's clinical needs often change over time.

The use of weapons in the application of restraint or seclusion is not a safe, appropriate health care intervention.

- For the purposes of this regulation, the term "weapon" includes, but is not limited to, pepper spray, mace, nightsticks, Tasers, cattle prods, stun guns, and pistols.
- Security staff may carry weapons as allowed by hospital policy, and State and Federal law. However, the use of weapons by security staff is considered a law enforcement action, not a health care intervention. The use of weapons by any hospital staff as a means of subduing a patient to place that patient in restraint or seclusion is not appropriate. If a weapon is used by security or law enforcement personnel on a person in a hospital (patient, staff, or visitor) to protect people or hospital property from harm, the situation should be handled as a criminal activity and the perpetrator placed in the custody of local law enforcement.

The use of handcuffs, manacles, shackles, other chain-type restraint devices, or other restrictive devices applied by non-hospital employed or contracted law enforcement officials for custody, detention, and public safety reasons are not governed by this rule. The use of such devices is considered law enforcement restraint and would not be considered safe, appropriate health care restraint interventions for use by hospital staff to restrain patients**.** The law enforcement officers who maintain custody and direct supervision of their prisoner (the hospital's patient) are responsible for the use, application, and monitoring of these restrictive devices in accordance with Federal and

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	State law. However, the hospital is still responsible for an appropriate patient assessment and the provision of safe, appropriate care to its patient (the law enforcement officer's prisoner).	
15.02.01 Physical restraint *A restraint is—* ▪ *Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move his or her arms, legs, body, or head freely* §482.13(e)(1)(i)(A)	☐ Compliant ☐ Not Compliant This definition applies to all uses of restraint in all hospital care settings. Under this definition, commonly used hospital devices and other practices could meet the definition of a restraint, such as: ▪ Tucking a patient's sheets in so tightly that the patient cannot move. ▪ Use of a "net bed" or an "enclosed bed" that prevents the patient from freely exiting the bed. **EXCEPTION:** Placement of a toddler in an "enclosed" or "domed" crib. ▪ Use of "Freedom" splints that immobilize a patient's limb. ▪ Using side rails to prevent a patient from voluntarily getting out of bed. ▪ Geri chairs or recliners, only if the patient cannot easily remove the restraint appliance and get out of the chair on his or her own. **Note:** Generally, if a patient can easily remove a device, the device would not be considered a restraint. In this context, "easily remove" means that the manual method, device, material, or equipment can be removed intentionally by the patient in the same manner as it was applied by the staff (e.g., side rails are put down, not climbed over; buckles are intentionally unbuckled; ties or knots are intentionally untied; etc.) considering the patient's physical condition and ability to accomplish objective (e.g., transfer to a chair, get to the bathroom in time).	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Determine whether the hospital's policy and procedures employ a definition or description of what constitutes a restraint that is consistent with the regulation. ▪ While touring hospital units look for restraints in use. Where a restraint is in use, check the medical record for appropriate documentation. ▪ Interview hospital staff to determine whether they know the definition of a restraint.

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15.02.02 Chemical restraint

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

A restraint is –

- *A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.*

§482.13(e)(1)(i)(B)

Drugs or medications that are used as part of a patient's standard medical or psychiatric treatment and are administered within the standard dosage for the patient's condition, would not be subject to the requirements of this standard.

These regulations are not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need therapeutic doses of medication to improve their level of functioning so that they can more actively participate in their treatment. Similarly, these regulations are not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia, anti-anxiety medication prescribed to calm a patient who is anxious, or analgesics prescribed for pain management. The regulatory language is intended to provide flexibility and recognize the variations in patient conditions.

Whether or not an order for a drug or medication is PRN or a standing-order does not determine whether the use of that drug or medication is considered a restraint. The use of PRN or standing-order drugs or medications is only prohibited if the drug or medication meets the definition of a drug or medication used as a restraint.

Criteria used to determine whether the use of a drug or medication, or combination of drugs or medications is a standard treatment or dosage for the patient's condition includes all the following:

- The drug or medication is used within the pharmaceutical parameters approved by the Food and Drug Administration (FDA) and the manufacturer for the indications that it is manufactured and labeled to address, including listed dosage parameters.
- The use of the drug or medication follows national practice standards established or recognized by the medical community, or professional

INTERVIEW AND DOCUMENT REVIEW

- Determine whether the hospital's policies and procedures employ a definition or description of what constitutes the use of drugs or medications as a restraint that is consistent with the regulation.
- Interview hospital staff to determine whether they can identify when the use of a drug or medication is considered a chemical restraint.

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medical associations or organizations.

- The use of the drug or medication to treat a specific patient's clinical condition is based on that patient's symptoms, overall clinical situation, and on the physician's or other licensed independent practitioner's (LIP) knowledge of that patient's expected and actual response to the medication.

The standard use of a drug or medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around them than would be possible without the use of the drug or medication. If the overall effect of a drug or medication, or combination of drugs or medications, is to reduce the patient's ability to effectively or appropriately interact with the world around them, then the drug or medication is not being used as a standard treatment or dosage for the patient's condition.

As with any use of restraint or seclusion, staff must conduct a comprehensive patient assessment to determine the need for other types of interventions before using a drug or medication as a restraint. For example, a patient may be agitated due to pain, an adverse reaction to an existing drug or medication, or other unmet care need or concern.

There are situations where the use of a drug or medication is clearly outside the standard for a patient or a situation, or a medication is not medically necessary but is used for patient discipline or staff convenience (neither of which is permitted by the regulation).

- **EXAMPLE 1:** A patient has Sundowner's Syndrome in which dementia becomes more apparent at the end of the day. The patient may become agitated, angry, or anxious at sundown. This may lead to wandering, pacing the floors, or other nervous behaviors. The staff finds the patient's behavior bothersome and asks the physician to order a high dose of a sedative to keep the patient in bed. The patient has no medical symptoms or condition that indicates the need for a sedative. In this case, for this

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

patient, the sedative is being used inappropriately as a restraint for staff convenience. Such use is not permitted by the regulation.

A drug or medication that is not being used as a standard treatment for the patient's medical or psychiatric condition, and that results in restricting the patient's freedom of movement would be a drug used as a restraint.

The regulation does not permit a drug or medication to be used to restrain the patient for staff convenience, to coerce or discipline the patient, or as a method of retaliation. While drugs or medications can be a beneficial part of a carefully constructed, individualized treatment plan for the patient, drug and medication use should be based on the assessed needs of the individual patient, and the effects of drugs and medications on the patient should be carefully monitored.

- **EXAMPLE 2:** A patient is in a detoxification program. The patient becomes violent and aggressive. Staff administers a PRN medication ordered by the patient's physician or other LIP to address these types of outbursts. The use of the medication enables the patient to better interact with others or function more effectively. In this case, the medication used for this patient is not considered a "drug used as a restraint." The availability of a PRN medication to manage outbursts of specific behaviors, such as aggressive, violent behavior is standard for this patient's medical condition (i.e., drug or alcohol withdrawal). Therefore, this patient's medication does not meet the definition of "drug used as a restraint" since it is a standard treatment or dosage for the patient's medical or psychiatric condition.

If a drug or medication is used as a standard treatment (as previously defined) to address the assessed symptoms and needs of a patient with a particular medical or psychiatric condition, its use is not subject to the requirements of this regulation. However, the patient would still need to receive assessments, monitoring, interventions, and care that are appropriate for that patient's needs.

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The regulation supports existing state laws that provide more vigorous promotion of the patient's choice and rights. Therefore, when a state's law prohibits the administration of drugs against the wishes of the patient without a court order, the state law applies.

15.02.03 Non-restraints

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

A restraint does not include –

- *Devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).*

§482.13(e)(1)(i)(C)

The devices and methods described below generally would not be considered restraints.

MEDICAL-SURGICAL CARE DEVICES

- An IV arm board to stabilize an IV line is generally not considered a restraint unless the arm board is tied down (or otherwise attached to the bed) or the entire limb is immobilized such that the patient cannot access his or her body.
- A mechanical support used to achieve proper body position, balance, or alignment to allow greater freedom of mobility than would be possible without the use of such support is not considered a restraint. For example, some patients lack the ability to walk without the use of leg braces, or to sit upright without neck, head, or back braces.
- A medically necessary positioning or securing device used to maintain the position, limit mobility, or temporarily immobilize the patient during medical, dental, diagnostic, or surgical procedures.

Recovery from anesthesia that occurs when the patient is in a critical care or post-anesthesia care unit is considered part of the surgical procedure; therefore, medically necessary restraint use in this setting is acceptable. However, if the intervention is maintained when the patient is transferred to another unit or recovers from the effects of the anesthesia (whichever occurs first), a restraint order would be necessary and the requirements of standard 15.02.00 would apply.

OBSERVATION, INTERVIEW AND DOCUMENT REVIEW

- Determine whether the hospital's policies and procedures employ a definition or description of what constitutes a restraint that is consistent with the regulation.
- While touring hospital units look for bed side rail use to determine whether it is consistent with the definition of a restraint.
  - ☐ Where bed side rails are being used as a restraint, check the medical record for appropriate documentation.
- Interview hospital staff to determine whether they know the definition of a restraint, particularly with respect to use of bed side rails.

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- Many types of hand mitts.
  - Pinning or otherwise attaching those same mitts to bedding or using a wrist restraint in conjunction with the hand mitts **would** meet the definition of restraint and the requirements would apply.
  - If the mitts are applied so tightly that the patient's hand or fingers are immobilized, this **would** be considered restraint and the requirements would apply.
  - If the mitts are so bulky that the patient's ability to use their hands is significantly reduced, this **would** be considered restraint and the requirements would apply.

Note: Because the definition of physical restraint does not name each device and situation that can be used to immobilize or reduce the ability of the patient to move his or her arms, legs, body, or head freely, each patient situation should be considered on a case-by-case basis.

In addition, if a patient can easily remove a device, the device would not be considered a restraint.

In this context, "easily remove" means that the manual method, device, material, or equipment can be removed intentionally by the patient in the same manner as it was applied by the staff (e.g., side rails are put down, not climbed over; buckles are intentionally unbuckled; ties or knots are intentionally untied; etc.) considering the patient's physical condition and ability to accomplish the objective (e.g., transfer to a chair, get to the bathroom in time).

AGE OR DEVELOPMENTALLY APPROPRIATE PROTECTIVE SAFETY INTERVENTIONS

Safety interventions (such as stroller safety belts, swing safety belts, high chair lap belts, raised crib rails, and crib covers) that a safety-conscious child care provider outside a health care setting would use to protect an infant,

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toddler, or preschool-aged child would not be considered restraint or seclusion for the purposes of this regulation.

- The use of these safety interventions needs to be addressed in the hospital's policies or procedures.

PHYSICAL ESCORT

A physical escort would include a "light" grasp to escort the patient to a desired location.

- If the patient can easily remove or escape the grasp, this would not be considered physical restraint.
- However, if the patient cannot easily remove or escape the grasp, this would be considered physical restraint and all the requirements would apply.

PHYSICAL HOLDING

The regulation permits the physical holding of a patient for the purpose of conducting routine physical examinations or tests.

However, patients do have the right to refuse treatment. See standards 15.01.02 and 15.01.04 [§482.13(b)(2)]. This includes the right to refuse physical examinations or tests.

- Holding a patient in a manner that restricts the patient's movement against their will is considered restraint. This includes holds that some members of the medical community may term "therapeutic holds." Many deaths have occurred while employing these practices.
- Physically holding a patient can be just as restrictive, and just as dangerous, as restraining methods that involve devices. Physically holding a patient during a forced psychotropic medication procedure is considered a restraint and is not included in this exception.
- For the purposes of this regulation, a staff member picking up, redirecting, or holding an infant, toddler, or preschool-aged child to

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comfort the patient is not considered restraint.

PHYSICAL HOLDING FOR FORCED MEDICATIONS

The application of force to physically hold a patient in order to administer a medication against the patient's wishes, is considered restraint.

- The patient has a right to be free of restraint and, in accordance with standard 15.01.04 [§482.13(b)(2)], also has a right to refuse medications, unless a court has ordered medication treatment.
- A court order for medication treatment only removes the patient's right to refuse the medication.
- Additionally, in accordance with state law, some patients may be medicated against their will in certain emergency circumstances.

In both circumstances above, health care staff is expected to use the least restrictive method of administering the medication to avoid or reduce the use of force, when possible.

- The use of force in order to medicate a patient, as with other restraint, must have a physician's order prior to the application of the restraint (use of force).
- If physical holding for forced medication is necessary with a violent patient, the one-hour face-to-face evaluation requirement would also apply.

In certain circumstances, a patient may consent to an injection or procedure, but may not be able to hold still for an injection or cooperate with a procedure. Under such circumstances, and at the patient's request, staff may "hold" the patient to safely administer an injection (or obtain a blood sample, or insert an intravenous line, if applicable) or to conduct a procedure. This is not considered restraint.

SIDE RAILS

A restraint does not include methods that protect the patient from falling out

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of bed. Examples include:

- Raising the side rails when a patient is: on a stretcher, recovering from anesthesia, sedated, experiencing involuntary movement, or on certain types of therapeutic beds to prevent the patient from falling out of the bed.

  The use of side rails in these situations protects the patient from falling out of bed and, therefore, would not be subject to the requirements of standard (e).

- However, side rails are frequently not used as a method to prevent the patient from falling out of bed, but instead, used to restrict the patient's freedom to exit the bed.
- The use of side rails to prevent the patient from exiting the bed would be considered a restraint and would be subject to the requirements of standard 15.02.00.

The use of side rails is inherently risky, particularly if the patient is elderly or disoriented. Frail, elderly patients may be at risk for entrapment between the mattress or bed frame and the side rail.

Disoriented patients may view a raised side rail as a barrier to climb over, may slide between raised, segmented side rails, or may scoot to the end of the bed to get around a raised side rail and exit the bed. When attempting to leave the bed by any of these routes, the patient is at risk for entrapment, entanglement, or falling from a greater height posed by the raised side rail, with a possibility for sustaining greater injury or death than if the patient had fallen from the height of a lowered bed without raised side rails. In short, the patient may have an increased risk for a fall or other injury by attempting to exit the bed with the side rails raised. The risk presented by side rail use should be weighed against the risk presented by the patient's behavior as ascertained through individualized assessment.

When the clinician raises all four side rails to restrain a patient, defined in this regulation as immobilizing or reducing the ability of a patient to move his or

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her arms, legs, body, or head freely to ensure the immediate physical safety of the patient, then the requirements of this rule apply.

- Raising fewer than four side rails when the bed has segmented side rails would not necessarily immobilize or reduce the ability of a patient to move freely as defined in the regulation.

  For example, if the side rails are segmented and all but one segment are raised to allow the patient to freely exit the bed, the side rail is not acting as a restraint and the requirements of this rule would not apply.

- If a patient is not physically able to get out of bed regardless of whether or not the side rails are raised, raising all four side rails would not be considered restraint because the side rails have no impact on the patient's freedom of movement.

Side rails that are not a restraint

- When a patient is on a bed that constantly moves to improve circulation or prevent skin breakdown, raised side rails are a safety intervention and are not viewed as restraint.
- When a patient is placed on seizure precautions and all side rails are raised, the use of padded side rails should protect the patient from harm including falling out of bed in the event of a seizure.
- Placement in a crib with raised rails is an age-appropriate standard safety practice for every infant or toddler. Therefore, placement of an infant or toddler in the crib with raised rails would not be considered restraint.
- If the patient is on a stretcher (a narrow, elevated, and highly mobile cart used to transport patients and to evaluate or treat patients), there is an increased risk of falling from a stretcher without raised side rails due to its narrow width, and mobility. In addition, because stretchers are elevated platforms, the risk of patient injury due to a fall is significant. Therefore, the use of raised side rails on stretchers is not considered restraint but a prudent safety intervention.

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	The use of a seat belt when transporting a patient in a wheelchair is not considered restraint.	
15.02.04 Seclusion	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Seclusion is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. *Seclusion may only be used for the management of violent or self-destructive behavior.* §482.13(e)(1)(ii)	Seclusion may only be used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Seclusion is not just confining a patient to an area, but involuntarily confining the patient alone in a room or area where the patient is physically prevented from leaving. If a patient is restricted to a room alone and staff are physically intervening to prevent the patient from leaving the room or giving the perception that threatens the patient with physical intervention if the patient attempts to leave the room, the room is considered locked, whether the door is actually locked or not. In this situation, the patient is being secluded. A patient physically restrained alone in an unlocked room does not constitute seclusion. Confinement on a locked unit or ward where the patient is with others does not constitute seclusion. **Timeout** is not considered seclusion. Timeout is an intervention in which the patient consents to being alone in a designated area for an agreed upon timeframe from which the patient is not physically prevented from leaving. Therefore, the patient can leave the designated area when he/she chooses.	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Determine whether the hospital's policy and procedures employ a definition or description of what constitutes seclusion that is consistent with the regulation. ▪ While touring hospital units look for cases where a patient is in seclusion. ▪ Interview hospital staff to determine whether they know the definition of seclusion.

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15.02.05 Least restrictive interventions

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Restraint or seclusion may only be used when less restrictive interventions have been determined to be ineffective to protect the patient, a staff member, or others from harm.

The type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, a staff member, or others from harm.

When restraint or seclusion is used, there must be documentation in the patient's medical record of the following:

- ***A description of the patient's behavior and the intervention used.***
- ***Alternatives or other less restrictive interventions attempted (as applicable).***
- ***The patient's condition or symptom(s) that warranted the use of the restraint or seclusion.***
- ***The patient's response to the interventions(s) used, including the rationale for continued use of the intervention.***

§482.13(e)(2-3)
§482.13(e)(16)(ii-v)

A comprehensive assessment of the patient must determine that the risks associated with the use of the restraint or seclusion is outweighed by the risk of not using the restraint or seclusion.

Less restrictive interventions do not always need to be tried, but less restrictive interventions must be determined by staff to be ineffective to protect the patient or others from harm prior to the introduction of more restrictive measures.

Alternatives attempted or the rationale for not using alternatives must be documented.

The underpinning of this regulation is the concept that safe patient care hinges on looking at the patient as an individual and assessing the patient's condition, needs, strengths, weaknesses, and preferences. Such an approach relies on caregivers who are skilled in individualized assessment and in tailoring interventions to the individual patient's needs after weighing factors such as the patient's condition, behaviors, history, and environmental factors.

The patient's behavior should be documented in descriptive terms to evaluate the appropriateness of the interventions used.

The documentation should include a detailed description of the patient's physical and mental status assessments, and of any environmental factors (e.g., physical, milieu, activities, etc.) that may have contributed to the situation at the time of the intervention.

The use of restraint or seclusion must be selected only when less restrictive measures have been judged to be ineffective to protect the patient or others from harm.

It is not always appropriate for less restrictive alternatives to be attempted

INTERVIEW AND DOCUMENT REVIEW

- Does the severity of the behavior justify seclusion or restraint usage by identifying an immediate and serious danger to the physical safety of the patient or others?
- Were other, less restrictive interventions tried and documented, or is there evidence that alternatives were considered and determined to be insufficient?
- Interview staff that have been in a position to restraint patients to verify how they assessed the patient and determined the least restrictive interventions that would be effective to protect the patient, staff, or others from harm.
- **Is there clear documentation in the patient's medical record describing the steps or interventions used prior to the use of the needed restraint or seclusion? That is, what documentation is in the medical record to explain the rationale for the use of restraint or seclusion?**
- **If the time of restraint or seclusion**

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	prior to the use of restraint or seclusion. **When a patient's behavior presents an immediate and serious danger to his- or herself, or others, immediate action is needed.** ▪ **For example, when a patient physically attacks someone, immediate action is needed.** **While staff should be mindful of using the least intrusive intervention, it is critical that the intervention selected be effective in protecting the patient or others from harm.** **A comprehensive, individualized patient assessment is necessary to identify the most appropriate intervention to effectively manage a patient's condition or symptom(s).** **When using a restraint or seclusion intervention, the patient's condition or symptom(s) must be identified and documented in the patient's medical record.**	**use is lengthy, look for evidence that the symptoms necessitating the use of restraint or seclusion have persisted.** ▪ **Is there evidence to indicate that the staff have evaluated whether or not the restraint or seclusion can be safely discontinued?** ▪ **Does the patient's medical record include a clear description of the patient's behavior that warranted the use of restraint or seclusion?** ▪ **Was the intervention employed appropriate for the identified behavior?** ▪ **What was the effect of less restrictive interventions, if attempted by staff?** ▪ **Does the patient's medical record include descriptions of the impact of the intervention on the patient behavior that resulted in the use of restraint or seclusion?** ▪ **Does the patient's medical record include a detailed assessment of the patient's response to the intervention and a well-reasoned plan for the continued use of restraint or seclusion?**

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15.02.06 Safe application *The use of restraint or seclusion must be –* ▪ *implemented in accordance with safe and appropriate restraint and seclusion techniques as determined by hospital policy in accordance with State law.* §482.13(e)(4)(ii)	☐ Compliant ☐ Not Compliant The use of restraint or seclusion must never act as a barrier to the provision of other interventions to meet the patient's needs.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Policies and procedures reflect current standards of practice regarding safe and appropriate restraint and seclusion techniques. □ Are there any references to or indication that state laws were reviewed and incorporated? ▪ Through review of medical records that include patients who required the use of restraint or seclusion to manage violent, self-destructive behaviors, and non-violent, non-self-destructive behaviors: □ After restraints were applied, an immediate assessment ensured they were properly and safely applied. □ Policies and procedures were followed. □ Whether the use of restraint or seclusion was effective in achieving the purpose for which it was ordered. If not, were timely changes made? □ Was there any evidence of injury to the patient?

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15.02.07 Restraint or seclusion: Modification of the plan of care *The use of restraint or seclusion must be –* ▪ *in accordance with a written modification to the patient's plan of care.* §482.13(e)(4) §482.13(e)(4)(i)	☐ Compliant ☐ Not Compliant An order for restraint or seclusion must result in a modification of the individualized plan of care. **PLAN OF CARE** The individualized plan of care describes the rationale for restraint or seclusion use. ▪ The plan lists the interventions selected, patient monitoring, and re-assessments. ▪ The plan addresses the frequency and content of the patient re-assessments including vital signs, safety, comfort, mental status, skin integrity/circulation checks, hydration, toileting, and readiness for release from restraint or seclusion, as outlined by hospital policy. The use of restraint or seclusion (including drugs or medications used as restraint as well as physical restraint) must be documented in the patient's plan of care or treatment plan. ▪ The use of restraint or seclusion constitutes a change in a patient's plan of care. The regulation does not require that a modification to the patient's plan of care be made before initiating or obtaining an order for the use of restraint or seclusion. The use of a restraint or seclusion intervention should be reflected in the patient's plan of care or treatment plan based on an assessment and evaluation of the patient. The plan of care or treatment plan should be reviewed and updated in writing within a timeframe specified by hospital policy.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review at least five medical records of patients who required restraint or seclusion to verify: ▪ Does the plan of care or treatment reflect a process of assessment, intervention, and evaluation when restraint or seclusion is used? ▪ Has the plan of care been modified to reflect the use of restraint or seclusion based on the patient assessment? ▪ Has the plan of care been reviewed and updated according to hospital policy? ▪ Are patient safety assessments and monitoring documented in the progress notes linked to the patient care plan, per hospital policy, e.g., vital signs, circulation and skin integrity checks, readiness for release of restraint? ▪ Is there evidence of assessment of the identified problem or of an individual patient assessment? ▪ Does the patient's plan of care reflect that assessment? □ What was the goal of the intervention? □ What was the described

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		intervention? □ Who is responsible for implementation? ▪ Did the physician or other LIP write orders that included a time limit? Were these orders incorporated into the plan of care? ▪ Was the patient informed of the changes in his or her treatment plan or plan of care? ▪ After the discontinuation of the restraint or seclusion intervention, was this information documented in an update of the plan of care or treatment plan?
15.02.08 Orders for restraint or seclusion *The use of restraint or seclusion must be –* ▪ *in accordance with the order of a physician or other licensed practitioner who is responsible for the care of the patient as specified under 42 CFR §482.12(c) and authorized to order restraint or seclusion by hospital policy in accordance with State law.* §482.13(e)(5)	☐ Compliant ☐ Not Compliant Hospitals must have policies and procedures for the initiation of restraint or seclusion that identify the categories of LIPs that are permitted to order restraint or seclusion in that hospital, consistent with State law. The regulation requires that a physician or other LIP responsible for the care of the patient to order restraint or seclusion prior to the application of restraint or seclusion. In some situations, the need for a restraint or seclusion intervention may occur so quickly that an order cannot be obtained prior to the application of restraint or seclusion. In these emergency application situations, the order must be obtained either during the emergency application of the restraint or seclusion, or immediately (within a few minutes) after the restraint or	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review at least five medical records of patients who required restraint or seclusion to verify: ▪ Each use of restraint or seclusion has been ordered by a physician or LIP authorized by the State and hospital policy. ▪ The physician or LIP who ordered each use of restraint or seclusion is identified.

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seclusion has been applied.

- The failure to immediately obtain an order is viewed as the application of restraint or seclusion without an order.
- The hospital should address this process in its restraint and seclusion policies and procedures. The policies and procedures should specify who can initiate the emergency application of restraint or seclusion prior to obtaining an order from a physician or other LIP.

LICENSED INDEPENDENT PRACTITIONER (LIP)
For the purpose of ordering restraint or seclusion, an LIP is any practitioner permitted by State law and hospital policy as having the authority to independently order restraints or seclusion for patients.

- A resident who is authorized by State law and the hospital's residency program to practice as a physician can carry out functions reserved for a physician or LIP by the regulation.
- A medical school student holds no license, and his/her work is reviewed and must be countersigned by the attending physician; therefore, he or she is not licensed or independent. A medical school student does not qualify as an LIP.

PROTOCOLS
A protocol cannot serve as a substitute for obtaining a physician's or other LIP's order prior to initiating each episode of restraint or seclusion use.

- If a hospital uses protocols that include the use of restraint or seclusion, a specific physician or LIP order is still required for each episode of restraint or seclusion use. The philosophy that serves as a foundation for the regulation is that restraint or seclusion use is an exceptional event, not a routine response to a certain patient condition or behavior.
- Each patient must be assessed, and interventions should be tailored to meet the individual patient's needs. The creation of a protocol can run

- A physician or LIP order was obtained prior to the initiation of restraint or seclusion.
  - □ When emergency application of restraint or seclusion was necessary, verify that a physician or LIP order was obtained immediately (within a few minutes) after application of the restraint or seclusion.
- Hospital policies and medical staff bylaws use clinical practice guidelines that describe the responsibilities of medical staff and clinicians who are privileged to order restraint and seclusion.
  - □ Do the hospital's written policies identify what categories of practitioners the state recognizes as an LIP or as having the authority to order restraint and seclusion?
  - □ Do the hospital's written policies conform to state law?
  - □ Does the hospital have established policies for who can initiate restraint or seclusion?
- Does the hospital apply protocols for the use of restraint or seclusion? If so, is the use of protocols consistent with the requirements of the regulation?

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	counter to this philosophy if it sets up the expectation that restraint or seclusion will be used as a routine part of care.	▪ **Do physician's or other LIP's orders specify the reason for restraint or seclusion, the type of restraint, and the duration of restraint or seclusion?**
15.02.09 Use of standing or PRN orders *Orders for the use of restraint or seclusion must never be written as a standing order or on an as needed basis (PRN).* §482.13(e)(6)	☐ Compliant ☐ Not Compliant This standard prohibits the use of standing or PRN orders for the use of restraint or seclusion. The ongoing authorization of restraint or seclusion is not permitted. ▪ Each episode of restraint or seclusion must be initiated in accordance with the order of a physician or other LIP. ▪ If a patient recently released from restraint or seclusion exhibits behavior that can only be handled through the reapplication of restraint or seclusion, a new order would be required. Staff cannot discontinue a restraint or seclusion intervention, and then re-start it under the same order. This would constitute a PRN order. ▪ A "trial release" constitutes a PRN use of restraint or seclusion and is not permitted by this regulation. For example, a patient is released from restraint or seclusion based on the staff's assessment of the patient's condition. If this patient later exhibits behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others that can only be handled using restraint or seclusion, a new order would be required. **Note**: A temporary, directly supervised release that occurs for the purpose of caring for a patient's needs (e.g., toileting, feeding, or range of motion exercises) is not considered a discontinuation of the restraint or seclusion intervention. As long as the patient remains under direct staff supervision, the	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review a random sample of medical records for patients who have been restrained or secluded. ▪ Review orders, progress notes, flow sheets, and nursing notes to: □ Ensure there are no restraint orders written as PRN or as standing orders. □ Determine if restraint or seclusion is being improperly implemented on a PRN basis.

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restraint is not considered to be discontinued because the staff member is present and is serving the same purpose as the restraint or seclusion.

The use of PRN orders for drugs or medications is only prohibited when a drug or medication is being used as a restraint. See standard 15.02.02 for additional detail.

- A drug or medication is deemed to be a restraint only if it is not a standard treatment or dosage for the patient's condition and the drug or medication is a restriction to manage the patient's behavior or restricts the patient's freedom of movement.
- Using a drug to restrain a patient for staff convenience is expressly prohibited.

EXCEPTIONS

- **Geri chair**. If a patient requires the use of a Geri chair with the tray locked in place for the patient to safely be out of bed, a standing or PRN order is permitted. Given that a patient may be out of bed in a Geri chair several times a day, it is not necessary to obtain a new order each time.
- **Raised side rails.** If a patient's status requires that all bedrails be raised (restraint) while the patient is in bed, a standing or PRN order is permitted. It is not necessary to obtain a new order each time the patient is returned to bed after being out of bed.
- **Repetitive self-mutilating behavior**. If a patient is diagnosed with a chronic medical or psychiatric condition, such as Leasch-Nyhan Syndrome, and the patient engages in repetitive self-mutilating behavior, a standing or PRN order for restraint to be applied in accordance with specific parameters established in the treatment plan would be permitted. Since the use of restraints to prevent self-injury is needed for these types of rare, severe, medical, and psychiatric conditions, the specific requirements (one-hour face-to-face evaluation, time-limited orders, and evaluation every 24 hours before renewal of the order) for

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the management of violent or self- destructive behavior do not apply.

15.02.10 Physician notification of restraint and seclusion use

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The attending physician must be consulted as soon as possible if the attending physician did not order the restraint or seclusion.

§482.13(e)(7)

The intent of this standard is to ensure that the physician who has overall responsibility and authority for the management and care of the patient is aware of the patient's condition and of the restraint or seclusion intervention. It is important to consult with the attending physician to promote continuity of care, to ensure patient safety, and to elicit information that might be relevant in choosing the most appropriate intervention for the patient. The attending physician may have information regarding the patient's history that may have a significant impact on the selection of a restraint or seclusion intervention or an alternative intervention, and the subsequent course of treatment. Therefore, consultation should occur as soon as possible.

Hospital policies and procedures should address the definition of "as soon as possible" based on the needs of their particular patient population(s). However, any established time frames must be consistent with "as soon as possible."

The attending physician is the MD/DO responsible for the management and care of the patient.

Hospital medical staff policies determine who is considered the attending physician.

The hospital CoPs do permit the patient to be under the care of a treating LIP other than a physician.

- Section 42 CFR §482.12(c)(1) requires every Medicare patient to be under the care of a Doctor of Medicine or Osteopathic Medicine; or, within the scope of their respective licenses, a Doctor of Dental Surgery or dental medicine, a Doctor of Podiatry, a chiropractor, or a clinical psychologist.

INTERVIEW AND DOCUMENT REVIEW

Review a random sample of medical records for patients who have been restrained or secluded.

- Review for documentation that the attending physician was notified immediately if the attending physician did not order the restraint or seclusion.
- Review the hospital's policies and procedures regarding consultation with the attending physician if the attending physician did not order the restraint or seclusion.
- Interview staff to determine if actual practice is consistent with written hospital policies and procedures.

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	▪ The individual overseeing the patient's care may be the attending physician or a health professional practicing with the delegated authority or supervision of an MD/DO as permitted by State law and hospital policy. When the attending physician of record is unavailable, responsibility for the patient must be delegated to another physician, who would then be considered the attending physician. This provision does not specify that consultation with the attending physician be face-to-face. The consultation can occur via telephone. Hospital policy provides practice expectations: 1. If the attending physician did not order the restraint or seclusion, the attending physician must be consulted as soon as possible. This requirement may be achieved through a telephone call. The attending physician is notified to ensure continuity of care, to ensure patient safety, and to obtain other relevant information about the care of the patient. 2. When the attending physician is not available and has delegated patient responsibility to another physician, the covering physician is considered the attending physician.	
15.02.11 Non-violent restraint: Renewal orders *Unless superseded by State law that is more restrictive –* ▪ *Each order for restraint used to ensure the physical safety of the non-violent or non-self-destructive patient may be renewed as authorized by hospital policy.* §482.13(e)(8)(iii)	☐ Compliant ☐ Not Compliant Hospitals have the flexibility to determine time frames for the renewal of orders for restraint of the non-violent, non-self-destructive patient. These time frames should be addressed in hospital policies and procedures. When the physician or LIP renews an order or writes a new order authorizing the continued use of restraint or seclusion, there must be documentation in the medical record that describes the patient's clinical needs and supports the continued use of restraint or seclusion. **Renewal order timeframes should support an ongoing evaluation of the**	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the hospital policy on renewal of restraint orders for the management of non-violent, non-self-destructive patient behavior. ▪ Interview staff and review the medical record documentation to ensure that practice is consistent with the hospital

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	need for continued use of restraints. It is recommended that renewal orders are obtained each calendar day.	policy. ▪ **Does hospital policy align with medical record documentation of restraint duration orders?**
15.02.12 Violent restraints and/or seclusion: Time limited renewal orders *Unless superseded by State law that is more restrictive --* *(i) Each order for restraint or seclusion used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others may only be renewed in accordance with the following limits for up to a total of 24 hours:* *(A) 4 hours for adults 18 years of age or older;* *(B) 2 hours for children and adolescents 9 to 17 years of age; or* *(C) 1 hour for children under 9 years of age.* §482.13(e)(8)(i) §482.13(e)(8)(i)(A-C)	☐ Compliant ☐ Not Compliant Patients of all ages are vulnerable and at risk when restrained or secluded to manage violent or self-destructive behavior. Therefore, time limits have been established for each order for restraint or seclusion used to manage violent or self-destructive behavior. State law may require more restrictive time limits. ▪ These time limits do not apply to orders for restraint used to manage non-violent or non-self-destructive behavior. However, the requirement that restraint use be ended at the earliest possible time applies to all uses of restraint. CMS does not specify criteria for differentiating between emergency situations where the patient's behavior is violent or self-destructive and jeopardizes the immediate physical safety of the patient, a staff member, or others, and non-emergency use of restraint. Clinicians are adept at identifying various behaviors and symptoms and can readily recognize violent and self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others. Asking clinicians to act based on an evaluation of the patient's behavior is no different than relying on the clinical judgment that they use daily in assessing the needs of each patient and taking actions to meet those individual needs. The standard identifies maximum time limits on the length of each order for restraint or seclusion based on age. ▪ The physician or other LIP has the discretion to write the order for a	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review a random sample of medical records for patients who have been restrained or secluded. ▪ When restraint or seclusion is used to manage violent or self-destructive behavior, do orders contain the appropriate time frames based on the patient's age? □ Does the total number of hours covered by an order or its renewal exceed 24 hours? ▪ If more restrictive state laws apply, are they being followed? ▪ Is a renewal order for restraint or seclusion based on a comprehensive individual patient assessment? □ Is there evidence in the patient's medical record that the symptoms necessitating the continued use of restraint or seclusion have persisted?

shorter length of time.

- The length-of-order requirement identifies critical points at which there is mandatory contact with a physician or other LIP responsible for the care of the patient. In addition, the time limits do not dictate how long a patient should remain in restraint or seclusion.
- Staff is expected to continually assess and monitor the patient to ensure that the patient is released from restraint or seclusion at the earliest possible time. Restraint or seclusion may only be employed while the unsafe situation continues.
- The intervention must be discontinued at the earliest possible time, regardless of the length of time identified in the order.

  For example, if a patient's behavior is no longer violent or self-destructive 20 minutes after the intervention is initiated, then the restraint or seclusion should be discontinued, even if the order was given for up to 4 hours.

  If restraint or seclusion is discontinued prior to the expiration of the original order, a new order must be obtained prior to reinitiating the use of restraint or seclusion.

RENEWAL OF ORIGINAL ORDER FOR VIOLENT BEHAVIOR

At the end of the time frame, if the continued use of restraint or seclusion to manage violent or self-destructive behavior is deemed necessary based on an individualized patient assessment, another order is required.

- When the original order is about to expire, an RN must contact the physician or other LIP, report the results of his or her most recent assessment and request that the original order be renewed (not to exceed the time limits established in the regulation).
- Whether or not an onsite assessment is necessary prior to renewing the order is left to the discretion of the physician or other LIP in conjunction with a discussion with the RN who is over-seeing the care of the patient. Another one-hour face-to-face patient evaluation (see 42 CFR

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§482.13(e)(12) and the related interpretive guidance) is not required when the original order is renewed.

- The original restraint or seclusion order may only be renewed within the required time limits for up to a total of 24 hours. After the original order expires, a physician or other LIP must see and assess the patient before issuing a new order.

EXCEPTION: Repetitive self-mutilating behaviors –see standard 15.02.09 [§482.13(e)(6)] for additional information.

15.02.13 Violent restraints and/or seclusion: Renewal order after physician assessment

Unless superseded by State law that is more restrictive --

- *After 24 hours, before writing a new order for the use of restraint or seclusion for the management of violent or self-destructive behavior, a physician or other licensed practitioner who is responsible for the care of the patient and authorized to order restraint or seclusion by hospital policy in accordance with State law must see and assess the patient.*

§482.13(e)(8)(ii)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

VIOLENT OR SELF-DESTRUCTIVE BEHAVIOR

At a minimum, if a patient remains in restraint or seclusion for the management of violent or self-destructive behavior 24 hours after the original order, the physician or other LIP must see the patient and conduct a face-to-face re-evaluation before writing a new order for the continued use of restraint or seclusion.

Twenty-four hours of restraint or seclusion for the management of violent or self-destructive behavior is an extreme measure with the potential for serious harm to the patient.

State laws may be more restrictive and require the physician or other LIP to conduct a face-to-face re-evaluation within a shorter timeframe.

When the physician or other LIP renews an order or writes a new order authorizing the continued use of restraint or seclusion, there must be documentation in the patient's medical record that describes the findings of the physician's or other LIP's re-evaluation supporting the continued use of restraint or seclusion.

EXCEPTION: Repetitive self-mutilating behaviors – see standard 15.02.09

DOCUMENT REVIEW

If restraint or seclusion is used to manage violent or self-destructive behavior for longer than 24 hours, verify that:

- There is documentation of a new written order, patient assessment, and a re-evaluation by a physician or other LIP in the medical record.
  - ☐ Does the documentation provide sufficient evidence to support the need to continue the use of restraint or seclusion?
- The patient's plan of care or treatment plan addresses the use of restraint or seclusion.
- The patient's clinical response to the continued need for restraint or seclusion is documented.

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[§482.13(e)(6)] for additional information.

15.02.14 Violent restraints and/or seclusion: One-hour face-to-face assessment

When restraint or seclusion is used, there must be documentation in the patient's medical record of the one-hour face-to-face medical and behavioral evaluation if restraint or seclusion is used to manage violent or self-destructive behavior.

When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention –

(i) By a –

(A) Physician or other licensed practitioner.

(B) Registered nurse who has been trained in accordance with the requirements specified in paragraph (f) of 42 CFR 482.13.

States are free to have requirements by statute or regulation that are more restrictive than those contained in paragraph (e)(12)(i) of 42 CFR 482.13.

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

VIOLENT OR SELF-DESTRUCTIVE BEHAVIOR

When restraint or seclusion is used to manage violent or self-destructive behavior, a physician or other LIP, or a registered nurse (RN) or physician assistant (PA) trained in accordance with the requirements specified under standard 15.02.29 [§482.13(f)], must see the patient face-to-face within one-hour of the initiation of the intervention.

- This also applies when a drug or medication is used as a restraint to manage violent or self-destructive behavior.
- A telephone call or telemedicine methodology is not permitted.

If a patient's violent or self-destructive behavior resolves and the restraint or seclusion intervention is discontinued before the practitioner arrives to perform the one-hour face-to-face evaluation, the practitioner is still required to see the patient face-to-face and conduct the evaluation within an hour after the initiation of this intervention.

The fact that the use of a restraint or seclusion was warranted indicates a serious medical or psychological need for prompt evaluation of the patient behavior that led to the intervention. The evaluation would also determine whether there is a continued need for the intervention, factors that may have contributed to the violent or self-destructive behavior, and whether the intervention was appropriate to address the violent or self-destructive behavior.

EXCEPTION: Repetitive self-mutilating behaviors: see standard 15.02.11 for additional information.

States are free to have requirements that are more restrictive regarding the

INTERVIEW AND DOCUMENT REVIEW

Review clinical records of patients who recently required restraint or seclusion to verify:

- **The patient's medical record includes documentation of the1 hour face-to-face medical and behavioral evaluation when restraint or seclusion is used to manage violent or self-destructive behavior**?

- Review hospital policy regarding the one-hour face-to-face evaluation.
  - ☐ Does the hospital policy identify categories of practitioners authorized to conduct the one-hour face-to-face evaluation?
- Interview staff to verify that practice is consistent with hospital policy.

Prior to the survey, determine whether there are state provisions governing the use of restraint or seclusion that are more restrictive than those found in this section.

When state requirements are more

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.13(e)(12) §482.13(e)(12)(i) §482.13(e)(12)(i)(A-B) §482.13(e)(13) §482.13(e)(16)(i)	**types of practitioners who may conduct the one-hour face-to-face evaluation.** **Generally, states may have more restrictive requirements if they do not conflict with federal requirements**	**restrictive, apply those requirements instead of those found in this chapter.**
15.02.15 <u>Violent restraints and/or seclusion: One-hour face-to-face assessment components</u> *When restraint or seclusion is used for the management of violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others, the patient must be seen face-to-face within 1 hour after the initiation of the intervention to evaluate –* *(A) The patient's immediate situation.* *(B) The patient's reaction to the intervention.* *(C) The patient's medical and behavioral condition.* *(D) The need to continue or terminate the restraint or seclusion.* §482.13(e)(12)(ii) §482.13(e)(12)(ii)(A-D)	☐ Compliant ☐ Not Compliant The one-hour face-to-face evaluation includes both a physical and behavioral assessment of the patient that must be conducted by a qualified practitioner within the scope of their practice. An evaluation of the patient's medical condition would include a complete review of systems assessment, behavioral assessment, as well as review and assessment of the patient's history, drugs and medications, most recent lab results, etc. The purpose is to complete a comprehensive review of the patient's condition to determine if other factors, such as drug or medication interactions, electrolyte imbalances, hypoxia, sepsis, etc., are contributing to the patient's violent or self-destructive behavior. Training for an RN or PA to conduct the one-hour face-to-face evaluation would include competency to assess items A- D of this standard and all of the training requirements in standards 15.02.22-29 [§482.13(f)].	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Was the one-hour face-to-face evaluation conducted by a practitioner authorized by hospital policy in accordance with State law to conduct this evaluation? ▪ Does documentation of the one-hour face-to-face evaluation in the patient's medical record include all the listed elements of this requirement? ▪ Did the evaluation indicate whether changes in the patient's care were required, and, if so, were the changes made? ▪ If the one-hour face-to-face evaluations are conducted by RNs who are not advanced practice nurses (APN), verify: □ Documented training that demonstrates they are qualified to conduct a physical and behavioral assessment of the patient that

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		addresses the patient's immediate situation, the patient's reaction to the intervention, the patient's medical and behavioral condition, and the need to continue or terminate the restraint or seclusion. ▪ Is practice consistent with hospital policy and state law?
15.02.16 Violent restraints and/or seclusion: One-hour face-to-face assessment by a trained RN *If the face-to-face evaluation specified in* **standard 15.02.14** *is conducted by a trained registered nurse, the trained registered nurse must consult the attending physician or other licensed practitioner who is responsible for the care of the patient as soon as possible after the completion of the 1-hour face-to-face evaluation.* §482.13(e)(14)	☐ Compliant ☐ Not Compliant When a trained RN conducts the required face-to-face evaluation, he or she must consult the attending physician or other LIP responsible for the patient's care as soon as possible after the completion of the evaluation. Hospital policy should address the expected time frame for and the components of the consultation with the attending physician or other LIP consistent with "as soon as possible." This consultation should include, at a minimum, 1. a discussion of the findings of the one-hour face-to-face evaluation. 2. the need for other interventions or treatments. 3. the need to continue or discontinue the use of restraint or seclusion. A consultation that is not conducted prior to a renewal of the order would not be consistent with the requirement, "as soon as possible."	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review the relevant hospital restraint and seclusion policy to verify: ▪ The policy clarifies expectations regarding the requirement, "as soon as possible." ▪ Documentation in patient medical records indicates consultation with the attending physician or other LIP when the one-hour face-to-face evaluation was conducted by a trained RN. ▪ Is practice consistent with hospital policy?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

15.02.17 Monitoring of the patient

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed practitioner or trained staff that have completed the training criteria specified in paragraph (f) of 42 CFR 482.13 at an interval determined by hospital policy.

§482.13(e)(10)

Ongoing assessment and monitoring of the patient's condition by a physician, other LIP or trained staff is crucial for prevention of patient injury or death, as well as ensuring that the use of restraint or seclusion is discontinued at the earliest possible time.

POLICIES

Hospital policies are expected to guide staff in determining the type of restraint or seclusion used and appropriate intervals for assessment and monitoring based on the individual needs of the patient, taking into consideration variables such as the patient's condition, cognitive status, risks associated with the use of the chosen intervention, and other relevant factors.

Hospital policies should address:

1. Frequencies of monitoring and assessment should be appropriate for patient condition. **ACHC recommends that patients with violent or self-destructive behavior are monitored at least every 15 minutes, although patient condition may warrant continuous monitoring. The recommendation for non-violent patients in restraints is monitoring at least every two hours.**
2. Assessment content (e.g., vital signs, circulation, hydration needs, elimination needs, level of distress and agitation, mental status, cognitive functioning, skin integrity, etc.).
3. Providing for nutritional needs, range of motion exercises, and elimination needs.
4. Mental status and neurological evaluations.

Except for the simultaneous use of restraint and seclusion, one-to-one observation with a staff member in constant attendance is not required by this regulation unless deemed necessary based on a practitioner's clinical

DOCUMENT REVIEW

Review hospital policies regarding assessment and monitoring of a patient in restraint or seclusion.

- What evidence do you find that the hospital's monitoring policies are put into practice for all restrained or secluded patients?
- Do hospital policies identify which categories of staff are responsible for assessing and monitoring the patient?
- Do hospital policies include time frames for offering fluids and nourishment, toileting/elimination, range of motion, exercise of limbs and systematic release of restrained limbs? Is this documented in the patient's medical record?

Review patient medical records:

- Was there a valid rationale for the decision regarding the frequency of patient assessment and monitoring documented in the medical record?
- Was documentation consistent, relevant, and reflective of the patient's condition?
- Are time frames described for how often a patient is monitored for vital

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	judgment. For example: ▪ placing staff at the bedside of a patient with wrist restraints may be unnecessary. ▪ For a more restrictive or risky intervention and/or a patient who is suicidal, self-injurious, or combative, staff may determine that continual face-to-face monitoring is needed. ▪ The hospital is responsible for providing the level of monitoring and frequency of reassessment that will protect the patient's safety. Hospitals have flexibility in determining which staff performs the patient assessment and monitoring. This determination must be in accordance with the practitioner's scope of clinical practice and state law. ▪ For example, assessment and monitoring are activities within a registered nurse's scope of practice. However, some trained, unlicensed staff may perform components of monitoring (e.g., checking the patient's vital signs, hydration, and circulation; the patient's level of distress and agitation; or skin integrity), and may also provide for general care needs (e.g., eating, hydration, toileting, and range of motion exercises). Standard 15.02.21 (42 CFR §482.13(f)) requires that before applying restraints, implementing seclusion, or performing associated monitoring and care tasks, staff must be trained and able to demonstrate competency in the performance of these actions.	signs, respiratory and cardiac status, and skin integrity checks? ▪ Is there documentation of ongoing patient monitoring and assessment (e.g., skin integrity, circulation, respiration, intake and output, hygiene, injury, etc.)? ▪ Is the patient's mental status assessed? Is this documented in the medical record? ▪ Is the patient assessed regarding continued need for the use of seclusion or restraint? ▪ Is there adequate justification for continued use and is this documented? ▪ Is the level of supervision appropriate to meet the safety needs of the patient who is at a higher risk for injury (e.g., self-injurious, suicidal)?
15.02.18 <u>Discontinuation of restraints</u> *Restraint or seclusion must be discontinued at the earliest possible time, regardless of the length of time identified in the order.*	☐ Compliant ☐ Not Compliant Restraint or seclusion may only be employed while an unsafe situation continues. Once the unsafe situation ends, the use of restraint or seclusion must be discontinued.	This standard is not met as evidenced by: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** ▪ Does the hospital have policies and procedures for ending restraint or seclusion?

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§482.13(e)(9)	The hospital policies and procedures should address, at a minimum: ▪ Categories of staff that the hospital authorizes to discontinue restraint or seclusion in accordance with State law; and ▪ The circumstance under which restraint or seclusion is to be discontinued. Staff members are expected to assess and monitor the patient's condition on an ongoing basis to determine whether restraint or seclusion can safely be discontinued. ▪ The regulation requires that these interventions be ended as quickly as possible. ▪ The decision to discontinue the intervention should be based on the determination that the patient's behavior is no longer a threat to self, staff members, or others.	□ Do the policies include a requirement to end the restraint or seclusion as soon as is safely possible? ▪ Does the medical record contain evidence that the decision to continue or discontinue the use of restraint or seclusion was based on an assessment and re-evaluation of the patient's condition? ▪ Interview staff to determine whether they are aware that use of a restraint or seclusion must be discontinued as soon as is safely possible.
15.02.19 <u>Simultaneous use of restraint and seclusion</u> *All requirements specified under this paragraph are applicable to the simultaneous use of restraint and seclusion.* *Simultaneous restraint and seclusion use is only permitted if the patient is continually monitored:* *(i) Face-to-face by an assigned, trained staff member; or* *(ii) By trained staff using both video and audio equipment. This monitoring must be in close proximity to the*	☐ Compliant ☐ Not Compliant When the simultaneous use of restraint and seclusion is employed, there must be adequate documentation that justifies the decision for simultaneous use as well as vigilance in continuously monitoring the patient so that the patient's care needs are met. All requirements specified in standards 15. 02.00-.28 [under CFR §482.13(e)] apply to the simultaneous use of restraint and seclusion. The simultaneous use of restraint and seclusion is not permitted unless the patient is continually monitored by trained staff, either through face-to-face observation or through the use of both video and audio equipment. **VIDEO AND AUDIO EQUIPMENT** Monitoring with video and audio equipment further requires that staff perform the monitoring in close proximity to the patient. For the purposes of	This standard is not met as evidenced by: **<u>OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW</u>** ▪ Review the hospital's policy regarding simultaneous use of restraint and seclusion to determine whether it provides for continual monitoring and otherwise complies with all requirements of 42 CFR §482.13. ▪ Conduct document review and staff interviews to determine if practice is consistent with the hospital policy and required uninterrupted audio and visual

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patient. §482.13(e)(15)	this requirement, "continually" means ongoing without interruption. The use of video and audio equipment does not eliminate the need for frequent monitoring and assessment of the patient. An individual who is physically restrained alone in his or her room is not necessarily being simultaneously secluded. The individual's privacy and dignity should be protected to the extent possible during any intervention. ▪ The purpose of restraining a patient alone in his or her room may be to promote privacy and dignity versus simultaneously using seclusion and restraint. While this distinction may be difficult to make, it is helpful to consider whether the patient would, in the absence of the physical restraint, be able to voluntarily leave the room. If so, then the patient is not also being secluded. However, if the physical restraint were removed and the patient was still unable to leave the room because the door was locked or staff were otherwise physically preventing the patient from doing so, then the patient is also being secluded. Staff must take extra care to protect the safety of the patient when interventions that are more restrictive are used. Monitoring must be appropriate to the intervention chosen, so that the patient is protected from possible abuse, assault, or self-injury during the intervention.	monitoring is provided. □ Is the staff member monitoring the patient with video and audio equipment trained and in close proximity to ensure prompt emergency intervention if a problem arises? □ Does the video equipment cover all areas of the room or location where the patient is restrained or secluded? □ Is the audio and video equipment located in an area that assures patient privacy? ▪ Is the equipment appropriately maintained and in working condition?
15.02.20 Physician training requirements	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Physician and other licensed practitioner training requirements must be specified in hospital policy. *At a minimum, physicians and other*	At a minimum, physicians and other LIPs authorized to order restraint and seclusion must have a working knowledge of hospital policy regarding the use of restraint and seclusion. Physicians receive training in the assessment, monitoring, and evaluation of a patient's condition as part of their medical school education. However, physicians generally do not receive training	**DOCUMENT REVIEW** ▪ Review the hospital policy regarding restraint and seclusion training requirements for physicians and other

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
licensed practitioners authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion. §482.13(e)(11)	regarding application of restraint or implementation of seclusion as part of their basic education. ▪ Depending on the level and frequency of involvement that a physician or other LIP has in the performance of these activities, additional training may or may not be necessary to ensure the competency of these individuals in this area. ▪ Hospitals have the flexibility to identify training requirements above this minimum requirement based on the competency level of their physicians and other LIPs, and the needs of the patient population(s) that they serve. The hospital is in the best position to determine if additional physician or other LIP training is necessary based on the model of care, level of physician competency, and the needs of the patient population(s) that the hospital serves.	LIPs. □ Are the minimum training requirements addressed? ▪ Review medical staff credentialing and privileging files to determine if physicians or other LIPs involved in restraint and seclusion activities have completed the required training.
15. 02.21 <u>Staff training requirements: Use of restraints or seclusion</u> *The patient has the right to safe implementation of restraint or seclusion by trained staff.* §482.13(f)	☐ Compliant ☐ Not Compliant Without adequate staff training and competency, the direct care staff, patients, and others are placed at risk. Patients have a right to the safe application of restraint or seclusion by trained and competent staff. Staff training and education play a critical role in the reduction of restraint and seclusion use in a hospital.	This standard is not met as evidenced by: **<u>OBSERVATION AND DOCUMENT REVIEW</u>** ▪ Verify that the hospital has a staff training and education program that protects the patient's right to safe implementation of restraint or seclusion. ▪ Observe patients in restraint or seclusion to verify safe application of the restraint or seclusion.

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15.02.22 Training intervals

Training Intervals –

Staff must be trained and able to demonstrate competency in the application of restraints, implementation of seclusion, monitoring, assessment, and providing care for a patient in restraint or seclusion –

(i) Before performing any of the actions specified in this [chapter].

(ii) As part of orientation.

(iii) Subsequently on a periodic basis consistent with hospital policy.

§482.13(f)(1)(i-iii)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

All staff designated by the hospital as having direct patient care responsibilities, including contract or agency personnel, must demonstrate the competencies specified in standards 15.02.21-15.02.30 [§482.13(f)] prior to participating in the application of restraints, implementation of seclusion, monitoring, assessment, or care of a patient in restraint or seclusion.

- These competencies must be demonstrated initially as part of orientation and subsequently on a periodic basis consistent with hospital policy. Hospitals have the flexibility to identify a time frame for ongoing training based on the level of staff competency, and the needs of the patient population(s) served.

Once initial training takes place, training must be provided frequently enough to ensure that staff possesses the requisite knowledge and skills to safely care for restrained or secluded patients in accordance with the regulations.

- The results of skills and knowledge assessments, new equipment, or QAPI data may indicate a need for targeted training or more frequent or revised training.

Hospitals are required to have appropriately trained staff for the proper and safe use of seclusion and restraint interventions.

- It would not be appropriate for a hospital to routinely call upon a law enforcement agency or agencies as a means of applying restraint or initiating seclusion.

If hospital security guards, or other non-healthcare staff, as part of hospital policy, may assist direct care staff, when requested, in the application of restraint or seclusion, the security guards, or other non-healthcare staff, are also expected to be trained and able to demonstrate competency in the safe application of restraint and seclusion.

DOCUMENT REVIEW

- Does the hospital have a documented training program addressing the use of restraint and seclusion interventions employed by the hospital?
- Does the hospital have documented evidence that all levels of staff, including agency or contract staff, that have direct patient care responsibilities and any other individuals who may be involved in the application of restraints (e.g., security guards) have been trained and are able to demonstrate competency in the safe use of seclusion and the safe application and use of restraints?

Review and verify restraint and seclusion education staff training documentation for all new employees and contract staff.

- Does the training include demonstration of required competencies?
- What areas were included in this training program?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

15.02.23 Training content

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

- *Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.*

§482.13(f)(2)(i)

The term "appropriate staff" includes all staff that apply restraint or seclusion, monitor, assess, or otherwise provide care for patients in restraint or seclusion.

Training for an RN to conduct the one-hour face-to-face evaluation would include all the training requirements in standards 15.02.29-.39 (§482.13(f)) as well as content addressing:

- Evaluation of the patient's immediate situation.
- the patient's reaction to the intervention.
- the patient's medical and behavioral condition.
- the need to continue or terminate the restraint or seclusion.

An evaluation of the patient's medical condition would include a:

- complete review of systems assessment.
- behavioral assessment.
- review and assessment of the patient's history, medications, most recent lab results, etc.

All staff, including contract or agency personnel, designated by the hospital as having direct patient care responsibilities are required to receive training in the areas of clinical techniques used to identify patient and staff behaviors, events and environmental factors that may trigger circumstances that warrant the use of restraint or seclusion.

This training should be targeted to the specific needs of the patient populations being served, and to the competency level of staff. Staff must be able to employ a broad range of clinical interventions to maintain the safety of the patient and others.

The hospital is expected to provide education and training at the appropriate

INTERVIEW AND DOCUMENT REVIEW

- Does the hospital educational program include techniques related to the specific patient populations being served?
- Does the hospital educational program include techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of restraint or seclusion?
- Does the hospital educational program provide more in-depth training in the areas included in the regulation for staff members who routinely provide care to patients who exhibit violent or self-destructive behavior (e.g., staff who work in the emergency department or psychiatric unit)?
- Interview staff to assess their knowledge of the restraint and seclusion techniques addressed in this requirement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

level to the appropriate staff based upon the specific needs of the patient population being served.

- For example, staff routinely providing care for patients who exhibit violent or self-destructive behavior that jeopardizes the immediate physical safety of the patient, a staff member, or others (such as in an emergency department or on a psychiatric unit) generally require more in-depth training in the areas included in the regulation than staff routinely providing medical/surgical care.
- Hospitals may develop and implement their own training programs or use an outside training program.
- Individuals providing staff training must be qualified as evidenced by education, training, and experience.

At a minimum, physicians and other LIPs authorized to order restraint or seclusion by hospital policy in accordance with State law must have a working knowledge of hospital policy regarding the use of restraint and seclusion.

Hospitals have the flexibility to identify training requirements above this minimum based on the competency level of their physicians and other LIPs and the needs of the patient population that they serve.

15.02.24 Training requirements: Nonphysical intervention

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:

- *The use of nonphysical intervention skills.*

Although there may be circumstances in which the use of restraint or seclusion is necessary to prevent a patient situation from escalating, staff often skillfully intervene with alternative techniques to redirect a patient, engage the patient in constructive discussion or activity, or otherwise help the patient maintain self-control and avert escalation.

The use of nonphysical intervention skills does not mean attempting a complex series of interventions or a lengthy checklist of steps to initiate before restraining or secluding a patient. Rather, a whole toolbox of possible

INTERVIEW AND DOCUMENT REVIEW

- Does the hospital training program address the use of nonphysical intervention skills?
- Interview staff to assess their non-physical intervention skills.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.13(f)(2)(ii)	interventions can be implemented over the course of a patient's treatment based upon the assessment of an individual patient's responses.	
15.02.25 Training requirements: Least restrictive intervention *The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:* ▪ *Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.* §482.13(f)(2)(iii)	☐ Compliant ☐ Not Compliant Safe patient care hinges on looking at the patient as an individual and assessing the patient's condition, needs, strengths, weaknesses, and preferences. Such an approach relies on caregivers who are skilled in individualized assessment and in tailoring interventions to individual patient's needs after weighing factors such as the patient's condition, behaviors, history, and environmental factors.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Does the hospital educational program address choosing the least restrictive intervention based on an individualized assessment of the patient's medical or behavioral status or condition? ▪ Does the hospital educational program address how to conduct an assessment of a patient's medical and behavioral conditions? ▪ Does the hospital educational program address types of interventions appropriate to the specific needs of the patient population(s) served and ranging from less to more restrictive? ▪ Interview staff to determine if they are able to demonstrate the abilities addressed in this requirement.
15.02.26 Training requirements: Safe application *The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the*	☐ Compliant ☐ Not Compliant Patients have a right to the safe application of restraint or seclusion by trained and competent staff.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Is all staff identified by the hospital as

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
specific needs of the patient population in at least the following: ▪ *The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).* §482.13(f)(2)(iv)		direct caregivers, including contract or agency personnel, trained and able to demonstrate competency in the safe use of all types of restraints or seclusion used in the hospital? ▪ Does the hospital educational program address recognition and response to patient signs of physical and psychological distress? □ Is staff able to identify signs of physical and psychological distress in a timely manner? □ Is staff able to respond to and appropriately treat signs of physical and psychological distress? ▪ Review hospital data (i.e., incident reports, patient injury or death reports, etc.) to identify any patterns of patient injuries or death that may indicate that staff are not adequately trained to recognize and respond to patient signs of physical and psychological distress.
15.02.27 Training requirements: Restraint removal *The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:*	☐ Compliant ☐ Not Compliant The use of restraint or seclusion must be ended at the earliest possible time regardless of the length of time identified in the order. Staff must be trained and demonstrate competency in the ability to identify specific patient behavioral changes that may indicate that restraint or	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Does the hospital educational program address identification of specific behavioral changes that may indicate that restraint or

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ *Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.* §482.13(f)(2)(v)	seclusion is no longer necessary and can be safely discontinued.	seclusion is no longer necessary? ▪ Interview staff to determine if they are able to demonstrate the abilities addressed in this requirement.
15.02.28 Training requirements: Patient monitoring *The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:* ▪ *Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the one-hour face-to-face evaluation.* §482.13(f)(2)(vi)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Does the hospital's education program address monitoring the physical and psychological needs of patients who are restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the one-hour face-to-face evaluation? ▪ Does the hospital educational program address the specific requirements for the training of RNs that the hospital authorizes to conduct the one-hour face-to-face evaluation? ▪ Interview staff to determine if they are able to demonstrate the competencies addressed in this regulation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
15.02.29 Training requirements: CPR training *The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population in at least the following:* ▪ *The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.* §482.13(f)(2)(vii)	☐ Compliant ☐ Not Compliant When restraint or seclusion techniques are used, patients are placed at a higher risk for injuries or even death. Hospital staff need to assess their patient population and identify likely scenarios, develop a first aid training that addresses those scenarios, and provide that "first aid" training to all staff that care for restrained or secluded patients. ▪ Hospitals are not required to use any particular recognized first aid course. ▪ Such courses may not adequately address the immediate interventions, the "first aid," that needs to be rendered to a restrained or secluded patient who is in distress or injured. The goal is for staff to be able to render the appropriate "first aid" required if a restrained or secluded patient is in distress or injured. For example, a patient is found hanging in a vest restraint, a restrained patient is choking on food, a secluded suicidal patient is found hanging, a secluded suicidal patient has cut himself, etc.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Does the hospital's education program address first aid techniques? ▪ Does the hospital educational program include, or provide for, staff training and certification in cardiopulmonary resuscitation (including provisions for recertification)? ▪ Is appropriate staff certified in cardiopulmonary resuscitation?
15.02.30 Trainer requirements *Individuals providing staff training must be qualified as evidenced by education, training, and experience in techniques used to address patients' behaviors.* §482.13(f)(3)	☐ Compliant ☐ Not Compliant Hospitals may develop and implement their own training programs or use an outside training program. Trainers should demonstrate a high level of knowledge regarding all the requirements of these regulations as well as the hospital's policies and procedures that address these requirements.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review personnel files of individuals responsible for providing staff education and training. ▪ Do the individuals providing the education and training possess education, training, and experience to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		qualify them to teach the staff? ▪ Are they qualified to identify and meet the needs of the patient population(s) being served? ▪ Does the hospital have a system for documenting and ensuring that the individuals providing education and training have the appropriate qualifications required by this regulation?
15.02.31 Training documentation *The hospital must document in the staff personnel records that the training and demonstration of competency were successfully completed.* §482.13(f)(4)	☐ Compliant ☐ Not Compliant Staff personnel records must contain documentation that the training and demonstration of competency were successfully completed initially during orientation and on a periodic basis consistent with hospital policy.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of personnel records, including contract or agency staff, to determine if the training and demonstration of competency have been completed during orientation and periodically, consistent with hospital policy.
15.02.32 Death related to restraint or seclusion: Reporting requirements *Hospitals must report deaths associated with the use of seclusion or restraint.* *(1) With the exception of deaths described under* [item (2) below] (*paragraph (g)(2) of 42 CFR 482.13),*	☐ Compliant ☐ Not Compliant "Reasonable to assume" applies only to those deaths that occur on days 2-7 after restraint or seclusion has been discontinued. The requirement applies regardless of the type of restraint that was used on the patient. In other words, it applies to all uses of restraint or seclusion where the patient has died on days 2-7 after the restraint or seclusion was	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review hospital policies. ▪ Does the hospital have restraint/seclusion death reporting

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) *Each death that occurs while a patient is in restraint or seclusion.*

(ii) *Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.*

(iii) *Each death known to the hospital that occurs within one week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.*

§482.13(g)(1)

discontinued, and it is reasonable to assume the use of the restraint or seclusion contributed to the patient's death. In a case where only two-point soft wrist restraints were used and there was no seclusion, it may reasonably be presumed that the patient's death was not caused by the use of restraints.

- In cases involving death within one week after the use of restraint or seclusion where the intervention may have contributed to the patient's death, it is possible that the patient's death might occur outside the hospital and that the hospital might not learn of the patient's death, or that there might be a delay in the hospital's learning of the patient's death.
- The reports required under 42 CFR §482.13(g)(1) must be submitted to the CMS Regional Office by telephone, facsimile, or electronically, as determined by the Regional Office no later than close of the next business day following the day in which the hospital knows of the patient's death. The report must include basic identifying information related to the hospital, the patient's name, date of birth, date of death, name of attending physician/ practitioner, primary diagnosis(es), cause of death (preliminary, in case a final, official cause of death is not yet available), and type(s) of restraint or seclusion used. CMS makes a standard form available for hospitals to use in submitting the required reports.

Hospitals must document in the patient's medical record the date and time each reportable death associated with the use of restraint or seclusion was reported to the CMS Regional Office.

CMS REGIONAL OFFICE PROCESS

After reviewing the submitted information, the Regional Office will determine whether an on-site investigation of the circumstances surrounding the patient's death is warranted and may direct the State Survey Agency to conduct a survey.

policies and procedures that addresses responsibilities and systems for identifying restraint/seclusion-associated deaths reportable to CMS and for implementing the reporting and recordkeeping requirements?

- Can the hospital provide examples of restraint/seclusion-associated deaths that were reported to CMS?

<u>If Yes</u>:

Review the report and medical records to determine whether:

- □ The reports met the criteria for reporting.
- □ Were submitted on time.
- □ Were complete.
- □ The date and time the death reported to CMS was entered into the patient's medical record.

<u>If No</u>:

- □ Ask how the hospital ensures that there were no reportable restraint/seclusion-associated deaths.
- □ If the hospital's system relies upon staff identification of reportable deaths, interview several applicable staff members to determine whether they are aware of the hospital's policy

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

§482.13(g)(1)(i-iii)

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:

(i) *Any death that occurs while a patient is in such restraints.*

(ii) *Any death that occurs within 24 hours after a patient has been removed from such restraints.*

§482.13(g)(2)
§482.13(g)(2)(i-ii)

(3) The staff must document in the patient's medical record the date and time the death was:

(i) *Reported to CMS for deaths described in* item (1) above *(paragraph (g)(1) of 42 CFR 482.13), or*

(ii) *Recorded in the internal log or other system for deaths described in* item (2) above *(paragraph (g)(2) of 42 CFR 482.13).*

§482.13(g)(3)
§482.13(g)(3)(i-ii)

HOSPITAL RESTRAINT DEATH LOG

Use of the log or tracking system is limited only to patient deaths meeting one of these two criteria. Examples of patient deaths associated with restraints that must still be reported to CMS include:

- Deaths occurring during or within 24 hours of discontinuation of 2-point soft, cloth-like non-rigid wrist restraints used in combination with any other restraint device or with seclusion

  or

- Deaths associated with the use of other types of wrist restraints, such as 2-point rigid or leather wrist restraints.

These cases would not be included in this internal log or tracking system and would require reporting the death to CMS using telephone, fax, or electronically.

The two-point soft wrist restraint death report must be entered into the internal log or tracking system within 7 days of the patient's death.

Depending on the size and nature of the patient population the hospital serves and the types of services it provides, there will likely be variations in the frequency of restraint use as well as in the incidence of patient deaths.

Surveyors should adjust their expectations for the volume of log or tracking system entries accordingly.

- For example, hospitals with intensive care units might be more likely to use both soft, 2-point wrist restraints and to have seriously ill patients who die as a result of their disease while such restraints are being used or within 24 hours after their discontinuance.
- A rehabilitation hospital would be expected to use such restraints less frequently, and to have patients who die less frequently while hospitalized.

The log or tracking system must be available in written, i.e., hard copy, or and know when and where to report internally a restraint/ seclusion-associated death.

  □ Ask if there have been any patient deaths that meet the reporting requirements.

- Interview staff in various types of inpatient units, including a psychiatric unit if applicable, to determine whether they are aware of any patients who died while in restraints or seclusion or within one day of restraint or seclusion discontinuation, excluding cases involving only the use of two-point soft wrist restraints and no seclusion.
  If Yes:

  □ check whether the hospital has any evidence that these cases were reported to CMS.

DEATH REPORT LOG:

- Does the hospital have restraint/seclusion death reporting policies and procedures that address responsibilities and systems for identifying restraint/seclusion-associated deaths that must be recorded in an internal hospital log/tracking system, and for implementing the reporting and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(4) For deaths described in paragraph (g)(2) of 42 CFR 482.13 [item (2) below]*, entries into the log or other system must be documented as follows:*

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

§482.13(g)(4)
§482.13(g)(4)(i-iii)

electronic form immediately upon CMS's request.

- CMS will specify the form in which the information is to be provided.
- Generally, CMS would request access to the log or tracking system during an on-site survey by CMS staff or State surveyors acting on CMS's behalf when assessing compliance with restraint/seclusion requirements.
- However, CMS may also request that a copy of portions or the entire log or tracking system be provided, even though no survey is in progress. Accreditation organizations conducting hospital inspections in accordance with a CMS-approved Medicare hospital accreditation program are also entitled to immediate access to the log or tracking system.

The hospital is not required to make the contents of the log or tracking system available to any other outside parties, unless required to do so under other Federal or State law.

The hospital must document in the patient's medical record the date and time the death report entry was made into the log or tracking system.

Refer to CMS electronic form "CMS-10455" https://restraintdeathreport.gov1.qualtrics.com/jfe/form/SV_5pXmjIw2WAzto8J

recordkeeping requirements?

- Ask the hospital how it ensures that each death that must be captured in the log/tracking system is identified and entered.
- Interview inpatient unit staff to determine whether they have had patients who die while 2-point soft wrist restraints are being used without seclusion or within 24 hours of their discontinuance.
  - □ If yes, ask the hospital to demonstrate that it has recorded such deaths.
- If the hospital's log or tracking system relies upon staff identification of reportable deaths, interview several applicable staff members to determine whether they are aware of the hospital's policy and know when and where to report internally a restraint/seclusion-associated death.
- Review the log/tracking system for patient deaths associated with use of only 2-point soft wrist restraints to determine if:
  - □ Each entry was made within 7 days of the patient's death; and
  - □ Each entry contains all the information required under the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		regulation. ▪ Is the hospital able to make the log or tracking system available immediately on request? ▪ Review a sample of medical records of patients whose deaths were entered in the log or tracking system. □ Does the medical record indicate that only soft, 2-point wrist restraints were used? ▪ Is there documentation in the medical record of the entry into the log or tracking system?
SAFETY		
15.03.00 Safety and security of hazardous items *Bio-hazardous materials, sharp instruments, medications, chemicals, and infectious waste are secured and inaccessible to patients and visitors in all areas of the hospital, emergency department, and outpatient settings.* §482.13(c)(2)	☐ Compliant ☐ Not Compliant Bio-hazardous materials, infectious waste, sharp instruments, and medications include, but are not limited to: ▪ Needles ▪ Syringes ▪ Medications (including patient self-administered medications) ▪ Chemicals and chemical waste ▪ Cleaning agents ▪ Chemotherapy waste ▪ Radioactive waste ▪ Contaminated patient care items, such as bloody dressings	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify that: ▪ Patient areas are free of bio-hazardous waste, infectious waste, chemicals, cleaning agents, etc. ▪ Medications, needles, and syringes are secured and inaccessible to unauthorized individuals.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Surgical instruments are promptly removed from patient rooms, examination rooms, or clinics to prevent inadvertent exposure of patients, staff, and unauthorized individuals. Sharps containers are closed, secured, and out of reach by unauthorized individuals. The contents of carts are secured, including, but not limited to: ▪ medication carts. ▪ resuscitation carts. ▪ anesthesia carts. ▪ OB hemorrhage carts. ▪ malignant hyperthermia carts.	
15.03.01 Identifying patients at risk **The hospital identifies patients at risk and implements appropriate mitigation strategies to provide care in a safe setting.** §482.13(c)(2)	☐ Compliant ☐ Not Compliant **IDENTIFY PATIENTS AT RISK** The facility has a policy that describes how it identifies patients at risk and how it evaluates effectiveness of the screening. It is important to note that not all patients with psychiatric conditions or a history of a psychiatric condition are cared for in psychiatric hospitals or psychiatric units of acute care hospitals. For example, individuals at risk of suicide, demonstrating behavior that places self or others at risk, a history of violent behavior, expressions of self-harm, violence behavior toward others, etc. in the emergency department, inpatient areas, or outpatient locations of the hospital. **PATIENT RISK ASSESSMENT TOOL** There are numerous models and versions of patient risk assessment tools available to identify patients at risk for harm to self or others. No one size fits all tool is available. The Patient Risk Assessment Tool used should be	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review policy and procedures and interview staff to determine the Patient Risk Assessment tools adopted by the hospital. ▪ Ask staff how the risk assessment tool is modified to ensure it is appropriate for the care area. ▪ Review policy and procedures and interview staff to determine how the hospital defines continuous visual observation or 1:1 observation in which a staff member is assigned to observe

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	appropriate to the patient population, care setting, and staff competency. All hospitals are expected to implement a patient risk assessment strategy, but it is up to the hospital to implement the appropriate strategies. For example, a patient risk assessment strategy in a post-partum unit would most likely not be the same risk assessment strategy utilized in the emergency department.	only one patient at all times.
15.03.02 Environmental safety risks *The patient has the right to receive care in a safe setting.* *§482.13(c)(2)*	☐ Compliant ☐ Not Compliant **ENVIRONMENTAL RISK ASSESSMENT** The hospital must implement environmental risk assessment strategies appropriate to the specific care environment and patient population. The risk assessment must be appropriate to the unit and should consider the possibility that the unit may sometimes care for patients at risk for harm to self or others. The use of such risk assessment tools may be used as a way for the hospital to assess for safety risks in all patient care environments to minimize environmental risks and to document the assessment findings. Environmental risk assessment tool content may include prompts for staff to assess items such as, but not limited to: 1. Ligature risks including, but are not limited to, handrails, doorknobs, door hinges, shower curtains, exposed plumbing/pipes, soap and paper towel dispensers on walls, power cords on medical equipment or call bell cords, and light fixtures or projections from ceilings, etc. 2. Unattended items such as utility or housekeeping carts that contain hazardous items (mops, brooms, cleaning agents, hand sanitizer, etc.) 3. Unsafe items brought to patients by visitors in locked psychiatric units of hospitals and psychiatric hospitals. 4. Windows that can be opened or broken.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Observe patient care environments for unattended items such as utility or housekeeping carts that contain hazardous items that may pose a safety risk to patients, visitors, and staff. Examples of these items could include cleaning agents, disinfectant solutions, mops, brooms, tools, etc. ▪ Interview staff in patient care areas to determine how the hospital has trained staff to identify risks in the care environment and if found, how staff report those findings.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	5. Unprotected lighting fixtures. 6. Staffing levels inadequate for appropriate patient observation and monitoring.	
15.03.03 Emergency care during clinical deterioration **An approved policy and procedure must be in place for early recognition and response to signs of patient deterioration, ensuring prompt rescue and treatment.**	☐ Compliant ☐ Not Compliant **Early response to clinical deterioration may reduce cardiopulmonary arrests and patient mortality.** **The organization has a policy and procedures approved by the Medical Staff that address:** **1. Identification of and response to clinical deterioration.** **2. Written criteria for assessment(s) and when to seek additional assistance, e.g., activation of a Rapid Response System.** **3. Documentation requirements for vital signs, treatments, medications, and patient response to treatments addressing clinical deterioration.** **4. Coordination of care if assessment identifies the need to transfer the patient to another level of care.** **A Rapid Response System is an effective process for assembling doctors, nurses, and other medical professionals to respond to a patient with early signs of clinical deterioration. The intent of a Rapid Response System is to provide interventions to prevent further deterioration.**	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** **Verify:** ▪ **Written policies and procedures are approved by the Medical Staff. The policy describes the required assessments and identifies all required elements.** ▪ **Medical records meet documentation requirements.** ▪ **Procedures clearly indicate communication method for and documentation of response to patient deterioration.**
15.03.04 Clinical emergency supplies **The organization maintains an adequate inventory of supplies and equipment to respond to a medical emergency.**	☐ Compliant ☐ Not Compliant **The organization has a policy or process which defines what supplies and equipment are required for medical emergencies. Policies should address:**	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ How contents are secured after use and during transport to be restocked. ▪ Individuals authorized to transport carts. ▪ Process to clean and restock carts. ▪ Secure locations with limited access where carts may be stored prior to use by floors/departments. ▪ Policy defines the process and frequency of checking for outdated supplies in carts and emergency trays/boxes. ▪ Frequency of cart/tray/box lock check (at minimum once per day). **Adequate equipment must be available to respond to emergencies in more than one location simultaneously.** **Adequate equipment must be available to respond to all patients populations under the scope of services, e.g., if the facility treats bariatric, neonatal or pediatrics patients, appropriately sized resuscitation equipment is immediately available.** **At a minimum the following equipment must be available:** ▪ Defibrillator. ▪ Oxygen tank. ▪ Suction equipment/vacuum. ▪ Bag valve mask (BVM) device. ▪ Medication (as applicable, based on type of emergency cart).	**Verify:** ▪ A policy or process defining required emergency equipment exists. ▪ Adequate supplies are available. ▪ Supplies address all patient populations.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
15.03.05 Identify patients correctly	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital has a written patient safety policy that requires at least two methods for patient identification prior to medication administration, testing, treatment, and procedures.	**Correct patient identification is a safety measure to ensure each patient receives the correct medicine, testing, and treatment. Factors for identification might include:** ▪ **Patient's first and last name** **AND** ▪ **Date of birth** **OR** ▪ **Medical Record number.** **Hospital policy details the process to identify and validate patient identity when the patient is unable to confirm identity.**	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** **Verify:** ▪ **The hospital has the required policy.** ▪ **Validate through the observation of patient care that the policy is followed consistently.**

16

NURSING SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
16.00.00 CONDITION OF PARTICIPATION: Nursing Services *The hospital must have an organized Nursing Service that provides 24-hour nursing services.* *The nursing services must be furnished or supervised by a registered nurse.* §482.23	☐ Compliant ☐ Not Compliant Nursing services are available 24 hours a day for inpatients. A registered nurse is available to plan, provide and/or supervise the nursing care of patients. The hospital must have an organized nursing service and must provide on premise nursing services 24 hours a day, 7 days a week with at least one registered nurse furnishing or supervising the service 24 hours a day, 7 days a week. (Exception: small rural hospitals operating under a waiver as discussed at standard 16.00.05 [42 CFR §482.23(b)(1)]). The nursing service must be integrated into the hospital-wide QAPI plan.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** Interview the chief nursing officer to verify: ▪ There is a hospital-employed RN scheduled on every shift in every location where nursing care is provided. □ Review the organizational chart(s) for nursing services in all locations where the hospital provides nursing services. □ Is the nursing service integrated into the hospital-wide QAPI plan? ▪ A hospital employed, unit-based RN is accountable for oversight of patient care on every shift and in every location where care is provided. □ Use care plans, medical records, patient interviews, investigative reports, staffing schedules, nursing policies and procedures, and QAPI activities to determine the adequacy of the department. ▪ Review job descriptions for all nursing personnel including the director's position description. ▪ Select at least one patient from every inpatient care unit to interview for

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		information relative to the delivery of nursing services. ▪ Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Other sources of information to use in the evaluation of the nursing services are: □ nursing care plans □ medical records □ patients, family members, □ accident and investigative reports □ staffing schedules □ nursing policies and procedures, and QAPI activities and reports.
16.00.01 For future use		
16.00.02 For future use		
16.00.03 Nursing organization	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital must have a well-organized service with a plan of administrative authority and delineation of responsibilities for patient care. *The director of the nursing service must be*	The hospital may have only one nursing service hospital-wide and the single nursing service must be under the direction of one RN. The director of the nursing service must be a currently licensed RN and he/she is responsible for the operation of the nursing service. The operation of the nursing service would include the quality of the patient care provided	**DOCUMENT REVIEW** ▪ Review the organizational chart or plan for nursing services to verify: □ The organizational chart(s) displays lines of authority that

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

a licensed registered nurse. He or she is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the hospital.

§482.23(a)

by the nursing service.

The director of the nursing service must determine and provide the types and numbers of nursing care personnel necessary to provide nursing care to all areas of the hospital.

The organization will include various configurations of the following hospital personnel as determined necessary by the hospital and the Director of Nursing:

- Assistant/Associate Director(s)
- Supervisors/Coordinators
- Head Nurses/Nurse Managers
- Staff Nurses
- Unit Secretaries/Clerks
- Nurse's Aide/Orderlies.

The nurse executive is licensed in the state in which patient care is provided, supervised, or directed.

The educational qualifications of the nurse executive are established at the facility level and must be appropriate to the scope and complexity of patient care services provided.

The nurse executive is responsible for standards of nursing practice and standards of nursing care, nursing budget, policies, and procedures for patient care and QAPI in clinical areas.

Standards and policies are reviewed at least every three years and approved by the Chief Nursing Officer.

The nursing executive participates in a collaborative interchange at the senior management level.

The organizational chart explains the reporting responsibilities of the Assistant/Associate directors, head nurses/managers, staff nurses and nurse's delegate responsibility within the nursing department.

- □ The hospital has only one nursing service hospital-wide and the single nursing service is under the direction of one RN.

- Review the DON position description.
  - □ Verify the nursing director meets the requirements.
  - □ Verify that it delegates to the DON specific duties and responsibilities for operation of the service.
- Verify that the director is currently licensed in accordance with state licensure requirements.
- Verify that the DON is involved with or approved the development of the nursing service staffing policies and procedures.
- Verify that the DON approves the nursing service patient care policies and procedures.
  - □ Have these documents been approved within the past three years?

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	aides/techs to the nurse executive.	
16.00.04 Staffing and delivery of care *The nursing service must have adequate numbers of licensed registered nurses, licensed practical (vocational) nurses, and other personnel to provide nursing care to all patients as needed.* *There must be supervisory and staff personnel for each department or nursing unit to ensure, when needed, the immediate availability of a registered nurse for the care of any patient.* §482.23(b)	☐ Compliant ☐ Not Compliant The budget for the nursing service (based upon historical and projected data) indicates the minimum required staff and the flexible ranges for staffing. The nursing service must ensure that patient needs are met by ongoing assessments of patients' needs and provision of nursing staff to meet those needs. There must be sufficient numbers, types, and qualifications of supervisory and staff nursing personnel to respond to the appropriate nursing needs and care of the patient population of each department or nursing unit. There must be a RN on the premises and on duty at all times. ▪ Every inpatient unit/department/location within the hospital-wide nursing service must have adequate numbers of RNs physically present at each location to ensure the immediate availability of a RN for the bedside care of any patient. ▪ A RN would not be considered immediately available if the RN was working on more than one unit, building, floor in a building, or provider (distinct part SNF, RHC, excluded unit, etc.) at the same time. Staffing schedules must be reviewed and revised as necessary to meet the patient care needs and to make adjustments for nursing staff absenteeism.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Is there evidence that the budget is approved by governance as part of the overall hospital budget? Is the budget is based upon reliable history and projections using a system that provides for at least one budgeted RN, per shift, per unit, unless a 24-hour nursing waiver has been granted? ▪ Obtain copies of actual and planned staffing for inpatient units for the week prior to the survey, and for a full week six months prior to the survey to verify: □ There is at least one employed RN, each shift, for each organized inpatient unit. ▪ Determine that there are written staffing schedules which correlate to the number and acuity of patients. ▪ Verify that there is supervision of personnel performance and nursing care for each department or nursing unit. ▪ To determine if there are adequate

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numbers of nurses to provide nursing care to all patients as needed, take into consideration:

- □ Physical layout and size of the hospital.
- □ Number of patients.
- □ Intensity of illness and nursing needs.
- □ Availability of nurses' aides and orderlies and other resources for nurses, e.g., housekeeping services, ward clerks etc.
- □ Training and experience of personnel.
- □ Do not count personnel assigned to areas other than bedside patient care.

▪ Review medical records to verify that patient care that is to be provided by nurses is being provided as ordered.

- □ Is appropriate care provided or are deficiencies identified upon review of patient medical records?

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16.00.05 <u>24-hour provision of services</u> *The hospital must provide 24-hour nursing services furnished or supervised by a registered nurse and have a licensed practical nurse or registered nurse on duty at all times, except for rural hospitals that have in effect a 24-hour nursing waiver granted under §488.54(c) of 42 CFR 488.54.* §482.23(b)(1)	☐ Compliant ☐ Not Compliant The hospital must provide nursing services 24 hours a day, 7 days a week. An LPN can provide nursing services if an RN, who is immediately available for the bedside care of those patients, supervises that care. **EXCEPTION:** Section 42 CFR 488.54(c) sets forth certain conditions under which rural hospitals of 50 beds or fewer may be granted a temporary waiver of the 24-hour registered nurse requirement by the regional office. "Rural" is defined as all areas not delineated as "urbanized" areas by the Census Bureau in the most recent census. "Temporary" is defined as a one-year period or less and the waiver cannot be renewed.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review the nurse staffing schedule for a one-week period. If there are concerns regarding insufficient RN coverage, review the staffing schedules for a second week period to determine if there is a pattern of insufficient coverage. ▪ Verify that there is at least one RN for each unit on each tour of duty, 7 days a week, 24 hours a day. Additional nurses may be required for vacation or absenteeism coverage. **EXCEPTION:** If the hospital has a temporary waiver of the 24-hour RN requirement in effect, verify and document the following: ▪ 50 or fewer inpatient beds. ▪ The character and seriousness of the deficiencies do not adversely affect the health and safety of patients. ▪ The hospital meets all the other statutory requirements in §1861(e)(1-8). ▪ The hospital has made and continues to make a good faith effort to comply with the 24-hour nursing requirement. □ Identify the recruitment efforts and

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		methods used by the hospitals' administration by requesting copies of advertisements in newspapers and other publications as well as evidence of contact with nursing schools and employment agencies. □ Document that the salary offered by the hospital is comparable to three other hospitals, located nearest to the facility. ▪ The hospital's failure to comply fully with the 24-hour nursing requirement is attributable to a temporary shortage of qualified nursing personnel in the area in which the hospital is located. ▪ A registered nurse is present on the premises to furnish the nursing service during at least the daytime shift, 7 days a week. ▪ On all tours of duty not covered by a registered nurse, a licensed practical (vocational) nurse is in charge.
16.00.06 Licensure *The nursing service must have a procedure to ensure that the hospital nursing personnel for whom licensure is required have valid and current licensure.*	☐ Compliant ☐ Not Compliant The licensure verification process conforms with State laws regarding copying/not copying the license. The process is applied to employee, agency, and contractual providers. The hospital's procedure must ensure that all nursing personnel have valid and current licensure that complies with State licensure laws.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the nursing service licensure verification policies and procedures. □ Is licensure verified for each

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§482.23(b)(2)	Furthermore, the Condition of Participation (CoP) Compliance with Federal, State, and local laws (standard 01.00.00 [§482.11]) requires the hospital to assure that personnel meet applicable standards (such as continuing education, certification or training) required by State or local law.	individual nursing services staff person for whom licensure is required? □ Review hospital personnel records or records kept by the nursing service to determine that RNs, LPNs, and other nursing personnel for whom licensure is required have current valid licenses. ▪ Verify that the facility has a licensure verification mechanism that conforms with state mandates. □ Is the licensure policy employed for all individual employee and non-employee nursing personnel practicing in the hospital for whom licensure is required?
16.00.07 For future use		
16.00.08 For future use		
16.00.09 Supervision of care *A registered nurse must supervise and evaluate the nursing care for each patient.* §482.23(b)(3)	☐ Compliant ☐ Not Compliant An RN must supervise the nursing care for each patient. An RN must evaluate the care for each patient upon admission and when appropriate on an ongoing basis in accordance with accepted standards of nursing practice and hospital policy.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review staffing schedules and assignments to verify that an RN is assigned to supervise and evaluate the nursing care furnished to each patient.

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Evaluation would include assessing the patient's care needs, patient's health status/conditioning, as well as the patient's response to interventions.

16.00.10 Plan of care

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must ensure that the nursing staff develops and keeps current a nursing care plan for each patient that reflects the patient's goals and the nursing care to be provided to meet the patient's needs.

The nursing care plan may be part of an interdisciplinary care plan.

§482.23(b)(4)

Nursing care planning starts upon admission. It includes planning the patient's care while in the hospital as well as planning for discharge to meet post-hospital needs.

A nursing care plan is based on assessing the patient's nursing care needs (not solely those needs related to the admitting diagnosis). The assessment considers the patient's treatment goals and, as appropriate, physiological and psychosocial factors and patient discharge planning. The plan develops appropriate nursing interventions in response to the identified nursing care needs.

The nursing care plan is kept current by ongoing assessments of the patient's needs and of the patient's response to interventions and updating or revising the patient's nursing care plan in response to assessments.

The nursing care plan is part of the patient's medical record and must comply with the medical records requirements at 42 CFR §482.24.

Hospitals can develop the nursing care plan as part of a larger, coordinated interdisciplinary plan of care. This method may serve to promote communication among disciplines and reinforce an integrated, multi-faceted approach to care, resulting in better patient outcomes. The interdisciplinary plan of care does not minimize or eliminate the need for a nursing care plan. It does, however, serve to promote the collaboration between members of the patient's health care team.

The required documentation for the nursing component of an interdisciplinary care plan remains the same.

- For other components, the hospital should follow the policies that it uses

DOCUMENT REVIEW

- Select a sample of nursing or interdisciplinary care plans. Approximately 6-12 plans should be reviewed. For each plan reviewed, with respect to the nursing care component, is/does it:
  - ☐ Initiated as soon as possible after admission for each patient?
  - ☐ Describe patient goals and address, as appropriate, the physiological and psychosocial factors as well as discharge planning?
  - ☐ Consistent with the attending MD/DO's plan for medical care?
  - ☐ Revised as the needs of the patient changes?
  - ☐ Implemented in a timely manner?

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	to document services provided by other disciplines, such as services provided by physical therapists, occupational therapists, speech-language pathologists, and others. ▪ Documentation should follow the standards of practice for those disciplines in addition to any specific requirements that the hospital might want to establish. ▪ The documentation must also comply with the requirements of the medical records requirement at §482.24.	
16.00.11 Care assignments	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
A registered nurse must assign the nursing care of each patient to nursing personnel in accordance with the patient's needs and the specialized qualifications and competence of the nursing staff available. §482.23(b)(5)	The director of the nursing service and the hospital must ensure that nursing personnel with the appropriate education, experience, licensure, competence and specialized qualifications are assigned to provide nursing care for each patient in accordance with the individual needs of each patient.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Review the nursing assignments for at least three weeks of staffing plans against the patient acuity to determine the requirements are met. Determine: □ Did an RN make the assignments? □ Did assignments take into consideration the complexity of patient's care needs and the competence and specialized qualification of the nursing staff? ▪ Ask the charge nurse what considerations are necessary when making staff assignments. Answers must include: □ Patient needs. □ Complexity of patients.

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		□ Any special needs of individual patients. □ Competence of nursing personnel. □ Qualifications of nursing personnel □ Education of nursing personnel □ Experience of nursing personnel.
16.00.12 For future use		
16.00.13 Nurses adhere to policies *All licensed nurses who provide services in the hospital must adhere to the policies and procedures of the hospital.* *The director of nursing service must provide for the adequate supervision and evaluation of the clinical activities of all nursing personnel which occur within the responsibility of the nursing services regardless of the mechanism through which those personnel are providing services (that is, hospital employee, contract, lease, other agreement, or volunteer).* §482.23(b)(6)	☐ Compliant ☐ Not Compliant The hospital must ensure that there are adequate numbers of clinical nursing personnel to meet its patients nursing care needs. In order to meet the patient's needs, the hospital may supplement its hospital-employed licensed nurses with volunteer and or contract nonemployee, licensed nurses. The hospital and the director of the nursing service are responsible for: ▪ the clinical activities of all nursing personnel, including supervision and evaluation. This would include the clinical activities of all non-employee nursing personnel (contract or volunteer). ▪ ensuring that all licensed nurses know the hospital's policies and procedures in order to adhere to those policies and procedures. Non-employee licensed nurses who are working at the hospital must adhere to the policies and procedures of the hospital.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Review the method for orienting non-employee licensed nurses to hospital policies and procedures. The orientation must include at least the following: □ The hospital and the unit □ Emergency procedures □ Nursing service policies and procedures □ Safety policies and procedures ▪ If the hospital uses non-employee nursing personnel, are they supervised by an RN who is a regular employee of the hospital?

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		▪ Are non-employee personnel appropriately oriented prior to providing care? ▪ Verify that non-employee personnel: □ Are licensed in accordance with State law. □ Are evaluated at least once a year. If the performance evaluation is not considered confidential, review two evaluations. ▪ Observe the care provided by non-employee nursing personnel. □ Do they know and adhere to hospital policies? □ Do they know appropriate emergency procedures? □ Are they adequately supervised by an appropriately experienced hospital employed RN?
16.00.14 Nurses working in outpatient departments *The hospital must have policies and procedures in place establishing which outpatient departments, if any, are not required under hospital policy to have a registered nurse present. The policies and procedures must:*	☐ Compliant ☐ Not Compliant **T**here are some outpatient services where it might not be necessary to have a registered nurse physically present. For example, while it is clearly necessary to have an RN present in an outpatient ambulatory surgery recovery unit, it might not be necessary to have an RN on-site at a hospital MRI facility that is outside the hospital building, but still on the hospital campus. The hospital is allowed to establish a policy that would specify which, if any, outpatient departments would not be required to have an RN physically present as well	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Ask the leadership if the organization has any outpatient departments that do not require an RN to be present. If yes, verify the organization has a written policy that includes the

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(i) Establish the criteria such outpatient departments must meet, taking into account the types of services delivered, the general level of acuity of patients served by the department, and the established standards of practice for the services delivered; *(ii) Establish alternative staffing plans;* *(iii) Be approved by the director of nursing;* *(iv) Be reviewed at least once every 3 years.* §482.23(b)(7) §482.23(b)(7)(i-iv)	as the alternative staffing plans.	required elements including criteria of the outpatient department, level of acuity of patient served, standards of practice, and alternative staffing plans.
16.00.15 For future use		
16.00.16 For future use		
16.01.01 Preparation and administration of drugs *Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, the orders of the practitioner or practitioners responsible for the patient's care as specified under* standards 01.01.12-.13 *[42 CFR §482.12(c]), and accepted standards of practice.*	☐ Compliant ☐ Not Compliant The increasing complexity of medical care and patient acuity present significant challenges that require an approach to medication administration that takes advantage of available technology while recognizing that it must be integrated into the medication administration work processes in a manner that meets the needs of patients and promotes their safety. The regulations in this standard [42 CFR §482.23(c) and 42 CFR §482.23(c)(1)] promote safety in the preparation and administration of drugs and biologicals	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify that there is an effective method for the administration of drugs. Confirm the following indicators: □ There are policies and procedures approved by the medical staff and governing body concerning

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i. *Drugs and biological may be prepared and administered on the orders of other practitioners not specified under 42 CFR §482.12(c) only if such practitioners are acting in accordance with State law, including scope-of-practice laws, hospital policies, and medical staff bylaws, rules and regulations.*

All drugs and biologicals must be administered by, or under supervision of, nursing or other personnel in accordance with Federal and State laws and regulations, including applicable licensing requirements, and in accordance with the approved medical staff policies and procedures.

§482.23(c)
§482.23(c)(1)
§482.23(c)(1)(i)
§482.23(c)(2)

to hospital patients by requiring preparation and administration by or under the supervision of nursing or other personnel in accordance with:

- Federal and state law.
- Accepted standards of practice.
- Orders of the practitioner(s) responsible for the patient's care, as specified under 42 CFR §482.12(c) or of another practitioner as permitted under State law, hospital policy and medical staff bylaws, rules and regulations.
- Medical staff-approved policies and procedures.

FEDERAL AND STATE LAW

Federal law regulates the approval and classification of drugs and biologicals. Individual states establish laws and regulations which specify the scope of practice for various types of licensed healthcare professionals, including which medications they may prescribe and administer, including controlled substances.

ACCEPTED STANDARDS OF PRACTICE

Hospital policies and procedures for the preparation and administration of all drugs and biologicals must not only comply with all applicable Federal and State laws, but also must be consistent with accepted standards of practice based on guidelines or recommendations issued by nationally recognized organizations with expertise in medication preparation and administration.

Examples of such organizations include, but are not limited to:

- American Society of Health-System Pharmacists (http://www.ashp.org/default.aspx)
- National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org)
- Institute for Healthcare Improvement (http://www.ihi.org/ihi)
- U.S Pharmacopeia (www.usp.org)

ordering of drugs and biologicals by practitioners.

  - ☐ There are policies and procedures approved by the medical staff covering who is authorized to administer medications, and that the policies are followed.
- Nursing staff authorized to administer drugs and biological are practicing within their State-permitted scope of practice.
- Are personnel other than nursing personnel administering drugs or biologicals?
  - ☐ If yes, are those personnel administering drugs or biologicals in accordance with Federal and State laws and regulations, including scope of practice laws, hospital policy, and medical staff by-laws, rules, and regulations.
- Verify that there are policies and procedures approved by medical staff addressing the timing of medication administration.
- Verify that the hospital has, consistent with its policies, identified medications that are:
  - ☐ Not eligible for scheduled dosing times.

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- Institute for Safe Medication Practices (www.ismp.org/Newsletters/acutecare/articles/20110113.asp)
- Infusion Nurses Society (http://www.ins1.org)

In addition, the Centers for Disease Control and Prevention (CDC) publishes evidenced-based practice guidelines and recommendations on medication preparation and administration practices, designed to reduce the risk of infection associated with these activities.

ORDERS OF AN AUTHORIZED PRACTITIONER

Drugs must be administered in response to an order from a practitioner, or on the basis of a standing order which is appropriately authenticated subsequently by a practitioner. See standard 16.01.03 concerning standing orders [42 CFR §482.23(c)(1)(ii)].

Generally, the ordering practitioner is the practitioner(s) responsible for the care of the patient in accordance with standard 01.01.12 [42 CFR §482.12(c)]. However, other practitioners not specified under §482.12(c) may write orders for the preparation and administration of drugs and biologicals, if they are acting in accordance with State law, including scope of practice laws, hospital policies and procedures, and medical staff bylaws, rules, and regulations.

This includes practitioners ordering outpatient services who do not have privileges in the hospital but who are permitted under their State scope of practice and authorized by hospital and medical staff policy to order outpatient services.

In accordance with standard practice, all practitioner orders for the administration of drugs and biologicals must include at least:

1. Patient's name.
2. Patient's age and weight, to facilitate dose calculation when applicable.

   Policies and procedures must address weight-based dosing for pediatric patients as well as in other circumstances identified in the hospital's policies. (Note that dose calculations are based on metric weight (kg, or

- ☐ Eligible for scheduled dosing times and are time-critical.
- ☐ Eligible for scheduled dosing times and are not time-critical.

- Verify the hospital has established total windows of time that do not exceed:
  - ☐ 1 hour for time-critical scheduled medications.
  - ☐ 2 hours for medications prescribed more frequently than daily, but no more frequently than every 4 hours.
  - ☐ 4 hours for medications prescribed for daily or longer administration intervals.
- Verify that the hospital's policy describes requirements for the administration of identified time-critical medications. Is it clear whether time-critical medications or medication types are identified as such for the entire hospital or are unit-, patient diagnosis-, or clinical situation-specific?
- Review a sample of medical records to determine whether medication administration conformed to an authorized practitioner's order, i.e., that there is an order from an

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g for newborns).

If a hospital permits practitioners to record weight in either pounds or using metric weight, the opportunity for error increases, since some orders would require conversion while others would not. Accordingly, hospitals must specify a uniform approach to be used by prescribing practitioners.

For example, a hospital could require all prescribers to use pounds or ounces and have the electronic ordering system or the pharmacy convert to metric.

2. Date and time of the order.
3. Drug name.
4. Dose, frequency, and route.
5. Dose calculation requirements, when applicable.
6. Exact strength or concentration, when applicable.
7. Quantity and/or duration, when applicable.
8. Specific instructions for use, when applicable.
9. Name of the prescriber.

MEDICAL STAFF APPROVED POLICIES AND PROCEDURES

The hospital's medical staff must approve policies and procedures for medication administration, consistent with the requirements of Federal and State law and accepted standards of practice. It is recommended that the medical staff consult with nurses, pharmacists, Quality Assessment and Performance Improvement program staff, and others in developing these policies and procedures.

The adopted policies and procedures must address key issues related to medication administration, which include but are not limited to:

A. **Personnel Authorized to Administer Medication**

All drugs and biologicals are administered by, or under the supervision of, authorized practitioner, or an applicable standing order, and that the correct medication was administered to the right patient at the right dose via the correct route, and that timing of administration complied with the hospital's policies and procedures. Check that the practitioner's order was still in force at the time the drug was administered.

- Observe the preparation of drugs and their administration to patients [medication pass] in order to verify that procedures are being followed.
  - □ Is the patient's identity confirmed prior to medication administration?
  - □ Are procedures to assure the correct medication, dose, and route followed?
  - □ If immediate-use CSPs are prepared outside of the pharmacy, are practices consistent with USP<797>?
  - □ Are drugs administered in accordance with the hospital's established policies and procedures for safe and timely medication administration?
  - □ Does the nurse remain with the

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nursing or other personnel, in accordance with Federal or State law and approved medical staff policies and procedures. State law requirements include licensure requirements.

Policies and procedures must identify categories of licensed personnel and the types of medications they are permitted to prepare and administer, in accordance with state laws. The policies and procedures must also address education and training for all personnel preparing and administering drugs and biologicals.

Medication preparation and administration education and training is typically included in hospital orientation or other continuing education for nursing staff and other authorized healthcare personnel. Training or continuing education topics regarding medication preparation and administration may include but are not limited to:

- Safe handling and preparation of authorized medications.
- Knowledge of the indications, side effects, drug interactions, compatibility, and dose limits.
- Equipment, devices, special procedures, and/or techniques required for medication administration.

Policies and procedures must address the required components of the training and if the training provided during hospital orientation imparts sufficient education or whether ongoing in-services or continuing education will be required to demonstrate competence.

B. **Basic Safe Practices for Medication Administration**

The hospital's policies and procedures must reflect accepted standards of practice that require the following be confirmed prior to each administration of medication (often referred to as the "five rights" of medication administration practice):

1. **Right Patient**: the patient's identity— acceptable patient identifiers include, but are not limited to:
   a. The patient's full name; an identification number assigned by

patient until oral medication is taken?

- Are patients assessed by nursing and/or other staff, per hospital policy, for their risk to their prescribed medications?
  - □ Are patients who are at higher risk and/or receiving high-alert medications monitored for adverse effects?
  - □ Are staff knowledgeable about intervention protocols when patients experience adverse medication-related events?
- Interview personnel who administer medication to verify their understanding of the policies regarding timeliness of medication administration.
  - □ Are they able to identify time-critical and non-time-critical scheduled medications? Medications not eligible for scheduled dosing times?
  - □ Are they able to describe requirements for the timing of administration of time critical and non-time critical medications in accordance with the hospital's policies?

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the hospital; or date of birth.

b. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible) or other means outlined in the hospital's policy.

c. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration to ensure that the medication is being given to the correct patient.

2. **Right Medication**: to ensure that the medication being given to the patient matches that prescribed for the patient and that the patient does not have a documented allergy to it.
3. **Right Dose:** to ensure that the dosage of the medication matches the prescribed dose, and that the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low).
4. **Right Route:** to ensure that the method of administration – orally, intramuscular, intravenous, etc., is the appropriate one for that particular medication and patient.
5. **Right Time:** to ensure adherence to the prescribed frequency and time of administration.

Note: the "5 rights" focus specifically on the process of administering medications. The medication process is generally recognized as consisting of five stages:

1. ordering/prescribing.
2. transcribing and verifying.
3. dispensing and delivering.
4. administering.
5. monitoring/reporting.

Errors may occur in other components of the process, even when there is strict adherence to the "5 rights" of medication administration, for

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example when there has been a prescribing or a dispensing error. Hospitals are also expected to comply with requirements under the Pharmaceutical Services CoP at 42CFR §482.25 and the patient safety requirements under the Quality Assessment and Performance Improvement CoP at 42CFR §482.21, using a comprehensive systems approach to all components of the medication process.

Hospitals are encouraged to promote a culture in which it is not only acceptable, but also strongly encouraged, for staff to bring to the attention of the prescribing practitioner questions or concerns they have regarding medication orders. Any questions about orders for drugs or biologicals are expected to be resolved promptly, whether they arise prior to the preparation, dispensing, or administration of the medication.

HEALTHCARE-ASSOCIATED INFECTIONS

Hospitals must also ensure staff adherence to accepted standards of practice required to prevent healthcare-associated infections related to medication preparation and/or administration. Adherence to these standards is assessed under the infection control CoP at Chapter 7 (42 CFR 482.42).

Compounded sterile preparations (CSPs) may also be a source of healthcare-associated infection if proper precautions are not followed.

The applicable standards of practice for safe sterile compounding are, at a minimum, the standards published in The United States Pharmacopeia National Formulary Chapter <797> ("Pharmaceutical Compounding – Sterile Preparations") and other relevant USP/NF Chapters (USP <797>). (See standard 25.01.02 (§482.25(b)(1)) for more information on the role of USP/NF standards and discussion of the term compounding.")

Hospitals must ensure that they meet all currently accepted standards for safe preparation and administration for CSPs, whether they are the type of CSP that must be compounded in an aseptic pharmacy location that meets USP <797> standards for low, medium, or high-level risk CSPs or

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are "immediate-use CSPs" prepared outside of the pharmacy.

Immediate-use CSP

Nurses commonly prepare sterile medications that are categorized by USP <797> as "immediate-use CSPs," which are needed for immediate or emergency use for a particular patient and are not to be stored for anticipated needs.

The following USP <797> standards apply when preparing an immediate-use CSP:

1. Preparation of an immediate-use CSP must only involve "simple transfer of not more than three commercially manufactured…sterile nonhazardous products from the manufacturer's original containers and not more than two entries into any one container or package (e.g. bag, vial) of sterile infusion solution or administration container/ device."
2. "Administration begins not later than one hour following the start of the preparation of the CSP (if not, the CSP must be appropriately discarded)."
3. Meticulous aseptic technique must be followed during all phases of preparation. If the CSP is not administered to the patient as soon as it is ready, "the finished CSP is under continuous supervision to minimize the potential for contact with non-sterile surfaces…," contamination and/or confusion with other CSPs.
4. "Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer…," the CSP must be labeled with at least:
   - Patient identification information;
   - The names and amounts of all ingredients;
   - The name or initials of the person who prepared it; and
   - The exact one hour "beyond use date" (see below).

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A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the U.S. Food and Drug Administration's (FDA) approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer's approved labeling.

Beyond Use Date (BUD)

- A drug or biological is also outdated after its "beyond-use date" (BUD), which may be reached before the expiration date, but never later.
- The BUD is the date and time after which the medication must not be used, stored, or transported.
- The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded medication.
- The BUD is to be based on information provided by the manufacturer, whenever such information is available. The hospital must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer.
- The policies and procedures must be based on accepted professional principles which are equivalent to, or more stringent than, those described in the USP/NF (USP).[1]
- According to Chapters <795> and <797> of the USP, the BUD must be safe for patients, and determined conservatively. The section in USP <797> entitled "Determining Beyond-Use Dates," which addresses sterile compounding, notes that "the truly valid evidence for

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predicting beyond-use dating can be obtained only through product-specific experimental studies." It provides an example of testing considered more appropriate for certain types of CSPs such as "CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity…."
It also provides examples of important issues that a pharmacist must be able to critically interpret and evaluate when consulting literature sources in the process of determining a BUD; and distinguishes between reviewing literature specific to a particular drug, composition, concentration of ingredients, fill volume, container, storage conditions and duration of use, etc., versus merely reviewing available publications or tables. The former is the preferred approach, while the latter results in a "theoretical BUD," which has an inherent likelihood of inaccuracy or error.

[1] All references to "USP" herein are from: United States Pharmacopeial Convention. USP on Compounding: A Guide for the Compounding Practitioner.

C. **Timing of Medication Administration**

Appropriate timing of medication administration must take into account the complex nature and variability among medications; the indications for which they are prescribed; the clinical situations in which they are administered; and the needs of the patients receiving them.

The chemical properties, mechanism of action, or therapeutic goals of some medications require administration at the exact time prescribed, or within a narrow window of its prescribed scheduled time, to avoid compromising patient safety or achievement of the intended therapeutic effect. However, the therapeutic effect of many other medications is uncompromised by a much broader window of time for administration.

Consequently, the application of a uniform required window of time

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before or after the scheduled time for the administration of all medications, without regard to their differences, could undermine the ability of nursing staff to prioritize nursing care activities appropriately.

This could also result in staff work-arounds that jeopardize patient safety due to the imposition of unrealistic or unnecessary time constraints for medication administration. Instead, hospital policies and procedures must specifically address the timing of medication administration, based on the nature of the medication and its clinical application, to ensure safe and timely administration.

The policies and procedures must address at least the following:

1. Medications not eligible for scheduled dosing times.
2. Medications eligible for scheduled dosing times.
3. Administration of eligible medications outside of their scheduled dosing times and windows.
4. Evaluation of medication administration timing policies, including adherence to them.

D. **Medications or Categories of Medication Not Eligible for Scheduled Dosing Times**

The policies and procedures must identify medications or categories of medication which are not eligible for scheduled dosing times, either in general or in specific clinical applications.

These are medications that require exact or precise timing of administration, based on diagnosis type, treatment requirements, or therapeutic goals. The policies and procedures must reflect consideration of factors including, but not limited to, the pharmacokinetics of the prescribed medication; specific clinical applications; and patient risk factors.

Examples of medications that hospitals may choose to identify as not

eligible for scheduled dosing times may include, but are not limited to:

- STAT doses (immediate).
- First time or loading doses (initial large dose of a drug given to bring blood, tissue, or fluid levels to an effective concentration quickly).
- One-time doses; doses specifically timed for procedures.
- Time-sequenced doses; doses timed for serum drug levels.
- Investigational drugs.
- Drugs prescribed on an as needed basis (PRN doses).

The policies and procedures must ensure timely administration of such medications. In addition, they must specify if the policy for the administration of these medications will be applied hospital-wide or only for specific diagnosis types, hospital units or clinical situations.

E. <u>Medications Eligible for Scheduled Dosing Times</u>

Medications eligible for scheduled dosing times are those prescribed on a repeated cycle of frequency, such as once a day, BID (twice a day), TID (three times a day), hourly intervals (every 1, 2, 3 or more hours), etc.

The goal of this scheduling is to achieve and maintain therapeutic blood levels of the prescribed medication over a period of time.

Medication administration policies and procedures typically establish standardized dosing times for the administration of all 'scheduled' medications.

- For example, medications prescribed for BID (twice a day) administration might, under a given hospital's policies and procedures, be scheduled to be administered at 8am and 8pm.
- Another hospital might choose to schedule BID medications at 7:30 am and 7:30 pm.
- Use of these standardized times facilitates the medication administration process, e.g., by providing to the hospital's pharmacy

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that morning doses of all BID drugs must be dispensed and delivered to patient units in time for the scheduled administration.

- For the nursing staff, the scheduled administration time might prompt prioritization of additional activities that may be required, in the case of particular drugs, such as vital sign assessment or the collection and review of blood work, to ensure safe and timely medication administration.

Policies and procedures for medications eligible for scheduled dosing times must also address:

- first dose medications, including parameters within which nursing staff may use their own judgment regarding the timing of the first and subsequent doses, which may fall between scheduled dosing times.
- retiming of missed or omitted doses.
- medications that will not follow scheduled dosing times.
- patient units that are not subject to following the scheduled dosing times.

F. <u>Time-Critical Scheduled Medications</u>

Time-critical scheduled medications are those for which an early or late administration of greater than thirty minutes might cause harm or have significant, negative impact on the intended therapeutic or pharmacological effect.

Accordingly, scheduled medications identified under the hospital's policies and procedures as time-critical must be administered within thirty minutes before or after their scheduled dosing time, for a total window of 1 hour.

It is possible for a given medication to be time- critical for some patients, due to diagnosis, clinical situation, various risk factors, or therapeutic intent, but not time-critical for other patients.

Therefore, hospital policies and procedures must address the process for

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determining whether specific scheduled medications are always time-critical, or only under certain circumstances, and how staff involved in medication administration will know when a scheduled medication is time-critical.

Examples of time-critical scheduled medications/medication types may include, but are not limited to:

- Antibiotics
- Anticoagulants
- Insulin
- Anticonvulsants
- Immunosuppressive agents
- Pain medication (non-IV)
- Medications prescribed for administration within a specified period of time of the medication order
- Medications that must be administered apart from other medications for optimal therapeutic effect
- Medications prescribed more frequently than every 4 hours.

G. <u>Non-Time-Critical Scheduled Medications</u>

Non-time critical scheduled medications are those for which a longer or shorter interval of time since the prior dose does not significantly change the medication's therapeutic effect or otherwise cause harm.

For such medications, greater flexibility in the timing of administration is permissible. Specifically:

- Medications prescribed for daily, weekly, or monthly administration may be within two hours before or after the scheduled dosing time, for a total window that does not exceed four hours.
- Medications prescribed more frequently than daily but no more

frequently than every four hours may be administered within 1 hour before or after the scheduled dosing time, for a total window that does not exceed two hours.

H. Missed or Late Administration of Medications

The hospital's policies and procedures must address the actions to be taken when medications eligible for scheduled dosing times are not administered within their permitted window of time.

This includes doses which may have been missed due to the patient being temporarily away from the nursing unit, for example, for tests or procedures; patient refusal; patient inability to take the medication; problems related to medication availability; or other reasons that result in missed or late dose administration.

Policies and procedures must also outline guidelines for the administration and timing of new medications which are initiated between standardized dosing times.

These policies and procedures must identify parameters within which nursing staff can use their own judgment regarding the rescheduling of missed or late doses and when notification of the physician or other practitioner responsible for the care of the patient is required prior doing so. In either case, the reporting of medication errors that are the result of missed or late dose administration must be reported to the attending physician in accordance with requirements at 42 CFR §482.25(b)(6). See interpretative guidance at standard 25.01.10 (§482.25(b)(6)) for more details on internal reporting requirements.

I. Evaluation of Medication Administration Timing

Hospitals must periodically evaluate their medication administration timing policies, including staff adherence to the policies, to determine whether they assure safe and effective medication administration.

Consistent with the QAPI requirements at standard 12.00.03 (42 CFR 482.21(c)(2)), medication errors related to the timing of medication

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administration must be tracked and analyzed to determine their causes. Based on the results of the evaluations of the policies and the medication administration errors, the medical staff must consider whether there is a need to revise the policies and procedures governing medication administration timing.

J. <u>Assessment/Monitoring of Patients Receiving Medications</u>

Observing the effects medications have on the patient is part of the medication administration process. Patients must be carefully monitored to determine whether the medication results in the therapeutically intended benefit, and to allow for early identification of adverse effects and timely initiation of appropriate corrective action.

Depending on the medication and route/delivery mode, monitoring may need to include assessment of:

- Clinical and laboratory data to evaluate the efficacy of medication therapy, to anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels.
- Physical signs and clinical symptoms relevant to the patient's medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc.

Certain types of medications are considered inherently high risk for adverse drug events. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal to patients. In addition, certain factors place some patients at greater risk for adverse effects of medication.

Factors including, but not limited to, age, altered liver and kidney function, a history of sleep apnea, patient weight (obesity may increase apnea or smaller patients may be more sensitive to dose levels of medications), asthma, history of smoking, drug-drug interactions, and

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first-time medication use may contribute to increased risk.

Consideration of patient risk factors as well as the risks inherent in a medication must be taken into account when determining the type and frequency of monitoring. Further, to enhance continuity of care/safe medication administration, it is essential to communicate all relevant information regarding patients' medication risk factors and monitoring requirements during hand-offs of the patient to other clinical staff, such as when patients are transferred internally from one unit to another, during shift report at change of shift, etc. This would apply to hand-offs involving not only to nursing staff, but also to any other types of staff who administer medications, e.g., respiratory therapists.

Adverse patient reactions, such as anaphylaxis or opioid-induced respiratory depression, require timely and appropriate intervention, per established hospital protocols, and must also be reported immediately to the practitioner responsible for the care of the patient. See standard 16.01.07/25.01.10 [42CFR §482.23(c)(5)/42CFR §482.25(b)(6)] concerning reporting of adverse medication-related events.

An example of vigilant post-medication administration monitoring in the case of a high-alert medication where patient factors may increase risk would be regularly checking vital signs, oxygen level via pulse oximetry, and sedation levels of a post-surgical patient who is receiving pain medication via a patient-controlled analgesia (PCA) pump. Narcotic medications, such as opioids, are often used to control pain but also have a sedating effect. Timely assessment and appropriate monitoring is essential in all settings in which opioids are administered, to permit intervention to counteract respiratory depression should it occur. See also the discussion of the requirements for intravenous medications at standard 16.01.06 [42 CFR §482.23(c)(4)].

As part of the monitoring process, staff are expected to include the patient's reports of his/her experience of the medication's effects. When

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monitoring requires waking the patient in order to assess effects of the medications, the patient and/or the patient's representative must be educated about this aspect of the monitoring process. Hospitals are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

Hospital policies and procedures are expected to address how the manner and frequency of monitoring, considering patient and drug risk factors, are determined, as well as the information to be communicated at shift changes, including the hospital's requirements for the method(s) of communication.

K. <u>Documentation</u>

Note that documentation of medication administration is addressed in the Medical Records CoP (chapter 10), and at standard 16.01.06 [42 CFR §482.24(c)], which specifies the required content of the medical record.

Within this regulation 42 CFR §482.24(c)(vi) requires that the record contain: "All practitioners' orders, nursing notes, reports of treatment, medication records, radiology, and laboratory reports, and vital signs and other information necessary to monitor the patient's condition."

Documentation is expected to occur after actual administration of the medication to the patient; advance documentation is not only inappropriate but may result in medication errors. Proper documentation of medication administration actions taken, and their outcomes is essential for planning and delivering future care of the patient. See the guidance for the various parts of chapter 10 [42 CFR §482.24(c)] concerning documentation in the medical record. Deficiencies in documentation would be cited under the applicable Medical Records standard.

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16.01.02 Pain assessment and reassessment **Observing the effects of pain medications is part of the medication administration process. Patient pain is monitored for efficacy of medication administration and to allow for early identification of adverse effects and timely initiation of appropriate corrective action.**	☐ Compliant ☐ Not Compliant **Patients have the right to pain management through assessment, intervention, and reassessment. Each patient has the right to expect his/her report of pain to be accepted and to have interventions provided.** **Hospital policies and procedures address the manner and frequency of monitoring, the use of standardized tool(s), documentation requirements for assessment and reassessment, and information to be communicated at shift changes including the hospital's requirements for the method(s) of communication.** **COMPREHENSIVE PAIN ASSESSMENT** **A comprehensive pain assessment includes patient's acceptable level of pain, pain history (including pain identification and assessment), and medication and non-medication interventions used in the past that were effective.** **Pain assessment/reassessment uses a standardized tool and includes onset/duration, intensity or level of pain (based on facility approved assessment scales), quality of pain and location as well as hemodynamic and physiological assessment. Pain scales approved by the facility are appropriate for the age and condition of the patient. Examples of tools include:** ▪ **Visual Analogue Scale/Graphic Rating Scale** ▪ **Numerical Rating Scale** ▪ **Verbal Rating Scale** ▪ **Pain Drawing** **Pain assessment occurs before administration of pain medication and as needed after administration while meeting the criteria of nationally recognized standards of practice as defined in policy.**	This standard is not met as evidenced by: **<u>OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW</u>** **Verify:** ▪ **There is an effective method assessment and reassessment of pain medication administration.** ▪ **There are policies and procedures for pain assessment and reassessment. These policies have been approved by appropriate individuals/committees.** ▪ **Patients are assessed and reassessed by nursing per hospital policy and during acceptable evidence-based timeframes?** ▪ **Interview personnel who administer pain medications to verify their understanding of assessment and reassessment regarding pain medication management.** ▪ **Interview patients to verify that their pain is assessed and reassessed in a method they understand.**

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	ONGOING MONITORING **Depending on the medication and route/delivery mode, monitoring may include assessment of:** ▪ **Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects. For some medications, including opioids, this may include clinical data such as respiratory status, blood pressure, and oxygenation and carbon dioxide levels.** ▪ **Physical signs and clinical symptoms relevant to the patient's medication therapy, including but not limited to, somnolence, confusion, agitation, unsteady gait, pruritus, etc. Certain types of medications are considered inherently high risk for adverse drug events.** **The assessment and monitoring process must be explained to the patient and/or the patient's representative, to communicate the rationale for vigilant monitoring. In addition, hospitals are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.**	
16.01.03 Medication orders ▪ *Drugs and biologicals may be prepared and administered on the orders contained within pre-printed and electronic standing orders, order sets, and protocols for patient orders only if such orders meet the requirements of* standard 01.01.14 [*42 CFR §482.12(c)(3)*].	☐ Compliant ☐ Not Compliant All orders for drugs and biologicals, with the exception of influenza and pneumococcal vaccines, must be documented and signed by a practitioner who is responsible for the care of the patient, as specified under 42 CFR §482.12(c), or who is another practitioner who is authorized by hospital policy and medical staff bylaws, rules and regulations, and who is acting in accordance with State law, including scope of practice laws. **Flu and Pneumonia Vaccines**	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the hospital's policy for drug and biological orders. Does it require that all administration of drugs or biologicals be based on either an applicable standing order or the order of a practitioner who is responsible for the care of the patient or otherwise

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- *With the exception of influenza and pneumococcal vaccines, which may be administered per physician-approved hospital policy after an assessment of contraindications, orders for drugs and biologicals must be documented and signed by a practitioner who is authorized to write orders by hospital policy and in accordance with State law, and who is responsible for the care of the patient.*
  - *Orders for drugs and biologicals may be documented and signed by other practitioners only if such practitioners are acting in accordance with State law, including scope of practice laws, hospital policies, and medical staff bylaws, rules, and regulations.*

§482.23(c)(1)(ii)
§482.23(c)(3)
§482.23(c)(3)(iii)

Influenza and pneumococcal vaccines may be administered per physician-approved hospital policy, i.e., hospital policy approved by the physician members of the medical staff. There must be an assessment of contraindications prior to administration of the vaccine(s). There is no requirement for authentication by a practitioner when influenza and pneumococcal vaccines are administered to a patient in accordance with hospital policy and State law.

STANDING ORDERS

Nurses or other personnel authorized by hospital policy and in accordance with State law may administer drugs and biologicals in accordance with pre-printed and electronic standing orders, order sets, and protocols for patient orders, collectively referred to in this guidance as "standing orders," to address well-defined clinical scenarios involving medication administration.

The requirements governing the hospital's development and use of standing orders are found at the Medical Records CoP, at standard 10.01.05 [42 CFR §482.24(c)(3)].

For the nursing services requirement under 42 CFR §482.23(c)(1)(ii), compliance assessment focuses on whether nurses comply with the hospital's established standing orders policies and procedures when administering drugs or biological in accordance with a standing order.

authorized by hospital policy medical staff policy and in accordance with State law to write orders?

- Interview nursing staff to determine whether they initiate medications in accordance with standing orders.
  - ☐ Are they familiar with the hospital's policies and procedures for using standing orders?
  - ☐ Are they following the policies and procedures? Ask to see the protocol for a standing order used by nursing staff and ask nursing staff to explain how their practice conforms to the protocol.
- Review a sample of open and closed patient medical records. Although the regulation applies to both inpatient and outpatient medical records, the sample should be weighted to include more inpatient records.
- Determine whether all orders for drugs and biologicals, with the exception of influenza and pneumococcal vaccines, are included in the patient's medical record and authenticated by a practitioner who is authorized to write orders by hospital and medical staff policy and in accordance with State law, and who is responsible for the care of the patient.

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		▪ Determine whether all standing orders which were initiated by a nurse were authenticated by an authorized practitioner. ▪ Determine whether all orders for drugs and biologicals contain the required elements. ▪ Verify that the prescribing practitioner has reviewed and authenticated the orders in accordance with medical staff policy and/or applicable State laws.
16.01.04 <u>Verbal orders</u> *If verbal orders are used, they are to be used infrequently.* §482.23(c)(3)(i)	☐ Compliant ☐ Not Compliant The use of verbal orders must not be a common practice. Verbal orders pose an increased risk of miscommunication that could contribute to a medication or other error, resulting in a patient adverse event. Verbal orders should be used only to meet the care needs of the patient when it is impossible or impractical for the ordering practitioner to write the order or enter it into a computer (in the case of a hospital with an electronic prescribing system) without delaying treatment. Verbal orders are not to be used for the convenience of the ordering practitioner. (71 FR §68679) Hospitals are expected to develop appropriate policies and procedures that govern the use of verbal orders and minimize their use, policies which: ▪ Describe situations in which verbal orders may be used as well as limitations or prohibitions on their use. ▪ Provide a mechanism to establish the identity and authority of the	This standard is not met as evidenced by: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** ▪ Are there policies and procedures in place to minimize the use of verbal orders? ▪ Interview direct care staff to determine whether actual practice is consistent with verbal order policies and procedures. ▪ Review both open and closed patient medical records for the use of verbal orders. □ Were the policies and procedures for the use of verbal orders followed? ▪ Does the number of verbal orders

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practitioner issuing a verbal order.

- List the elements required for inclusion in the verbal order process.
- Define the types of personnel who may issue and receive verbal orders.
- Establish protocols for clear and effective communication and verification of verbal orders.
- The content of verbal orders must be clearly communicated. CMS expects nationally accepted read-back verification practice to be implemented for every verbal order. (71 FR §68680)

As required by standard 10.00.03 [42 CFR §482.24(b)], all verbal orders must be promptly documented in the patient's medical record and signed by the individual receiving the order.

found in the sampled records suggest routine use? The number of verbal orders is not in itself evidence of noncompliance but should result in more focused analysis. For example:

- □ Is there a pattern to the use of verbal orders? Some patterns might make sense – e.g., for orders entered between midnight and 7a.m., it might be plausible that it was impossible for the prescribing practitioner to write/ computer-enter the order. On the other hand, if one patient care unit has a high proportion of verbal orders, while another does not, this might be a flag for inconsistent implementation of the hospital's policies and procedures for verbal orders.
- □ Are verbal orders used frequently for certain types of situations, and if so, is it reasonable to assume that it is impossible or impractical for the prescribing practitioners to write/enter the orders in such situations?

- Do certain practitioners use verbal orders frequently? From the limited number of records sampled it may be difficult to detect trends related to

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		specific practitioners, but if a surveyor finds such evidence, further investigation is warranted to determine if it is evidence of noncompliance.
16.01.05 Accepting verbal orders *When verbal orders are used, they must only be accepted by persons who are authorized to do so by hospital policy and procedures consistent with Federal and State law.* §482.23(c)(3)(ii)	☐ Compliant ☐ Not Compliant A verbal order for drugs and biologicals may only be accepted by an individual who is permitted by Federal and State law and hospital policy to accept verbal orders. Consistent with the requirements of standard 10.00.03 [42 CFR §482.24(b)], the person who received the verbal order must promptly document it in the medical record.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Determine whether the hospital has policies and procedures, consistent with Federal and State law, governing who is authorized to accept verbal orders. ▪ Review open and closed patient medical records containing verbal orders for drugs and biologicals. □ Determine whether the orders were accepted and documented by authorized hospital personnel. ▪ Interview several direct care staff to determine if they are permitted to take verbal orders for drugs and biologicals and determine whether such staff have been authorized to do so in accordance with hospital policy.

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16.01.06 Administration of blood products and IV medications

Blood transfusions and intravenous medications must be administered in accordance with State law and approved medical staff policies and procedures.

§482.23(c)(4)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

See also the discussion of high-risk/high-alert medications in the guidance for standards in chapter 25, section 25.01 [42 CFR §482.25(b)].

HOSPITAL POLICIES AND PROCEDURES: BLOOD TRANSFUSIONS AND IV MEDICATIONS

Hospital policies and procedures for blood transfusions and IV medications must be based on accepted standards of practice, and must address at least the following:

Vascular Access Route

Patients may require a form of vascular access to deliver blood or medications, either venous or arterial, based on the desired treatment plan.

Safe administration of blood transfusions and IV medications includes the correct choice of vascular access.

IV medications, such as fluids, antibiotics, and chemotherapy, may require specific types of access, such as peripheral or central catheters versus implanted port devices, based on the medication's chemical properties or safety concerns.

- Hospital policies and procedures must address which medications can be given intravenously via what type of access.

Other Patient Safety Practices

In addition to the basic safe practices that apply to all medication administration (See earlier standards in this chapter and section –16.01--for further discussion of safe medication administration practices, and medication administration in general [42 CFR §482.23(c)]). There are additional safe practices specific to IV medication administration including but not limited to:

- Tracing invasive lines and tubes prior to administration to ensure the

INTERVIEW AND DOCUMENT REVIEW

- Verify the hospital has a special training program for administering blood transfusions and intravenous medications that includes:
  - ☐ Fluid and electrolyte balance.
  - ☐ Blood components.
  - ☐ Venipuncture techniques, demonstrations, and supervised practice.
- Interview nursing staff on different units who administer IV medications and blood transfusions. Are staff knowledgeable with respect to:
  - ☐ Venipuncture techniques.
  - ☐ Safe medication administration practices, including general practices applying to all types of medications and practices concerning IV tubing and infusion pumps.
  - ☐ Maintaining fluid and electrolyte balance.
  - ☐ Patient assessment for risk related to IV medications and appropriate monitoring.

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medication is to be administered via the proper route (for example, peripheral catheter versus epidural catheter connections).

- Avoiding forcing connections when the equipment offers clear resistance.
- Verifying proper programming of infusion devices (concentrations, flow rate, dose rate).

Patient Monitoring

As discussed in the medication administration guidance standard 16.01.01 [42 CFR §§482.23(c)(1), (c)(1)(i) and (c)(2)], patients must be monitored for the effects of medications. To the extent that IV medications have a more rapid effect on the body, it is important that staff administering medications understand each medication and its monitoring requirements.

Policies and procedures for IV medication administration must address appropriate IV medication monitoring requirements, including assessment of patients for risk factors that would influence the type and frequency of monitoring.

- For example, a 50-year-old patient with a history of renal failure is receiving IV vancomycin to treat a wound infection. The hospital policy for IV antibiotics, including vancomycin, requires the patient's kidney function to be monitored daily with blood draws. Based on review of the lab results, a practitioner responsible for the care of the patient would be expected to determine on a timely basis whether or not the antibiotic dose needs to be adjusted to protect kidney function or prevent drug toxicity while achieving the desired therapeutic effects. Staff administering the medication would be expected to review the lab results as well, and to raise with a practitioner responsible for the care of the patient any concerns they might have about whether an adjustment in the medication is needed.

HOSPITAL POLICIES AND PROCEDURES: PATIENT MONITORING

Hospital policies and procedures related to monitoring patients receiving IV medications are expected to address, but are not limited to, the following:

- □ Early detection and intervention for IV opioid-induced respiratory depression in post-operative patients.
- □ With respect to blood transfusions:
  - Blood components.
  - Process for verification of the right blood product for the right patient.
  - Transfusion reactions: identification, treatment, and reporting requirements.

- Review the files for a sample of staff who administer blood products and IV medications, for evidence that competency was assessed and training was provided as appropriate.
- If possible, observe blood transfusion and IV medication administration to assess staff adherence to accepted standards of practice.
  - □ Were safe medication administration practices used?
  - □ Was the transfused patient correctly identified and matched to the correct blood product prior to administration?
  - □ Was the appropriate access used

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Monitoring for Fluid & Electrolyte Balance

Whenever IV medications and blood transfusions are administered, the patient may become at risk for fluid and electrolyte imbalance. Hospital policies and procedures must address monitoring and treatment for fluid and electrolyte imbalances that may occur with blood transfusions and IV medications.

Monitoring Patients Receiving High-alert Medications, including IV Opioids

Policies and procedures related to IV medication administration must address those medications the hospital has identified as high-alert medications and the monitoring requirements for patients receiving such drugs intravenously.

- At a minimum, hospitals are expected to address monitoring for over-sedation and respiratory depression related to IV opioids for post-operative patients.

Opioids

The sedating effects of opioids make it difficult at times to properly assess the patient's level of sedation. It can be erroneously assumed that patients are asleep when they are actually exhibiting progressive symptoms of respiratory compromise - somnolence, decreased respiratory rate, and decrease in oxygen levels. These symptoms, if unrecognized, can progress to respiratory depression and even death.

Certain characteristics place patients receiving opioids at higher risk for over-sedation and respiratory depression. These additional factors include, but are not limited to:

- Snoring or history of sleep apnea.
- No recent opioid use or first-time use of IV opioids.
- Increased opioid dose requirement or opioid habituation.
- Longer length of time receiving general anesthesia during surgery.
- Receiving other sedating drugs, such as benzodiazepines, antihistamines, sedatives, or other central nervous system depressants.

for IV medications?

- □ Were appropriate steps taken with regard to IV tubing and infusion pumps?
- □ Are patients being monitored post-infusion for adverse reactions?

- If staff appear to not be following accepted standards of practice for patient risk assessment related to IV medications, particularly opioids, and appropriate monitoring of patients receiving IV medications and/or blood transfusions, review policies and procedures for IV medication administration and blood transfusion to determine if they address safe practices considerations.
- Review a sample of medical records of patients that received a blood transfusion and/or IV medications.
  - □ Are blood transfusions and IV medications administered in accordance with State law and approved hospital policies and medical staff policies and procedures?
  - □ Determine the identity of staff who administered blood components and/or IV

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- Preexisting pulmonary or cardiac disease.
- Thoracic or other surgical incisions that may impair breathing.

Patients Receiving IV Opioids Post-Operatively

The effects of IV opioids in post-operative patients must be monitored vigilantly via serial assessments of pain, respiratory status, and sedation levels.

Hospitals must have policies and procedures related to the use of high-alert medications, including IV opioids for post-operative patients.

Policies and procedures must address, at a minimum,

The process for patient risk assessment, including who conducts the assessments, and based on the results of the assessment, monitoring frequency and duration, what is to be monitored, and monitoring methods.

Whether and under what circumstances practitioners prescribing IV opioids are allowed to establish protocols for IV opioid administration and monitoring that differ from the hospital-wide policies and procedures.

The frequency of the serial assessments and duration of the monitoring timeframe for post-operative patients receiving IV opioids must be determined based on at least the following considerations:

- Patient risk for adverse events.
- Opioid dosing frequency and IV delivery method (push or patient-controlled analgesia (PCA)).
- Duration of IV opioid therapy.

Regardless of these factors, at a minimum monitoring must include:

Vital signs (blood pressure, temperature, pulse, respiratory rate).

Pain level.

Respiratory status.

Sedation level. Sedation levels are important indicators for the clinical effects

medications and review their employee records.

- Do they have documented special training?

- Review personnel files of staff that administered blood transfusions and IV medications. Is there evidence that the competency of these staff was assessed with respect to:
  - □ Maintaining fluid and electrolyte balance;
  - □ Venipuncture techniques;
  - □ With respect to blood transfusions:
    - Blood components.
    - Blood administration procedures per hospital policy, State law, and nationally recognized standards of practice.
    - Patient monitoring requirements, including frequency and documentation of monitoring.
    - Process for verification of the right blood product for the right patient.
    - Transfusion reactions: Identification, treatment, and reporting requirements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

of opioids. Sedation is a useful assessment parameter to observe the effects of opioids since sedation typically precedes respiratory depression.

NURSING ASSESSMENT
In addition to vigilant nursing assessment at appropriate intervals, hospitals may choose to use technology to support effective monitoring of patients' respiratory rate and oxygen levels.

The assessment and monitoring process must be explained to the patient and/or the patient's representative, to communicate the rationale for vigilant monitoring, including that it might be necessary to awaken the patient in order to assess effects of the medications. In addition, hospitals are encouraged to educate the patient and his/her representative and/or family members about notifying nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.

Adverse patient reactions require timely and appropriate intervention, per established protocols, and must also be reported immediately to the practitioner responsible for the care of the patient. (See the guidance for standard 16.01.07 [§482.23(c)(5)] and standard 25.01.10 [§482.25(b)(6)], concerning reporting of adverse medication-related events.)

BLOOD COMPONENTS AND BLOOD ADMINISTRATION PROCEDURES
The collection, testing, preparation, and storage of blood and blood components are regulated by the Food and Drug Administration. However, administration of blood products via transfusion is governed by 42 CFR §482.23(c)(4). Blood transfusions can be lifesaving. However, like IV medications, blood transfusions are not without risk of harm to patients.

Transfusion reactions and/or errors can be fatal.

In addition to the safe practices and other safety considerations that apply to all IV medication administration, policies and procedures must address blood administration procedures that are consistent with accepted standards of transfusion practice, including but not limited to:

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- How to identify, treat, and report any adverse reactions the patient may Confirming prior to each blood transfusion:
    a. the patient's identity.
    b. verification of the right blood product for the right patient.

The standard of practice calls for two qualified individuals, one of whom will be administering the transfusion, to perform the confirmation.

Requirements for patient monitoring, including frequency and documentation of monitoring.

Experience during or related to transfusion.

STAFF TRAINING AND COMPETENCIES
Intravenous (IV) medications and blood transfusions must be administered by qualified personnel, regardless of whether they are practitioners or non-practitioners.

Generally, IV medications and blood transfusions are administered to patients by registered nurses, consistent with State law governing scope of practice, and approved medical staff policies and procedures.

- Among other things, personnel must be able to demonstrate competency in venipuncture, in accordance with State law and hospital policy. If other types of vascular access are used, staff must have demonstrated competency in appropriate usage, care, and maintenance.
- Staff must be trained in early detection of and timely intervention for IV opioid-induced over-sedation and respiratory depression.

Education and training regarding these procedures are typically included in the nurse's hospital orientation.

- Content of the training must address each required component of the approved medical staff policies and procedures.
- Nursing staff who receive training for intravenous medication administration and/or blood transfusion administration during hospital

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

orientation or during other continuing education programs would meet the requirements of this regulation.

- Other non-physician personnel, for example, licensed practical nurses or licensed vocational nurses, with demonstrated competence may also administer IV medications and blood transfusions if they are acting in accordance with State law, including scope of practice law, and the hospital's approved medical staff policies and procedures.
- For non-practitioners, the appropriate competencies must be documented in the qualified staff person's employee record.
- All State law and scope of practice requirements must be met regarding the administration of intravenous medications and blood transfusions, as applicable.

The appropriate competencies must be documented in the qualified staff person's employee record.

Content of the training is based on nationally recognized standards for intravenous medication administration and blood transfusion and must address at least:

- Fluid and electrolyte balance.
- Venipuncture techniques, including both demonstration, and supervised practice.

For blood transfusion training:

- Blood components.
- Blood administration procedures based on hospital policy, State law, and nationally recognized standards of practice.
- Requirements for patient monitoring, including frequency and documentation of monitoring.
- The process for verification of the right blood product for the right patient.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Identification and treatment of transfusion reactions.

16.01.07 Adverse drug reactions, transfusion reactions and medical error reporting

There must be a hospital procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

§482.23(c)(5)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

ADVERSE DRUG REACTIONS AND DRUG ADMINISTRATION ERRORS

There is a similar but more detailed and prescriptive requirement concerning internal hospital reporting of adverse drug reactions, drug administration errors and incompatibilities at standard 25.01.10 under the Pharmaceutical Services CoP [42 CFR §482.25(b)(6)]. Therefore, it is not necessary for hospitals to establish a different procedure in the case of adverse drug reactions and drug administration errors for such events when nurses administer drugs or transfusions. Refer to standard 25.01.10 [42 CFR §482.25(b)(6)] for what must be reported, to whom, and in what timeframe.

Failure to make required reports concerning adverse drug reactions and errors in administration of drugs will be cited at this standard when the drug was administered by a nurse, as well as under standard 25.01.10.

TRANSFUSION REACTIONS

Transfusion reactions can occur during or after a blood transfusion. A patient's immune system recognizes the foreign blood product and attempts to destroy the transfused cells. Incompatible blood products are typically the cause of transfusion reactions. Symptoms may include back pain, bloody urine, hives, chills, fainting, dizziness, fever, flank pain, and skin flushing. More serious complications may include acute kidney failure, anemia, respiratory distress, shock and even death. Transfusion reactions are serious and can be life-threatening.

POLICIES AND PROCEDURES

The hospital must have policies and procedures in place for the internal reporting of transfusion reactions.

INTERVIEW AND DOCUMENT REVIEW

- Review the hospital policy and procedure for internal reporting of transfusion reactions.

Note: For adverse drug events and medication administration errors, follow the survey procedures for standard 25.01.10 [§482.25(b)(6)]. Deficiencies are to be cited under both standards 16.01.07 and 25.01.10 when the drug or transfusion related to an adverse drug reaction, transfusion reaction or medication administration error relates to a drug or transfusion administered by a nurse.

- Interview nursing staff responsible for administering blood transfusions to determine whether they are familiar with and comply with the hospital's policies.
- Ask to see if there are any transfusion-related incident reports.
  - ☐ Is there evidence that the transfusion reaction was reported

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The policies must include procedures for reporting transfusion reactions immediately to the practitioner responsible for the care of the patient. The transfusion reaction must also be reported to the hospital-wide quality assessment performance improvement program as an adverse event, in accordance with the QAPI CoP at 42 CFR 482.21(c)(2). The transfusion reaction must be documented in the patient's medical record, including the prompt notification of the responsible practitioner.	immediately to the practitioner responsible for the patient's care? □ Was it reported to the hospital's QAPI program?
16.01.08 For future use		
16.01.09 Self-administration of medications: Hospital-issued medications *The hospital may allow a patient (or his or her caregiver/support person where appropriate) to self-administer both hospital-issued medications and the patient's own medications brought into the hospital, as defined and specified in the hospital's policies and procedures.* *If the hospital allows a patient to self-administer specific hospital-issued medications, then the hospital must have policies and procedures in place to:* *(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration.* *(B) Assess the capacity of the patient (or the patient's caregiver/support*	☐ Compliant ☐ Not Compliant Hospitals have the option of establishing a program for self-administration by patients, or, when applicable, patient caregivers or support persons, of hospital-issued medications. The existence of this regulatory option does not mean that a hospital must offer medication self-administration programs or that a patient has a right to self-administer their medications. A hospital program for patient self-administration of hospital-issued medications could be beneficial for the appropriate patients if the proper precautions are taken in designing and implementing such a program. Generally, such a program would apply only to inpatients, but there may be circumstances under which a hospital finds it appropriate to permit self-administration of hospital-issued medications by outpatients or their caregivers/support persons. Among the potential benefits of medication self-administration, teaching patients or their caregivers/support persons adherence to the proper medication regimen could reduce hospital inpatient length of stay and also might have a positive effect on continued compliance with the regimen after discharge, potentially avoiding an emergency department visit or inpatient	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ If the hospital permits patient self-administration of hospital-issued medications: ▪ Review the hospital's policies and procedures to verify that they address: □ Limitations on medications not eligible for self-administration or patient conditions which exclude self-administration. □ Orders for self-administration of medication. □ Requirements, if any, for supervision of self-administration. □ Assessment of self-medication

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

person where appropriate) to self-administer the specified medication(s).

(C) Instruct the patient (or the patient's support person where appropriate) in the safe and accurate administration of the specified medication(s).

(D) Address the security of the medication(s) for each patient.

(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

§482.23(c)(6)
§482.23(c)(6)(i)
§482.23(c)(6)(i)(A-E)

readmission secondary to post-hospital patient medication administration errors and noncompliance.

Hospitals have the discretion to establish policies providing for different levels of patient self-administration, and may make these levels across-the-board, patient-specific, or medication-specific. For example, a hospital may choose whether a nurse must be present to supervise the self-administration, and whether this supervision requirement could vary according to the type of medication or the capacity of the individual patient (or the patient's caregiver/support person).

A hospital may also determine through its policies and procedures whether supervision requirements must be addressed in the practitioner's order or whether this may be left to the discretion of the nurse who assesses the patient.

A hospital may choose to exclude certain medications from patient self-administration, for example, because they pose too great a medication security challenge, or because the manner in which they must be administered does not lend itself to safe self-administration. It must be clear in the hospital's policies and procedures whether it has established such a policy and what kind of limitations it has established for its program of patient self-administration of hospital-issued medications.

The medical staff, nursing, and pharmacy departments are to collaborate in developing policies and procedures governing self-administration of hospital-issued medications which are approved by the governing body.

REQUIRED ELEMENTS OF A SELF-ADMINISTRATION PROGRAM
If the hospital chooses to develop programs for self-administration of hospital-issued medications by patients (and/or their caregiver/support persons), the following must be in place:

1. **An order allowing the patient to administer hospital-issued medications.**
   The order must be consistent with the hospital's policy concerning self-

capacity.

- □ Instruction in self-medication.
- □ Security of self-administered medications.
- □ Documentation of self-administration.

- Ask for a list of current inpatients for whom self-administration of hospital-issued medications is permitted.
  - □ Interview several of these patients (or their caregivers/support persons when applicable) to verify that they received instruction on how to administer their medications.
- Interview nurses caring for the selected patients to verify:
  - □ Knowledge of hospital policies and procedures regarding supervision of self-medication.
  - □ How they assess a patient's (or patient's caregiver/support person's) capacity to self-administer medication. When concerns arise, how do they communicate them to the responsible practitioner? Does the hospital permit a return to nurse administration of medications in response to temporary reduction in

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	administration of hospital-issued medications and be written by a practitioner who is responsible for the care of the patient and who is authorized to order medications, in accordance with hospital policies and procedures, State law, including scope of practice laws, and medical staff by-laws, rules, and regulations. **2. A documented assessment of the capacity of the patient (or their caregiver/support person) to successfully administer medications for which self-administration has been authorized.** Nurses are expected to exercise clinical judgment and to inform the practitioner responsible for the care of the patient about any reservations the nurse might have about an individual patient's (or caregiver/support person's) capacity to safely self-administer medications. The assessment must be documented and must highlight the findings that are affirmative – i.e., support patient-self-administration – and those that are negative – i.e., call into question patient self-administration. The nurse is also expected to document any discussions with the practitioner responsible for the care of the patient regarding the nurses' concerns about patient's (or caregiver/support person's) capacity to safely self-administer medications. Hospitals may, as a matter of policy, permit a nurse to return to nurse administration for particular doses of a medication for which there is a self-administration order, without a discussion with the responsible practitioner if, based on the nurse's assessment, the patient's capacity has been temporarily diminished and there is no caregiver/support person who is assisting the patient with self-administration of medication. For example, a patient who has just had an invasive test or procedure may not be fully alert for a period thereafter, or the parent of a minor patient, who is administering medications to the patient may for whatever reasons not be available and a scheduled medication dose is close to being overdue.	patient capacity or absence of the patient's caregiver/support person? If so, how do the nurses make this assessment? □ How they instruct a patient (or patient's caregiver/support person's) in medication self-administration. □ How self-administered medications are secured. □ How they document self-administration of medications. ▪ Review the medical records for the selected patients for documentation of: □ An order for self-administration of specific medication(s). □ A nurse assessment of the patient's (or patient's caregiver/support person's) capacity to self-administer medication. □ Documentation of nurse instruction to the patient or (or patient's caregiver/support person) in safe and appropriate techniques for self-administration of medication. □ Documentation of self-administration times and doses, as

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	3. Instruction in self-administration. As part of the assessment of the patient's self-administration capacity, nurses are expected to identify the patient's (or the patient's caregiver/support person's) education and/or training needs. These needs may be related to type of medication, unique individual medication requirements, delivery route, dosage and scheduling, equipment (e.g., syringes, pill-cutters, measuring containers, etc.) intravenous access, potential adverse side effects and what to do if they occur, infection control measures, storage, medication disposal, among others. Education and training needs, and how they were addressed, must be documented in the medical record. **4. Security of the self-administered medications.** The security of a patient's self-administered medications is extremely important but does not lend itself well to a one-size-fits-all regulatory requirement. There are Federal and State laws, including the Pharmaceutical Services CoP, which require a higher level of security for certain medications (for example, controlled substances). Hospitals are expected to comply with these already-established requirements and laws, and generally should not include such medications as part of a patient self-administration program. Patient-controlled Analgesia (PCA) pumps are a special variant of patient self-administration. Such pumps allow patients, within tightly controlled, pre-determined parameters with respect to dosage and minimum time intervals between doses, to release an intravenous dose of a controlled substance pain medication that has been pre-loaded into the PCA pump in a manner that prevents tampering by an unauthorized person. PCA pumps are considered secure despite their use of controlled substances. PCA pumps allow for the self-administration of intravenous (IV) medications to patients. See the interpretive guidelines for standard 16.01.06 [§482.23(c)(4)] concerning assessment and monitoring requirements for post-surgical patients receiving IV opioids, including via	reported by the patient or (or patient's caregiver/support person) or directly observed by a nurse.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

patient-controlled analgesia (PCA) pumps, in and out of the post-anesthesia care and intensive care units.

Hospitals are also free to exclude other medications besides controlled substances from their patient self-administered medication programs when the hospital has concerns over its capacity to address the safety and security of these other medications for patients.

A hospital may choose to have a policy where it maintains a list of medications that it excludes from self-administration entirely, due to security concerns. It may choose to have a policy that addresses the security of a particular medication on a patient-by-patient basis. Or it may establish a policy that is a combination of both approaches to medication security. (77 FR 29052, May 16, 2012)

5. **Documentation of medication administration.**
   A nurse must document the self-administration of a medication. In cases where the nurse directly supervised the self-administration, the nurse is expected to indicate that the medication administration was observed and confirmed. Where direct nurse supervision is not required, the nurse is required to document only what the patient, or the patient's caregiver/support person, reports to the nurse as to the time and amount of medication administered. Nurses are expected to assess whether the reports of the patient or patient's caregiver/support person indicate, with respect to timing and dosage, that the patient is receiving the medication as ordered.

16.01.10 <u>Self-administration of medications: Medications brought into the hospital</u>

If the hospital allows a patient to self-administer his or her own specific medications brought into the hospital,

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Hospitals have the option of establishing a program for self-administration by patients, or, when applicable, patient caregivers or support persons, of medications the patient brings himself or herself to the hospital. The

<u>OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW</u>

If the hospital permits patient self-

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

then the hospital must have policies and procedures in place to:

(A) Ensure that a practitioner responsible for the care of the patient has issued an order, consistent with hospital policy, permitting self-administration of medications the patient brought into the hospital.

(B) Assess the capacity of the patient (or the patient's caregiver/support person where appropriate) to self-administer the specified medication(s) and also determine if the patient (or the patient's caregiver/supplier person where appropriate) needs instruction in the safe and accurate administration of the specified medication(s).

(C) Identify the specified medication(s) and visually evaluate the medication(s) for integrity.

(D) Address the security of the medication(s) for each patient.

(E) Document the administration of each medication, as reported by the patient (or the patient's caregiver/support person where appropriate), in the patient's medical record.

§482.23(c)(6)(ii)
§482.23(c)(6)(ii)(A-E)

existence of this regulatory option does not mean that a hospital must offer medication self-administration programs or that a patient has a right to retain and self-administer medications they bring with them from home.

A hospital program for patient self-administration of medications the patient brings from home could be beneficial for the appropriate patients if the proper precautions are taken in designing and implementing such a program. Generally, such a program would apply only to inpatients, but there may be circumstances under which a hospital finds it appropriate to permit self-administration of medications that outpatients or their caregivers/support persons bring with them.

Among the potential benefits of permitting self-administration of medications the patient brings from home is that problems are avoided related to the hospital's formulary not including a particular medication that a patient needs to continue to take during his/her hospital stay, and the patient prefers to avoid medication substitution. The hospital also gains an opportunity to identify suboptimal patient medication administration techniques for these drugs and to provide instruction designed to ensure that the patient is administering his/her medications properly.

Hospitals have the discretion to establish policies providing for different levels of patient self-administration, and may make these levels across-the-board, patient-specific, or medication-specific.

For example, a hospital may choose whether or not a nurse must be present to supervise the self-administration, and whether this supervision requirement could vary according to the type of medication or the capacity of the individual patient (or the patient's caregiver/support person).

A hospital may also determine through its policies and procedures whether supervision requirements must be addressed in the practitioner's order or whether this may be left to the discretion of the nurse who assesses the patient.

A hospital may choose to exclude certain medications from patient self-administration of medications brought from home:

- Review the hospital's policies and procedures to verify that they address:
  - ☐ Limitations on medications not eligible for self-administration or patient conditions which exclude self-administration.
  - ☐ Orders for self-administration of medication.
  - ☐ Requirements, if any, for supervision of self-administration.
  - ☐ Assessment of self-medication capacity.
  - ☐ Instruction in self-medication.
  - ☐ Security of self-administered medications.
  - ☐ Documentation of self-administration.
- Ask for list of current inpatients for whom self-administration of medications brought from home is permitted.
  - ☐ Interview of several of these patients (or their caregivers/support persons when applicable) to ask if that they received instruction on how to self-administer their medications

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

administration, for example, because they pose too great a medication security challenge. It must be clear in the hospital's policies and procedures whether it has established such a policy and what kind of limitations it has established for its program of patient self-administration of medications the patient brings from home.

It is expected that the medical staff, nursing, and pharmacy departments are to collaborate in developing policies and procedures for self-administration of medications the patient brings from home which are approved by the governing body.

REQUIRED ELEMENTS OF A SELF-ADMINISTRATION PROGRAM

If the hospital chooses to develop programs for self-administration of medications brought from home by patients (and/or their caregiver/support persons), the following must be in place:

1. **An order allowing the patient to administer medications brought from home.**

   The order must be consistent with the hospital's policy concerning self-administration of medications brought from home and be written by a practitioner who is responsible for the care of the patient and who is authorized to order medications, in accordance with hospital policies and procedures, State law, including scope of practice laws, and medical staff by-laws, rules, and regulations.

2. **A documented assessment.**

   A documented assessment of the capacity of the patient (or their caregiver/support person) to successfully administer the medication(s) specified in the order, including a determination whether the patient (or their caregiver/support person) needs instruction in the safe and accurate administration of the specified medication(s).

   Nurses are expected to exercise their clinical judgment and to inform the practitioner responsible for the care of the patient about any reservations the nurse might have about an individual patient's (or caregiver/support

consistent with hospital policy.

- Interview nurses caring for the selected patients to verify:
  - □ Knowledge of hospital policies and procedures regarding supervision of self-medication.
  - □ How they assess a patient's (or patient's caregiver/support person's) capacity to self-administer medication. When concerns arise, how do they communicate them to the responsible practitioner? Does the hospital permit a return to nurse administration of medications in response to temporary reduction in patient capacity or absence of the patient's caregiver/support person? If so, how do the nurses make this assessment?
  - □ How they instruct a patient (or patient's caregiver/support person's) in medication self-administration when educational needs have been identified.
  - □ How self-administered medications are secured.
  - □ How they document self-administration of medications.
- Review the medical records for the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

person's) capacity to safely self-administer medications.

The assessment must be documented and must highlight the findings that are affirmative – i.e., support patient-self-administration – and negative – i.e., call into question patient self-administration.

The nurse is also expected to document any discussions with the practitioner responsible for the care of the patient regarding the nurses' concerns about patient's (or caregiver/support person's) capacity to safely self-administer medications. (77 FR 29052, May 16, 2012)

Hospitals may, as a matter of policy, permit a nurse to return to nurse administration for particular doses of a medication for which there is a self-administration order, without a discussion with the responsible practitioner if, based on the nurse's assessment, the patient's capacity has been temporarily diminished and there is no caregiver/support person who is assisting the patient with self-administration of medication.

- □ For example, a patient who has just had an invasive test or procedure may not be fully alert for a period thereafter, or the parent of a minor patient, who is administering medications to the patient may for whatever reasons not be available and a scheduled medication dose is close to being overdue.

As part of the assessment of the patient's self-administration capacity, nurses are expected to identify whether the patient (or the patient's caregiver/support person) needs instruction in the safe and accurate administration of the specified medication(s). See standard 16.01.09 for additional information.

Even though the patient has been taking the medication at home, the patient (or the patient's caregiver/support person) may not be using optimal administration techniques. Patient needs may be related to type of medication, unique individual medication requirements, delivery route, dosage and scheduling, equipment (e.g., syringes, pill-cutters,

selected patients for documentation of:

- □ An order for self-administration of specific medication(s).
- □ A nurse assessment of the patient's (or patient's caregiver/support person's) capacity to self-administer medication and whether there are educational needs that have been met.
- □ Documentation of the identification and visual assessment of medications brought from home.
- □ Documentation of self-administration times and doses, as reported by the patient or (or patient's caregiver/support person) or directly observed by a nurse.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

measuring containers, etc.) intravenous access, potential adverse side effects and what to do if they occur, infection control measures, storage, medication disposal, among others. Education and training needs identified, and how they were addressed, must be documented in the medical record.

3. **Identification/visual evaluation for integrity.**
   Hospitals must have policies and procedures addressing how they will identify the medications the patient has brought from home. Identification is important because the label on the patient's container may not accurately reflect the contents. Further, the medication might have expired or have not been stored correctly in the patient's home, requiring hospitals to at least conduct a visual inspection to see if the medication appears to have retained its integrity. A visual inspection for integrity may not be definitive, but the regulation does not require use of more complex methods.

4. **Security of the self-administered medications.**
   The security of a patient's self-administered medications is extremely important but does not lend itself well to a one-size-fits-all regulatory requirement. There are Federal and State laws, including the Pharmaceutical Services CoP, which require a higher level of security for certain medications (for example, controlled substances). Hospitals are expected to comply with these already-established requirements and laws, and generally should not include such medications as part of a patient self-administration program.
   Hospitals are also free to exclude other medications besides controlled substances from their patient self-administered medication programs when the hospital has concerns over its capacity to address the safety and security of these other medications for patients.

   A hospital may choose to have a policy where it maintains a list of medications brought from home that it excludes from self-administration entirely, due to security concerns. It may choose to have a policy that

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	addresses the security of a particular medication on a patient-by-patient basis. Or it may establish a policy that is a combination of both of these approaches to medication security. 5. **Documentation of medication administration.** Under the regulation, a nurse must document the self-administration of a medication. In cases where the nurse directly supervised the self-administration, the nurse is expected to indicate that the medication administration was observed and confirmed. On the other hand, where direct nurse supervision is not required, the nurse is required to document only what the patient, or the patient's caregiver/support person, reports to the nurse as to the time and amount of medication administered. Nurses are expected to assess whether the reports of the patient or patient's caregiver/support person indicate, with respect to timing and dosage, that the patient is receiving the medication as ordered. See standard 16.01.10 for additional information.	
16.02.00 For future use		
16.02.01 For future use		
16.02.02 Patients at risk	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Patients at-risk for developing the following complications are identified on admission or during the hospital stay: 1. Pressure ulcers 2. Deep vein thrombosis (DVT/ venous thromboembolism (VTE) 3. Aspiration	The medical complications of pressure ulcers, DVT/VTE, aspiration, malnutrition and falls can be prevented with proactive risk assessment, thereby improving outcomes and the quality of care for at-risk patients. Implement a facility wide "falls program" using evidence-based interventions to prevent and reduce patient fall-related injuries. The "fall program" must be reviewed at least annually for efficiency and effectiveness.	**DOCUMENT REVIEW** ▪ Review the admission assessment policy. □ The admission assessment policy addresses the five required risk assessments and defines when reassessment would be required.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
4. Malnutrition 5. Fall Risk/Prevention	Suggested added information: ▪ Risk assessments must be documented in the medical record. ▪ Those patients who have been identified to be at risk must have related care plans and preventative measures put in place.	The policy must also include a plan, process, or intervention to be implemented to prevent complications in at-risk patients. ▪ Examine ten medical records to verify: □ The medical record contains risk assessments for each of the five required elements completed on admission and periodically as indicated by patient status change throughout the admission.
16.02.03 Availability of policies Nursing staff have access to clinical and administrative policies and procedures.	☐ Compliant ☐ Not Compliant Staff know how to access policies and procedures. Policies, procedures, and Standards of Practice are consistent with local, State and Federal laws and regulations governing nursing practice. Standards of Practice reflect evidenced-based practices, when applicable. References to national practice groups such as the Association of Operating Room Nurses (AORN) are cited.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview staff to verify that they are knowledgeable regarding the availability of clinical and administrative policies and procedures. ▪ Review policies and procedures and Standards of Practice. □ Are references to national practice groups cited, as applicable?

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RESPIRATORY CARE

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
17.00.00 CONDITION OF PARTICIPATION: Respiratory services *The hospital must meet the needs of the patients in accordance with acceptable standards of practice.* *The following requirements apply if the hospital provides respiratory care services.* *§482.57*	☐ Compliant ☐ Not Compliant This is an optional hospital service. If a hospital provides care to patients who require respiratory care services, the hospital must meet the needs of those patients, in accordance with acceptable standards of practice. However, if a hospital provides any degree of respiratory care to its patients, the hospital must comply with the requirements of this Condition of Participation. Acceptable standards of practice include compliance with applicable standards that are set forth in federal or state laws, regulations, or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations. (e.g., American Medical Association, American Association for Respiratory Care, American Thoracic Association, etc.). The hospital's respiratory services must be integrated into its hospital-wide QAPI program.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** If the hospital provides any degree of respiratory care services, verify that: ▪ The type and amount of respiratory care provided meets the needs of the patients and is delivered in accordance with accepted standards of practice. ▪ The hospital's respiratory services are integrated into its hospital-wide QAPI program.
17.00.01 Organization and staffing *The organization of the respiratory care services must be appropriate to the scope and complexity of the services offered.* *§482.57(a)*	☐ Compliant ☐ Not Compliant The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the services offered by the hospital in accordance with acceptable standards of practice. The scope of diagnostic and/or therapeutic respiratory services offered by the hospital should be defined in writing and approved by the medical staff.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the hospital's organizational chart to determine the relationship of respiratory care services to other services provided by the hospital. ▪ Review the hospital policies and procedures to verify that the scope of

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		the diagnostic and/or therapeutic respiratory care services provided is defined in writing and approved by the medical staff.
17.00.02 Medical director *There must be a director of respiratory care services who is a doctor of medicine or osteopathic medicine with the knowledge, experience and capabilities to supervise and administer the service properly.* *The director may serve on either a full time or part time basis.* *§482.57(a)(1)*	☐ Compliant ☐ Not Compliant The service director must be an MD or DO and must demonstrate through education, experience and specialized training that he/she has the qualifications necessary to supervise and administer the service properly, appropriate to the scope and complexity of services offered. The physician providing medical direction (full time, part time) is knowledgeable of pulmonary (and cardiology) practices and techniques to lead and advise the cardiopulmonary staff. If the director serves on a part-time basis, the time spent directing the department should be appropriate to the scope and complexity of services provided.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview leaders and staff regarding the role and oversight activities conducted by the director to verify that: □ A medical director has been appointed and he/she has fixed lines of authority and delegated responsibility for operation of the service. □ The time spent by the Medical Director directing the department is appropriate to the scope and complexity of services provided. ▪ Review the service director's credentialing file to determine that he/she is an MD/DO and has the necessary education, experience and specialized training to supervise and administer the service properly.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
17.00.03 Staffing and qualifications *There must be adequate numbers of respiratory therapists, respiratory therapy technicians, and other personnel who meet the qualifications specified by the medical staff, consistent with State law.* *§482.57(a)(2)*	☐ Compliant ☐ Not Compliant There must be sufficient personnel available to respond to the respiratory care needs of the patient population being served.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview respiratory care staff regarding services provided, schedules, and availability of respiratory care staff throughout the day and week to determine that the number and type of staff available is appropriate to the volume and types of treatments furnished. If needed, review staffing and on-call schedules. ▪ Review a sample of personnel files for respiratory care staff to determine that the personnel meet the qualifications specified by the medical staff, consistent with state law. ▪ Review personnel files to validate current licensure, training and experience as required.
17.00.04 Policies and procedures *Services must be delivered in accordance with medical staff directives.* *§482.57(b)*	☐ Compliant ☐ Not Compliant There should be written policies for the delivery of respiratory care services that are developed and approved by the medical staff. The hospital must be in compliance with the written directives/policies. Appropriate to the scope of services provided, the written policies should address at least:	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review policies and procedures to assure that all required policies are current and approved by the medical staff.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	1. Equipment assembly, operation, and preventive maintenance. 2. Safety practices, including infection control measures for equipment, sterile supplies, biohazardous waste, posting of signs, and gas line identification. 3. Handling, storage, and dispensing of therapeutic gases to both inpatients and outpatients. 4. Cardiopulmonary resuscitation. 5. Procedures to follow in the advent of adverse reactions to treatments or interventions. 6. Pulmonary function testing. 7. Therapeutic percussion and vibration. 8. Bronchopulmonary drainage. 9. Mechanical ventilatory and oxygenation support. 10. Aerosol, humidification, and therapeutic gas administration. 11. Storage, access, control, administration of medications and medication errors. 12. Procedures for obtaining and analyzing blood samples (e.g., arterial blood gases). 13. Procedure for reporting medication errors and adverse drug events. 14. Patient care documentation requirements.	▪ Observe practice to assure practice is reflective of policy requirements. ▪ Review medical records to assure appropriate documentation in the medical record, in accordance with hospital policies.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
17.00.05 Qualified staff *Personnel qualified to perform specific procedures and the amount of supervision required for personnel to carry out specific procedures shall be designated in writing.* *§482.57(b)(1)*	☐ Compliant ☐ Not Compliant The hospital must have written policies to address, at a minimum: ▪ Each type of respiratory care service provided by the hospital. ▪ The qualifications, including job title, licensure consistent with State law, education, training and experience of personnel authorized to perform each type of respiratory care service and whether they may perform it without supervision. ▪ The type of personnel qualified to provide the direct supervision.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review treatment logs, job descriptions of respiratory care staff, and policies and procedures to verify: □ Duties and responsibilities of staff. □ Qualifications and education required, including licensure, consistent with State law. □ Specialized training or experience needed to perform specific duties. □ All required policies are current and approved by the medical staff.
17.00.06 Clinical laboratory testing *If blood gases or other clinical laboratory tests are performed in the respiratory care unit, the unit must meet the applicable requirements for laboratory services specified in* 42 CFR §*482.27.* §482.57(b)(2)	☐ Compliant ☐ Not Compliant ☐ Not Applicable Refer to standards in Chapter 22, Laboratory Services. The hospital must have written policies to address: ▪ Qualifications of personnel responsible for performing proficiency tests. ▪ Training requirements for performing proficiency tests. ▪ Proficiency testing procedures. ▪ Role of the medical director of respiratory care services. ▪ Reporting proficiency test results to the hospital QAPI Program and others, as necessary.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Each location where laboratory testing is conducted must have or be operating under a current CLIA certificate. ▪ Review policies and procedures to assure that all required policies are current and approved by the medical staff.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
17.00.07 Services provided *Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.* §482.57(b)(3)	☐ Compliant ☐ Not Compliant Respiratory care services must be ordered by a qualified and licensed practitioner who is responsible for the care of the patient. The practitioner must have medical staff privileges: ▪ to write orders for these services or ▪ for outpatient services, if hospital policy permits acceptance of orders from outside practitioners, the practitioner's order must meet the requirements at 42 CFR 482.54(c) (see standard 31.00.11). For practitioners who have medical staff privileges, such privileges must be granted in a manner consistent with the state's scope of practice law, as well as with hospital policies and procedures governing respiratory care services developed by the medical staff. Practitioners who may be granted privileges to order respiratory care services include physicians, and may also, in accordance with hospital policy, include: ▪ Nurse Practitioners. ▪ Physicians' Assistants. ▪ Clinical Nurse Specialists. ▪ Certified Registered Nurse Anesthetists. ▪ Certified Nurse Midwives (as long as they meet the parameters of this requirement). Although the following licensed professionals are also considered practitioners, in accordance with Section 1842(b)(18)(C) of the Social Security Act, they generally would not be considered responsible for the care of the patient with regard to respiratory care services or qualified to order respiratory care services:	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review medical records of patients receiving respiratory care services to determine: □ Who wrote the orders for the respiratory care services. □ If the practitioner is responsible for the care of the patient and privileged to write orders for respiratory care services. Verify the practitioner meets hospital medical staff policy criteria to order services as well as State law for ordering respiratory care services. ▪ Does the hospital permit acceptance of orders from outside practitioners who do not practice at the hospital? If so, evaluate for compliance with 42 CFR 482.54(c) (see standard 31.00.11).

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Clinical social worker (Section 1861(hh)(1) of the Act and as defined in 42 CFR §410.71). ▪ Clinical psychologist (for purposes of Section 1861(ii) of the Act). ▪ Registered dietitian or nutrition professional.	
17.00.08 Respiratory care services orders	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
All respiratory care services orders must be documented in the patient's medical record in accordance with the requirements at 42 CFR *§482.24.* §482.57(b)(4)	The patient's medical record must contain documentation of all respiratory care services ordered.	**DOCUMENT REVIEW** ▪ Review a sample of patient medical records who received respiratory care services. □ Verify respiratory care services orders are legible, complete, dated, timed, authenticated, and meet all other medical record requirements as specified at 42 CFR §484.24.
17.00.09 Therapeutic medical gases	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Policies and procedures describe all aspects of the use of therapeutic medical gases.	There are descriptions of medical gas storage, handling, dispersing, use, and the logging of routine periodic oxygen purity checks. Compliance with policies must be demonstrated.	**OBSERVATION AND DOCUMENT REVIEW** **Note**: The piped-in medical gases are considered a utility system (see Physical Environment). ▪ Review documentation of the results of the purity tests from the original acceptance report, and whenever the medical gas system is breached.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ Policies address storage, handling, dispensing, use, and documentation requirements for therapeutic medical gases. ▪ Verify compliance with storage, handling, dispersing, use, and documentation requirements for therapeutic medical gases.
17.00.10 Adverse drug reactions and medication errors The various types of potential adverse drug reactions are described in writing along with processes to follow when such may occur. Adverse drug reactions and medication errors will be reported with departmental QAPI data to the Quality Committee and to the Pharmacy and Therapeutics Committee and is analyzed for patterns, trends and opportunities for improvement.	☐ Compliant ☐ Not Compliant The policy is congruent with the pharmaceutical service definition for, and response to, adverse responses to medication administration.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ The service adverse drug reaction policy must support/enhance that from pharmacy. ▪ Review the minutes of the Pharmacy and Therapeutics Committee (function) and the QAPI Committee (function). Determine that the minutes acknowledge reported reactions/ errors. ▪ Interview staff to verify the process for reporting drug reactions and medication errors.
17.00.11 For future use		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
17.00.12 Equipment availability	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Resuscitative, ventilatory, and oxygenation devices are available for all sizes of patients that could be served by the organization.	Sufficient inventory exists to meet the predictable needs of the patient population. Arrangements exist to supplement this inventory to accommodate unusual census changes.	**OBSERVATION AND INTERVIEW** ▪ Observe for variety of needed supplies and equipment. ▪ Interview staff to determine that suitable arrangements exist to augment equipment needs.
17.00.13 Assessment	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Respiratory care patients receive a prompt assessment of their functional ability. Policies describe the timelines and characteristics of a respiratory assessment.	Other than in an emergency, an assessment is ordinarily completed: ▪ Within four hours of receipt of the inpatient order. ▪ Upon the initial visit for outpatients. In no case does the non-urgent inpatient assessment occur any later than 24 hours after receipt of the order. An initial assessment shall be conducted prior to any treatment administration.	**DOCUMENT REVIEW** ▪ Review ten patient records, including two outpatients. Verify that the records describe the timeliness and characteristics of an assessment.

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18

ANESTHESIA SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.00.00 CONDITION OF PARTICIPATION: Medical leadership for anesthesia services *If the hospital furnishes anesthesia services, they must be provided in a well-organized manner under the direction of a qualified Doctor of Medicine or Doctor of Osteopathic Medicine.* *The service is responsible for all anesthesia administered in the hospital*. §482.52	☐ Compliant ☐ Not Compliant A qualified physician is identified as the Medical Director of anesthesia services. A single anesthesia director must be responsible for the single hospital-wide anesthesia service. The provision of anesthesia services is an optional hospital service. However, if a hospital provides any degree of anesthesia service to its patients, the hospital must comply with all the requirements of this Condition of Participation (CoP). If a facility offers surgical or obstetric services, there shall be the provision for anesthesia services. "Anesthesia" involves the administration of a medication to produce a blunting or loss of: ▪ pain perception (analgesia) ▪ voluntary and involuntary movements. ▪ autonomic function and ▪ memory and/or consciousness, depending on where along the central neuraxial (brain and spinal cord) the medication is delivered. In contrast, "analgesia" involves the use of a medication to provide relief of pain through the blocking of pain receptors in the peripheral and/or central nervous system. The patient does not lose consciousness but does not perceive pain to the extent that may otherwise prevail. Anesthesia exists along a continuum. For some medications there is no bright line that distinguishes when their pharmacological properties bring about the physiologic transition from the analgesic to the anesthetic effects.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Request a copy of the organizational chart for anesthesia services. Review the position description to verify that an MD or DO has the authority and responsibility for directing all anesthesia services throughout the hospital. ▪ Look for evidence in the director's file of the director's appointment privileges and qualifications, consistent with the criteria adopted by the hospital's governing body. ▪ Confirm that the director's responsibilities include at least the following: □ Planning, directing, and supervising all activities of the service in all areas of the hospital. □ Establishing staffing schedules for coverage when the service is normally closed. □ Evaluating the quality and appropriateness of anesthesia services provided to patients as part of the hospital's QAPI program. ▪ The director of anesthesia is

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Furthermore, each individual patient may respond differently to different types of medications. The additional definitions below illustrate distinctions among the various types of "anesthesia services" that may be offered by a hospital. These definitions are generally based on American Society of Anesthesiologists definitions found in its most recent set of practice guidelines (Anesthesiology 2002; 96:1004-17).

- **General Anesthesia**: a drug-induced loss of consciousness during which patients are not arousable, even by painful stimulation. The ability to independently maintain ventilatory support is often impaired. Patients often require assistance in maintaining a patent airway, and positive pressure ventilation may be required because of depressed spontaneous ventilation or drug-induced depression of neuromuscular function. Cardiovascular function may be impaired. For example, a patient undergoing major abdominal surgery involving the removal of a portion or all of an organ would require general anesthesia in order to tolerate such an extensive surgical procedure. General anesthesia is used for those procedures when loss of consciousness is required for the safe and effective delivery of surgical services.
- **Regional Anesthesia**: the delivery of anesthetic medication at a specific level of the spinal cord and/or to peripheral nerves, including epidurals and spinals and other central neuraxial nerve blocks, is used when loss of consciousness is not desired but sufficient analgesia and loss of voluntary and involuntary movement is required. Given the potential for the conversion and extension of regional to general anesthesia in certain procedures, it is necessary that the administration of regional and general anesthesia be delivered or supervised by a practitioner as specified in 42 CFR §482.52(a).
- **Monitored Anesthesia Care (MAC)**: anesthesia care that includes the monitoring of the patient by a practitioner who is qualified to administer anesthesia as defined by the regulations at §482.52(a). Indications for MAC depend on the nature of the procedure, the patient's clinical

responsible for anesthesia services delivered in all areas of the hospital where applicable including operating room suites, both inpatient and outpatient, obstetrical suites, the radiology department, clinics, and outpatient surgery areas.

- Anesthesia services are integrated into the hospital-wide QAPI program.
- Request a copy of and review the hospital's anesthesia services policies and procedures.
  - □ Do they apply in all hospital locations where anesthesia services are provided?
  - □ Do they indicate the necessary qualifications that each clinical practitioner must possess in order to administer anesthesia as well as moderate sedation or other forms of analgesia?
  - □ Do they address what clinical applications are considered to involve analgesia, in particular moderate sedation, rather than anesthesia, based on identifiable national guidelines? What are the national guidelines that they are following and how is that documented?
- Does the hospital have a system by

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	condition, and/or the potential need to convert to a general or regional anesthetic. Deep sedation/analgesia is included in MAC. ▪ **Deep Sedation/Analgesia:** a drug-induced depression of consciousness during which patients cannot be easily aroused but respond purposefully following repeated or painful stimulation. The ability to independently maintain ventilatory function may be impaired. Patients may require assistance in maintaining a patent airway, and spontaneous ventilation may be inadequate. Cardiovascular function is usually maintained. Because of the potential for the inadvertent progression to general anesthesia in certain procedures, it is necessary that the administration of deep sedation/analgesia be delivered or supervised by a practitioner as specified in 42 CFR §482.52(a). ▪ **Moderate Sedation/Analgesia: (Conscious Sedation):** a drug-induced depression of consciousness during which patients respond purposefully to verbal commands, either alone or accompanied by light tactile stimulation. No interventions are required to maintain a patent airway, and spontaneous ventilation is adequate. Cardiovascular function is usually maintained. CMS, consistent with ASA guidelines, does not define moderate or conscious sedation as anesthesia (71 FR 68690-1). ▪ **Minimal Sedation**: a drug-induced state during which patients respond normally to verbal commands. Although cognitive function and coordination may be impaired, ventilator and cardiovascular functions are unaffected. This is also not anesthesia. ▪ **Topical or Local Anesthesia**: the application or injection of a drug or combination of drugs to stop or prevent a painful sensation to a circumscribed area of the body where a painful procedure is to be performed. There are generally no systemic effects of these medications, which also are not anesthesia, despite the name. ▪ **Rescue Capacity**: As stated above, because the level of sedation of a patient receiving anesthesia services is a continuum, it is not always possible to predict how an individual patient will respond. Further, no	which adverse events related to the administration of anesthesia and analgesia, including moderate sedation, are tracked and acted upon?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

clear boundary exists between some of these services. Hence, hospitals must ensure that procedures are in place to rescue patients whose level of sedation becomes deeper than initially intended, for example, patients who inadvertently enter a state of Deep Sedation/Analgesia when Moderate Sedation was intended.

- "**Rescue**" from a deeper level of sedation than intended requires an intervention by a practitioner with expertise in airway management and advanced life support. The qualified practitioner corrects adverse physiologic consequences of the deeper-than-intended level of sedation and returns the patient to the originally intended level of sedation. (Rescue capacity is not only required as an essential component of anesthesia services but is also consistent with the requirements under the Patients' Rights standard at §482.13(c)(2), guaranteeing patients care in a safe setting.)

Anesthesia services throughout the hospital (including all departments in all campuses and off-site locations where anesthesia services are provided) must be organized into one anesthesia service.

Areas where anesthesia services are furnished may include (but are not limited to):

- Operating room suite(s), both inpatient and outpatient.
- Obstetrical suite(s).
- Radiology department.
- Clinics.
- Emergency department.
- Psychiatry department.
- Outpatient surgery areas.
- Special procedures areas (e.g., endoscopy suite, pain management clinic, etc.).

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The anesthesia services must be under the direction of one individual who is a qualified MD or DO.

Consistent with the requirement at §482.12(a)(4) for it to approve medical staff bylaws, rules and regulations, the hospital's governing body approves, after considering the medical staff's recommendations, medical staff rules and regulations establishing criteria for the qualifications for the director of the anesthesia services. Such criteria must be consistent with State laws and acceptable standards of practice.

As previously mentioned, there is often no bright line, i.e., no clear boundary, between anesthesia and analgesia. This is particularly the case with moderate versus deep sedation, but also with respect to labor epidurals. However, the anesthesia services CoP establishes certain requirements that apply only when anesthesia is administered. Consequently, each hospital that provides anesthesia services must establish policies and procedures, based on nationally recognized guidelines that address whether specific clinical situations involve anesthesia versus analgesia. (It is important to note that anesthesia services are usually an integral part of "surgery", as we have defined that term in our guidance. Because the surgical services CoP at 42 CFR §482.51 requires provision of surgical services in accordance with acceptable standards of practice, this provides additional support for the expectation that anesthesia services policies and procedures concerning anesthesia are based on nationally recognized guidelines.)

We encourage hospitals to address whether the sedation typically provided in the emergency department or procedure rooms involves anesthesia or analgesia. In establishing such policies, the hospital is expected to take into account the characteristics of the patients served, the skill set of the clinical staff in providing the services, as well as the characteristics of the sedation medications used in the various clinical settings.

The regulation at 42 CFR 482.52(a) establishes the qualifications and, where applicable, supervision requirements for personnel who administer

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anesthesia. However, hospital anesthesia services policies and procedures are expected to also address the minimum qualifications and supervision requirements for each category of practitioner who is permitted to provide analgesia services, particularly moderate sedation. This expectation is consistent not only with the requirement under this CoP to provide anesthesia services in a well-organized manner, but also with various provisions of the Medical Staff CoP at §42 CFR 482.22 and the Nursing Services CoP at 42 CFR §482.23 related to qualifications of personnel providing care to patients. Taken together, these regulations require the hospital to assure that any staff administering drugs for analgesia must be appropriately qualified, and that the drugs are administered in accordance with accepted standards of practice. Specifically:

- The Medical Staff CoP at §42 CFR 482.22(c)(6) requires the medical staff bylaws, "Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges."
- The Nursing Services CoP requires at:
  - 42 CFR §482.23(b)(5) that nursing personnel be assigned to provide care based on "the specialized qualifications and competence of the nursing staff available."
  - 42 CFR §482.23(c) that, "Drugs and biologicals must be prepared and administered in accordance with Federal and State laws, …and accepted standards of practice."

AND

- 42 CFR §482.23(c)(3), "… If … intravenous medications are administered by personnel other than doctors of medicine or osteopathic medicine, the personnel must have special training for this duty."

The anesthesia services policies and procedures undergo periodic re-evaluation that includes analysis of adverse events, medication errors and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

other quality or safety indicators related not only to anesthesia, but also to the administration of medications in clinical applications that the hospital has determined involve analgesia rather than anesthesia. This expectation is also supported by the provisions of the QAPI CoP at 42 CFR §482.21, which requires the hospital to ensure its QAPI program, "…involves all hospital departments and services…"; "…focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors..."; "…track[s] quality indicators, including adverse patient events…"; "… use[s] the data collected to monitor the effectiveness and safety of the services and quality of care…"; and "…take[s] actions aimed at performance improvement…"

Hospitals are free to develop their own specific organizational arrangements in order to deliver all anesthesia services in a well-organized manner.

Although not required under the regulation to do so, a well-organized anesthesia service would develop the hospital's anesthesia policies and procedures in collaboration with several other hospital disciplines (e.g., surgery, pharmacy, nursing, safety experts, material management, etc.) that are involved in delivering these services to patients in the various areas in the hospital.

A well-organized anesthesia service must be integrated into the hospital's required QAPI program, in order to assure the provision of safe care to patients.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.00.01 Scope of service: Anesthesia *The organization of anesthesia services must be appropriate to the scope of the services offered.* *§482.52(a)*	☐ Compliant ☐ Not Compliant A written scope of services describes the anesthesia services provided throughout the organization at all locations, including outpatient services.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review the anesthesia service policy manual, the organizational chart, and the service description to verify: □ All locations in which anesthesia is administered are included. □ All techniques used to administer anesthesia are addressed.
18.00.02 Anesthesia providers *Anesthesia must be administered only by:* 1. A qualified anesthesiologist; 2. A Doctor of Medicine or Doctor of Osteopathic Medicine (other than an anesthesiologist); 3. A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law; 4. A certified registered nurse anesthetist (CRNA), as defined by42 CFR §410.69(b), who, unless exempted in accordance with paragraph (c) of 42 CFR 482.52, is under the supervision of the operating practitioner or of an	☐ Compliant ☐ Not Compliant **ADMINISTERING TOPICAL/LOCAL ANESTHETICS, MINIMAL SEDATION, MODERATE SEDATION** The requirements at 42 CFR §482.52(a) concerning who may administer anesthesia do not apply to the administration of topical or local anesthetics, minimal sedation, or moderate sedation. However, the hospital must have policies and procedures, consistent with State scope of practice law, governing the provision of these types of anesthesia services. Hospitals must assure that all anesthesia services are provided in a safe, well-organized manner by qualified personnel. **ADMINISTERING GENERAL ANESTHESIA, REGIONAL ANESTHESIA AND MONITORED ANESTHESIA, INCLUDING DEEP SEDATION/ANALGESIA** This level of anesthesia may only be administered by: ▪ A qualified anesthesiologist. ▪ A Doctor of Medicine or Doctor of Osteopathic Medicine (other than an	This standard is not met as evidenced by: **DOCUMENT REVIEW** □ Examine the medical staff bylaws/ policies. □ Review the qualifications of individuals authorized to administer general anesthesia, regional anesthesia and monitored anesthesia, including deep sedation/analgesia to determine if they satisfy the requirements at 482.52(a) and (c). □ Review at least three anesthesia provider files. □ Verify that there is

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anesthesiologist who is immediately available if needed; or

5. An anesthesiologist's assistant, as defined in Sec. 410.69 (b) of 42 CFR 410.69, who is under the supervision of an anesthesiologist who is immediately available if needed.

§482.52(a); §482.52(a)(1); §482.52(a)(2); §482.52(a)(3); §482.52(a)(4); §482.52(a)(5)

***State exemption**:*

1. A hospital may be exempted from the requirement for Doctor of Medicine/Doctor of Osteopathic Medicine supervision of CRNAs as described in paragraph (a)(4) of 42 CFR 482.52, if the State in which the hospital is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from MD/DO supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current

anesthesiologist).

- A dentist, oral surgeon or podiatrist who is qualified to administer anesthesia under State law.
- A CRNA who is supervised by the operating practitioner or by an anesthesiologist who is immediately available if needed.
- An anesthesiologist's assistant under the supervision of an anesthesiologist who is immediately available if needed.

Administration by an MD/DO/Dentist/Oral Surgeon/Podiatrist
The hospital's anesthesia services policies must address the circumstances under which a Doctor of Medicine or Doctor of Osteopathic Medicine who is not an anesthesiologist, a dentist, oral surgeon or podiatrist is permitted to administer anesthesia. In the case of a dentist, oral surgeon or podiatrist, administration of anesthesia must be permissible under State law and comply with all State requirements concerning qualifications.

Hospitals should conform to generally accepted standards of anesthesia care when establishing policies governing anesthesia administration by these types of practitioners as well as Doctors of Medicine or Doctors of Osteopathic Medicine who are not anesthesiologists.

Administration by a CRNA
Unless the hospital is located in a State that has chosen to opt out of the CRNA supervision requirements, a CRNA administering general, regional and monitored anesthesia must be supervised either by the operating practitioner who is performing the procedure, or by an anesthesiologist who is immediately available.

Hospitals should conform to generally accepted standards of anesthesia care when establishing policies for supervision by the operating practitioner.

An anesthesiologist is considered "immediately available" when needed by a CRNA under the anesthesiologist's supervision only if he/she is physically located within the same area as the CRNA, e.g., in the same operative /

documentation of current licensure and, as applicable, current certification for all persons administering anesthesia.

- □ Each has received privileges to administer anesthesia.
- □ Determine whether the state is an "opt-out state" and therefore permits CRNA's to administer anesthesia without supervision in accordance with 482.52(c).
- □ Review the hospital's policies and procedures governing supervision of CRNAs and anesthesiologist's assistants and determine whether they comply with the regulatory requirements.
- □ Review the qualifications of individuals authorized to furnish other anesthesia services, to determine if they are consistent with the hospital's anesthesia service policies.
- □ For hospitals in states with CRNA Exemption: Review the letter of exemption from the state governor. It is the facility's responsibility to obtain information that the hospital is exempt from the requirement for physician supervision of CRNAs

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
MD/DO supervision requirement, and that the opt-out is consistent with State law. 2. The request for exemption and recognition of State laws, and the withdrawal of the request may be submitted at any time and are effective upon submission. §482.52(c)(1) §482.52(c)(2)	procedural suite, or in the same labor and delivery unit, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed. If the hospital is located in a State where the Governor has submitted a letter to CMS attesting that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law, then a hospital may permit a CRNA to administer anesthesia without operating practitioner or anesthesiologist supervision. (A list of States that have opted out of the CRNA supervision requirement may be found at http://www.cms.hhs.gov/CFCsAndCoPs/02_Spotlight.asp) A CRNA is defined in 42 CFR §410.69(b) as a "registered nurse who: 1. Is licensed as a registered professional nurse by the State in which the nurse practices; 2. Meets any licensure requirements the State imposes with respect to non-physician anesthetists; 3. Has graduated from a nurse anesthesia educational program that meets the standards of the Council on Accreditation of Nurse Anesthesia Programs, or such other accreditation organization as may be designated by the Secretary; and 4. Meets the following criteria: i. Has passed a certification examination of the Council on Certification of Nurse Anesthetists, the Council on Recertification of Nurse Anesthetists, or any other certification organization that may be designated by the Secretary; or ii. Is a graduate of a program described in paragraph (3) of this definition and within 24 months after that graduation meets the requirements of	based on a letter submitted to the CMS by the Governor of the State. ▪ Verify the Bylaws/policies identify the qualifications of individuals authorized to deliver anesthesia. □ The privilege delineation process describes the scope of practice for each provider. In the case of non-physician providers there is indication of the accountability to the organized medical staff as deemed appropriate by the facility.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

paragraph (4)(i) of this definition."

Administration by an Anesthesiologist's Assistant
An anesthesiologist's assistant may administer anesthesia when under the supervision of an anesthesiologist.

The anesthesiologist must be immediately available if needed. An anesthesiologist is considered "immediately available" to assist the anesthesiologist's assistant under the anesthesiologist's supervision only if he/she is physically located within the same area as the anesthesiologist's assistant, e.g., in the same operative/procedural suite, or in the same labor and delivery unit, and not otherwise occupied in a way that prevents him/her from immediately conducting hands-on intervention, if needed.

An anesthesiologist's assistant is defined at 42 CFR §410.69(b) as a "person who-

1. Works under the direction of an anesthesiologist;
2. Is in compliance with all applicable requirements of State law, including any licensure requirements the State imposes on nonphysician anesthetists; and
3. Is a graduate of a medical school-based anesthesiologist's assistant education program that –
   - □ Is accredited by the Committee on Allied Health Education and Accreditation; and
   - □ Includes approximately two years of specialized basic science and clinical education in anesthesia at a level that builds on a premedical undergraduate science background."

ANESTHESIA SERVICES POLICIES
The medical staff bylaws or rules and regulations must include criteria for determining the anesthesia service privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges, as required by the regulations at 42 CFR §482.22(c)(6) for any type

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	of anesthesia services, including those not subject to the anesthesia administration requirements at 42 CFR §482.52(a). The hospital's governing body must approve the specific anesthesia service privileges for each practitioner who furnishes anesthesia services, addressing the type of supervision, if any, required. The privileges granted must be in accordance with State law and hospital policy. The type and complexity of procedures for which the practitioner may administer anesthesia must be specified in the privileges granted to the individual practitioner. Deficiencies related to these requirements should be cited under 42 CFR §482.22(c)(6). When a hospital permits operating practitioners to supervise a CRNA administering anesthesia, the medical staff bylaws or rules and regulations must specify for each category of operating practitioner, the type and complexity of procedures that category of practitioner may supervise. However, individual operating practitioners do not need to be granted specific privileges to supervise a CRNA.	
18.00.03 <u>Moderate sedation (conscious sedation)</u> The use of moderate sedation (conscious sedation) is limited to qualified individuals.	☐ Compliant ☐ Not Compliant Moderate sedation (conscious sedation) is the responsibility of the ordering practitioner; thus, there is to be evidence that this technique is included in the privilege delineation for those practitioners. There may be requirements, within Anesthesia policies, to document the advanced training and competencies of the Registered Nurses who give the medications and/or monitor patients having moderate sedation (conscious sedation).	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review at least three anesthesia provider files to verify: □ The qualifications including current certification with verifications are present in the files of the reviewed practitioners. □ Non-anesthesia practitioners who are using moderate sedation (conscious sedation) have

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

requested and have been granted privileges.

18.00.04 Required policies

Anesthesia services must be consistent with needs and resources.

Policies on anesthesia procedures must include the delineation of pre anesthesia and post anesthesia responsibilities.

§482.52(b)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The Anesthesia Standards of Practice (policy manual) addresses these issues consistent with federal, state, and other regulations.

This manual reflects review so that it conforms to any regulatory or practice changes. Policies are reviewed at least triennially.

Anesthesia services must be consistent with the needs and the resources of the hospital. Anesthesia policies, at a minimum, address:

1. How the hospital's anesthesia services needs will be met.
2. The delineation of pre- and post-anesthesia staff responsibilities including qualifications and supervision requirements for all personnel who administer anesthesia.
3. Delivery of anesthesia services consistent with recognized standards for anesthesia care. A well-designed anesthesia services policy includes:
   - ☐ Patient consent. **Policy defines the categories of practitioners eligible to obtain informed consent for the delivery of anesthesia. Informed consent requires a discussion of the risks, benefits, and alternatives to anesthesia. An individual acting within their scope of practice must participate in the discussion with the patient and/or patient's representative regarding the anesthesia plan of care, risks, benefits, and alternatives.**
     Documentation of the patient consent for anesthesia in included in the medical record. This may be accomplished through a separate written informed consent for the administration of anesthesia or integrated into the surgical informed consent if the practitioner responsible for the administration of anesthesia has participated

DOCUMENT REVIEW

- Review the policies developed on anesthesia procedures to verify that:
  - ☐ Delivery of care addresses the issues identified in Required Elements.
  - ☐ The Anesthesia Services manual addresses all required policies.
  - ☐ Policies are current.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	in the informed consent process and discussion of the planned anesthesia care. □ Infection control measures. □ Safety practices in all anesthetizing areas. □ Protocol for supportive life functions, e.g., cardiac and respiratory emergencies. □ Reporting requirements. □ Documentation requirements. □ Equipment requirements, as well as the monitoring, inspection, testing, and maintenance of anesthesia equipment in the hospital's biomedical equipment program.	
18.00.05 Pre-anesthesia Evaluation *The policies must ensure that the following are provided for each patient:* ▪ A pre-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of 42 CFR 482.52, performed within 48 hours prior to surgery or a procedure requiring anesthesia services. §482.52(b)(1)	☐ Compliant ☐ Not Compliant A pre-anesthesia evaluation must be performed for each patient who receives general, regional or monitored anesthesia. While current practice dictates that the patient receiving moderate sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, a pre-anesthesia evaluation performed by someone qualified to administer anesthesia as specified in 42 CFR §482.52(a) is not required because moderate sedation is **not** considered to be "anesthesia", and thus is not subject to that requirement under this regulation. The evaluation must be performed by someone qualified to administer anesthesia as specified in 42 CFR §482.52(a), i.e., only by: ▪ A qualified anesthesiologist. ▪ A Doctor of Medicine or Doctor of Osteopathic Medicine (other than an anesthesiologist).	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documents (collaborative statements/agreements, pre-operative records, medical staff bylaws, rules and regulations). ▪ Review recently closed patient medical records, include at least: □ One general anesthesia and one other technique, and □ At least one Moderate Sedation (Conscious Sedation) record for two practitioners using this technique. ▪ Determine if there is a State exemption

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under state law.
- A certified registered nurse anesthetist (CRNA), who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed.

OR

- An anesthesiologist's assistant who is under the supervision of an anesthesiologist who is immediately available if needed.

Although 42 CFR §482.12 (c)(1)(i) generally provides broad authority to physicians to delegate tasks to other qualified medical personnel, the more stringent requirements at 42 CFR §482.52(b)(1) do not permit delegation of the pre-anesthesia evaluation to practitioners who are not qualified to administer anesthesia.

The pre-anesthesia evaluation must be completed and documented within 48 hours immediately prior to any inpatient or outpatient surgery or procedure requiring anesthesia services. The delivery of the first dose of medication(s) for the purpose of inducing anesthesia, as defined above, marks the end of the 48-hour time frame.

In accordance with current standards of anesthesia care, some of the individual elements contributing to the pre-anesthesia evaluation may be performed prior to the 48-hour timeframe. However, under no circumstances may these elements be performed more than 30 days prior to surgery or a procedure requiring anesthesia services. Review of these elements must be conducted, and any appropriate updates documented, within the 48-hour timeframe.

The pre-anesthesia evaluation of the patient includes, at a minimum:

1. Elements that must be performed within the 48-hour timeframe:
   - □ Review of the medical history, including anesthesia, drug and allergy

for supervision of CRNAs. If a state exemption does not apply, determine that appropriate CRNA supervision was provided as required.

- Review a sample of inpatient and outpatient medical records for patients who had surgery or a procedure requiring administration of anesthesia.
  - □ Determine whether each patient had a pre-anesthesia evaluation by a practitioner qualified to administer anesthesia.
  - □ Determine whether each patient's pre-anesthesia evaluation included at least the elements described above.
  - □ Determine that the pre-anesthesia evaluation was updated, completed and documented within 48 hours prior to the delivery of the first dose of medication(s) given for the purpose of inducing anesthesia for the surgery or a procedure requiring anesthesia services.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

history; and

- □ Interview, if possible given the patient's condition, and examination of the patient.

2. Elements that must be reviewed and updated as necessary within 48 hours, but which may also have been performed during or within 30 days prior to the 48-hour time period, in preparation for the procedure:
   - □ Notation of anesthesia risk according to established standards of practice (e.g., ASA classification of risk);
   - □ Identification of potential anesthesia problems, particularly those that may suggest potential complications or contraindications to the planned procedure (e.g., difficult airway, ongoing infection, limited intravascular access);
   - □ Additional pre-anesthesia data or information, if applicable and as required in accordance with standard practice prior to administering anesthesia (e.g., stress tests, additional specialist consultation);
   - □ Development of the plan for the patient's anesthesia care, including the type of medications for induction, maintenance and post-operative care and discussion with the patient (or patient's representative) of the risks and benefits of the delivery of anesthesia.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.00.06 Intraoperative anesthesia record	☐ Compliant ☐ Not Compliant ☐ Not Applicable	This standard is not met as evidenced by:
The policies must ensure that the following are provided for each patient: ▪ *An intra-operative anesthesia record.* §482.52(b)(2)	There must be an intra-operative anesthesia record or report for each patient who receives general, regional or monitored anesthesia. While current practice dictates that the patient receiving moderate sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, an intra-operative anesthesia report is not required because, as explained above, moderate sedation is not "anesthesia". Current standard of care stipulates that an intra-operative anesthesia record, at a minimum, includes: ▪ Name and hospital identification number of the patient. ▪ Name(s) of practitioner(s) who administered anesthesia, and as applicable, the name and profession of the supervising anesthesiologist or operating practitioner. ▪ Name, dosage, route and time of administration of drugs and anesthesia agents. ▪ Techniques(s) used and patient position(s), including the insertion/use of any intravascular or airway devices. ▪ Name and amounts of IV fluids, including blood or blood products if applicable. ▪ Timed-based documentation of vital signs as well as oxygenation and ventilation parameters AND ▪ Any complications, adverse reactions, or problems occurring during anesthesia, including time and description of symptoms, vital signs, treatments rendered, and patient's response to treatment.	**DOCUMENT REVIEW** ▪ Review records to determine that each patient has an intraoperative anesthesia record that includes the required elements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.00.07 Post-anesthesia assessment	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The policies must ensure that the following are provided for each patient: ▪ *A post-anesthesia evaluation completed and documented by an individual qualified to administer anesthesia, as specified in paragraph (a) of 42 CFR 482.52, no later than 48 hours after surgery or a procedure requiring anesthesia services. The post anesthesia evaluation for anesthesia recovery must be completed in accordance with State law and with hospital policies and procedures that have been approved by the medical staff and that reflect current standards of anesthesia care.* §482.52(b)(3)	A post anesthesia evaluation must be completed and documented no later than 48 hours after surgery or a procedure requiring anesthesia services. The evaluation is required any time general, regional, or monitored anesthesia has been administered to the patient. While current practice dictates that the patient receiving moderate sedation be monitored and evaluated before, during, and after the procedure by trained practitioners, a post-anesthesia evaluation performed by someone qualified to administer anesthesia as specified in 42 CFR §482.52(a) is not required under this regulation. The post anesthesia evaluation must be completed and documented by any practitioner who is qualified to administer anesthesia; this need not be the same practitioner who administered the anesthesia to the patient. In accordance with §482.52(a), anesthesia must be administered only by: ▪ A qualified anesthesiologist. ▪ A Doctor of Medicine or Doctor of Osteopathic Medicine (other than an anesthesiologist). ▪ A dentist, oral surgeon, or podiatrist who is qualified to administer anesthesia under State law. ▪ A certified registered nurse anesthetist (CRNA), who, unless exempted in accordance with paragraph (c) of this section, is under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed. OR ▪ An anesthesiologist's assistant who is under the supervision of an anesthesiologist who is immediately available if needed. Although 42 CFR §482.12(c)(1)(i) provides broad authority to physicians to	**DOCUMENT REVIEW** ▪ Review facility policies that describe expectations for post-anesthesia assessments to verify there is one standard of care throughout the facility for the timeliness of completing the post-anesthesia assessment. ▪ Review a sample of medical records for patients who had surgery or a procedure requiring general, regional or monitored anesthesia to determine whether a post anesthesia evaluation was written for each patient. Verify that: □ The evaluation was conducted by a practitioner who is qualified to administer anesthesia. □ The evaluation was completed and documented within 48 hours after the surgery or procedure. □ The appropriate elements of a post-anesthesia evaluation are documented in the medical record.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

delegate tasks to other qualified medical personnel, the more stringent requirements of this regulation do not permit delegation of the post-anesthesia evaluation to practitioners who are not qualified to administer anesthesia.

The calculation of the 48-hour timeframe begins at the point the patient is moved into the designated recovery area.

The evaluation generally should not be performed immediately at the point of movement from the operative area to the designated recovery area. Rather, accepted standards of anesthesia care indicate that the evaluation should not begin until the patient is sufficiently recovered from the acute administration of the anesthesia so as to participate in the evaluation, e.g., answer questions appropriately, perform simple tasks, etc.

While the evaluation should begin in the PACU/ICU or other designated recovery location, it may be completed after the patient is moved to another inpatient location or, for same day surgeries, if State law and hospital policy permits, after the patient is discharged, so long as it is completed within 48 hours.

The 48-hour timeframe for completion and documentation of the post-anesthesia evaluation is an outside parameter. Individual patient risk factors may dictate that the evaluation be completed and documented sooner than 48 hours. This should be addressed by hospital policies and procedures.

For those patients who are unable to participate in the post anesthesia evaluation (e.g., post-operative sedation, mechanical ventilation, etc.), a post anesthesia evaluation should be completed and documented within 48 hours with notation that the patient was unable to participate.

DOCUMENTATION

This documentation should include the reason for the patient's inability to participate as well as expectations for recovery time, if applicable.

For those patients who require long-acting regional anesthesia to ensure

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

optimum medical care of the patient, whose acute effects will last beyond the 48-hour timeframe, a post-anesthesia evaluation must still be completed and documented within 48 hours. However, there should be a notation that the patient is otherwise able to participate in the evaluation, but full recovery from regional anesthesia has not occurred and is not expected within the stipulated timeframe for the completion of the evaluation.

The elements of an adequate post-anesthesia evaluation should be clearly documented and conform to current standards of anesthesia care, including:

1. Respiratory function, including respiratory rate, airway patency, and oxygen saturation.
2. Cardiovascular function, including pulse rate and blood pressure.
3. Mental status.
4. Temperature.
5. Pain.
6. Nausea and vomiting.
7. Postoperative hydration.

Depending on the specific surgery or procedure performed, additional types of monitoring and assessment may be necessary.

The medical staff is responsible to establish one standard of care throughout the facility for the assessment of patients following anesthesia.

One standard of care is required for all locations including, but not limited to the main operating room, outpatient surgery, ambulatory surgery centers, interventional radiology, nuclear medicine, obstetrics, cardiac catheterization lab, endoscopic services, and other procedure rooms in which general anesthesia, spinal anesthesia, regional anesthesia, epidural, or moderate sedation is administered.

Regardless of the location of the anesthesia, the post-anesthesia assessment must be completed within 48 hours. The facility will establish a process for

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	ensuring the post-anesthesia assessment is completed for patients who are discharged within 48 hours of the procedure.	
18.00.08 Equipment safety All anesthetizing equipment utilized is maintained to conform to Safe Medical Devices/Food Drug Administration requirements.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the anesthesia event record documents the anesthesia machine "number" and that it was "checked" prior to use. ▪ Request evidence of preventive maintenance consistent with manufacturer's recommendations, semi-annual gas waste, gas testing, and electrical safety testing.

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19

DIAGNOSTIC RADIOLOGY AND RADIATION THERAPY SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

19.00.00 CONDITION OF PARTICIPATION: Radiological Services

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must maintain, or have available, diagnostic radiological services.

If therapeutic services are also provided, they, as well as the diagnostic services, must meet the professionally approved standards for safety and personnel qualifications.

§482.26

Hospitals must offer diagnostic radiologic services and may also offer therapeutic radiologic services.

No matter where they are furnished in the hospital (including all departments on all campuses and off-site locations) radiologic services must satisfy professionally approved standards for safety and personnel qualifications.

Hospitals are expected to take a consistent approach in their policies and procedures for radiologic services safety and personnel qualifications throughout the hospital. This may be accomplished in several ways, including by having one organized radiologic service under the direction of the radiologist who supervises all ionizing radiology services (see 42 CFR §482.26(c)(1)), or by the governing body ensuring a uniform approach to radiologic services that are offered in multiple departments of the hospital.

WHAT IS INCLUDED IN RADIOLOGIC SERVICES?

Radiologic services encompass varied modalities used for the purpose of diagnostic or therapeutic medical imaging and radiation therapy. Each type of technology yields different information but all modalities use some form of radiation, which is a term for energy waves or particles that pass through a medium, such as light or radio signals through the air. Some use ionizing radiation, which has enough energy to potentially cause damage to DNA, while others use non-ionizing radiation to view the human body in order to diagnose, monitor, or treat medical conditions.

Most of the definitions and terms referred to in this guidance are based on technical information available on the U.S. Food and Drug Administration (FDA) website: http://www.fda.gov/Radiation-EmittingProducts/default.htm or from the Radiologic Society of North America's (RSNA) website, located at http://www.radiologyinfo.org.

DIAGNOSTIC & THERAPEUTIC RADIOLOGIC SERVICES

Diagnostic and therapeutic radiologic services may use the same modalities,

OBSERVATION, INTERVIEW AND DOCUMENT REVIEW

- Verify that radiological services are integrated into the hospital-wide QAPI program.
- Determine the diagnostic radiology services offered by reviewing the scope of service statements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

but for different purposes.

Diagnostic services are performed to determine a specific cause of the medical problem with which the patient presents (e.g., fractured bone, occluded artery, tumor), while therapeutic services are performed to treat a specific problem (e.g., stenting of an artery or embolization of a blood vessel, lithotripsy of a renal stone, external beam radiation therapy to a cancerous tumor).

Regardless of the purpose of the radiologic services, the risks to the patient and staff, if applicable, depend on the modality used, the length of the study/procedure, the size of the patient, the specifics of the device being used, and other factors.

MODALITIES THAT USE IONIZING RADIATION

- **Radiography (X-rays)** is a technique for generating and recording an x-ray pattern for the purpose of providing the user with a static image(s) after termination of the exposure. During a radiographic procedure, an x-ray beam is passed through the body. A portion of the x-ray is absorbed or scattered by the body's internal structure and the remaining x-ray pattern is transmitted to a detector, so that an image may be recorded for later evaluation. The recording of the pattern may occur on film or through electronic means (digital). X-rays are used to diagnose or treat patients by displaying images of the internal structure(s) of the body to assess the presence or absence of disease, foreign objects, and structural damage or anomaly.

  Examples include:

  - □ Verification of correct placement of invasive catheters, tubes, or devices.
  - □ Orthopedic evaluations for fractured or dislocated bones.
  - □ Chest x-ray to identify common conditions, such as congestive heart failure or pneumonia.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

□ Evaluations of radio-opaque foreign bodies in soft tissues.

□ Mammography.

Dual-energy X-ray absorptiometry (DEXA) is a form of medical imaging that uses very small amounts of ionizing radiation to measure bone mineral density and determine an individual's risk for bone fractures or establish the diagnosis of osteoporosis. The amount of radiation used is less than one-tenth the dose of a traditional chest X-ray and less than one day's exposure to natural radiation.

- **Computed Tomography (CT) scanning**, also called computerized axial tomography (CAT) scanning, is a medical imaging procedure that uses x-rays to show cross-sectional images of the body. A CT imaging system produces cross-sectional images or "slices" of areas of the body, like the slices in a loaf of bread. During a CT scan, a patient undergoes several consecutive and simultaneous X-rays that can be configured as a three-dimensional reconstruction of the part of the body that is being imaged. Thus, a CT scan delivers more ionizing radiation to the patient than radiography. CTs are better able to distinguish between different types of tissues in the body than radiography and, given its ability to image large areas over a short period of time, CT offers significantly improved resolution of many different structures in a variety of spatial configurations.

  Often a CT scan will be performed using x-ray dye or contrast agent, which can be administered by mouth or by vein. This technique further helps to identify the intestines or vasculature, which can assist with the diagnosis of disease or injury.

  Examples include:

  □ CT of the brain to distinguish between an ischemic or hemorrhagic stroke.

  □ CT of the abdomen and pelvis to evaluate for internal bleeding

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

following trauma.

- □ CT of the chest to determine the presence of a pulmonary embolus.
- □ CT of the aorta with intravenous contrast agent to determine a ruptured aneurysm.

- **Fluoroscopy** is a type of medical imaging that shows a continuous x-ray image on a monitor, much like an x-ray movie. It is used to diagnose or treat patients by displaying the movement of a body part, or of an instrument or x-ray dye (contrast agent) through the body.

  Fluoroscopy is used in many types of examinations and procedures.

  Examples include:

  - □ Barium upper GI (gastrointestinal) series and enemas (to view movement through the GI tract).
  - □ Catheter insertion (to direct the placement of a catheter in a blood vessel).
  - □ Orthopedic surgery (to view fracture treatments).
  - □ Angiography (to determine if there are blockages in arteries).

The amount of ionizing radiation that a patient and the medical staff receive during the procedure depends on the procedure's length and complexity.

Radiation Therapy

Ionizing radiation can also be used for therapeutic purposes, in which the energy is used to directly kill cancerous cells.

- **External beam therapy (EBT)** is a method to deliver a beam of high-energy x-rays to a patient's tumor. The beam is generated outside the patient and is targeted at the tumor site. The goal is to deposit the energy to kill the cancer cells while sparing the normal tissue. EBT is often used to treat cancers of the breast, head and neck, prostate, lung, and brain. It also can be used to provide palliative care for painful sites of metastases to bone.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- **Brachytherapy** is a type of radiation therapy in which radioactive material is placed directly inside or next to the tumor. This type of therapy allows for a higher dose of radiation to treat a smaller area and in a shorter time than with EBT. It can be either temporary, in which the radioactive material is placed inside or near a tumor for a specified amount of time, often via a catheter; or permanent, in which radioactive seeds or pellets are placed near or inside a tumor and left there permanently, eventually decaying so that the radioactivity diminishes to nothing. Brachytherapy is often used to treat solid tumors, including prostate, breast, and gallbladder cancer.

MODALITIES THAT USE NON-IONIZING RADIATION

- **Ultrasound imaging** (sonography) uses high-frequency sound waves to view soft tissues, such as muscles and internal organs. Because ultrasound images are captured in real-time, they can show movement of the body's internal organs as well as blood flowing through blood vessels. This imaging modality has no documented evidence of dangers to the patient or staff administering it, however, caution about the frequency of use has been encouraged, particularly in the imaging of fetuses. Ultrasound imaging is used in many types of examinations and procedures.

  Examples include:

  □ Doppler ultrasound (to visualize blood flow through a blood vessel).

  □ Echocardiogram (to view the heart).

  □ Fetal ultrasound (to view the fetus in pregnancy).

  □ Ultrasound-guided biopsies of suspicious masses.

  □ Doppler fetal heart rate monitors (to listen to the fetal heart beat).

  □ Lithotripsy to break up kidney stones; this procedure uses high energy sound waves (shock waves), but there is minimal risk to the patient and staff from this form of energy. Pre- and post-procedure

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

radiographs are taken of the patient, which confer the same risk as a standard X-ray of that part of the body.

- **Magnetic resonance imaging (MRI)** is a procedure that uses strong magnetic fields and radio waves to produce cross-sectional images of organs and internal structures in the body. Because the signal detected by an MRI machine varies depending on the water content and local magnetic properties of a particular area of the body, different tissues or substances can be distinguished from one another in the study image.

  MRI can give different information about structures in the body than can be obtained using a standard x-ray, ultrasound, or computed tomography (CT) exam. For example, an MRI study of a joint can provide detailed images of ligaments and cartilage, which are not visible using other modalities. In some cases, an MRI contrast agent is given by vein to show internal structures or abnormalities more clearly.

  In most MRI devices, an electric current is passed through coiled wires to create a temporary magnetic field in a patient's body. (In open-MRI devices, permanent magnets are used.) Radio waves are sent from and received by a transmitter/receiver in the machine, and these signals are used to produce digital images of the area of interest.

  MRI scans facilitate diagnosis or monitoring of treatments for a variety of medical conditions, including:

  □ Abnormalities of the brain and spinal cord.

  □ Tumors, cysts, and other abnormalities in various parts of the body.

  □ Injuries or abnormalities of the joints.

  □ Certain types of heart problems.

  □ Diseases of the liver and other abdominal organs.

  □ Causes of pelvic pain in women (e.g., fibroids, endometriosis).

  □ Suspected uterine abnormalities in women undergoing evaluation for infertility.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The hospital's radiological services, including any contracted services, must be integrated into its hospital-wide QAPI program. **Note:** The elements of the Condition's regulatory language (the Condition "stem" statement) are close, but not identical, to those found in the standards at 42 CFR §§482.26(a) and (b). We have, therefore, repeated elements of this Condition regulatory language in the standards below referencing 42 CFR §§482.26(a) and (b), in order to permit citation of deficiencies that are specific to requirements found in the Condition stem statement at either the standard or condition level, as appropriate. The manner or degree of noncompliance with the requirements of this Condition and its component standards determines whether there is substantial noncompliance with the Condition, warranting a Condition-level citation.	
19.00.01 Scope of service *The hospital must maintain, or have available, radiology services according to the needs of the patients.* *§482.26(a)*	☐ Compliant ☐ Not Compliant **MANDATORY AND OPTIONAL RADIOLOGIC SERVICES** The hospital must maintain, or have available, diagnostic radiological services according to the needs of the volume and types of patients the hospital serves. "Maintain" in this context means furnishing radiologic services on-site, while having them available means providing access to radiologic services even when they are not furnished on-site. For example: ▪ A psychiatric hospital may have limited or no radiologic services onsite, while making more extensive diagnostic services available under arrangement, at a site outside the psychiatric hospital. ▪ Conversely, a short-term acute care hospital with a busy emergency department that handles trauma, stroke, and other complex medical and	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review evidence of the scope and complexity of its diagnostic radiologic services. ▪ Ask how the hospital has determined that the services meet the needs of its patients. ▪ Verify that the hospital either maintains or makes available diagnostic radiologic services that can be provided promptly when needed. ▪ If the hospital has an emergency department, are diagnostic radiologic

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surgical cases would be expected to maintain a wider range of diagnostic radiologic services on-site that are ready to be furnished when needed.

A hospital's diagnostic radiologic services must be maintained or available at all times.

Multi-campus hospitals must have diagnostic radiologic services that can be furnished when needed in a clinically appropriate timeframe for each location providing inpatient, same-day surgery, and emergency services.

The scope and complexity of diagnostic radiological services maintained or available must be specified in writing, in order to demonstrate how the hospital meets the needs of its patients.

Therapeutic radiologic services are optional, but if they are offered, must also comply with the radiologic services requirements.

Radiological services may be provided by the hospital directly using its own staff, or through a contractual arrangement.

The hospital is responsible for ensuring that the services meet all the requirements of this regulation, regardless of whether they are provided directly or under arrangement. Diagnostic radiologic services provided under arrangement may be provided either on the hospital's campus or in an adjacent or other nearby, readily accessible facility so long as the services, including those required on an urgent or emergent basis, can be furnished within clinically appropriate timeframes.

Increasingly, hospitals are also separating the performance of radiologic studies, which may be done on-site or at a readily accessible facility off the hospital's campus, from the interpretation of the studies, which can be performed remotely by a teleradiology practitioner in a timely fashion.

- This practice is acceptable, so long as the teleradiology practitioner is privileged in accordance with the requirements of the Governing Body (42 CFR §482.12) and Medical Staff (42 CFR §482.22) CoPs.

services maintained or available at all times to support the emergency department?

- If the diagnostic radiologic services are not on the same campus as the hospital's emergency department, same-day surgery, inpatient locations, or other areas where services dependent upon radiologic services are provided:
  - □ Ask the hospital how it ensures that services are furnished within clinically required timeframes.
  - □ Does the hospital have an arrangement with an off-site facility to furnish diagnostic services when needed?
- How does the hospital ensure that staff authorized to interpret diagnostic studies are ready to furnish services within clinically required timeframes, either on-site or through telecommunications media that permit remote review and interpretation of studies?

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19.00.02 Safety for patients and personnel

The radiologic services, particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

§482.26(b)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must adopt and implement radiologic services policies and procedures that provide safety for affected patients and hospital personnel and which are consistent with accepted professional standards for radiologic services.

IONIZING RADIOLOGY PROCEDURES

Radiologic services modalities that use ionizing radiation have increased the ability to detect disease or injury early enough for a medical problem to be managed, treated, or cured. When applied and performed appropriately, these radiologic studies or procedures can maintain or improve health and save lives.

X-ray energy used in radiologic services also has a potential to harm living tissue. The most significant risks are:

- Cataracts and skin damage, but only at very high levels of radiation exposure.
- An increase in the possibility that a person exposed to x-ray energy will develop cancer later in life. The risk of developing cancer from radiologic services radiation exposure is generally very small, and it depends on at least three factors—the amount of the radiation dose, the age of the person exposed, and the sex of the person exposed:
  - □ The lifetime risk of cancer increases the larger the dose and the more x-ray studies or procedures a patient undergoes.
  - □ The lifetime risk of cancer is larger for a patient who received x-rays at a younger age than for one who receives them at an older age.
  - □ Women are at a somewhat higher lifetime risk than men for developing radiation-associated cancer after receiving the same exposures at the same ages.

OBSERVATION, INTERVIEW AND DOCUMENT REVIEW

- Verify that there are written hospital policies and procedures and protocols for specific radiologic services modalities that are based on identified professionally approved standards, and which address the ALARA principle as well as the other safety and risk-reduction measures discussed in the guidance.
  - □ Review evidence that safety protocols are reviewed periodically and, if applicable, updated.
  - □ Verify that if the radiologic services staff are familiar with the policies and procedures related to safety in general and specific clinical protocols.
  - □ Observe whether the policies and procedures are followed when radiologic services are delivered to patients.
  - □ Ask for the protocol(s) for one or more studies/procedure(s) you observed and check if they were followed.
- Verify that radiologic services staff are trained at appropriate intervals to

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MRI

MRIs are useful when a soft tissue injury or disease process is suspected and are generally considered at low risk of causing harm to patients or staff.

However, they also are not entirely risk-free. Potential risks include projectile risk of magnetic objects being sucked into the main magnet, thermal injury and burns, adverse effects on devices and leads implanted in patients, and hearing damage.

PROVISION OF SERVICES IN ACCORDANCE WITH PROFESSIONALLY APPROVED STANDARDS FOR SAFETY

1. All radiological services provided by the hospital, including both diagnostic and, if offered, therapeutic services, must be provided in accordance with acceptable standards of practice, including standards for safety.
2. Professionally approved standards include maintaining compliance with applicable Federal and State laws and regulations governing radiological services, including, but not limited to, facility licensure and/or certification requirements.
3. Professionally approved standards also include the recommendations or guidelines promulgated by expert governmental agencies, such as the U.S. Food and Drug Administration, as well as those issued by nationally recognized professional organizations, such as the American Medical Association, American College of Radiology, Radiological Society of North America, The Alliance for Radiation Safety in Pediatric Imaging, American Society of Radiologic Technologists, the American College of Cardiology, the American College of Neurology, the American College of Physicians, etc.
4. Generally, there are different standards for different imaging modalities used to provide radiologic services; there may also be different standards for diagnostic versus therapeutic uses, as well as for pediatric versus adult patients, etc. For example, the American College of Radiology has separate diagnostic radiology guidance documents for general radiology,

ensure that they are operating the equipment according to manufacturer's instructions and hospital policy

- Verify that radiologic services staff know how to respond to adverse events.
- Confirm that areas where radiologic services are provided are equipped with the equipment or materials to immediately respond to an adverse event.
- Ask the radiologist who supervises ionizing radiologic services how the hospital monitors the quality and safety of radiologic services.
- Verify that adverse events are analyzed for their causes and that preventive actions are taken (deficiencies to be cited both here and under the applicable QAPI citation).

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CT, MRI, and ultrasound, among others.

5. The hospital must be able to document the source standards that form the basis for its policies and procedures for each of its radiologic services modalities and/or settings.
   - □ For example, if one organization's standards are used for mammography services, another's for CT services, another's for MRI, and another's for pediatric X-rays, this must be clearly indicated.
6. To ensure safety and freedom from hazards, the hospital's radiologic services policies and procedures must include, but are not limited to, provisions addressing the following:
   - □ For ionizing radiation services, application of the fundamental principle of As Low as Reasonably Achievable or ALARA, which is defined by the U.S. Environmental Protection Agency (EPA) as "A principle of radiation protection philosophy that requires that exposures to ionizing radiation be kept as low as reasonably achievable, economic and social factors being taken into account.
   - □ The protection from radiation exposure is ALARA when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved." (See **Note**, below, for additional reference.) Although CMS does not interpret or enforce EPA guidance, the ALARA principle is considered an accepted standard of practice for ionizing radiation services to which hospitals must adhere.
   - □ Written protocols developed or approved by the radiologist responsible for the radiologic services, in conjunction with other qualified radiologic services personnel (e.g., a medical physicist, radiologic technologists, patient safety officers, etc.) designed to ensure that diagnostic studies and therapeutic procedures are routinely performed in a safe manner, utilizing parameters and specifications that are appropriate to the ordered study/procedure.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- □ The hospital must ensure that protocols for the various types of ionizing radiation diagnostic or therapeutic imaging modalities are designed to minimize the amount of radiation while maximizing the yield and producing diagnostically acceptable image quality.
- □ Existing protocols must be reviewed periodically and updated as needed. The rationale and details for changes to technical parameters must be documented.

Note: For Information Only – Not Required/Not to be Cited
Hospitals are encouraged to follow the recommendation in the EPA's Guidance Report No. 14 concerning patient radiation dosage.

The report states "As the ICRP [International Commission on Radiological Protection] has stated, 'Provided that the medical exposures of patients have been properly justified and that the associated doses are commensurate with the medical purpose, it is not appropriate to apply dose limits or dose constraints to the medical exposure of patients, because such limits or constraints would often do more harm than good' (ICRP 2007b).

While dose limits do not apply to medical exposures, radiation doses to patients should always be optimized. All responsible parties should always strive to minimize patient irradiation to the dose that is necessary to perform the procedure with adequate image quality.

The recommendation against establishing absolute dose limits should not discourage a facility from implementing diagnostic reference levels for imaging and interventional procedures. Exceeding these levels should prompt a review of practice at the facility as a quality assurance measure.

Dose notification and alert values for CT, notification levels for use during interventional procedures, and trigger levels for follow-up after interventional procedures are also appropriate QA measures..."(EPA Guidance Report No. 14, p.6)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

□ Policies and protocols to identify patients at high risk for adverse events for whom the radiologic study or procedure might be contraindicated, e.g., pregnant women, individuals with known allergies to contrast agents, individuals with implanted devices, etc. Policies would address the steps to be taken, and by which personnel, if an order is written for a radiologic study or procedure for an individual identified in the radiologic services policies as potentially at high risk (e.g., notify the ordering physician, cancel the procedure personally, etc.).

□ Specific requirements related to procedures to mitigate radiation hazards are discussed in the guidance for §482.26(b)(1).

□ Procedures to address risks associated with modalities that do not use ionizing radiation. For example, with respect to MRI:

- Measures to prevent magnetic materials from being closer than is safe to the MRI suite, per nationally recognized guidelines;
- If equipment and supplies, such as fire extinguishers and oxygen tanks, are located in the MRI area, they are MR-safe, i.e., they are non-ferromagnetic;
- Provision of adequate and effective hearing protection to patients, staff and others who might be in the MRI suite while the scans are taking place; and
- Measures to reduce the risk of thermal injuries/burns during MRI. This would include, but is not limited to, screening patients to identify those who may have metallic tattoos or metal in them, proper patient positioning, ensuring implants are MR Conditional, checking for electrically conductive materials that might be in close proximity to the patient and taking the appropriate precautions, and instructing the patient to immediately report any burning sensations experienced during the scan.

□ Training required by personnel permitted to enter areas where

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

radiologic services are provided.

- □ Training and, as applicable, qualifications, required for personnel who perform diagnostic imaging studies or therapeutic procedures utilizing radiologic services equipment. This includes proper operation of equipment per manufacturer's instructions and hospital policy.
- □ Areas where radiologic services are provided must be equipped with the necessary equipment or materials to immediately respond to potential adverse events. This could include, but is not limited to, things like a crash cart, emergency stop mechanisms, cleaning, and decontamination agents if applicable, etc.

Note: **For Information Only – Not Required/Not to be Cited**
Hospitals are encouraged to also address the following in their radiologic services:

- Encouraging physicians and other practitioners with privileges to order radiologic studies or procedures that utilize ionizing radiation to consider both the benefits and risks of the procedures.
- Recording and tracking the dosing patients receive. There are several nationally recognized quality assurance programs designed to assist health care providers in developing and maintaining this data, including, but not limited to:
  - □ The Alliance for Safety in Pediatric Imaging (www.Imagegently.org)
  - □ The Conference of Radiation Control Program Directors
  - □ The American College of Radiology data registry (http://nrdr.acr.org)
  - □ The Nationwide Evaluation of X-ray Trends (NEXT program)

Further, although the EPA's Guidance Report No. 14 was developed by an Interagency Working Group on Medical Radiation specifically to provide guidance to Federal facilities that use diagnostic and interventional X-ray equipment, it should also be useful to non-Federal medical facilities and hospitals are encouraged to review it. The Guidance Report addresses

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the following topics:

- Radiation Safety Standards and General Concerns
- Structural Shielding and Door Interlock Switches
- Requesting and Performing Studies Involving X-rays
- Technical Quality Assurance
- General Guidelines for Clinical Imaging, organized into separate sections for Medical and Dental, and further broken down by modality
- Imaging Informatics
- Recommendations for facility action

MEDICAL PHYSICISTS

- According to the American Association of Physicists in Medicine, the practice of Medical Physics means the use of principles and accepted protocols of physics to ensure the correct quality, quantity, and placement of radiation during the performance of a radiological procedure.
- Hospitals are not required under the regulations to have a medical physicist on staff or under contract.
- However, since radiologic services are required to be free from hazards to patients and hospital personnel, hospitals must ensure that qualified personnel, whether or not they are medical physicists, develop and carry out protocols and test, calibrate, and maintain radiologic services equipment and that there is a reliable means to validate the results.

Note: For Information Only – Not Required/Not to be Cited

An example of a definition of and qualifications for a medical physicist is provided by the American Association of Physicists in Medicine:

"For the purpose of providing clinical professional services, a Qualified Medical Physicist (QMP) is an individual who is competent to independently provide clinical professional services in one or more of the

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subfields of medical physics. The subfields of medical physics are:

- Therapeutic Medical Physics
- Diagnostic Medical Physics
- Nuclear Medicine Physics
- Medical Health Physics

…. A Qualified Medical Physicist meets each of the following credentials:

- Has earned a master's and/or doctoral degree in physics, medical physics, biophysics, radiological physics, medical health physics, or equivalent disciplines from an accredited college or university; and
- Has been granted certification in the specific subfield(s) of medical physics with its associate medical health physics aspects by an appropriate national certifying body and abides by the certifying body's requirements for continuing education." http://www.aapm.org/org/default.asp

Note: For Information Only – Not Required/Not to be Cited

The responsibilities of the medical physicist in a hospital may include:

- Protection of the patient and others from potentially harmful or excessive radiation.
- Establishment, with the approval of the Director of Radiologic Services, of adequate protocols to ensure accurate patient dosimetry.
- Measurement and characterization of radiation.
- Determination of delivered dose.
- Promotion of procedures necessary to ensure image quality.
- Development and direction of quality assurance programs.
- Assistance to other healthcare professionals in optimizing the balance between the beneficial and deleterious effects of radiation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Hospital are also encouraged to involve a medical physicist in the calibration of the radiologic services equipment and monitoring of radiation dosage exposures to staff.

QAPI

Consistent with the requirements under the Quality Assessment and Performance Improvement (QAPI) CoP at 42 CFR 482.21, the hospital must monitor the quality and safety of radiologic services.

Examples of indicators of potential quality and safety problems could include, but are not limited to:

- Improper patient preparation, such as inadequate intravenous access or lack of pre-medication, such that procedures must be cancelled or reordered;
- Repeats of the same studies in the hospital for the same patient within a short time span, which may be an indicator of poor image quality; or
- Diagnostic imaging studies or therapeutic procedures performed in a manner inconsistent with the applicable hospital written protocol.

Under the QAPI CoP, hospitals are required to undertake improvement activities in areas that represent high risk, high volume, or problem-prone areas.

- Problems identified in radiologic services may meet these criteria.
- In addition, adverse events related to radiologic services must be analyzed for their causes, and preventive actions must then be undertaken.
- Deficiencies identified related to tracking, analyzing, and addressing adverse event and quality indicator data and performance improvement activities must be cited under the applicable QAPI standards.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

19.00.03 Shielding

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Proper safety precautions must be maintained against radiation hazards.

This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use and disposal of radioactive materials;

§482.26(b)(1)

The hospital must adopt and implement written policies and procedures to ensure safety from radiation hazards.

The policies and procedures must include, but are not limited to, consideration of the following:

- Clear and easily recognizable signage identifying hazardous radiation areas.
- Limitations on access to areas containing radiologic services equipment.
- Appropriate use of shielding, including:
  - □ Types of personal protective shielding (e.g., lead aprons, lead gloves, protective eyewear, thyroid shields, portable individualized lead panels, stationary barriers) to be used, under what circumstances, for patients, including high-risk patients as identified in radiologic services policies and procedures, patient family members or support persons who may be needed to be with the patient during a study or procedure, and hospital personnel.
  - □ Lead and concrete barriers built into the walls and other structures of the imaging areas.
  - □ Identification and use of appropriate containers to be used for various radioactive materials, if applicable, when stored, in transport between locations within the hospital, in use, and during/after disposal.

ADDITIONAL POLICIES

The hospital policies must establish safety standards for at least the following:

1. Labeling of radioactive materials, waste, and hazardous areas.
2. Transportation of radioactive materials between locations within the hospital.
3. Security of radioactive materials, including determining who may have

OBSERVATION

Verify that:

- Personal shielding, supplies and equipment are properly maintained and routinely inspected by the hospital.
- Hazardous radiation materials are clearly labeled, properly stored in a safe manner in the requisite containers and disposed of in the appropriate manner.
- Proper shielding is applied to a patient who is undergoing a procedure using ionizing radiation.
- Staff members appropriately extricate themselves from the immediate exposure field while performing a study or procedure using ionizing radiation.
- Staff wear shielding as appropriate, per hospital policy.
- Verify the required policies have been approved by the medical staff within the past three years.

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access to radioactive materials and controlling access to radioactive materials.

4. Testing of equipment for radiation hazards.
5. Maintenance of personal radiation monitoring devices.
6. Proper storage of radiation monitoring badges when not in use.
7. Storage of radio nuclides and radiopharmaceuticals as well as radioactive waste.
8. Disposal of radionuclides, unused radiopharmaceuticals, and radioactive waste.
9. Methods of identifying pregnant patients
10. Periodic inspections of radiology equipment are conducted, current and problems identified are corrected in a timely manner.
11. Personnel are competent to use radiological equipment and perform procedures.

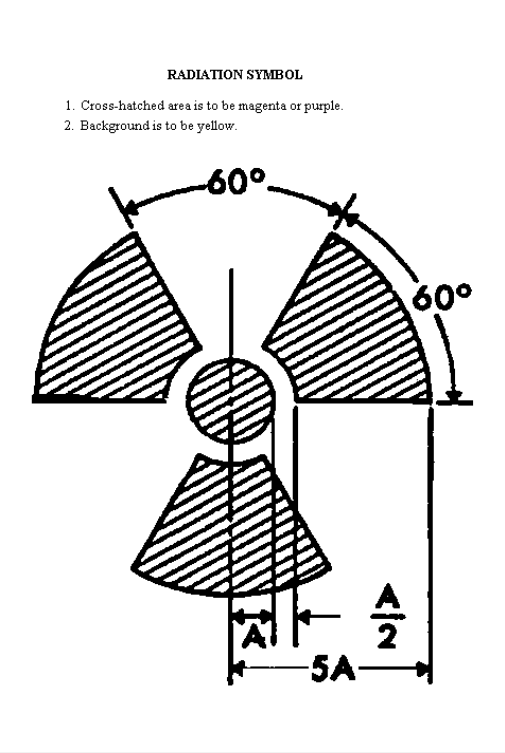
The hospital must implement and ensure compliance with its established safety standards.

Note: For Information Only – Not Required/Not to be Cited

The Occupational Health and Safety Administration (OSHA) has requirements for protecting hospital staff from radiation exposure, some of which are summarized below:

- "For information about exposure limits see: 29 CFR 1910.1096, Ionizing Radiation Standard. The standard also requires:…
- Each radiation area shall be conspicuously posted with a sign or signs bearing the radiation caution symbol, with the wording 'Caution Radiation Area' [29 CFR 1910.1096(e)(2)]"

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE



This document also discusses other tools to prevent radiation exposure. See: https://www.osha.gov/SLTC/etools/hospital/clinical/radiology/radiology.html#Radiation

As a reminder, although hospitals are required to comply with applicable OSHA requirements, surveyors conducting surveys on behalf of interpret or assess compliance with the requirements of OSHA or other Federal Agencies. Surveyors do assess compliance with Medicare requirements that may overlap or duplicate OSHA requirements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
19.00.04 Equipment inspections *Periodic inspection of equipment must be made and hazards identified must be promptly corrected.* *§482.26(b)(2)*	☐ Compliant ☐ Not Compliant The hospital must have policies and procedures in place to ensure that periodic inspections of radiology equipment are conducted, current and that problems identified are corrected in a timely manner. Equipment includes not only devices used to deliver diagnostic or therapeutic radiologic services, but also: ▪ Exposure meters, badges, or personal radiation monitoring devices used by staff, as well as ▪ Equipment the hospital uses to inspect or calibrate devices used to deliver diagnostic or therapeutic radiologic services. The hospital must ensure that equipment is inspected in accordance with manufacturer's instructions and Federal and State laws, regulations, and guidelines, and hospital policy, as applicable. **INSPECTIONS PERFORMED BY QUALIFIED PERSONNEL** Inspections and maintenance, including correction of identified hazards, must be performed by qualified employees (e.g., medical physicists, qualified biomedical technicians, etc.) or through contractual arrangements with vendors with appropriate expertise. Hospitals must follow the manufacturer's instructions as to how to inspect and maintain radiologic equipment. This includes acceptance testing (i.e., upon initial installation and after major upgrades) as well as ongoing inspection and maintenance. Documentation of preventive maintenance, quality control tests, service records, and major software/hardware upgrades must be maintained by the hospital and be readily available for inspection. The hospital must have a system in place, to identify and remedy equipment hazards in a timely manner. This system must include, but is not limited to:	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the inspection records (logs) to verify that periodic inspections are conducted in accordance with manufacturer's instructions, Federal and State laws, regulations, and manufacturer's instructions. ▪ Verify that inspection and maintenance activities were performed by qualified individuals. ▪ Verify that the maintenance logs show documentation of the calibration upon installation and after major upgrades or servicing. ▪ Review with the appropriate personnel the inspection schedule and the mechanism for identifying hazards, including accurate dosimetry determinations with phantom patients, as applicable. ▪ Verify that any problems identified through the testing and maintenance program are properly corrected in a timely manner and the correction is maintained over time.

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- Periodic and consistent calibration of equipment and,
- For equipment using ionizing radiation, monitoring of dosimetry parameters with phantoms to ensure that an accurate dose of radiation is delivered per the applicable protocol.

In addition, hospitals must also have a system to track all modifications made to the equipment that would significantly impact the accuracy of the dosage delivered.

- Any adverse events related to over- or under-dosing must be identified and addressed.

Note: For Information Only – Not Required/Not to be Cited
Requirements for Manufacturers re: Instructions that must be made available

Below is an FDA summary of its requirements for manufacturers of x-ray systems to make available to purchasers and, upon request, to other parties, information related to maintenance of the following types of systems:

- For all diagnostic x-ray systems, manufacturers are required to provide to purchasers, and, upon request, to others at a cost not to exceed the cost of publication and distribution, manuals or instruction sheets that include technical and safety information (21 CFR 1020.30(h). This information must include a schedule of the maintenance necessary to keep the equipment in compliance with §§1020.30, 1020.31, 1020.32, and 1020.33 (21 CFR
- 1020.30(h)(1)(ii)). Manufacturers are also required to provide to assemblers, and, upon request, to others at a cost not to exceed the cost of publication and distribution, instructions for assembly, installation, adjustment, and testing of specified components of diagnostic x-ray systems adequate to ensure that the products will comply with applicable provisions of §§1020.30, 1020.31, 1020.32,

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and 1020.33, when assembled, installed, adjusted, and tested as directed (21 CFR 1020.30(g)).

In addition to the requirements applicable to all diagnostic x-ray systems, there are also other requirements for specific systems:

- Manufacturers of fluoroscopic x-ray systems manufactured on or after June 10, 2006, are required to provide a schedule of maintenance for any system instrumentation associated with the display of air kerma information necessary to maintain the displays of air kerma rate and cumulative air kerma within the limits of allowed uncertainty specified by 21 CFR 1020.32(k)(6). And, if the capability for user calibration of the display is provided, adequate instructions for such calibration must be supplied (21 CFR 1020.30(h)(6)(i)).
- Manufacturers of computed tomography (CT) systems are required to provide a specific phantom or phantoms for quality assurance testing of specific system parameters on these systems (21 CFR 1020.33(d)(1)), and
- instructions on the use of the phantom(s), including a schedule of testing appropriate for the system and allowable variations for the indicated parameters (21 CFR 1020.33(d)(2)).
- Manufacturers of cabinet x-ray systems are required to provide purchasers, and others, upon request, at a cost not to exceed the cost of preparation and distribution, manuals and instructions. These documents must include, among other technical and safety information, a schedule of maintenance necessary to keep the system in compliance with 21 CFR 1020.40 (21 CFR 1020.40(c)(9)(i)).
- Cabinet x-ray systems that are intended to be assembled or installed by the purchaser must be accompanied by instructions for assembly, installation, adjustment and testing of the cabinet x-ray adequate to ensure that the system is in compliance with the applicable provisions of 21 CFR 1020.40 when assembled, installed, adjusted, and tested as

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	directed (21 CFR 1020.40(c)(9)(ii)).	
19.00.05 Exposure meters *Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.* §482.26(b)(3)	☐ Compliant ☐ Not Compliant This requirement applies to radiologic services personnel, as well as other hospital employees who may be regularly exposed to radiation due to working near radiation sources. This could include certain nursing and maintenance staff. The types or locations of employees who require monitoring for radiation exposure must be identified in the policies and procedures for the radiologic services developed or approved by the radiologist who supervises the services, in conjunction with the appropriately qualified radiation safety personnel. The monitoring of staff exposure must be documented by qualified personnel. Hospitals are expected to educate staff who are monitored for radiation exposure about the appropriate use of the monitoring meters or badges (or through use of a "personal radiation monitoring device," which employs modern technology for the same measurement purpose). Hospitals must educate staff on the importance of tracking their radiation exposure over various timeframes, such as the most recent month and year, as well as their cumulative exposure through work. Staff also must be educated about the appropriate storage of the meters and/or badges as well as the procedures to follow if the exposure device exceeds cumulative dosage parameters specified per hospital policy. The hospital is expected to proactively monitor staff cumulative dosage and take appropriate steps if an individual staff member's cumulative dosage level exceeds parameters specified per hospital policy.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that staff being monitored have been trained about the appropriate use and storage of their badges/meters. □ Are staff knowledgeable about their personal radiation exposure over various timeframes? ▪ Observe whether staff in categories or locations identified for monitoring have radiation-detecting meters or badges and that they appropriately wear and store them. □ Review records to verify that monitoring of staff exposure is documented. ▪ Ask the hospital what steps it takes if staff exposure exceeds parameters established per hospital policy. □ Can the hospital provide examples, or, if it asserts there have been no cases in the prior 12 – 24 months, do its records support this?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Note: For Information Only – Not Required/Not to be Cited

The Occupational Safety and Health Administration (OSHA) has requirements for protecting hospital staff from radiation exposure, some of which are summarized below:

- "For information about exposure limits see: 29 CFR 1910.1096, Ionizing Radiation Standard. The standard also requires:
- Every employer shall supply appropriate personnel monitoring equipment, such as film badges, pocket chambers, pocket dosimeters, or film rings, and shall require the use of such equipment [29 CFR 1910.1096(d)(2)]
- Employers shall maintain records of the radiation exposure of all employees for whom personnel monitoring is required under paragraph (d) of this section and advise each employee of his individual exposure at least yearly.

See: https://www.osha.gov/SLTC/etools/hospital/clinical/radiology/radiology.html#Radiation

As a reminder, although hospitals are required to comply with applicable OSHA requirements, surveyors conducting surveys on behalf of CMS do not interpret or assess compliance with the requirements of OSHA or other Federal Agencies.

Surveyors do assess compliance with Medicare requirements that may overlap or duplicate OSHA requirements.

19.00.06 Orders

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Radiologic services must be provided only on the order of practitioners with clinical

The medical staff and the governing body determine the necessary qualifications and clinical privileges that practitioners must have to order

OBSERVATION AND DOCUMENT REVIEW

- Review medical records to determine

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
privileges or, consistent with State law, of other practitioners authorized by the medical staff and the governing body to order the services. §482.26(b)(4)	diagnostic radiologic studies or therapeutic procedures. For outpatient services, the governing body and medical staff may also authorize practitioners who do not have hospital privileges to order such studies or procedures, as permitted under State law. ▪ For example, a hospital may decide that it will routinely accept orders from physicians in the communities it services for outpatient diagnostic studies, regardless of whether those physicians have privileges to practice in the hospital. See the guidance for §482.54(c) for more information on requirements related to outpatient orders from practitioners who do not hold privileges to practice at the hospital. The order must include information for the radiologic technologist about the study or procedure to be performed, and the technologist is expected to review this information prior to implementing the order. **Note: For Information Only – Not Required/Not to be Cited** Hospitals are strongly encouraged, but not required, to develop standard formats for practitioner's orders for radiologic services that clearly document the diagnostic or therapeutic purpose of the study/procedure, as well as any other pertinent information that may lead to altering the dose of radiation, including, but not limited to: ▪ Indication (reason) for the study/procedure. ▪ Previous imaging studies of the body part(s) under investigation. ▪ Additional relevant radiation exposure. ▪ Previous adverse events (e.g., over- or underexposure of dosing, allergic reaction to contrast dye) during radiologic procedures. In addition, hospitals are encouraged to adopt policies to ensure that the radiation technologist performing the study/procedure confirms the order with the ordering practitioner if there are any concerns about its appropriateness.	that there is an order for all radiologic services, and that the order was dated/timed and authenticated by an authorized practitioner prior to the diagnostic study or therapeutic procedure being performed. ▪ Observe whether a radiologic technologist confirms that there is an order from an authorized practitioner and reviews information included in the order before beginning a study or procedure.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
19.00.07 Physicist inspections	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
A radiation physicist, or equivalent, conducts inspections to identify hazards. Equipment is maintained in a safe manner.	Equipment is included on a regular preventive maintenance schedule. At least annual equipment inspections are conducted. The findings from inspections are corrected promptly. The procedures for compliance with regulatory agencies are to be approved at least annually by the physicist or regulatory agency authority. The physicist is to monitor doses administered to patients; validity and quantitative results; and absorbed doses of radiation in individual patients (as requested by the director).	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ That a physicist or regulatory agency authority has inspected the facility at periods no more than 12 months apart. ▪ Hazards were corrected immediately. ▪ Preventive maintenance schedules for equipment.
19.00.08 Equipment output monitoring	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
All radiation producing equipment emits radiation within acceptable limits. The output of this equipment is measured at least annually. Records of the radiation output are maintained.	Each radiation producing equipment is monitored for the level of radiation it emits at various settings; it is to be within acceptable limits, at least annually.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Verify that equipment emission/ output testing is documented for each piece of equipment under 19.00.07.
19.00.09 Approval of policies and procedures	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
All radiation safety policies and procedures are approved by the radiation safety committee. §482.26(c)	The radiation safety committee reviews and approves all policies within the organization relating to radiation safety at least every three years.	**DOCUMENT REVIEW** ▪ Verify that the policies and procedures have received approval from the radiation safety committee within the past three years.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
19.00.10 Personnel	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
§482.26(c)	The hospital must ensure that specific radiology personnel requirements are met.	**Note:** Score based on the results of scoring standards 19.00.11 & 19.00.13.
19.00.11 Medical supervision	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
A qualified full-time, part-time, or consulting radiologist must supervise the ionizing radiology services and must interpret only those radiologic tests that are determined by the medical staff to require a radiologist's specialized knowledge. *For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.* *§482.26(c)(1)*	The regulation defines a radiologist as an MD or DO who is qualified by education and experience in radiology. The medical staff must establish the specific criteria related to education and experience that must be met in order to be privileged as a radiologist in the hospital. **IONIZING RADIOLOGIC SERVICES** Ionizing radiologic services offered throughout the hospital must be under the supervision of a radiologist, who may be part-time, full-time, or consulting. This may be accomplished in several ways, including: ▪ By having one organized radiologic service under the direction of the supervising radiologist, OR ▪ By the governing body ensuring a uniform approach to ionizing radiologic services that are offered in multiple, separately organized departments of the hospital which collaborate with the supervising radiologist in developing their department-specific protocols for ensuring that these services are free from hazards for patients and personnel. The supervising radiologist, including, if applicable, a consultant who provides such supervision, must be privileged as a radiologist at the hospital. The extent of radiologic services provided by the hospital determines whether the	**INTERVIEW AND DOCUMENT REVIEW** ▪ Review the medical staff privileging criteria for a radiologist. ▪ Review the credentialing and privileging file of the supervising radiologist to verify that he or she meets the qualifications established by the medical staff and has been granted privileges as a radiologist. □ If the supervising radiologist is a part-time employee or consultant, ask him/her how much time/week is spent on supervising ionizing radiologic services. □ Is there any evidence of problems within the radiologic services that suggest lack of supervision? ▪ Determine whether the medical staff has reviewed and approved a policy identifying the types of diagnostic radiologic tests (studies) that require

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	supervising radiologist must carry out these responsibilities full or part-time. **POLICY** For diagnostic radiologic services using ionizing radiation, policies and procedures must, in addition to the requirements addressed in other portions of the radiologic services CoP, identify which types of radiologic tests require interpretation by a radiologist, as opposed to another type of practitioner holding privileges; the hospital's medical staff must approve this policy. **TELERADIOLOGY** When interpretation of radiologic tests (studies) is provided via telemedicine, the radiologist interpreting the radiological test must be licensed and/or meet the other applicable standards that are required by State or local laws in the state where the hospital (and, therefore, the patient) is located. The requirements concerning granting of privileges to teleradiologists are addressed in the medical staff (42 CFR §482.22) and governing body (42 CFR §482.12) CoP. The radiology director shall be: ▪ Knowledgeable of imaging and therapy service practices in order to lead and advise those providing and requesting services ▪ A member of the professional medical staff who maintains regular contact with administration and participates in Medical Staff activities. Supervision of the radiology services may only be performed by a radiologist who is a member of the medical staff. Supervision should include at least the following: 1. Ensuring that radiology reports are signed by the practitioner who interpreted them. 2. Assigning duties to radiology personnel appropriate to their level of training, experience, and licensure if applicable. 3. Enforcing infection control standards.	interpretation by a radiologist.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	4. Ensuring that emergency care is provided to patients who experience an adverse reaction to diagnostic agents in the radiology service. 5. Ensuring that files, scans, and other image records are kept in a secure area and are readily retrievable. 6. Training radiology staff on how to operate the equipment safely, perform tests offered by the facility and on the management of emergency radiation hazards and accidents.	
19.00.12 Personnel requirements The qualifications, training, functions, and responsibilities of imaging and therapy personnel are specified by the service director and approved by the physician director of the service.	☐ Compliant ☐ Not Compliant Professional criteria, Federal and State regulations (and licensing acts) guide the requirements for staff. A radiologic technologist (therapist, if appropriate) is on duty, or available "on call" at all times.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Determine that facility standards of practice for staff correlate to the listed guidelines. ▪ Determine that a technologist/ therapist is available to accomplish requested tests and needed procedures. ▪ Verify through review of employee files that the qualifications, training, functions and responsibilities for each staff member are defined and reflected in the file.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
19.00.13 Qualified personnel *Only personnel designated as qualified by the medical staff may use the radiological equipment and administer procedures.* §482.26(c)(2)	☐ Compliant ☐ Not Compliant The medical staff must develop policies, consistent with State law, that govern the designation of all personnel who are qualified to use the radiologic equipment and perform diagnostic or therapeutic studies or procedures. Qualifications must include appropriate training and demonstrated competence in the use of equipment and administration of procedures prior to being designated as qualified. Only designated individuals may use the equipment and perform studies or procedures. There should be written policies, developed and approved by the medical staff, consistent with State law, to designate which personnel are qualified to use the radiological equipment and administer procedures. The use of the radiologic equipment includes, but is not limited to, functions such as operating the equipment according to the manufacturer's instructions and hospital policy, and interfacing with specialized technology as needed. In addition to a radiologist, and although not specifically mentioned in the regulations, radiologic technologists are typically involved in the delivery of radiologic services in a hospital. Radiologic technologists are medical personnel who typically perform diagnostic imaging examinations and administer radiation therapy treatments, as permitted under State law. They are educated in anatomy, patient positioning, examination techniques, equipment protocols, radiation safety, radiation protection, and basic patient care. All radiologic technologists using radiologic equipment or performing studies/procedures must be designated to do so. Personnel also need to know how to respond to adverse events that may occur during a radiologic study or procedure.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Verify that the medical staff established criteria for personnel who use radiologic services equipment and perform studies or procedures. ▪ Determine which staff are using which pieces of radiological equipment. Review their personnel folders to determine if they meet the qualifications established by the medical staff for the tasks they perform. ▪ Verify that radiologic services staff are periodically trained and reassessed for competence to ensure that they are operating the equipment according to manufacturer instructions and hospital policy and know how to respond to adverse events related to their use of the equipment.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Hospitals are expected to regularly reassess staff competency and to provide periodic training needed to keep staff skills up-to-date. The hospital must document training completion dates and evidence of satisfactory competence. Staff that complete training but cannot demonstrate satisfactory competence must not be permitted to use radiologic equipment and/or administer procedures.	
19.00.14 Order requirement Each request for imaging services shall contain the reason(s) for the examination	☐ Compliant ☐ Not Compliant The order for an imaging examination shall include the pertinent reason(s) for conducting the procedure to ensure the proper services are provided.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review requests in radiology services to verify compliance; review other records as necessary.
19.00.15 Record maintenance *Records of radiologic services must be maintained.* *(1) The radiologist or other practitioner who performs radiology services must sign reports of his or her interpretations.* *(2) The hospital must maintain the following for at least 5 years:* (i) *Copies of reports and printouts.* (ii) *Films, scans, and other image records, as appropriate.* §482.26(d)	☐ Compliant ☐ Not Compliant The hospital must maintain records for all radiologic procedures performed. At a minimum, the records must include: 1. The orders for the services, 2. Copies of reports and printouts, and 3. Any films, scans, digital or other image records, as appropriate. Radiology films, image records, scans, digital files, reports, and printouts must be secure and properly stored for at least five years. If State law requires a longer period, the hospital must comply, but surveyors do not assess compliance with State law requirements as part of the Federal survey. Patient radiologic services records are considered patient medical records and the hospital must comply with the requirements of the medical records CoP	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the medical record storage and security standards for all radiology reports and films comply with those defined in Chapter 10, Medical Records Services. ▪ Determine whether the hospital maintains radiologic services records for at least 5 years after the study or procedure. (Assess them for compliance with the Medical Records CoP at §482.24 at the same time, but

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.26(d)(1) §482.26(d)(2) §482.26(d)(2)(i) §482.26(d)(2)(ii)	(§482.24). The standards in Chapter 10, Medical Records Services also apply. All reports of studies must be signed by the radiologist or other authorized practitioner (in the case of studies not designated as requiring a radiologist to interpret them) who reads and evaluates the findings of the study. Acceptable forms of signature include paper signatures as well as electronic signatures. The hospital should have written policies and procedures that ensure the integrity of authentication and protect the privacy of radiology records.	make sure to cite general medical record noncompliance under that CoP.) ▪ Request records for all different imaging modalities furnished by the hospital, to determine if the procedure for maintaining the records is consistent among all the radiologic services. ▪ Review radiologic records to determine that reports of studies are signed by the radiologist or other authorized practitioner (in the case of studies not designated as requiring a radiologist to interpret them) who read and evaluated the findings of the study.
19.00.16 <u>For future use</u>		
19.00.17 <u>Qualified physicians</u> Interpretations of imaging/therapy procedures are performed only by a qualified individual with Medical Staff delineated clinical privileges for such.	☐ Compliant ☐ Not Compliant Only individuals who have demonstrated their qualifications are granted the authority to interpret diagnostic studies or perform therapeutic procedures. The author authenticates reports.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Determine that individuals who interpret imaging examinations or perform therapeutic procedures have been granted delineated privileges for such.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

19.00.18 Contrast media

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The organization will utilize validated protocols to evaluate patients who are at risk for contrast media-induced renal failure and utilize a clinically appropriate method for reducing risk of renal injury based on the patient's kidney function evaluation.

Requirements to meet standard compliance are as follows:

1. Explicit organizational policies and procedures should be in place regarding the prevention of contrast media-induced nephropathy.
2. Ensure that the patient undergoing IV contrast procedures is hydrated sufficiently according to standard protocol.

Implementation approaches to be considered are as follows:

1. Check the serum creatinine level prior to scheduling a contrast study in a patient who has uncertain kidney function.
2. Use low osmolar contrast media to prevent contrast media-induced renal failure in a patient with impaired renal function.

Many radiologic procedures utilize iodine-containing contrast media. Adverse events resulting from the intravenous administration of contrast dye include allergic reactions, anaphylaxis, and kidney damage.

Contrast media-induced renal failure rarely occurs in patients with normal kidney function, but patients with pre-existing renal insufficiency or other conditions (e.g., diabetic nephropathy, dehydration, congestive heart failure, or concurrent administration of nephrotoxic drugs) are at risk for renal failure when given iodine-containing contrast media.

Screening protocols have been developed to identify patients who need baseline kidney function assessment (e.g., serum creatinine testing) and risk-reduction precautions such as the use of low osmolar contrast media.

DOCUMENT REVIEW

- Review organizational policies on the prevention of contrast media-induced nephropathy to validate that it defines the risk-assessment process and defines the method utilized for risk-reduction.
- Review a sampling of patient records. Determine the following are available:
  - ☐ Documentation of the assessment of risk for contrast media-induced renal failure; and
  - ☐ Implementation of risk reduction interventions.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
19.00.19 For future use		
19.00.20 Labeling of radiographs The organization has implemented a standardized protocol to prevent the mislabeling of radiographs. Minimally, the protocol includes: ▪ Flash/marking of x-ray images with the correct patient information in the darkroom (if applicable). Mark "left" or "right" on each radiographic image to prevent misinterpretation on the light box.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the facility has a protocol addressing all required elements. Review the protocol for compliance. ▪ Observe the process to validate implementation.

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EMERGENCY SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
EMERGENCY SERVICES DEPARTMENT The provision of emergency services is an optional service for Medicare participation but may be required by state law or regulation or the state's hospital licensing requirements.		If the facility does not have an emergency department, score provision of emergency services for patients in Chapter 1, Administration of the Organizational Environment, Standards 01.02.01 through 01.02.04.
20.00.00 CONDITION OF PARTICIPATION: Emergency Services *The hospital must meet the emergency needs of patients in accordance with acceptable standards of practice.* §482.55	☐ Compliant ☐ Not Compliant The hospital must meet the emergency needs of its patients in accordance with 482.12(f) even if it chooses not to provide emergency services in a dedicated emergency department. If the hospital provides emergency services, the hospital must comply with all the requirements of this Condition of Participation and provide those services in accordance with acceptable standards of practice. The hospital's emergency services must be integrated into the hospital-wide QAPI program. The facility written plan for the provision of care and services identifies the level of emergency services provided. This usually is patterned after Federal or State guidelines for "trauma" designations. Facilities which offer specialty services only, and very small - isolated facilities may opt to list their level of emergency service as "triage, stabilize and transport" providing only very basic levels of emergency care.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ The facility statements regarding scope of service identify/classify the level of emergency services to be provided. ▪ The hospital's emergency services are integrated into the hospital-wide QAPI program. If this Condition is identified as out of compliance, standard 01.02.01 or 01.02.03 and/or 01.02.04 related to the provision of emergency services also must be scored Not Compliant.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
20.00.01 Medical staff leadership	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
If emergency services are provided at the hospital, ▪ *The services must be organized under the direction of a qualified member of the Medical Staff.* §482.55(a) §482.55(a)(1)	If emergency services are provided at the hospital, the hospital must ensure that specific emergency services organization and direction requirements are met. The hospital's emergency services must be under the direction of a qualified member of the hospital's medical staff. The hospital's medical staff establishes criteria for the qualifications for the director of the hospital's emergency services in accordance with state law and acceptable standards of practice. A single emergency services director must be responsible for the hospital's emergency services.	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Emergency services are organized under the direction of a qualified member of the medical staff. ▪ The medical staff has established the qualifications for the emergency services director. ▪ A single physician member of the medical staff has been designated as director of the Emergency Service.
20.00.02 Integration	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
If emergency services are provided at the hospital, ▪ *The services must be integrated with other departments of the hospital.* §482.55(a)(2)	The hospital's emergency service/department must be integrated with the other departments of the hospital such as surgical services, lab, ICU, diagnostic services, etc. The hospital must demonstrate that its emergency services are truly integrated into its other departments. The integration must be such that the hospital can immediately make available the full extent of its patient care resources to assess and render appropriate care for an emergency patient. Emergency Services integration would include, at a minimum: ▪ Coordination and communication between the emergency department and other hospital services/departments. ▪ Physical access for emergency department patients to the services,	**INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that there are established procedures to assure integration with hospital services, including laboratory, radiology, and operating services to provide continuity of care.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

equipment, personnel, and resources of other hospital departments/services.

- The immediate availability of services, equipment, personnel, and resources of other hospital departments/services to emergency patients.
- That the provision of services, equipment, personnel, and resources of other hospital departments/services to emergency patients is within time frames that protect the health and safety of patients and is within acceptable standards of practice, including:
  - The length of time is takes to transport the emergency patient from the ED to another hospital department where needed interventions or diagnostic services will be rendered.
  - The length of time it takes to deliver equipment or supplies, or for the staff from the other departments to travel from their location to the emergency department in order to provide needed interventions, tests, care, or services.

Time is critical in the provision of emergency care. The hospital must be able to demonstrate how the hospital's other departments provide emergency patients the care and services needed within safe and appropriate times.

In emergency care situations, the time needed to provide the patient with appropriate diagnostic and care interventions can have a significant effect on the patient. Delays in diagnosis and the provision of needed interventions is likely to adversely affect the health and safety of patients who require emergency care. Therefore, a hospital that cannot demonstrate integration of its emergency services with its other departments (including radiological services, OR, intensive care, laboratory, etc.) would not be in compliance with the Emergency Services CoP.

URGENT CARE SERVICES

Many hospitals offer urgent care services on the hospital campus or in provider-based clinics in the communities they serve. Those clinics must be in

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	compliance with the hospital CoP. Hospitals may organize their urgent care clinics as part of their outpatient department or emergency services department. An urgent care clinic would be evaluated for compliance with the integration requirement in the Outpatient Services CoP (442 CFR §482.54(a)) rather than the integration requirement in the Emergency Services CoP when: ▪ The hospital holds out to the public as providing only urgent care services and possibly other services. ▪ Clearly advises the public that the urgent care clinic is not an emergency services department. ▪ It does not meet the EMTALA definition of dedicated emergency department. In most urgent care situations, the time, qualified personnel, equipment, and other resources needed to provide the patient with appropriate diagnostic and care interventions are less than needed in emergency situations.	
20.00.03 Policies and procedures	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
If emergency services are provided at the hospital, ▪ *Policies and procedures governing medical care provided in the Emergency Service are established by and are a continuing responsibility of the Medical Staff.* §482.55(a)(3)	The hospital's medical staff must establish policies and procedures governing the medical care provided in the emergency service or emergency department. The medical staff must have had ongoing/continuing assessment of the medical care provided in the emergency service or department. Emergency service or emergency department policies must be current and revised as necessary based on the ongoing monitoring conducted by the medical staff and the emergency service or department QAPI activities. These policies and procedures are developed in collaboration with the nursing staff assigned to the service. Emergency Service policies and procedures comply with federal, state and local laws and are reflective of current guide-	**DOCUMENT REVIEW** Verify: ▪ Policies and procedures for emergency medical services (including triage of patients) are established, evaluated, and updated on an ongoing basis. ▪ The emergency service maintains a current manual of Policies and Procedures, which have been collaboratively developed, established,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	lines for trauma and crises practices as promulgated by emergency medical and nursing organizations.	evaluated, updated, and approved by the professional medical staff. ▪ The policies have been approved by the medical staff within the last three years.
20.00.04 Required policies and procedures The Emergency Services policies address, at a minimum: 1. The mechanism for initial evaluation and triage of patients. (See §489.20 and §489.24 for EMTALA Standards.) 2. The mechanisms for providing sufficient diagnostic and stabilization services for persons whose care will be managed by transfer to another acute care facility 3. The determination. of the level of service to be provided is under the direction of a physician member of the staff. 4. The assessment of each patient by a registered nurse. 5. The provision of services appropriate to the assessed needs of the patient, which results in a disposition plan. 6. The mechanisms for evaluating the quality and appropriateness of emergency services provided.	☐ Compliant ☐ Not Compliant No patient is denied access to evaluation and care based upon inability to pay. Most of the required policies are straightforward. Note that item #5 may be inclusive of services which are impacted by federal, state, or local laws; that is, persons presenting with alleged/suspected abuse, neglect, violence, animal bites, industrial injury, burns, etc., which require mandated reporting and collection/preservation of evidence. Determine that there is a mechanism for patient encounter reviews. The process includes: ▪ Persons (including visitors) presenting at an area of a hospital on the hospital's main campus other than a dedicated ED must receive a Medical Screening Exam (MSE) only if they request, or have a request made on their behalf, for examination or treatment for what may be an Emergency Medical Condition (EMC). ▪ Where there is no verbal request, a request will nevertheless be considered to exist if a prudent layperson observer would conclude, based on the person's appearance or behavior, that the person needs emergency examination or treatment.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ Policies address the eight requirements of the standard. ▪ There is a policy which defines the process to evaluate and conduct a medical screening examination (MSE) in non-ED main campus locations. ▪ There is compliance with all required policies.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

7. Provision of care for disasters.
8. The mechanism for management of medical emergencies in non-Emergency Department (ED) settings on the hospital main campus, unless present in a non-Emergency Services hospital policy.

20.00.05 Emergency services: Medical staff supervision

The hospital must ensure the emergency services personnel requirements are met.

The emergency services must be supervised by a qualified member of the medical staff.

§482.55(b)
§482.55(b)(1)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

A qualified member of the medical staff must supervise the provision of emergency services.

Since 42 CFR §482.55(a)(1) requires that emergency services must be organized under the direction of a qualified member of the medical staff, the requirement for supervision at 42 CFR §482.55(b)(1) must be distinguished from the prior requirement.

- In this context, "supervision" implies a more immediate form of oversight by a qualified member of the medical staff during all times the hospital makes emergency services available.
- A supervisor may be briefly absent from the emergency department but is expected to be in the hospital and immediately available to provide direction and/or direct care during the operating hours of the emergency department.

The medical staff must establish criteria, in accordance with State law, regulations, and guidelines, delineating the qualifications a medical staff member must possess to be granted privileges for the supervision of the provision of emergency care services.

Qualifications include necessary education, experience, and specialized

DOCUMENT REVIEW

Verify:

- A qualified member of the medical staff is designated to supervise emergency services.
- A qualified member of the medical staff is physically present in the ED and available to supervise the provision of services at all times the hospital offers emergency services.
- The medical staff has established qualifications for medical staff to be granted privileges for the supervision of emergency care services.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

training, consistent with state law and acceptable standards of practice.

20.00.06 Personnel: Staffing and staff qualifications

There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

§482.55(b)(2)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must staff the emergency department with the appropriate numbers and types of professionals and other staff who possess the skills, education, certifications, specialized training, and experience in emergency care to meet the written emergency procedures and needs anticipated by the facility.

The hospital must determine the categories and numbers of MD/DOs, specialists, RNs, EMTs and emergency department support staff the hospital needs to meet its anticipated emergency needs.

The medical staff must establish criteria, in accordance with State law and regulations and acceptable standards of practice delineating the qualifications required for each category of emergency services staff (e.g., emergency physicians, specialist MD/DO, RNs, EMTs, mid-level practitioners, etc.).

As a suggested practice the hospital should conduct periodic assessments of its emergency needs to anticipate the policies, procedures, staffing, training, and other resources that may be needed to address likely demands.

Additionally, the hospital should work cooperatively with Federal, State, and local emergency preparedness agencies and officials to identify likely risks to the community (e.g., natural disasters, mass casualties, terrorist acts, etc.), to anticipate demands and resources needed by the hospital emergency services, and to develop plans, methods and coordinating networks to address those anticipated needs.

Medical staff policies define coverage of the service, either by call back or by coverage; this may be by physicians who are contracted. In any case, there are specific delineations for emergency practices for all staff providing care

INTERVIEW AND DOCUMENT REVIEW

- Verify that there are enough medical and nursing personnel qualified in the needs anticipated by the facility. There are specific duties assigned for emergency care personnel and a clear chain of command.
- Interview staff to determine that they are knowledgeable, within their own level of participation in emergency care including:
  - □ Parenteral administration of electrolytes, fluids, blood, and blood components.
  - □ Care and management of injuries to extremities and central nervous system.
  - □ Prevention of contamination and cross infection.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	and services. Depending upon the case load and complexity of the service, nursing staff may be assigned to the service or may be "on call" from another area; in any event, each patient presenting for service has his/her emergency nursing needs planned and supervised by a registered nurse.	
20.00.07 Staff training Staff providing emergency services have training and experience in providing care to the types of patients anticipated by the facility. At a minimum, staff are competent in accomplishing rapid assessment and developing intervention plans, as appropriate to the facility mission, for emergencies relating to: ▪ Cardiac crises ▪ Obstetric/gynecologic crises ▪ Orthopedic/neurologic crises ▪ Endocrine crises ▪ Psychiatric crises ▪ Substance abuse ▪ Childhood diseases and conditions ▪ Trauma: highway, industrial, school, domestic	☐ Compliant ☐ Not Compliant Staff orientation schedules and ongoing education programs are designed to enhance documented competencies appropriate to the level of participation for each provider in the foci of care which is probable for the facility. Staff competencies relate to: ▪ Triage. ▪ Parenteral administration of electrolytes, fluids, blood, and blood components. ▪ Care and management of injuries to the extremities and the central nervous system. ▪ Principles of asepsis and the reduction of potential cross infections. ▪ Cardio-pulmonary resuscitation. ▪ Emotional support and intervention to persons in crises situations.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify that: ▪ Medical and nursing staff have identified core competencies and mechanisms for enhancing these. ▪ Mechanisms have been established to evaluate ongoing competencies, such as by means of "skills" testing and/or certifications. ▪ Staff competency validation has been completed and is appropriate for the scope of services and type of patients served.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Epidemiologic crises
- Pain management

20.00.08 Records

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

There is a record for each patient presented for emergency services.

Specific issues to be addressed include:

- Onset and duration of entry complaint.
- Time and method of arrival.
- Triage status upon arrival.
- Treatment attempted prior to arrival.
- Assessment(s), problem list(s), plan(s).
- Testing results, and treatment rendered.
- Patient responses to treatment.
- Disposition of the case.
- Further care needs, with plan for same.
- Time and condition at discharge.

Multidisciplinary assessments and plans of care outline principles that apply to the emergency setting.

In addition to the assessment and medical record's principles, certain characteristics are unique to the Emergency Services record. The facility provides the necessary systems to record these data.

Emergency services records are copied, as appropriate, to the physician who will be providing follow-up care.

A discharge summary is required on all patient medical records, including outpatient records.

DOCUMENT REVIEW

Verify:

- The format for documenting emergency services care incorporates the principles noted in Chapter 10 Medical Records and those in this standard.
- A mechanism exists to provide legible and timely copies of emergency care records to the physician providing follow-up care.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
20.00.09 Emergency room log Permanent logs shall be maintained of persons seeking emergency care. These may be manual or electronic; periodically, electronic records are "backed up" to ensure the integrity of the information in the event of computer failure. The register provides data regarding: ▪ Date, time, and mode of arrival ▪ Age, sex, and name of patient ▪ Nature of complaint ▪ Name of physician responsible for care ▪ Brief description of services provided ▪ Disposition (treated/released, admitted to facility, transferred to another acute facility, or death in ER) ▪ Condition on discharge ▪ Time of discharge	☐ Compliant ☐ Not Compliant The data maintained in the permanent register of emergency care patients provides useful data to the facility for long range planning. Additionally, the data may be used in determining statistical sampling for quality and utilization management studies.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that a permanent register of emergency registrants exists and that all parameters are included. □ If the register is electronic, verify that the information is periodically backed up to preserve the integrity of the register from computer failure.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
20.00.10 Change in treatment plan log A separate log shall be maintained as part of the quality management program for the emergency service. The log provides information about patients whose initial treatment plan later required modification based upon significant variation in the final interpretation of radiographic, cardiographic, or laboratory findings.	☐ Compliant ☐ Not Compliant Maintenance of the treatment log is the responsibility of the physician director with the assistance of the emergency nurse manager. This log may be sequestered in the service area if such is requested by the facility Risk Manager.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the treatment log to verify that the three required recall situations (radiographic, cardiographic, and laboratory findings) are actively maintained with outcomes of such recalls noted (contact made/not made).

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21

DISCHARGE PLANNING

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

21.00.00 CONDITION OF PARTICIPATION: Discharge planning

The hospital must have an effective discharge planning process that focuses on the patient's goals and treatment preferences and includes the patient and his or her caregivers/support person(s) as active partners in the discharge planning for post-discharge care.

The discharge planning process and the discharge plan must be consistent with the patient's goals for care and his or her treatment preferences, ensure an effective transition of the patient from hospital to post-discharge care, and reduce the factors leading to preventable hospital readmissions.

The hospital's policies and procedures must be specified in writing.

§482.43

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

This CoP applies to all types of hospitals and requires all hospitals to conduct appropriate discharge planning activities for all inpatients. It applies to patients who are admitted to the hospital as inpatients. This CoP does not apply to patients who appear in a hospital emergency department but are not admitted as hospital inpatients.

Note: Hospitals should ensure their discharge practices comply with applicable Federal civil rights laws, which are not addressed in these standards.

Hospital discharge planning is a process that involves determining the appropriate post-hospital discharge destination for a patient; identifying what the patient requires for a smooth and safe transition from the hospital to his/her discharge destination; and beginning the process of meeting the patient's identified post-discharge needs.

Newer terminology, such as "transition planning" or "community care transitions" is preferred by some, since it moves away from a focus primarily on a patient's hospital stay to consideration of transitions among the multiple types of patient care settings that may be involved at various points in the treatment of a given patient. This approach recognizes the shared responsibility of health care professionals and facilities as well as patients and their support persons throughout the continuum of care, and the need to foster better communication among the various groups.

When the discharge planning process is well executed, and absent unavoidable complications or unrelated illness or injury, the patient continues to progress towards the goals of his/her plan of care after discharge. However, it is not uncommon in the current health care environment for patients to be discharged from inpatient hospital settings only to be readmitted within a short timeframe for a related condition. Some readmissions may not be avoidable. Some may be avoidable but are due to

DOCUMENT REVIEW

- Verify that the hospital has written policies and procedures for discharge planning.
- Evaluate compliance with each standard within the discharge planning CoP. Following standard practice, depending on the manner and degree of deficiencies identified related to specific discharge planning standards, determine whether deficiencies in one or more of these areas rises to the level of substantial, i.e., condition-level, noncompliance with this CoP.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

factors beyond the control of the hospital that discharged the patient. On the other hand, a poor discharge planning process may slow or complicate the patient's recovery, may lead to readmission to a hospital, or may even result in the patient's death.

Under the discharge planning CoP, hospitals are expected to employ a discharge planning process that improves the quality of care for patients and reduces the chances of readmission.

Under the regulation,

- hospitals are required to have a discharge planning process that applies to all inpatients.
- discharge planning is not required for outpatients.

The discharge planning CoP provides for a four-stage discharge planning process:

1. Screening all inpatients to determine which ones are at risk of adverse health consequences post-discharge if they lack discharge planning.
2. Evaluation of the post-discharge needs of inpatients identified in the first stage, or of inpatients who request an evaluation, or whose physician requests one.
3. Development of a discharge plan if indicated by the evaluation or at the request of the patient's physician.
4. Initiation of the implementation of the discharge plan prior to the discharge of an inpatient.

The hospital is required to specify in writing its discharge planning policies and procedures. The policies and procedures must address all the requirements of this chapter [42 CFR 482.43(a) – 482.43(c)]. The hospital must take steps to assure that its discharge planning policies and procedures are implemented consistently.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

The discharge planning CoP specifically addresses the role of the patient, or the patient's representative, by requiring the hospital to develop a discharge planning evaluation at the patient's request, and to discuss the evaluation and plan with the patient. This is consistent with standards 15.01.10 and 15.01.11 [42 CFR 482.13(b)(1) & (2)], that provide the patient has the right to participate in the development and implementation of his/her plan of care, and to make informed decisions regarding his/her care. Further, the specific discharge planning evaluation requirement to assess a patient's capability for post-discharge self-care requires the hospital, as needed, to actively solicit information not only from the patient or the patient's representative, but also from family/friends/support persons.

Note: While not a requirement, due to the increasing complexity of services offered in the outpatient setting, hospitals may wish to consider an abbreviated post-hospital planning process for certain categories of outpatients, such as patients discharge from observation services, same day surgery, and certain emergency department discharges.

21.00.01 Discharge planning process

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital's discharge planning process must identify, at an early stage of hospitalization, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.

If a hospital does not voluntarily adopt a policy of developing a discharge plan for every inpatient, then the hospital must evaluate all inpatients to identify those for whom the lack of an adequate discharge plan is likely to result in an adverse impact on the patient's health.

Note: For Information – Not Required/Not to be Cited

Given the high level of readmissions that hospitals experience, a hospital would be well advised to assume that every inpatient requires a discharge plan to reduce the risk of adverse health consequences post-discharge. Providing a discharge plan for every inpatient means the hospital avoids the problems that can result from a screening process that fails to predict adequately which patients need a discharge plan to

OBSERVATION AND DOCUMENT REVIEW

Determine whether hospital policy addresses identification, at an early stage of hospitalization, all patients who are likely to suffer adverse health consequences upon discharge or readmission if there is inadequate discharge planning.

□ In every inpatient unit surveyed is there evidence of timely screening to determine if a discharge planning

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

§482.43(a)

avoid adverse consequences.

This does not mean that every discharge plan will be equally detailed or complex; some may be comparatively simple, for example, focusing on clear instructions for self-care for patients whose post-care needs may be readily met in their home environment. Other patients may have complex needs for care after discharge.

It is common for many patients to be discharged with a need for numerous on-going services/therapies, such as intravenous (IV) medications, intensive physical and occupational therapy, remote monitoring, wound care, etc. The key is that the discharge plan must reflect a thorough evaluation of the patient's post hospital care needs and must address the needs identified.

While there is no single nationally-accepted tool or criteria for identifying those patients who require discharge planning, the following factors have been identified as important:

- the patient's functional status and cognitive ability.
- the type of post-hospital care the patient requires, and whether such care requires the services of health care professionals or facilities.
- the availability of the required post-hospital health care services to the patient.
- the availability and capability of family and/or friends to provide follow-up care in the home.

POLICIES AND PROCEDURES

For hospitals that do not develop a discharge plan for every inpatient, the hospital's discharge planning policies and procedures must document the criteria and screening process it uses to identify patients likely to need discharge planning, including the evidence or basis for the criteria and process. They must also identify which staff are responsible for carrying out

evaluation is needed? (Not applicable in hospitals that require a discharge planning evaluation for all inpatients.)

- Conduct discharge tracers for several open and closed inpatient records to determine:
  - □ When was the screening done to identify inpatients needing a discharge planning evaluation? **NOTE:** If the hospital conducts an evaluation for all inpatients, or if it documents in the medical record screening of an inpatient before or at time of admission, or at least 48 hours prior to discharge, it is in compliance.
  - □ For patients whose stay was less than 48 hours is there any evidence of a screening to determine if discharge planning was needed?
  - □ Can hospital staff demonstrate that the hospital's criteria and screening process for a discharge planning evaluation are correctly applied?
- For patients not initially identified as in need of a discharge plan, is there a process for updating this determination based on changes in the patient's condition or circumstances?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

the evaluation to identify patients likely to need discharge planning.

The identification of patients must be made at an early stage of the patient's hospitalization. This is necessary in order to allow time to complete discharge planning evaluations and develop appropriate discharge plans, for those patients who need them.

Ideally the identification process will be completed when the patient is admitted as an inpatient, or shortly thereafter. However, no citations will be made if the identification of patients likely to need discharge planning is completed at least 48 hours in advance of the patient's discharge and there is no evidence that the patient's discharge was delayed due to the hospital's failure to complete an appropriate discharge planning evaluation on a timely basis or that the patient was placed unnecessarily in a setting other than where he/she was admitted from primarily due to a delay in discharge planning.

For example, a delay in identification of a patient in need of discharge planning might result in discharging the patient to a nursing facility, because such placements can be arranged comparatively quickly, when the patient preferred to return home, and could have been supported in the home environment with arrangement of appropriate community services.

LESS THAN 48 HOURS STAY
If the patient's stay is less than 48 hours, hospitals must nevertheless ensure that they are screened so that, if needed, the discharge planning process is completed before the patient's discharge.

Changes in the patient's condition may warrant development of a discharge plan for a patient not identified during the initial screening process. The hospital's discharge planning policies and procedures must address how the staff responsible for discharge planning will be made aware of changes in a patient's condition that require a discharge planning evaluation.

If a patient is transferred to another hospital, any pertinent information concerning the identification of the patient's post-hospital needs should be in

- □ Does the discharge planning policy address changes in patient condition that would call for a discharge planning evaluation of patients not previously identified as in need of one?
- □ Are inpatient unit staff aware of how, when, and whom to notify of changes in the patient's clinical condition that might warrant a change in the discharge planning process?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	the patient's medical record that is transferred with the patient. The receiving hospital then becomes responsible for the discharge planning process for the patient.	
21.00.02 Discharge planning evaluation *A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-hospital services, including, but not limited to, hospice care services, post-hospital extended care services, home health services, and non-health care services and community-based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.* §482.43(a)(2)	☐ Compliant ☐ Not Compliant Unless the hospital has adopted a voluntary policy of developing an evaluation for every inpatient, the hospital must also have a process for making patients, including the patient's representative, and attending physicians aware that they may request a discharge planning evaluation, and that the hospital will perform an evaluation upon request. In contrast to the screening process, the evaluation entails a more detailed review of the individual patient's post-discharge needs to identify the specific areas that must be addressed in the discharge plan. The evaluation must consider the patient's likelihood of needing post-hospital services and the availability of such services. If neither the patient nor the patient's family or informal caregiver(s) are able to address all of the required care needs, then the evaluation must determine whether there are community-based services that are available to meet the patient's needs while allowing the patient to continue living at home. Such health care services include, but are not limited to: ▪ Home health, attendant care, and other community-based services. ▪ Hospice or palliative care. ▪ Respiratory therapy. ▪ Rehabilitation services (PT, OT, speech, etc.). ▪ End Stage Renal Dialysis services.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that hospital policy addresses processes to provide discharge planning evaluation to patients identified by admission screening, upon patient/family request, and upon request of the physician. □ In every unit with inpatient beds surveyed, is there evidence of discharge planning evaluation activities? ▪ Are staff members who are responsible for discharge planning evaluation correctly following the hospital's policies and procedures? ▪ If the hospital does not require a discharge planning evaluation for all inpatients: □ Does the hospital have a standard process for notifying patients, their representative, and physicians that they may request a discharge planning evaluation and that the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Pharmaceuticals and related supplies.
- Nutritional consultation/supplemental diets.
- Medical equipment and related supplies.

Services may also include those that are not traditional health care services, but which may be essential to a patient's ongoing ability to live in the community, including, but not limited to:

- Home and physical environment modifications.
- Transportation services.
- Meal services.
- Household services, such as housekeeping, shopping, etc.

Some of the information related to needed services will emerge from the required evaluation of the patient's ability to receive care in the home, either as self-care or provided by someone else. All patients, even those with a high capability for self-care, are likely to require some follow-up ambulatory health care services, e.g., a post-discharge appointment with their surgeon, specialist or primary care physician, or a series of appointments for physical or occupational therapy. Some patients might have more complex care needs which nevertheless may still be met in the home setting, depending on the specific clinical needs and the services available in the patient's community.

- For example, some patients require wound care that exceeds the capabilities of their family or others who act as informal caregivers. But they may be able to receive enough care in the home setting through a home health service if such services are available. Some patients with chronic conditions may prefer to remain in their home and would be able to do so using available community-based services, but also require financial supports, such as Medicaid-financed home and community-based waiver services. If such supports are not immediately available at the time of discharge while an application for waiver services is pending, the evaluation should consider the availability of other short term

hospital will conduct an evaluation upon request?

- □ Can discharge planning and unit nursing staff describe the process for a patient or the patient's representative to request a discharge planning evaluation?
- □ Interview patients and their representatives. If they say they were not aware they could request a discharge planning evaluation, can the hospital provide evidence they received notice of their right?
- □ Interview attending physicians to see if they are aware they can request a discharge planning evaluation. If they are not aware, can the hospital provide evidence of how they inform the medical staff about this?

- Review a sample of cases to determine if the discharge planning evaluation documents the patient's (or the patient's representatives) goals and preferences for post-discharge placement and care.
- Review a sample of cases to determine if the discharge planning evaluation includes an assessment of:
  - □ The patient's post-discharge care needs being met in the environment

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

supports that would allow the patient to be discharged home.

If the result of the evaluation is that the patient cannot receive required care if he/she returns to home, then an assessment must be made of options for transfer to another inpatient or residential health care facility that can address the patient's needs, including other types of hospitals, such as rehabilitation hospitals; skilled nursing facilities; assisted living facilities; nursing homes; or inpatient hospice facilities.

If prior to the hospital admission the patient was a resident in a facility that he or she wishes to return to, such as an assisted living or nursing facility or skilled nursing facility, the evaluation must address whether that facility has the capability to provide the post-hospital care required by the patient. The post-discharge care requirements may be different than the care that was previously provided. This requires dialogue and cooperation between hospitals and post-hospital care facilities in the area served by the hospital, as well as with the physicians who provide care to patients in either or both settings.

Long term care facilities often express concern that hospitals discharge patients to their facilities with care needs that exceed their care capabilities, necessitating sending the patient to the emergency department for care and possible readmission. On the other hand, hospitals often express concern that long term care facilities send patients to the emergency department with ambulatory care-sensitive conditions, i.e., conditions that either do not require an acute level of care, or which could have been prevented from escalating to an acute level had appropriate primary care been provided in a timely manner.

While hospitals cannot address these concerns in isolation, they are expected to be knowledgeable about the care capabilities of area long term care facilities and to factor this knowledge into the discharge planning evaluation.

CAPABILITIES OF COMMUNITY SERVICES

Hospitals are expected to have knowledge of the capabilities and capacities of

from which he/she entered the hospital.

- □ The patient's care needs immediately upon discharge, and whether those needs are expected to remain constant or lessen over time.
- □ The patient's insurance coverage (if applicable) and how that coverage might or might not provide for necessary services post-hospitalization.

- For patients admitted from home, does the evaluation include whether:
  - □ The patient can perform activities of daily living (personal hygiene and grooming, dressing and undressing, feeding, voluntary control over bowel and bladder, ambulation, etc.)?
  - □ The patient's or family/other support person's ability to provide self-care/care?
  - □ The patient's need for specialized medical equipment or home modification?

    If yes, did the evaluation include an assessment of whether the equipment is available or if the modifications can be made to safely discharge the patient to that

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

not only of long-term care facilities, but also of the various types of service providers in the area where most of the patients it serves receive post-hospital care, in order to develop a discharge plan that not only meets the patient's needs in theory, but also can be implemented.

- This includes knowledge of community services, as well as familiarity with available Medicaid home and community-based services (HCBS), since the State's Medicaid program plays a major role in supporting post-hospital care for many patients.

If the hospital is one with specialized services that attract a significant number of patients who will receive their post-hospital care in distant communities, the hospital is expected to take reasonable steps to identify the services that will be available to the patient.

Once the determination has been made that services will be necessary post-discharge, the team must then determine availability of those services or identify comparable substitutions. Included in the evaluation is coordination with insurers and other payors, including the State Medicaid agency, as necessary to ensure resources prescribed are approved and available.

Note: For Information – Not Required/Not to be Cited

Although not required under the regulations, hospitals would be advised to develop collaborative partnerships with post-hospital care providers to improve care transitions of care that might support better patient outcomes. This includes not only skilled nursing facilities and nursing facilities, but also providers of community-based services. For example, Centers for Independent Living (CIL) and Aging and Disability Resource Centers (ADRC) are resources for community-based services and housing available to persons with disabilities and older adults.

Hospitals can find local CIL's at http://www.ilru.org/html/publications/directory/index.html.

- The ability to pay out of pocket for services must also be discussed with

setting?

- If the patient or family/support person is unable to meet care needs or there are additional care needs above their capabilities, did the evaluation include an assessment of available community-based services to meet post-hospital needs?
- For patients admitted from a nursing facility, skilled nursing facility or assisted living facility did the evaluation assess whether the prior facility has the capability to provide necessary post-hospital services to the patient (i.e. is the same, higher, or lower level of care required and can those needs be met?)
  - □ If yes, is there any documentation that the patient's care needs fall within the capabilities of the facility?
- Are the results of the discharge planning evaluation documented in the medical record?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

the family or other support persons.

- Although hospitals are not expected to have definitive knowledge of the terms of any given patient's insurance coverage or eligibility for community-based services, or for Medicaid coverage, they are expected to have a general awareness of these matters and their impact on the patient's post-discharge needs and prospects for recovery. For example, if the patient is a Medicare beneficiary, the hospital is expected to be aware of Medicare coverage requirements for home health care or admission to a rehabilitation hospital, a skilled nursing facility, or a long-term care hospital, etc. and to make the beneficiary aware that they may have to pay out of pocket for services not meeting the coverage requirements.
- Similarly, for Medicaid, they should know coverage options for home health, attendant care, and long-term care services or have contacts at the State Medicaid agency that can assist with these issues. As noted above, hospitals are also expected to have knowledge of community resources to assist in arranging services. Some examples include Aging and Disability Resource Centers and Centers for Independent Living (see box above).

Standards for patients' rights include "the right to participate in the development and implementation of his or her plan of care" and CMS views discharge planning as part of the patient's plan of care). Related rights include "the right to make informed decisions regarding his/her care" and "...being involved in care planning and treatment."

- Accordingly, hospitals are expected to engage the patient, or the patient's representative, actively in the development of the discharge evaluation, not only as a source of information required for the assessment of self-care capabilities, but also to incorporate the patient's goals and preferences as much as possible into the evaluation.
- A patient's goals and preferences may be, in the hospital's view,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

unrealistic. Identifying divergent hospital and patient assessments of what is realistic enables a discussion of these differences and may result in an assessment and subsequent development of a discharge plan that has a better chance of successful implementation.

In general, the goal upon discharge is for a patient to be able to return to the setting in which they were living prior to admission. This may be the patient's home in the community or residence in a nursing home. In the case of transfer from another hospital, generally the preferred goal is to return the patient to the setting from which he/she presented to the transferring hospital.

The evaluation must consider what the patient's care needs will be immediately upon discharge, and whether those needs are expected to remain constant or lessen over time.

- If the patient was admitted from his/her private residence, the evaluation must include an assessment of whether the patient can address his/her care needs through self-care.
- The evaluation must include assessment of whether the patient will require specialized medical equipment or permanent physical modifications to the home, and the feasibility of acquiring the equipment or the modifications being made. If the patient is not able to provide some or all of the required self-care, the evaluation must also address whether the patient has family or friends available who are willing and able to provide the required care at the times it will be needed, or who could, if willing, be trained by the hospital sufficiently to provide the required care.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

21.00.03 Discharge plan developed or supervised by RN or social worker

Any discharge planning evaluation or discharge plan required under this paragraph must be developed by, or under the supervision of, registered nurse, social worker, or other appropriately qualified personnel.

§482.43(a)(5)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The patient's discharge planning evaluation must be developed by a registered nurse, a social worker, or by other appropriately qualified personnel, or by a person who is supervised by such personnel.

State law governs the qualifications required to be considered a registered nurse or a social worker.

The hospital's written discharge planning policies and procedures must specify the qualifications for personnel other than registered nurses or social workers who develop or supervise the development of the evaluation.

The qualifications must include such factors as previous experience in discharge planning, knowledge of clinical and social factors that affect the patient's functional status at discharge, knowledge of community resources to meet post-discharge clinical and social needs, and assessment skills.

All personnel performing or supervising discharge planning evaluations, including registered nurses and social workers, must have knowledge of clinical, social, insurance/financial and physical factors that must be considered when evaluating how a patient's expected post-discharge care needs can be met.

It is acceptable for a hospital to include new staff who may not have had previous discharge planning experience, but who are being trained to perform discharge planning duties and whose work is reviewed by qualified personnel.

INTERVIEW AND DOCUMENT REVIEW

- Review a sample of cases to verify that the discharge planning evaluation was developed by an RN, a social worker, or by other qualified personnel, as defined in the hospital discharge planning policies and procedures, or by someone they supervise. To assess this:
  - ☐ Review the hospital's written policy and procedure governing who is responsible for developing or supervising the development of the discharge planning evaluation.
  - ☐ Does the policy permit someone other than a RN or social worker to be responsible for developing or supervising such evaluations?

    If yes, does the policy specify the qualifications of the personnel other than a RN or social worker to perform this function?
- Determine which individual(s) is (are) responsible for developing or supervising discharge planning evaluations.
  - ☐ Review personnel files to verify that they are qualified and meet the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		hospital's criteria for developing/supervising the discharge planning evaluation. If they are not, are they supervised by an individual who is an RN, social worker or other staff qualified according to the hospital's policies who reviews their discharge planning evaluations before they are finalized? ▪ Ask personnel who supervise or develop discharge planning evaluations to give examples illustrating how they apply their knowledge of clinical, social, insurance/financial and physical factors when performing an evaluation.
21.00.04 Timeliness of evaluation *Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-hospital care will be made before discharge and to avoid unnecessary delays in discharge.* §482.43(a)(1)	☐ Compliant ☐ Not Compliant After a patient has been identified as needing an evaluation, or after a request for an evaluation has been made by the physician, patient and/or patient's representative, the evaluation must be completed timely. This means there must be sufficient time after completion to allow arrangements for post-hospital care to be made, without having to delay the patient's discharge in order to do so or requiring the patient to transfer to a different setting from where he/she was admitted from primarily due to the delay in making appropriate arrangements. ▪ The comparatively short average length of stay of a short-term acute care hospital inpatient necessitates prompt attention to patients' discharge	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that hospital policy addresses timely completion of the discharge planning evaluation. ▪ Review a sample of cases to verify that the discharge planning evaluation was completed on a timely basis to allow for appropriate arrangements to be made for post-hospital care and to avoid delays in discharge. In order to assess this:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	planning needs in that type of hospital. ▪ Failure to complete the evaluation in a timely manner could make it more difficult to implement the patient's final discharge plan, and/or may cause an unnecessary delay in the patient's discharge from the hospital. While other types of hospitals with a longer average length of stay may be able to complete the evaluation at a later point after admission, they too must complete it on a timely basis to avoid delays in discharge. Where a team approach is used by the hospital in developing the discharge planning evaluation, there must be a process to promote efficient collaboration among team members to complete the evaluation in a timely manner. Changes in patient condition throughout the hospitalization warrant adjustments to the discharge plan.	□ Determine when the discharge planning evaluation was initiated. If the evaluation was not begun within 24 hours of the request or identification of the need for an evaluation, ask why. □ Is there a pattern of delayed start or completion of the evaluation? If so, is the delay due to circumstances beyond the hospital's control (e.g., inability to reach the beneficiary's support person(s), continuing changes in the patient's condition) and/or is the delay due to the hospital's failure to develop timely discharge planning evaluations?
21.00.05 Documentation in the medical record *The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).* §482.43(a)(3)	☐ Compliant ☐ Not Compliant The hospital must include the discharge planning evaluation in the patient's medical record for it to guide the development of the patient's discharge plan. Timely placement of the evaluation in the medical record facilitates communication among members of the patient's healthcare team who should participate in a multidisciplinary process to develop and implement the discharge plan. The evaluation and subsequent planning process may be a continuous one and hospitals may choose not to divide the process into distinct documents. The results of the discharge planning evaluation must be discussed with the	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ Discharge planning evaluation results are included in the medical record. ▪ Discharge planning evaluation results are discussed with the patient or the patient's representative.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

patient or the patient's representative.

- Documentation of this communication must be included in the medical record, including if the patient rejects the results of the evaluation.
- It is not necessary for the hospital to obtain a signature from the patient (or the patient's representative, as applicable) documenting the discussion.

The patient or the patient's representative must be actively engaged in the development of the plan, so discussion of the evaluation results represents a continuation of this active engagement. It would not be appropriate for a hospital to conduct an evaluation without the participation of the patient or the patient's representative, and then present the results of the evaluation to the patient as a finished product, since this would place the patient in a passive position that is not consistent with the requirements of the patients' rights standards 15.01.10 through 15.01.12.

21.00.06 For future use

21.00.07 Physician's request for discharge planning

Upon the request of a patient's physician, the hospital must arrange for the development and initial implementation of a discharge plan for the patient.

§482.43(a)(4)

☐ Compliant ☐ Not Compliant

If a patient is not identified through the hospital's discharge planning evaluation process as requiring a discharge plan, the patient's physician may nevertheless request a discharge plan. The hospital must develop a discharge plan when requested to do so by the patient's physician.

If the hospital's policies and procedures call for a discharge plan for every hospital inpatient, then it is not necessary to include a separate provision in those policies requiring development of a plan upon physician request, since such a provision would be superfluous.

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

- Does the hospital have a standard process for notifying physicians that they may request a discharge plan evaluation and that the hospital will develop a plan upon request?
- Interview attending physicians to see if they are aware that they can request a discharge plan. If they are not, can the hospital provide evidence of how they

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		inform the medical staff about this?
21.00.08 For future use		
21.00.09 Re-evaluation of patient condition *The hospital's discharge planning process must require regular reevaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.* §482.43(a)(6)	☐ Compliant ☐ Not Compliant Changes in a patient's condition may warrant adjustments to the discharge plan. Hospitals must have in place either a routine reassessment of all plans or a process for triggering a reassessment of the patient's post-discharge needs, capabilities and discharge plan when significant changes in the patient's condition or available supports occur.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that policy addresses the reassessment of the discharge plan for changes in the patient's condition. ▪ Review a sample of cases to determine if any significant changes in the patient's condition were noted in the medical record that changed post-discharge needs, and if the discharge plan was updated accordingly. □ Ask staff responsible for discharge planning when and how they reassess a patient's discharge plan. If none of the records being reviewed suggest a need to revise the discharge plan, ask for one or more clinical records that document reassessment.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

21.00.10 Selection of a post-acute care provider

The hospital must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, SNF, IRF, or LTCH data on quality measures and data on resource use measures. The hospital must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

For those patients discharged home and referred for HHA services, or for those patients transferred to a SNF for post-hospital extended care services, or transferred to an IRF or LTCH for specialized hospital services, the following requirements apply, in addition to those set out at paragraphs (a) and (b) of this section:

(1) The hospital must include in the discharge plan a list of HHAs, SNFs, IRFs, or LTCHs that are available to the patient, that are participating in the Medicare program, and that serve the geographic area (as defined by the HHA) in which the patient resides, or in the case of a SNF, IRF, or LTCH, in

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must include a list of Medicare-participating home health agencies (HHAs) and skilled nursing facilities (SNFs) in the discharge plan for those patients for whom the plan indicates home health or post-hospital extended care services are required.

- "Extended care services" are defined as items or services furnished in a skilled nursing facility (SNF). SNFs included on the list must be located in a geographic area that the patient or patient's representative indicated he/she prefers.
- For Home Health Agencies (HHAs) the list must consist of Medicare-participating HHAs that have requested the hospital to be listed and which serve the geographic area where the patient lives. Hospitals may expect the HHA to define its geographic service area when it submits its request to be listed.

During the discharge planning process, the hospital must inform the patient of his/her freedom to choose among Medicare-participating post-hospital providers and must not direct the patient to specific provider(s) or otherwise limit which qualified providers the patient may choose among.

Hospitals have the flexibility either to develop their own lists or to print a list of skilled nursing facilities and home health agencies in the applicable geographic areas from the CMS websites, Nursing Home Compare (www.medicare.gov/NHcompare) and Home Health Compare **(**www.medicare.gov/homehealthcompare**).**

If hospitals develop their own lists, they are expected to update them at least annually.

Note: For Information – Not Required/Not to be Cited

Hospitals may also refer patients and their families to the Nursing Home Compare and Home Health Compare websites for additional information

DOCUMENT REVIEW

- Review a sample of cases of patients discharged to HHAs or SNFs to determine if, when applicable, the hospital provided the patient with lists of Medicare-participating HHAs or SNFs. In making this determination:
  - ☐ Is there documentation of a list of multiple HHAs or SNFs being provided (including electronically) to the patient?
  - ☐ If not, is there documentation for an acceptable rationale for providing only one option, e.g., the patient's home is included in the service area of only one Medicare-participating HHA that requested to be included on hospital lists, or there is only one Medicare-participating SNF in the area preferred by the patient?
- Ask to see examples of lists of HHAs and SNFs provided to patients prior to discharge.
- Ask the hospital if it has any disclosable financial interests in any HHA or SNF on its lists, or if an HHA or SNF has a disclosable financial interest in the hospital.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

the geographic area requested by the patient. HHAs must request to be listed by the hospital as available.

(i) This list must only be presented to patients for whom home health care post-hospital extended care services, SNF, IRF, or LTCH services are indicated and appropriate as determined by the discharge planning evaluation.

(ii) For patients enrolled in managed care organizations, the hospital must make the patient aware of the need to verify with their managed care organization which practitioners, providers or certified suppliers are in the managed care organization's network. If the hospital has information on which practitioners, providers or certified supplies are in the network of the patient's managed care organization, it must share this with the patient or the patient's representative.

(iii) The hospital must document in the patient's medical record that the list was presented to the patient or to the patient's

regarding Medicare-certified skilled nursing facilities and home health agencies, as well as Medicaid-participating nursing facilities.

The data on the Nursing Home Compare website include an overall performance rating, nursing home characteristics, performance on quality measures, inspection results, and nursing staff information.

Home Health Compare provides details about every Medicare-certified home health agency in the country. Included on the website are quality indicators such as managing daily activities, managing pain and treating symptoms, treating wounds and preventing pressure sores, preventing harm, and preventing unplanned hospital care.

The hospital might also refer the patient and their representatives to individual State agency websites, Long-Term Care Ombudsmen Program, Protection and Advocacy Organizations, Citizen Advocacy Groups, Area Agencies on Aging, Centers for Independent Living, and Aging and Disability Resource Centers for additional information on long term care facilities and other types of providers of post-hospital care. Having access to the information found at these sources may assist in the decision-making process regarding post-hospital care options.

If the patient is enrolled in a managed care insurance program that uses a network of exclusive or preferred providers, the hospital must make reasonable attempts, based on information from the insurer, to limit the list to HHAs and SNFs that participate in the insurer's network of providers.

If the hospital has a disclosable financial interest in an HHA or SNF on a patient's list, or an HHA or SNF on the list has a disclosable financial interest in the hospital, these facts must also be stated on the list provided to the patient. Surveyors are not expected to know the requirements for a disclosable financial interest under Part 420, Subpart C, but hospitals are expected to know and comply with these requirements, and to identify for the surveyor whether there are such disclosable financial interests between

- □ If yes, is this stated clearly on the lists?

- Interview staff members involved with the discharge planning process to describe how patient preferences are taken into account in the selection of post-hospital HHA or SNF services.
- Ask the hospital to identify current patients for whom HHA or SNF services are planned. Interview the patient or the patient's family to ask them:
  - □ Were they presented with a list of HHAs or SNFs, as applicable, to choose from?
  - □ Did the hospital emphasize their freedom of choice?
  - □ Did the hospital arrange for their referral/transfer to an HHA or SNF reflecting their preferences? If not, did the hospital explain why their choice was not feasible?
  - □ If applicable, were they made aware of disclosable financial interest?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
representative. *(2) The hospital, as part of the discharge planning process, must inform the patient or the patient's representative of their freedom to choose among participating Medicare providers and suppliers of post-discharge services and must, when possible, respect the patient's or the patient's representative's goals of care and treatment preferences, as well as other preferences they express. The hospital must not specify or otherwise limit the qualified providers or suppliers that are available to the patient.* *(3) The discharge plan must identify any HHA or SNF to which the patient is referred in which the hospital has a disclosable financial interest, as specified by the Secretary, and any HHA or SNF that has a disclosable financial interest in a hospital under Medicare. Financial interests that are disclosable under Medicare are determined in accordance with the provisions of part 420, subpart C, of this chapter.* §482.43(a)(8) §482.43(c)	the hospital and any specific HHAs or SNFs to which they refer/transfer patients. When the patient or the patient's family has expressed a preference, the hospital must attempt to arrange post-hospital care with an HHA or SNF, as applicable, which meets these preferences. If the hospital is unable to make the preferred arrangement, e.g., if there is no bed available in the preferred SNF, it must document the reason the patient's preference could not be fulfilled and must explain that reason to the patient.	

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

§482.43(c)(1)
§482.43(c)(1)(i-iii)
§482.43(c)(2-3)

21.00.11 Transmission of patient's necessary medical information

The hospital must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

§482.43(b)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must take steps to ensure that patients receive appropriate post-hospital care by arranging, as applicable, transfer to appropriate facilities or referrals to follow-up ambulatory care services.

"Appropriate facilities, agencies, or outpatient services" refers to entities such as:

- skilled nursing facilities
- nursing facilities
- home health agencies
- hospice agencies
- mental health agencies
- dialysis centers
- suppliers of durable medical equipment
- suppliers of physical and occupational therapy, physician offices, etc. which offer post-acute care services that address the patient's post-hospital needs identified in the patient's discharge planning evaluation.

The term does not refer to non-healthcare entities, but hospitals also are encouraged to make appropriate referrals to community-based resources that offer transportation, meal preparation, and other services that can play an essential role in the patient's successful recovery.

"Appropriate facilities" may also include other hospitals to which a patient is

DOCUMENT REVIEW

- Verify that hospital policy addresses transfer or referral of patients along with necessary medical information to appropriate facilities, agencies, or outpatient services, as needed.
- Review a sample of records for patients with a discharge plan who were discharged home to verify:
  - ☐ Necessary medical information was sent to a practitioner with which the patient has an established relationship prior to the first post-discharge appointment or within seven days of discharge, whichever comes first.
  - ☐ For patients without an established relationship with a practitioner, information was provided on potential primary care providers, such as health clinics, if available.
- For patients transferred to another inpatient facility, was necessary

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

transferred for follow-up care, such as:

- rehabilitation hospitals
- long term care hospitals
- even other short-term acute care hospitals.

Necessary medical information must be provided not only for patients being transferred, but also for those being discharged home, to make the patient's physician aware of the outcome of hospital treatment or follow-up care needs. This is particularly important since the increasing use of hospitalists in the inpatient hospital setting means the patient's physician may have had no interaction with the patient throughout the hospital stay.

When the hospital provides the patient's physician with necessary medical information promptly, among other things, this provides an opportunity for the patient's physician to discuss with the hospital care team changes to the patient's preadmission medication regimen or other elements of the post-discharge care plan about which the physician may have questions. Facilitating opportunities for such communication and dialogue enhances the likelihood of better patient outcomes after discharge.

The "medical information" that is necessary for the transfer or referral includes, but is not limited to:

1. Brief reason for hospitalization (or, if hospital policy requires a discharge summary for certain types of outpatient services, the reason for the encounter) and principal diagnosis.
2. Brief description of hospital course of treatment.
3. Patient's condition at discharge, including cognitive and functional status and social supports needed.
4. Medication list (reconciled to identify changes made during the patient's hospitalization) including prescription and over-the-counter medications and herbal. (Note, an actual list of medications needs to be included in the discharge information, not just a referral to an electronic list available

medical information ready at time of transfer and sent to the receiving facility with the patient?

- When applicable, there is documentation in the medical record of providing the results of tests, pending at time of discharge, to the patient and/or post-hospital provider of care?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

somewhere else in the medical record.)

5. List of allergies (including food as well as drug allergies) and drug interactions.
6. Pending laboratory work and test results, if applicable, including information on how the results will be furnished.
7. For transfer to other facilities,
   - □ A copy of the patient's advance directive, if the patient has one.
8. For patients discharged home:
   - □ Brief description of care instructions reflecting training provided to patient and/or family or other informal caregiver(s).
   - □ If applicable, list of all follow-up appointments with practitioners with which the patient has an established relationship and which were scheduled prior to discharge, including who the appointment is with, date and time.
   - □ If applicable, referrals to potential primary care providers, such as health clinics, if available, for patients with no established relationship with a practitioner.

The regulation requires transfer or referral "along" with necessary medical information.

- In the case of a patient being transferred to another inpatient or residential health care facility, the necessary information must accompany the patient to the facility.

In the case of a patient discharged home who is being referred for follow-up ambulatory care, the transmittal of the information to the patient's physician may take place up to seven days after discharge or prior to the first appointment for ambulatory care services that may have been scheduled, whichever comes first.

- If the patient's physician is not yet able to accept the information

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

electronically from the hospital, the hospital may provide the information to the patient with instructions to give this information to the physician at their next appointment.

Note: For Information – Not Required/Not to be Cited

Scheduling of follow-up appointments for ambulatory care services by the hospital prior to discharge has been found to be an effective tool to ensure prompt follow-up and reduce the likelihood of a preventable readmission. This follow-up visit shortly after discharge provides an opportunity for the patient to address any issues or concerns experienced after the inpatient stay.

It also provides an opportunity for the primary care physician or practitioner to review and reinforce the post-hospital plan of care with the patient, for rehabilitation therapy to begin in a timely manner, to clarify any concerns related to medication reconciliation or other adjustments to the patient's pre-hospital regimen, etc.

It is recognized that hospitals have certain constraints on their ability to accomplish patient transfers and referrals:

- They must operate within the constraints of their authority under State law.
- A patient may refuse transfer or referral.
- There may be financial barriers limiting a facility's, agency's, or ambulatory care service provider's willingness to accept the patient. In such cases the hospital does not have financial responsibility for the post-acute care services. However, hospitals are expected to be knowledgeable about resources available in their community to address such financial barriers, such as Medicaid services, availability of Federally Quality Health Centers, Area Agencies on Aging, etc., and to take steps to make those resources available to the patient. For example, in most States, hospitals work closely with the Medicaid program to expedite enrollment of patients eligible for Medicaid.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

21.00.12 Assess the discharge planning process

The hospital must assess its discharge planning process on a regular basis.

The assessment must include ongoing, periodic review of a representative sample of discharge plans, including those patients who were readmitted within 30 days of a previous admission, to ensure that the plans are responsive to patient post-discharge needs.

§482.43(a)(7)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must reassess the effectiveness of its discharge planning process on an ongoing basis. Since the QAPI CoP at **standard 12.00.00** [42 CFR §482.21] requires that the QAPI program be hospital-wide, the discharge planning reassessment process is considered an integral component of the overall hospital QAPI program.

The hospital must have a mechanism in place for ongoing reassessment of its discharge planning process.

- The reassessment process must include a review of discharge plans in closed medical records to determine whether they were responsive to the patient's post-discharge needs.
- One indicator of the effectiveness of the discharge plan is whether the discharge was followed by a preventable readmission.
- Accordingly, hospitals are expected to track their readmission rates and identify potentially preventable readmissions.

Typically, readmissions at 7, 15, 30 days, or even longer, after discharge are tracked by analysts studying readmissions to short-term acute care hospitals.

- Hospitals must choose at least one interval to track. Since there are National Quality Forum-endorsed readmissions measures that use a 30-day interval, and since such measures are permitted by law to be used by CMS for payment-related purposes, it might be prudent for a hospital to track its 30-day readmissions rate, but other intervals are permissible. It is understood that information on post-discharge admissions to other hospitals may not be readily available, but all hospitals are expected to track readmissions to their own facility, and to do so on an ongoing basis, i.e., at least quarterly. Hospitals are expected to document their methodology for tracking their readmissions rates.

INTERVIEW AND DOCUMENT REVIEW

- Review hospital policies and procedures to determine whether the discharge planning process is reassessed on an ongoing basis, i.e., at least quarterly.
- Does the hospital's discharge planning reassessment policy include tracking and analysis of readmissions?
  - □ Do staff know how to obtain data on readmissions that enables them to review the discharge plans for the initial admission?
  - □ Ask them to identify medical records for patients who were readmitted and to show you documentation of the review of the discharge planning process for the initial admission.
- Does the hospital QAPI program include an ongoing re-assessment of the discharge planning process including:
  - □ Rate of re-admissions?
  - □ The effectiveness of the discharge planning process for patient readmissions?
- Does the assessment of readmissions

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Once the hospital has identified potentially preventable readmissions, it is expected to conduct an in-depth review of the discharge planning process for a sample of such readmissions (at least 10% of potentially preventable readmissions, or 15 cases/quarter, whichever is larger is suggested but not required) in order to determine whether there was an appropriate discharge planning evaluation, discharge plan, and implementation of the discharge plan. ▪ Hospitals are also expected to follow up on trends identified through analysis of their readmissions, such as: □ a concentration of readmissions related to post-surgical infections. □ discharges from a particular service or unit. □ discharges to a particular extended care facility or home health agency. □ discharges with the same primary diagnosis on the first admission, etc. Such clustering or concentration may identify areas requiring more follow-up analysis and potential remedial actions. ▪ Having identified factors that contribute to preventable readmissions, hospitals are expected to revise their discharge planning and related processes to address these factors. ▪ Consistent with the requirements under the QAPI CoP, the hospital's governing body, medical leadership and administrative leadership are all expected to ensure that identified problems are addressed, with further ongoing reassessment to achieve improvement.	include an evaluation of whether the readmissions were potentially preventable? □ Is there evidence of in-depth analysis of a sample of discharge plans in cases where preventable readmissions were identified? □ Is there evidence that the hospital took action to address factors identified as contributing to preventable readmissions?
21.01.01 **For future use**		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
21.01.02 Discharge instructions The hospital must provide the inpatient or inpatient's representative with discharge instructions written in lay terminology at time of discharge. The discharge instructions must include the following elements: 1. Reason for hospitalization and condition at the time of discharge. 2. Medications to be taken after discharge including, resuming pre-admission medications, how and when to take medications, and how to obtain medications. 3. Complications which may occur and actions to take should these happen post-discharge. 4. A list of follow-up appointments for tests and clinic visits for the patient to make after discharge.	☐ Compliant ☐ Not Compliant Studies report that one in five hospitalizations is complicated by a post-discharge adverse event as patients are often unprepared for discharge or do not understand their medications. Factors that contribute to hospital readmission include, but are not limited to: ▪ Lack of a medication reconciliation resulting in unexplained medication discrepancies between pre-admission and post-discharge medication lists. ▪ Discharge medication prescription errors.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the medical record of recently discharged patients to ensure written discharge instructions contain the elements required.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
21.01.03 Discharge follow-up call The discharge process includes a telephone follow-up two to three days after discharge for patients identified to be at risk for adverse health consequences upon discharge.	☐ Compliant ☐ Not Compliant Hospital policy identifies those patients that may potentially benefit from a follow-up telephone call post discharge to avoid adverse health consequences or readmission. The medical staff approved discharge protocol should assign professionals qualified to conduct the discharge follow-up telephone call to the patient/ patient's representative. Staff placing the calls should be familiar with the patient's discharge plan. ▪ A script for the caller to use to identify conditions that require immediate evaluation, including a referral to the primary care physician or a return to the Emergency Department. The discharge planning policy identifies individuals qualified by education, title, experience, and training to perform the follow-up telephone calls. Often, a registered nurse, case manager, or a social worker is responsible for the follow-up telephone call. It is not mandatory that the bedside RN make the follow-up patient phone calls. However, this individual should be an RN with experience, knowledge, and training to recognize potentially emergent situations when speaking with the patient. As the follow-up call is an assessment of high-risk patients, it would not be appropriate to have a secretary, unit clerk, or pharmacy technician to conduct the discharge follow-up telephone call. Recognizing the high volume of patients that experience medication-related adverse drug events or readmissions, facilities may include a well-qualified clinical pharmacist to conduct medication counseling and reconciliation at time of discharge with a follow-up telephone call within 48 hours of discharge.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine whether hospital policy has identified: □ Patients at risk for adverse health consequences or readmission that potentially may benefit from a post-discharge telephone call; □ Persons "qualified" to conduct the discharge follow-up telephone call. ▪ Review the medical record to ensure attempts have been made to contact the patient two to three days post-discharge. It is appropriate to leave a generic message asking patient to return call when able. There should be documentation supporting this activity.

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22

LABORATORY SERVICES

INTRODUCTION

Each laboratory within a hospital and each lab service location or reference laboratory used by a hospital must be certified under the Clinical Laboratory Improvement Amendments (CLIA) [42 CFR §493].

The requirements listed below relate to the Medicare Conditions of Participation for Hospitals. They do not represent a full survey of Laboratory Services. HFAP offers a full laboratory accreditation program with deeming authority under CLIA. Contact us for additional information.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
22.00.00 CONDITION OF PARTICIPATION: Laboratory services - Scope of services	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients. *The hospital must ensure that all laboratory services provided to its patient are performed in a facility certified in accordance with* 42 CFR 493. §482.27	The hospital must maintain or have available laboratory services whenever its patients need those services. The hospital may make laboratory services available directly, through contractual agreements, or through a combination of direct and contractual services. The scope and complexity of the hospital laboratory service must be adequate to meet the needs of its patients. The hospital must maintain, or have available, adequate laboratory services to meet the needs of its patients at each campus or off-campus location of the hospital. All laboratory services, whether direct or contractual, whether conducted in a lab or in another location, must be provided in accordance with Clinical Laboratory Improvement Act (CLIA) requirements. Every hospital laboratory service must be operating under a current CLIA certificate appropriate to the level of services performed. The hospital's laboratory services, including any contracted services, must be integrated into its hospital-wide QAPI program. Patient laboratory results and all other laboratory clinical patient records are considered patient medical records and the hospital must comply with the requirements of the Medical Records CoP (Chapter 10).	**DOCUMENT REVIEW** ▪ Identify the total number of laboratories, the location of each laboratory, and every location where laboratory procedures are performed. ▪ Verify that the laboratory service and all laboratory locations are integrated into the hospital-wide QAPI program. ▪ If laboratory services are contracted, verify that the review of the quality of those services is integrated into the hospital-wide QAPI Program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
22.00.01 Accreditation/Certification of laboratory services	☐ Compliant ☐ Not Compliant Laboratory testing including Point of Care (POC) may be performed in the main laboratory, ancillary laboratories throughout the facility, or in areas such as respiratory therapy, cardiopulmonary, emergency room, intensive care units, and nursing units. The CLIA certification may be accomplished by having one certificate for the entire hospital's laboratory services, by having one certificate for each laboratory, or by the hospital having a mixture. Whatever the arrangement, all laboratory services must be provided in accordance with CLIA requirements and under a current CLIA certificate, even when those laboratory services take place outside of a lab.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify that each clinical area performing testing within the hospital, or reference laboratory used by the hospital, has been accredited/certified under 42 CFR §493 (CLIA). A CLIA certificate and proof of accreditation should evidence this. ▪ Determine which services are provided directly by the facility and which are provided through contractual agreements. ▪ Determine if the referral laboratory is CLIA-certified for the appropriate test specialty. ▪ If the hospital provides laboratory services in multiple locations, verify that all laboratory services are operating under a current CLIA certificate. ▪ Examine records and determine if the services, including emergency services, are provided in accordance with the hospital's policies.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

22.00.02 Emergency service availability

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Emergency laboratory services must be available 24 hours a day.

§482.27(a)(1)

The hospital must provide emergency laboratory services 24 hours a day, 7 days a week.

These onsite emergency services may be provided directly by the hospital or through onsite contracted laboratory services. Emergency lab services include collection, processing, and provision of results to meet a patient's emergency laboratory needs.

MULTIPLE HOSPITAL CAMPUSES
In a hospital with multiple hospital campuses, these emergency laboratory services must be available onsite 24/7 at each campus.

The medical staff must determine which laboratory services are to be immediately available to meet the emergency laboratory needs of patients who may be currently at the hospital or those patients who may arrive at the hospital in an emergency condition. The emergency laboratory services (procedures, tests, personnel) available should reflect the scope and complexity of the hospital's operation and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice.

OFF-CAMPUS LOCATIONS
At a hospital with off-campus locations the medical staff must determine which, if any, laboratory services must be immediately available to meet the emergency laboratory needs of the patients who are likely to seek care at each off-campus location.

The emergency laboratory services available must reflect the scope and complexity of the hospital's operations at the location and be provided in accordance with Federal and State law, regulations and guidelines and acceptable standards of practice.

INTERVIEW AND DOCUMENT REVIEW

- Identify the hours of availability for laboratory services.
  - □ Verify that emergency laboratory services are available onsite 24/7.
- Review the written description of the emergency laboratory services. Review records (including accession records, worksheets, and test reports) to verify the 24-hour availability of emergency services and that those services are provided when required.
  - □ Verify that the scope of required emergency testing onsite has been defined by the medical staff.
  - □ Is the scope of services available consistent with needs defined by the medical staff?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The services must be available during the hours of operation of that location.	
22.00.03 Laboratory services description	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
A written description of services provided must be available to the medical staff and other staff as appropriate. §482.27(a)(2)	The written description of available laboratory services is reviewed and approved by the medical staff at least every three years and more often, as necessary.	**OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Review the written description of the laboratory services provided, including those furnished on routine and stat basis (either directly or under an arrangement with an arrangement with an outside facility). □ The description should include turnaround time for test results and inclusion into the medical record. Availability of results must be timely and complete to provide accurate information to all practitioners providing care. □ Verify that the description of services is accurate and current. ▪ Verify that the written description is available to medical staff and unit-based staff.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
22.00.04 Tissue specimens *The laboratory must make provision for proper receipt and reporting of tissue specimens.* §482.27(a)(3)	☐ Compliant ☐ Not Compliant The laboratory must have written instructions for the collection, preservation, transportation, receipt, and reporting of tissue specimen results.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review tissue records (accession records, worksheets, and test reports) to determine whether the laboratory follows the written protocol.
22.00.05 Required tissue examination *The medical staff and a pathologist must determine which tissue specimens require a macroscopic (gross) examination and which require both macroscopic and microscopic examinations.* §482.27(a)(4)	☐ Compliant ☐ Not Compliant Laboratory written policies, approved by the medical staff and a pathologist, must identify: ▪ Tissue specimens that require a macroscopic examination. ▪ Tissue specimens that require both macroscopic and microscopic examination.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the hospital has a written policy for examination requirements. ▪ Review the written policies and tissue reports to assure that tissue specimens are examined in accordance with the written policies. ▪ Verify that the policies are in accordance with these requirements and other federal and state laws, regulations, and guidelines.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
22.01.01 Potentially infectious blood and blood components *(1) Potentially HIV infectious blood and blood components are prior collections from a donor –* *(i) Who tested negative at the time of donation but tests reactive for evidence of HIV infection on a later donation.* *(ii) Who tests positive on the supplemental (additional, follow-up testing required by FDA* *and* *(iii) For whom the timing of seroconversion cannot be precisely estimated.* *(2) Potentially hepatitis C virus (HCV) infectious blood and blood components are the blood and blood components identified in 21 CFR §610.47.* *(3) Services furnished by an outside blood collecting establishment.* *If a hospital regularly uses the services of an outside blood collecting establishment, it must have an agreement with the blood collecting establishment that governs the procurement, transfer, and availability of blood and blood components.*	☐ Compliant ☐ Not Compliant The intent of this regulation is that the hospital to have a system in place to take appropriate action when notified that blood or blood components it received are at increased risk of transmitting HIV or HCV.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the policy reflecting the process for handling HIV or HCV blood components to verify that the policy contains all the required content. ▪ Review the documentation following notification of an infectious unit. Was the policy followed?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

The agreement must require that the blood collecting establishment notify the hospital –

(i) Within three calendar days if the blood collecting establishment supplied blood and blood components collected from a donor who tested negative at the time of donation but tests reactive for evidence of HIV or HCV infection on a later donation or who is determined to be at increased risk for transmitting HIV or HCV infection.

(ii) Within 45 days of the test of the results of the supplemental (additional, more specific) test for HIV or HCV, as relevant, or other follow-up testing required by FDA.

(iii) Within three calendar days after the blood collecting establishment supplied blood and blood components collected from an infectious donor, whenever records are available, as set forth at 21CFR §610.48(b)(3).

(4) Quarantine of blood and blood components pending completion of testing.

If the blood collecting establishment

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(either internal or under an agreement) notifies the hospital of the reactive HIV or HCV screening test results, the hospital must determine the disposition of the blood or blood component and quarantine all blood and blood components from previous donations in inventory.

(i) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is negative, absent other informative test results, the hospital may release the blood and blood components from quarantine.

(ii) If the blood collecting establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is positive, the hospital must –

(A) Dispose of the blood and blood components; and

(B) Notify the transfusion recipients as set forth in paragraph (b)(6) of 42 CFR 482.27.

(iii) If the blood collecting

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

establishment notifies the hospital that the result of the supplemental (additional, more specific) test or other follow-up testing required by FDA is indeterminate, the hospital must destroy or label prior collections of blood or blood components held in quarantine as set forth at 21 CFR §610.46(b)(2), §610.47(b)(2), and §610.48(c)(2).

(5) Recordkeeping by the hospital. The hospital must maintain –

(i) Records of the source and disposition of all units of blood and blood components for at least 10 years from the date of disposition in a manner that permits prompt retrieval; and

(ii) A fully funded plan to transfer these records to another hospital or other entity if such hospital ceases operation for any reason.

(6) Patient notification.

If the hospital has administered potentially HIV or HCV infectious blood or blood components (either directly through its own blood collecting establishment or under an agreement) or released such blood or blood components to another entity or appropriate individual, the hospital

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

must take the following actions:

(i) Make reasonable attempts to notify the patient, or to notify the attending physician, or the physician who ordered the blood or blood component and ask the physician to notify the patient, or other individual as permitted under paragraph (b)(10) of this section, that potentially HIV or HCV infectious blood or blood components were transfused to the patient and that there may be a need for HIV or HCV testing and counseling.

(ii) If the physician is unavailable or declines to make the notification, make reasonable attempts to give this notification to the patient, legal guardian or relative.

(iii) Document in the patient's medical record the notification or attempts to give the required notification.

(7) Time frame for notification.

For donors tested on or after February 20, 2008.

For notifications resulting from donors tested on or after February 20, 2008 as set forth at 21 CFR §610.46 and 21 CFR §610.47 the notification effort begins when the blood collecting

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

establishment notifies the hospital that it received potentially HIV or HCV infectious blood and blood components. The hospital must make reasonable attempts to give notification over a period of 12 weeks unless—

(i) The patient is located and notified

or

(ii) The hospital is unable to locate the patient and documents in the patient's medical record the extenuating circumstances beyond the hospital's control that caused the notification timeframe to exceed 12 weeks.

(8) Content of notification.

The notification must include the following information:

(i) A basic explanation of the need for HIV or HCV testing and counseling.

(ii) Enough oral or written information so that an informed decision can be made about whether to obtain HIV or HCV testing and counseling.

(iii) A list of programs or places where the person can obtain HIV or HCV testing and counseling, including any requirements or restrictions

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

the program may impose.

(9) Policies and procedures.

The hospital must establish policies and procedures for notification and documentation that conform to Federal, State, and local laws, including requirements for the confidentiality of medical records and other patient information.

(10) Notification to legal representative or relative.

If the patient has been adjudged incompetent by a State court, the physician or hospital must notify a legal representative designated in accordance with State law.

If the patient is competent, but State law permits a legal representative or relative to receive the information on the patient's behalf, the physician or hospital must notify the patient or his or her legal representative or relative.

For possible HIV infectious transfusion recipients that are deceased, the physician or hospital must inform the deceased patient's legal representative or relative. If the patient is a minor, the parents or legal guardian must be notified.

§482.27(b)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
22.01.02 Exposure resulting in HIV conversion The laboratory has a written policy that identifies the procedure for reporting to public health officials when an HIV conversion is identified.	☐ Compliant ☐ Not Compliant Hospital policy outlines the procedure for notifying public health officials.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that a written policy exists. □ If such an incident occurred look for compliance with policies.
22.01.03 General blood safety issues *For look-back activities only related to new blood safety issues that are identified after August 24, 2007, hospitals must comply with FDA regulations as they pertain to blood safety issues in the following areas:* *(1) Appropriate testing and quarantining of infectious blood and blood components.* *(2) Notification and counseling of recipients that may have received infectious blood and blood components.* §482.27(c)(1) §482.27(c)(2)	☐ Compliant ☐ Not Compliant **LOOK-BACK REQUIREMENTS** The hospital must establish, maintain, and follow an appropriate system for the following actions: 1. All previously collected in-date blood and blood components that has tested reactive for evidence of HIV/HCV infection, except for pooled blood components intended solely for further manufacturing into products that are manufactured using validated clearance procedures, when notified by the collecting establishment, must be quarantined. 2. Release from quarantine, destroy, or relabel quarantined in-date blood and blood components consistent with the results of the supplemental (additional, more specific) test performed, or the results of the reactive screening test if there is no available supplemental test that is approved by, or if an IND or IDE, is exempted for such use by the FDA. 3. When the supplemental test for HIV/HCV is positive or when the screening test is reactive and there is no available supplemental test that is approved by, or if under an IND or IDE is exempted for such use by the FDA, you must notify transfusion recipients of previous collections of blood and blood components at increased risk of transmitting HIV/HCV infection, or the recipient's physician of record or a legal representative or relative if the recipient is a minor, deceased,	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review policies and procedures to determine an appropriate system for look-back requirements is in place. ▪ Verify the policy is followed. **Note**: Reference CFR §610.46 AND CFR §610.47 at: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=610.46

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	adjudged incompetent by a state court, or, if the recipient is competent but state law permits a legal representative or relative to receive information on behalf of the recipient. You must make reasonable attempts to perform the notification within 12 weeks after receiving the supplemental test results for evidence of HIV/HCV infection from the collecting establishment, or after receiving the donor's reactive screening test result for HIV/HCV.	
22.02.01 Point of care testing	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
When the facility performs blood gases or other laboratory tests in the respiratory care unit or any other unit in the facility, they shall meet the applicable requirements for the general laboratory services.	Other laboratory tests include any Point of Care (POC) test performed in any nursing or ancillary department.	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Determine whether the respiratory unit or other units in the facility are under the policies and review of the general laboratory manager or an individual designated by the medical director listed on the applicable CLIA certificate. ▪ Verify that all laboratory testing done outside the lab is overseen by the lab, and meets all requirements for competency testing, quality control, and monitoring.

23

NUCLEAR MEDICINE

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

23.00.00 CONDITION OF PARTICIPATION: Nuclear medicine services

If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.

§482.53

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

This is an optional hospital service.

If a hospital provides any degree of nuclear medicine services to its patients, **it** must comply with the requirements of this Condition of Participation.

If nuclear medicine services are provided under arrangement, the governing body must ensure that the services are provided in a safe and effective manner, per standard 01.01.22 [42 CFR §482.12(e)].

Acceptable standards of practice include maintaining compliance with applicable federal and state laws, regulations, and guidelines governing the use of nuclear medicine, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized professional organizations (e.g., the American Medical Association, American College of Radiology, etc.).

The hospital's nuclear medicine services must be integrated into its hospital-wide QAPI program.

WHAT IS NUCLEAR MEDICINE AND WHAT IS ITS USE?

Nuclear medicine uses radioactive material to diagnose or treat a variety of diseases and conditions.

DIAGNOSTIC NUCLEAR MEDICINE

When a diagnostic nuclear medicine study is performed, a patient inhales, swallows, or is injected with a small amount of a radiopharmaceutical that accumulates in a specific organ or area of the body. A radiopharmaceutical is a drug that contains a radioactive component. The energy emitted by the radioactive material is detected by a device, processed and measured by a computer, and then displayed as an image on a screen or on film that is then interpreted by a radiologist specially trained in nuclear medicine or another physician with specialized training as a nuclear medicine physician. The

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

Note: Score based on the aggregate results of scoring of the §482.53 standards and sub-standards in this chapter. The manner or degree of noncompliance with the requirements of this Condition and its component standards must be evaluated to determine whether noncompliance warrants a Condition-level citation.

Does the hospital provide nuclear medicine services? If yes, identify the type(s) of services and the location where each service is provided. Verify that:

- Appropriate equipment and types and numbers of qualified personnel furnish services consistent with the scope and accepted standards of practice.
- The organization has the required policies, procedures, documents, and practices to minimize hazards to patients and personnel.
- The organization has conducted inspections and testing, as required.
- Determine that the hospital's nuclear medicine services are integrated into the hospital-wide QAPI program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

image(s) provide details on both the structure and function of organs and tissues.

For some studies, nuclear medicine techniques are combined with other medical imaging devices, such as CT scans or MRIs, in which the same machine can deliver, detect, and process several types of images at the same time. The technique of combining various imaging modalities is called hybrid imaging. Hybrid imaging can provide more precise information and accurate diagnoses and is predominantly used in the diagnosis and treatment of cancer.

Nuclear medicine diagnostic imaging scans are commonly performed to:

- Visualize heart blood flow and function, e.g., a cardiac stress test or myocardial perfusion scan; this is the most frequent use of nuclear medicine diagnostic imaging.
- Diagnose blood clots in the lungs (pulmonary emboli) with a ventilation/perfusion (V/Q) scan.
- Identify areas of infection, inflammation, or cancer metastases with a bone scan.
- Localize lymph nodes prior to surgery.
- Determine gastrointestinal tract muscle function by measuring time for swallowing and emptying.
- Determine the functioning and perfusion of many other organs, including the thyroid gland, kidneys, brain, and gall bladder.

THERAPEUTIC NUCLEAR MEDICINE

Nuclear medicine can also be used to treat various diseases and conditions. For these types of procedures, a specific radiopharmaceutical agent is used to deliver a specific amount of radioactivity to a targeted cell type or organ. The energy emitted by the radioactive agent incapacitates or kills the diseased cells of that targeted tissue, and thus limits the exposure of healthy tissue to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

radioactivity.

Examples of therapies that use nuclear medicine include (but are not limited to):

- Radioactive iodine to treat hyperthyroidism (Graves' disease);
- Radioactive antibodies that target specific forms of lymphoma;
- Radioactive agents to relieve pain in areas of bony metastases.

23.00.01 Organization and staffing

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The organization of the nuclear medicine service must be appropriate to the scope and complexity of the services offered.

(1) There must be a director who is a doctor of medicine or osteopathy qualified in nuclear medicine.

(2) The qualifications, training, functions and responsibilities of the nuclear medicine personnel must be specified by the service director and approved by the medical staff.

§482.53(a)
§482.53(a)(1-2)

The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the services offered by the hospital in accordance with acceptable standards of practice.

The scope of nuclear medicine services offered by the hospital should be defined in writing and approved by the Medical staff.

The scope of nuclear medicine services offered by the hospital, including which types of diagnostic studies and/or therapeutic procedures are provided, where they are provided in the hospital, and the appropriately-trained staff and equipment needed to provide these services must be specified in writing.

Hospitals may choose to provide nuclear medicine services in one location or at several different locations in the hospital, including, but not limited to, inpatient and outpatient locations of the radiology, cardiology, and oncology departments. The organization of the nuclear medicine service must encompass the full scope and complexity of nuclear services offered throughout the hospital.

MEDICAL DIRECTOR FOR NUCLEAR MEDICINE

The hospital is required to have a director responsible for nuclear medicine

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

Review the hospital policies and procedures to verify that:

- The scope of the nuclear medicine services offered is specified in writing.
- There are nuclear medicine policies developed by the director of nuclear medicine governing provision of these services in every part of the hospital offering nuclear medicine services.
- The organization has a Medical Director of the Nuclear Medicine department.
- The hospital has a written description of the qualifications of the nuclear medicine services director.
- The service director is a DO or MD and has the necessary education,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

services offered throughout the hospital.

The director must be a Doctor of Medicine (MD) or Osteopathic Medicine (DO) and must demonstrate through education, experience and specialized training that he/she is qualified in nuclear medicine. Nuclear medicine physicians utilize radioactive materials to diagnose and treat disease either by interpreting the images created by radioisotopes or by prescribing and evaluating therapeutic interventions involving radiopharmaceuticals.

Typically, these MDs/DOs initially specialize in radiology or internal medicine and then complete subspecialty training in nuclear medicine.

The hospital must describe in writing the qualifications it requires for the director of nuclear medicine services.

OTHER NUCLEAR MEDICINE PERSONNEL

Although not mentioned specifically in the regulation, there are several different categories of personnel that may typically be involved in the provision of nuclear medicine services, including (but not limited to):

- Nuclear medicine pharmacists: these individuals are pharmacists who specialize in preparing, dispensing, and distributing radiopharmaceuticals.
- Nuclear medicine technologists: these individuals are trained to administer radioactive materials and perform the specific imaging procedures and often process the images for interpretation.
- Nuclear medicine physicists.

The hospital must specify in writing the qualifications, training, functions and responsibilities of each category of personnel used by the hospital, whether personnel are employees or contractors, in the delivery of nuclear medicine services.

The written specifications must be developed by the Director and approved by the hospital's medical staff.

Qualifications include at a minimum, job title, education, experience, experience and specialized training in nuclear medicine, per the hospital's written policies.

- The qualifications, training, functions and responsibilities of the various categories of nuclear medicine staff the hospital uses are specified by the director and approved by the medical staff.
- Nuclear medicine staff t meet the prescribed qualifications and have received ongoing training as required in the hospital's policies and procedures as evidenced by personnel file review.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	specialized training, and licensure/certification, consistent with any applicable federal and state law. The specifications must also address ongoing training for personnel.	
23.00.02 For future use		
23.00.03 For future use		
23.00.04 Delivery of service *Radioactive materials must be prepared, labeled, used, transported, stored, and disposed of in accordance with acceptable standards of practice.* *There is proper storage and disposal of radioactive material.* §482.53(b) §482.53(b)(2)	☐ Compliant ☐ Not Compliant The hospital must establish, in writing, and implement policies and procedures addressing the use of radioactive materials within the hospital. The policies and procedures must be based on acceptable standards of practice for the medical use of radioactive materials and must address, at a minimum: 1. Security of radioactive materials at every stage and location of their use within the hospital, including determining who may have access to them, implementing procedures to control access, and a system to track the receipt, usage, and disposal of all radioactive materials. 2. Safe storage of radioactive materials, including radioactive waste awaiting disposal outside the hospital. 3. Clear, recognizable labeling of radioactive materials, waste, and hazardous areas in all locations of the hospital, including during the preparation of such materials, if applicable. 4. Safe and secure transport of radioactive materials between locations within the hospital. 5. Safe handling with the appropriate personal and container protections, as applicable, by personnel who prepare and administer	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Verify through observation and document review that radioactive materials are prepared, labeled, used, transported, stored, and disposed of in accordance with hospital policies that are based on acceptable standards of practice. ▪ Ask the hospital to demonstrate how it limits access to radioactive materials at all times. ▪ Verify that the hospital maintains accurate records of the receipt, distribution, and disposal of radioactive materials, including radiopharmaceuticals. ▪ If the hospital prepares radiopharmaceuticals on site, observe

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

radiopharmaceuticals within the hospital.

6. Protection of patients from radiation hazards, including screening for high-risk patients (for example, possible pregnancy, multiple nuclear medicine studies, children, etc.).
7. Maintenance and proper use of personal radiation monitoring devices (dosimeters) for staff working in the vicinity of radiopharmaceuticals, according to manufacturer's instructions, particularly regarding the appropriate placement of the dosimeter on the body, as indicated on the dosimeter.
8. Safe and secure disposal of radioactive waste, including unused but unneeded radioactive materials as well as, when extra precautions are applicable, human waste products.

the preparation to verify that proper safety precautions are utilized to protect staff from excess radiation and once prepared, stored in appropriate containers. If the radiopharmaceuticals are obtained from an outside source, verify that the receipt and storage are appropriately tracked.

- Verify that a clear, recognizable label for nuclear material is appropriately displayed in all relevant areas throughout the hospital and on all radioactive materials.
- Verify that safety precautions are followed in the operations of the nuclear medicine service and that personnel and patients maintain and wear appropriate body shielding (e.g., lead aprons, lead gloves, thyroid shields) when appropriate.
- Observe a staff member deliver a nuclear medicine procedure to a patient, paying particular attention to adherence to hospital safety protocols during the delivery of the radiopharmaceutical.
- Through interview and observation, determine if staff use their dosimeters according to manufacturer's instructions, particularly in the appropriate placement of the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

dosimeter on the body, as indicated on the dosimeter.

- Ask the responsible staff to demonstrate how they ensure safe transport of radioactive materials in the hospital.
- Interview the responsible staff to determine whether the appropriate container protection devices—e.g., lead for gamma emitters—are being used for storage and administration of radioactive materials.
- Ask staff to show the policy for disposal methods for radioactive waste or unused material and to explain how they ensure that these procedures are followed.
- Identify how the hospital disposes of unneeded radio nuclides and radio pharmaceuticals.
  - □ Are these methods in accordance with federal and state laws, regulations and guidelines?
  - □ Are the methods described in hospital policy?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

23.00.05 In-house preparation of radiopharmaceuticals

In-house preparation of radio pharmaceuticals is by, or under the supervision of, an appropriately trained registered pharmacist or doctor of medicine or osteopathic medicine.

§482.53(b)(1)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

If the hospital prepares radio pharmaceuticals in-house, such preparation must be performed by, or supervised by, a registered pharmacist or MD/DO who is qualified through education, experience, and training, in the preparation of radio pharmaceuticals, consistent with federal and state law.

This allows other appropriately trained hospital staff to prepare in-house radiopharmaceuticals under the oversight of a registered pharmacist or MD/DO. It is no longer required to have the physical presence in the hospital at all times by one of these professionals, particularly during off-hours when such a professional would not be routinely present.

POLICIES AND PROCEDURES

- Hospitals must establish policies and procedures for in-house preparation of radiopharmaceuticals, including by nuclear medicine technologists under supervision.
- The policies and procedures must identify the qualifications, roles and responsibilities of staff preparing radiopharmaceuticals under supervision.
- Hospitals are expected to develop policies and procedures with respect to supervision of nuclear medicine technologists and the in-house preparation of radiopharmaceuticals.
- Most hospitals follow the supervision recommendations of the Society of Nuclear Medicine and Molecular Imaging. **Regardless of the source of professional guidelines chosen, the hospital** must be able to explain the basis for the supervision policies and procedures it has developed.
- Policies are reviewed and approved by the medical staff at least every three years.

COMPETENCIES

The hospital must ensure that all staff who are involved in the preparation

OBSERVATION AND DOCUMENT REVIEW

- If radio pharmaceuticals are prepared in-house, verify that the preparation is performed by, or supervised by, a registered pharmacist or MD/DO who is qualified through education, experience, and training, consistent with federal and state law.
- Verify that the facility policies address the identification, qualification, and training of professionals eligible to:
  - □ Prepare radiopharmaceuticals and
  - □ Provide supervision of nuclear medicine personnel and the in-house preparation of pharmaceuticals.
- Verify that the facility has adopted evidence-based guidelines regarding the in-house preparation of radiopharmaceuticals.
- Review personnel records of pharmacists, MDs/DOs and nuclear medicine personnel involved in the preparation and supervision of radio pharmaceuticals to verify they have required qualifications per State law and hospital policy.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	and/or supervision of radiopharmaceuticals are trained and demonstrate competencies in accordance with acceptable standards of practice.	▪ Verify the hospital has policies regarding the supervision of nuclear medicine personnel and the in-house preparation of radio pharmaceuticals. ▪ Ask the supervising pharmacist or MD/DO how technicians who prepare radio pharmaceuticals are supervised. Are the supervision policies based on the 12 recommendations of the Society of Nuclear Medicine and Molecular Imaging? If not, what is the basis for the supervision policies? □ Ask what policies/procedures the hospital uses to assure proper preparation. □ Ask what guidelines the hospital relies upon for radio pharmaceutical preparation.
23.00.06 For future use		
23.00.07 Shielding requirements Adequate shielding will be provided to protect patients, personnel, and the facility from radiation exposure.	☐ Compliant ☐ Not Compliant Appropriate devices are readily available and used to reduce the potential of radiation overexposure for patients, staff, equipment, and building. There is suitable shielding in areas where patients and staff could be exposed to radiation. Proper storage containers and/or handling procedures are used for radioactive materials and waste.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify that: ▪ Policies and procedures are in place regarding shielding and other safety devices. ▪ Criteria have been developed for

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Precautions are taken to protect patients who may be pregnant. (The facility determines what ages are vulnerable.)	determining persons who are vulnerable to pregnancy. ▪ Aprons and other shields are checked at least annually for cracks or more frequently if mandated by state law. ▪ Protective devices are readily available and used by the staff.
23.00.08 Monitoring of exposure Personnel who are at risk for exposure to radiation are monitored for levels of radiation.	☐ Compliant ☐ Not Compliant Personnel identified to be "at risk" are issued and consistently wear exposure meters or badge tests to measure radiation exposure. Monthly radiation exposure checks are conducted. Exposure records for each person are maintained and readily accessible. Radiological personnel as well as other employees determined to be at risk have access to their exposure reports. A physicist or qualified radiologist shall review the records. Results of the findings are to be reviewed and approved by the hospital radiation safety group and the safety team.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine whether the facility has identified other staff beyond the nuclear medicine department to be "at risk." ▪ Confirm that a physicist or radiologist has reviewed and signed each employee radiation exposure report. ▪ Verify staff knowledge of these procedures and the results of their tests. ▪ Verify that the exposure results are reviewed by an appropriate hospital safety group.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
23.00.09 Nuclear Regulatory Commission licensure	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
All isotopes shall be handled in accordance with Nuclear Regulatory Commission (NRC) regulations.	Federal, state, and local regulations governing radiation safety are adopted and implemented for protection from ionizing radiation. Licenses from regulatory bodies are readily available.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that policies meet the standard and there is compliance. ▪ Determine that the licenses are current.
23.00.10 Laboratory testing	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
If laboratory tests are performed in the nuclear medicine service, the service must meet the applicable requirement for laboratory services specified in 42 CFR §482.27. §482.53(b)(3)	Any laboratory tests performed in connection with nuclear medicine services must comply with the hospital Condition of Participation of laboratory services, including a requirement to comply with 42 CFR Part 493, which establishes the Clinical Laboratory Improvement Act (CLIA) requirements for laboratories. All in-vitro tests and all in-vivo procedures classified under radio bioassay must be performed in accordance with the requirements of 42 CFR §482.27 including quality control calibration and record retention, etc. See chapter 22, Laboratory Services, for applicable standards.	**DOCUMENT REVIEW** ▪ Review the nuclear medicine department against all standards in Chapter 22 if lab tests are being performed in the nuclear medicine service. ▪ The applicable survey procedures for the laboratory services Condition of Participation must be used. ▪ Verify that the nuclear medicine lab has a CLIA license, as appropriate.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

23.00.11 Facilities

Equipment and supplies must be appropriate for the types of nuclear medicine services offered and must be maintained for safe and efficient performance.

The equipment must be maintained in safe operating condition; and inspected, tested, and calibrated at least annually by qualified personnel.

§482.53(c)
§482.53(c)(1-2)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The nuclear medicine service must use equipment and supplies that are designed and, when applicable, approved to be used in conjunction with radioactive materials.

Equipment must be maintained so that it operates safely to minimize hazards to patients and hospital personnel as much as possible. Accordingly, it must be inspected, tested, and calibrated by personnel with the necessary qualifications.

Personnel may be either hospital employees or contracted. Personnel must follow the manufacturer's quality assurance instructions for acceptance testing (upon installation and after major upgrades) and maintenance testing.

The hospital must have a policy and procedure for staff who operate the equipment to follow if they suspect a malfunction.

Inspections, testing and calibration must occur at least annually unless required to be more frequent according to the manufacturer's instructions.

The findings from inspections are corrected promptly.

The nuclear medicine service must function in accordance with applicable federal and state regulations and guidelines governing radiation safety.

- For more information, see 21 CFR Subpart J, "Radiological Health," and 10 CFR, Chapter 1, Part 20, "U.S. Nuclear Regulatory Commission Standards for Protection Against Ionizing Radiation."

Reagents must be labeled to ensure proper identification, use, storage and safe handling and date of preparation and assay.

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

- Does the hospital have documentation confirming that the equipment and supplies used in the nuclear medicine services are appropriate for use with radioactive materials?
- Is the hospital able to demonstrate how personnel, whether employees or contractors, who inspect, test, calibrate, and maintain nuclear medicine services equipment are qualified to do so?
- Review equipment maintenance records to verify that:
  - ☐ Equipment is tested, calibrated, and otherwise maintained at least annually, following the manufacturer's recommended procedures.
  - ☐ If the manufacturer requires more frequent than annual testing and maintenance that the hospital adheres to the manufacturer's prescribed schedule.
- Ask nuclear medicine services staff who operate equipment what they would do if they suspected a malfunction.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		□ Does the hospital have a policy to address this and are staff familiar with it?
23.00.12 For future use		
23.00.13 Handling and disposal of radium elements Procedures clearly define handling and disposal methods for radium elements, their disintegration products, and radioactive isotopes.	☐ Compliant ☐ Not Compliant Mechanisms are established and implemented for proper handling and removal of the hazardous elements of radiation materials and wastes.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify that policies and procedures address the handling and removal of radioactive materials within the facility. ▪ Verify compliance with the policies on handling and storage.
23.00.14 Approval of policies and procedures All radiation safety policies and procedures are approved by the Radiation Safety and the Radiation Safety Committee (Team).	☐ Compliant ☐ Not Compliant The Safety Team and the Radiation Safety subcommittee reviews and approves all policies within the organization relating to radiation safety at least every three years.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that policies and procedures have received approval from the Safety Team and the Radiation Safety subcommittee within the past three years.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
23.00.15 Order requirements	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Each request for nuclear medicine services shall contain the reason(s) for the examination.	Orders for a nuclear medicine exam shall include the pertinent reason(s) for conducting the procedure to insure that the proper services are being provided.	**DOCUMENT REVIEW** Review requests in the radiology services department to verify compliance; review other records as necessary.
23.00.16 Medical record requirements	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital must maintain signed and dated reports of nuclear medicine interpretations, consultations, and procedures. *(1) The hospital must maintain copies of nuclear medicine reports for at least 5 years.* *(2) The practitioner approved by the medical staff to interpret diagnostic procedures must sign and date the interpretation of these tests.* §482.53(d) §482.53(d)(1-2)	The hospital must maintain records for all nuclear medicine procedures performed. Nuclear medicine patient records, including interpretations, consultations, and procedures are patient medical records and the hospital must comply with the Medical Records CoP (§482.24 – Chapter 10). Nuclear medicine patient records, like all patient medical records, must be maintained for at least five years. If State law requires a longer period, the hospital must comply, but surveyors do not assess compliance with State law requirements as part of the Federal survey. Each report of an interpretation of a nuclear medicine diagnostic study must be signed and dated by the practitioner who made the interpretation, as authorized by the medical staff. Deficient nuclear medicine medical records practices related to these two requirements must be cited under this regulation; depending on the specific facts, citation under the Medical Records CoP might also be appropriate. Bulls-eye films and other nuclear image records shall be maintained so as to be readily produced upon request for at least five years.	**OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Observe the record storage for record retention space, organization, ability to retrieve, and security. ▪ Verify compliance with all applicable standards in Chapter 10 - Medical Records. ▪ Verify that copies of nuclear medicine reports are maintained for at least 5 years. ▪ Verify that reports of nuclear medicine interpretations are signed and dated only by the practitioner who interpreted the study's results, as authorized by the medical staff to perform these interpretations.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

23.00.17 For future use

23.00.18 For future use

23.00.19 Documentation requirements

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must maintain records of the receipt and distribution of radio-pharmaceuticals.

§482.53(d)(3)

Hospitals receive their radiopharmaceuticals from manufacturers, either for further in-house preparation, or ready to use.

Regardless of the source of the material, the hospital must have records that track the movement of the radiopharmaceuticals upon receipt, throughout the hospital.

The records must specify:

1. The type of radiopharmaceutical.
2. The location in the hospital where it was received, stored and dispensed.
3. The amount received or dispensed at each location.
4. The staff member receiving or dispensing.
5. When applicable, how/when it is disposed of and by whom. This would also include, when applicable, the type and amount of any radiopharmaceuticals returned to the source vendor.

Additional information, including special transport instructions or precautions, may be included.

The hospital must also have policies and procedures that address how often it reviews these records and how it reconciles discrepancies between inventory on hand and records of receipt, distribution, use, disposal and/or return to the source vendor.

Records are kept of radiopharmaceuticals and radionuclides from the point of

INTERVIEW AND DOCUMENT REVIEW

- Review the records relating to the inventory, administration, and disposal. Request the most recent documentation for the delivery of radiopharmaceuticals. Verify:
  - ☐ All radio pharmaceuticals and radionuclides that entered the facility are still in the inventory or transferred via administration to a patient or disposal.
  - ☐ Radionuclides are not delivered during non-business hours and left unsecured.
  - ☐ The hospital maintains accurate records of the receipt and distribution of radio pharmaceuticals.
- Ask the hospital to demonstrate how it maintains accurate records of the receipt and distribution of radiopharmaceuticals at all locations

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	entering the facility to the points of administration and final disposal. The records are to indicate: ▪ the date received and method of receipt. ▪ Activity. ▪ identity of recipients. ▪ dates of administration. ▪ dates of disposal.	throughout the hospital. ▪ Ask what the hospital's policy is for frequency of review of the records; is there evidence that the hospital complies with its policy? ▪ Ask the hospital to explain how it addresses discrepancies in the records. ▪ What actions does it take to determine whether there are errors in the records versus unaccounted for loss of materials? ▪ If applicable, what further actions are taken to locate unaccounted for radioactive materials? ▪ If applicable, what further actions are taken to prevent future recordkeeping errors?
23.00.20 Qualified ordering practitioners *Nuclear medicine services must be ordered by practitioners whose scope of Federal or State licensure and whose defined privileges allow such referrals.* §482.53(d)(4)	☐ Compliant ☐ Not Compliant Nuclear medicine services may only be ordered by practitioners holding privileges that permit them to do so, consistent with State scope of practice law. However, for outpatient services, consistent with the provisions of 42 CFR §482.54, the governing body and medical staff may also authorize practitioners who do not have hospital clinical privileges to order such studies or procedures, as permitted under State law.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review service policies and several outpatient requisitions to verify compliance with this standard and with medical staff bylaws, rules and regulations. ▪ Verify that nuclear medicine services are ordered only by practitioners who have privileges to do so or, for

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		outpatient services when authorized consistent with the provisions of §482.54, by other practitioners authorized to do so by the medical staff, consistent with federal and state law.
23.00.21 STANDARD: Nuclear medicine services *If the hospital provides nuclear medicine services, those services must meet the needs of the patients in accordance with acceptable standards of practice.* *§482.53*	☐ Compliant ☐ Not Compliant Nuclear medicine services must be provided in accordance with acceptable standards of practice. Acceptable standards of practice include maintaining compliance with applicable Federal and State law and regulations governing the use of nuclear medicine, including facility licensure requirements, as well as standards and recommendations promoted by nationally recognized professional organizations. Examples of nationally recognized professional organizations in the area of nuclear medicine include, but are not limited to, organizations such as the American College of Radiology, the Radiological Society of North America, the Society of Nuclear Medicine and Molecular Imaging, the American Society of Nuclear Cardiology, and the American Association of Physicists in Medicine. If nuclear medicine services are provided under arrangement, the governing body must, in accordance with §482.12(e), ensure that the services are provided in a manner that complies with the requirements of the nuclear medicine CoP. **MINIMIZING THE RISKS OF NUCLEAR MEDICINE** Nuclear medicine studies and procedures provide useful diagnostic information and targeted therapies for patients. However, since they use radioactive materials that produce high energy, there are also risks associated with the exposure to radioactivity. Specifically, the risk involves exposure to ionizing radiation, which is a form of energy given off by atomic particles that	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** If nuclear medicine services are offered, determine the type(s) of services provided and the location where each service is provided. ▪ Ask the director of nuclear medicine services how the hospital ensures that the services are provided in accordance with acceptable standards of practice. ▪ Can the director point to accepted guidelines or state or other federal law that support the hospital's nuclear medicine policies and procedures? ▪ Can the director explain how the hospital's policies, procedures, and protocols are consistent with ALARA principles? ▪ Observe one or more nuclear medicine studies to determine whether the staff follows the hospital's protocols for that

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

can cause damage to DNA in various living tissues.

The most significant risks include, but are not limited to:

- A small increase in the possibility that a person exposed to ionizing radiation will develop cancer later in life.
- The risk of developing cancer from nuclear medicine radiation exposure is generally small and depends on at least three factors—the amount of the radiation dose, the age of the patient or staff member at the time of the exposure, and the sex of the person exposed:
- The lifetime risk of cancer increases the larger the dose and the greater the number of studies or treatments involving radioactivity which he/she undergoes;
- The lifetime risk of cancer is larger for a patient who received exams that involve radioactivity at a younger age, since less mature cells are more radiosensitive; and
- Women are at somewhat higher lifetime risk than men for developing radiation-associated cancers after receiving the same exposures at the same age.

In order to minimize the risks of ionizing radiation and maximize patient safety during nuclear medicine studies and procedures, hospitals are expected to apply the fundamental principle of "As Low as Reasonably Achievable" or "ALARA," which is defined by the U.S. Environmental Protection Agency (EPA) as "A principle of radiation protection philosophy that requires that exposures to ionizing radiation be kept as low as reasonably achievable, economic and social factors being taken into account.

The protection from radiation exposure is ALARA when the expenditure of further resources would be unwarranted by the reduction in exposure that would be achieved." (Federal Guidance Report No. 14, Radiation Protection Guidance for Diagnostic and Interventional X-ray Procedures, p. 100, November, 2014). Although CMS does not interpret or enforce EPA guidance, the ALARA principle is considered an accepted standard of practice for

study. Ask the staff after the observation to show you the applicable protocol and explain how they complied with it.

Note:

- Identification of CMS standard-level deficiencies within the Condition of Participation should be cited here if non-compliance does not rise to the Condition level.
- Do NOT include ACHC standard deficiencies in this evaluation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

nuclear medicine that hospitals must adhere to.

Hospitals are expected to be able to demonstrate how they incorporate ALARA into their nuclear medicine services.

They are also expected to have nuclear medicine policies and procedures that take into consideration classes of patients who may be at higher risk for over-exposure, as well as the radiation exposure of staff when preparing, storing, transporting, administering and disposing of radioactive materials.

Note: For Information Only: Not Required/Not to be Cited

- Hospitals are encouraged to develop protocols for the use of radiopharmaceuticals designed to achieve an optimal balance between minimizing the amount of radiation exposure while maximizing the diagnostic image quality or therapeutic benefit.
- The risk of excessive exposure for both patients and staff can be reduced by designing and implementing nuclear medicine study protocols that:
- Minimize the distance between the source of radiation and its target; and
- Follow published guidelines for administered activity, i.e., the amount of radiation administered by the radiopharmaceutical.

QAPI

In addition, the hospital's nuclear medicine services must be integrated into its hospital-wide Quality Assessment and Performance Improvement (QAPI) program, as required by 42 CFR §482.21.

Consistent with these requirements, the hospital must monitor the quality and safety of nuclear medicine services.

Examples of nuclear medicine indicators of potential quality and safety problems could include, but are not limited to:

- Incidents of improper patient preparation, such as inadequate intravenous access or lack of pre-medication, such that procedures must

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

be cancelled or reordered;

- Incidents of the wrong radiopharmaceutical being used, i.e., not the radiopharmaceutical prescribed for the patient, or of the wrong dose of the prescribed radiopharmaceutical being administered, or of use of the wrong route of administration for the prescribed radiopharmaceutical.
- Repeats of the same diagnostic studies within a short time span, which may be an indicator of poor image quality; or
- Diagnostic studies or therapeutic procedures performed in a manner inconsistent with the applicable hospital written protocol.

In addition, the hospital is also required to track medical errors and adverse events related to nuclear medicine services.

- Adverse events related to nuclear medicine services must be analyzed for their causes, and preventive actions must then be undertaken.
- Deficiencies identified related to tracking, analyzing, and addressing adverse event and quality indicator data and performance improvement activities must be cited under the applicable QAPI standards.

24

NUTRITIONAL SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
24.00.00 CONDITION OF PARTICIPATION: Food and dietetic services	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital must have organized dietary services that are directed and staffed by adequate qualified personnel. *However, a hospital that has a contract with an outside food management company may be found to meet this Condition of Participation if the company has a dietician who serves the hospital on a full-time, part-time, or consultant basis, and if the company maintains at least the minimum standards specified in this section and provides for constant liaison with the hospital medical staff for recommendations on dietetic policies affecting patient treatment.* §482.28	The services can be provided directly or by a contracted food management group. The hospital's food and dietetic services must be organized, directed, and staffed in such a manner to ensure that the nutritional needs of the patients are met in accordance with practitioners' orders and acceptable standards of practice. The hospital should have written policies and procedures that address at least the following: 1. Availability of a diet manual and therapeutic diet menus to meet patients' nutritional needs. 2. Frequency of meals served. 3. System for diet ordering and patient trays delivery. 4. Accommodation of non-routine occurrences (e.g., parenteral nutrition (tube feeding), total parenteral nutrition, peripheral parenteral nutrition, change in diet orders, early/late trays, nutritional supplements, etc.). 5. Integration of the food and dietetic service into the hospital-wide QAPI and Infection Control programs. 6. Guidelines for acceptable hygiene practices of food service personnel. 7. Guidelines for kitchen sanitation. The same standards apply whether the food and dietetic services are provided by the hospital directly, through a contractual agreement, or by off-site vendor. The hospital must be in compliance with Federal and State licensure requirements for food and dietary personnel as well as food service standards, laws, and regulations.	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** **Note**: Score the Condition based on scoring results from the remainder of the chapter. The survey of the Food and Dietetic Services standards (including staff qualifications, transportation, food safety, and whether the hospital is meeting the nutritional needs of its patients) is coordinated by one surveyor. However, each surveyor, as he/she conducts his/her survey assignments, should assess the hospital's compliance with the Food and Dietetic Services standards.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
24.00.01 Organization §482.28(a)	☐ Compliant ☐ Not Compliant The hospital must ensure that the specific food and dietetic services organization requirements are met.	This standard is not met as evidenced by: **Note:** Score this standard based on the results of scoring from standards 24.00.02 through 24.00.05.
24.00.02 Food and dietetic services *The hospital must have a full-time employee who:* (i) *Serves as director of the food and dietetic services,* (ii) *Is responsible for daily management of the dietary services, and* (iii) *Is qualified by experience or training.* §482.28(a)(1) §482.28(a)(1)(i-iii)	☐ Compliant ☐ Not Compliant The service director must be a full-time employee who has been granted the authority and delegated responsibility by the hospital's governing body and medical staff for the operation of the dietary services. This authority and delegated responsibility includes, the daily management of the service, implementing training programs for dietary staff, and assuring that established policies and procedures are maintained that address at least the following: 1. Safety practices for food handling. 2. Emergency food supplies. 3. Orientation, work assignments, supervision of work and personnel performance. 4. Menu planning, purchasing of foods and supplies, and retention of essential records (e.g., cost, menus, personnel, training records, QAPI reports, and etc.). 5. Nutritional services QAPI program. The service director must demonstrate, through education, experience and/or specialized training, the qualifications necessary to manage the service, appropriate to the scope and complexity of the food service operations.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the director of food and dietetic services is a full-time employee. ▪ Review the service director's job description to verify that it is position-specific and that responsibility and authority for the direction of the food and dietary service has been clearly delineated. ▪ Review the service director's personnel file to verify that he/she has the necessary education, experience, and training to manage the service, appropriate to the scope and complexity of food service operations. ▪ Verify that nutrition services are integrated with the hospital-wide QAPI program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The food service director may or may not be a Registered Dietitian. It is not required that the food service director report to a Registered Dietitian. Food service directors in a transitional role will be evaluated on a case-by-case basis. Temporary reporting structures will be acceptable only if active recruitment for an appropriately qualified candidate is in progress.	
24.00.03 Dietitian services *There must be a qualified dietitian,* ▪ *full-time,* ▪ *part-time or* ▪ *on a consultant basis.* §482.28(a)(2)	☐ Compliant ☐ Not Compliant A qualified dietitian must supervise the nutritional aspects of patient care. Responsibilities of a hospital dietitian may include, but are not limited to: ▪ Approving patient menus and nutritional supplements. ▪ Patient, family, and caretaker dietary counseling. ▪ Performing and documenting nutritional assessments and evaluating patient tolerance to therapeutic diets when appropriate. ▪ Collaborating with other hospital services (e.g., medical staff, nursing services, pharmacy service, social work service, etc.) to plan and implement patient care as necessary in meeting the nutritional needs of the patients. ▪ Maintaining pertinent patient data necessary to recommend, prescribe, or modify therapeutic diets as needed to meet the nutritional needs of the patients. Qualification is determined on the basis of education, experience, specialized training, State licensure or registration when applicable, and maintaining professional standards of practice. If the qualified dietitian does not work full-time, and when the dietitian is not available, the hospital must make adequate provisions for dietary consultation that meets the needs of the patients. The frequency of	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the dietitian's personnel files to verify that he/she is qualified based on education, experience, specialized training, and, if required by State law, is licensed, certified, or registered by the State. ▪ If the dietitian is not full time, determine that the number of hours spent working is appropriate to serve the nutritional needs of the patients, and that the hospital makes adequate provisions for coverage with the dietitian is not available.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	consultation depends on the total number of patients, their nutritional needs and the number of patients requiring therapeutic diets or other nutritional supplementation.	
24.00.04 Staffing Qualifications *There must be administrative and technical personnel competent in their respective duties.* §482.28(a)(3)	☐ Compliant ☐ Not Compliant Administrative and technical personnel must be competent in their assigned duties. This competency is demonstrated through education, experience, and specialized training appropriate to the task(s) assigned. Personnel files should include documentation that the staff member has the required qualifications and is competent in their respective duties. Dietetic administrative personnel may include diet clerk or secretarial positions. Dietetic technical personnel may include certified or noncertified dietary positions. For dietetic technicians who provide technical support under the supervision of RDs, it is preferred that these are registered through the Commission on Dietetic Registration as "Dietetic Technician, Registered" (DTR). Food service personnel include those staff responsible for food preparation, the tray line, and dish machine operators.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review personnel files for both administrative and technical staff. Determine they have appropriate credentials as required and have received adequate training and are competent in their respective duties. □ Duties are consistent with assignments in the service. □ There is evidence of appropriate credentials, adequate training, and competency evaluations for both administrative and technical personnel. ▪ Visit the kitchen to observe personnel. Check assignment sheets for staffing. □ Verify there is ample staff to meet the nutritional needs of patients.
24.00.05 For future use		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

24.00.06 Diets: Menus must meet the needs of patients

Individual patient nutritional needs must be met in accordance with recognized dietary practices.

§482.28(b)
§482.28(b)(1)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Each hospital patient for whom the hospital is providing one or more meals or nutrition must have their nutritional needs met in a manner that is consistent with recognized dietary practices.

Affected patients include all inpatients and those patients in observation status whose stay is sufficiently long that they must be fed. According to the U.S. Department of Agriculture's (USDA) Food and Nutrition Center the nationally recognized source for recommended dietary intakes allowances is the Institute of Medicine Food and Nutrition Board's Dietary Reference Intakes (DRIs), which are designed to provide recommended nutrient intakes for use in a variety of settings.

The DRIs are a set of four reference values:

1. Recommended Dietary Allowance (RDA) is the average daily dietary intake of a nutrient that is sufficient to meet the requirement of nearly all (97-98%) healthy persons.
2. Adequate Intake (AI) for a nutrient is similar to the Estimated Safe and Adequate Daily Dietary Intakes (ESADDI) and is only established when an RDA cannot be determined. Therefore, a nutrient either has an RDA or an AI. The AI is based on observed intakes of the nutrient by a group of healthy persons.
3. Tolerable Upper Intake Level (UL) is the highest daily intake of a nutrient that is likely to pose no risks of toxicity for almost all individuals. As intake above the UL increases, risk increases.
4. Estimated Average Requirement (EAR) is the amount of a nutrient that is estimated to meet the requirement of half of all healthy individuals in the population.

THERAPEUTIC DIETS

Meeting individual patient nutritional needs may include the use of

INTERVIEW AND DOCUMENT REVIEW

- Can the dietician demonstrate how the menus meet the nutritional needs of patients? For example, does the service rely upon DRIs, including RDAs, in developing menus?
- Can the dietician demonstrate patients are assessed for special nutritional needs and how those specialized needs are met?
- When observing care in inpatient units (or observation units where meals are provided), ask staff how patients are assessed for nutritional needs.
  - □ Ask them how they monitor patients identified as having specialized needs.
  - □ Is there evidence that therapeutic diets are provided as ordered?
- Does the sample of records under review include patients identified with special nutritional needs? If not, ask to see records for several such patients. Determine if there is evidence of monitoring the dietary intake and nutritional status of patients identified as having special nutritional needs.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

therapeutic diets. Therapeutic diets refer to a diet ordered as part of the patient's treatment for a disease or clinical condition, to eliminate, decrease, or increase certain substances in the diet (e.g., sodium or potassium), or to provide mechanically altered food when indicated.

Patients must be assessed for their risk for nutritional deficiencies or need for therapeutic diets and/or other nutritional supplementation.

Examples of patients who may have specialized dietary needs and may require a more detailed nutritional assessment include, but are not limited to:

- All patients requiring artificial nutrition by any means (i.e., enteral nutrition (tube feeding), total parenteral nutrition, or peripheral parenteral nutrition).
- Patients whose medical condition, surgical intervention, or physical status interferes with their ability to ingest, digest or absorb nutrients.
- Patients whose diagnosis or presenting signs/symptoms indicates a compromised nutritional status (e.g., anorexia nervosa, bulimia, electrolyte imbalances, dysphagia, malabsorption, end stage organ diseases, etc.).
- Patients whose medical condition can be adversely affected by their nutritional intake (e.g., diabetes, congestive heart failure, patients taking certain medications, renal diseases, etc.).

Patients who refuse the food served should be offered substitutes that are of equal nutritional value to meet their basic nutritional needs.

PLAN OF CARE

The care plan for patients identified as having specialized nutritional needs must address those needs as well as monitoring of their dietary intake and nutritional status.

The methods and frequency of monitoring could include one or more of the following, as well as other methods:

- Patient weight (BMI, unintended weight loss or gain).

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Intake and output.
- Lab values.

24.00.07 Diet Orders

All patient diets, including therapeutic diets, must be ordered by a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff and in accordance with State law governing dietitians and nutrition professionals.

§482.28(b)(2)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Patient diets, including therapeutic diets, must be provided in accordance with orders from a practitioner responsible for the care of the patient, or by a qualified dietitian or qualified nutrition professional who is permitted to order diets under State law and authorized to do so by the medical staff.

Diets must be based on an assessment of the patient's nutritional and therapeutic needs and documented in the patient's medical record (including documentation about the patient's tolerance to any therapeutic diet ordered).

DIET-ORDERING PRIVILEGES

The hospital's governing body may choose, when permitted under State law and upon recommendation of the medical staff, to grant qualified dietitians or qualified nutrition professionals diet-ordering privileges.

QUALIFIED DIETICIAN

In many cases state law determines what criteria an individual must satisfy to be a "qualified dietician." State law may define the term to mean a "registered dietician" registered with a private organization, such as the Commission on Dietetic Registration or state law may impose different or additional requirements.

QUALIFIED NUTRITIONIST

- Terms such as "nutritionists," "nutrition professionals," "certified clinical nutritionists," and "certified nutrition specialists" are also used to refer to individuals who are not dieticians, but who may also be qualified under state law to order patient diets.
- It is the responsibility of the hospital to ensure that individuals are

DOCUMENT REVIEW

- Review patient records to verify that diet orders are provided as prescribed by:
  - ☐ the practitioner(s) responsible for the care of the patient
  - ☐ a qualified dietician

  or
  - ☐ qualified nutrition professional.
- If diet orders are prescribed by a dietitian or other nutrition professional, review their records to verify that he or she was appointed to the medical staff with diet-ordering privileges, or was granted diet-ordering privileges without being appointed to the medical staff.
  - ☐ Ask the hospital how it determines whether the dietician/nutrition professional is qualified under state law.
  - ☐ Review staff records to verify that dieticians/nutrition professionals

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	qualified under state law before appointing them to the medical staff or granting them privileges to order diets. If the hospital chooses NOT to grant diet-ordering privileges to dietitians or other nutrition professionals, even when permitted under state law, the patient's diet must be prescribed by a practitioner responsible for the patient's care. In this situation, a dietician or nutrition professional who does not have privileges to order diets may nevertheless assess a patient's nutritional needs and provide recommendations or consultations for patients to a practitioner responsible for the care of the patient.	demonstrate the required qualifications.
24.00.08 Diet manual *A current therapeutic diet manual approved by the dietitian and medical staff must be readily available to all medical, nursing and food service personnel*. §482.28(b)(3)	☐ Compliant ☐ Not Compliant The therapeutic diet manual must be approved by the dietitian and the medical staff within the last three years. The publication or revision date of the approved therapeutic diet manual must not be greater than 5 years old. The therapeutic diet manual must be available to all medical, nursing and food service personnel. **The therapeutic diet manual must be in accordance with nationally recognized nutritional guidelines and standards of practice that are appropriate for the patient population (e.g., pediatrics).** **EMERGENCY PLAN** A plan is in place to ensure the diet manual is readily available in the event of a power outage, internet/intranet interruptions, or computer failure. Staff is trained in these alternative methods.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify that the therapeutic diet manual is current and ▪ Has been approved by both the medical staff and a qualified Dietitian within the past three years. ▪ Is in accordance with current nationally-recognized standards, such as RDA or DRI. ▪ Is readily available to MD/DOs, nursing, and food service personnel. ▪ Is accessible at each nursing station for nursing and medical staff and is also available to food service and dietetic staff. ▪ Includes the different types of therapeutic diets routinely ordered at

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		the facility ▪ Is consistently used as guidance for ordering and preparing patient diets. ▪ Staff is knowledgeable of alternate methods of accessing the diet manual.
24.00.09 For future use		
24.00.10 Nutrition counseling and education Patients and their families are counseled, as appropriate, on the therapeutic diet regime, food - drug interactions, and nutrition-related topics.	☐ Compliant ☐ Not Compliant Nutrition counseling is provided to achieve knowledge regarding healthy food choices consistent with the ordered therapeutic diet. Food or drug products, which may result in interference or interaction, are taught in a manner that the patient (family) can understand. Patient education materials are often prepared by various hospital disciplines. Materials relating to therapeutic diets or food-drug interactions are developed in collaboration with a registered dietitian	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Determine the Standards of Practice and mechanisms used for patient (family) teaching. ▪ Verify that food - drug interaction teaching aids have been conjointly devised by nutrition and pharmacy services even if these are utilized by nursing staff. Teaching aids are available in the language of the patient. ▪ Review 10 appropriate patient records to verify documentation of education on nutrition counseling and/or food-drug interactions.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
24.00.11 Outcomes management/ QAPI systems	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
For both food service and clinical nutrition services a process is in place to monitor, improve and report quality and outcomes of services provided.	Food service directors and Registered Dietitians are accountable to implement systems to reliably measure quality and outcomes of food and nutrition services, to act on those results as needed and to report results to stakeholders. A comprehensive outcomes management/QAPI program is in place and consists of: ▪ National benchmarks are used as appropriate. ▪ Integration with the facility-wide quality and outcomes initiatives program. ▪ Identification and analysis of less-than-optimal performance and outcomes. ▪ Nutrition Services monitoring to consider: 1. Implementation of the four steps of the Nutrition Care Process and Screening. 2. Effectiveness of the nutrition screening and referral system. 3. A risk analysis/audit procedure to verify the accuracy of meals/that nutrition served to patients are as prescribed. For more information, refer to "Academy of Nutrition and Dietetics Outcomes Management Publications."	**INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that: □ Policies and procedures define systems for measuring quality and outcomes of services. □ Verify the food service and clinical nutrition services participate in the facility wide QAPI program. □ Documentation of a minimum of two QAPI projects: ▪ One food service initiative and ▪ One nutrition service initiative. ▪ Interview staff about the quality and outcomes projects, methodology, results, and refinements to services made.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
24.00.12 Emergency preparedness plan The Emergency preparedness plan of the facility addresses methods for ensuring the nutritional needs of patients and personnel during an internal or external emergency or disaster.	☐ Compliant ☐ Not Compliant The hospital emergency preparedness plan describes the strategies for ensuring nutritional needs are met during situations in which hospital services or utilities are disrupted. The plan outlines methods for meeting the nutritional needs of patients, visitors, and personnel while awaiting evacuation or the return to normal hospital operations. It is recommended that hospitals work with the community leaders when developing the emergency plan. In the event of a community disaster, the hospital will need priority status for the delivery of fuel, food, water, and other supplies. During a disaster, the facility may experience a disruption in one or multiple services, such as: ▪ Loss of water, gas, fuel, or electricity. ▪ Equipment failure, e.g., dishwashing machines, pumps, refrigeration, cooking appliances. ▪ Disruption with the delivery and grocery and food preparation items. The emergency preparedness plan anticipates the possible disruptions and prepares strategies, in advance, for ensuring continuity of services. For example, how would the hospital meet patient nutritional needs in the event of: ▪ A loss of electricity/power? Alternative methods for heating foods and water used for cooking should be identified. ▪ A disruption with delivery of food products? The facility might choose to: □ Obtain agreements with food suppliers for priority grocery delivery □ Calculate the volume of food, drinking water, paper products, and utensils needed to feed the patients, staff, and visitors for at least	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the hospital emergency preparedness plan addresses methods for ensuring the nutritional needs of patients and personnel are met during internal and external emergencies, including major disruption of delivery and sanitation infrastructures.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	three days. □ Store a three-day inventory of: ▪ Fresh and frozen foods ▪ Dairy products ▪ Drinking water ▪ Paper products ▪ Special dietary requirements, e.g., diabetic, Kosher, and vegetarian diets	
24.01.01 Food service department: General requirements The food service department is governed by current policies.	☐ Compliant ☐ Not Compliant The food service department collaborates with other departments as necessary to ensure the needs of their patients are met. Food service has a policy manual in place. Policies are reviewed minimally every three years and revised, as necessary.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ Policies reflect collaborative efforts between food service and other departments, e.g., pharmacy and patient care services. ▪ Policies are reviewed every three years and revised as necessary.
24.01.02 Policy requirements: Tube feedings Food service policies address the role of the department regarding the storage, distribution, and administration of enteral/tube feedings.	☐ Compliant ☐ Not Compliant The food service department collaborates with dietetic services, patient care services, and Pharmacy, as applicable, in development of policies relative to enteral/tube feedings, specifically: ▪ Storage	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ The required policies are in place. ▪ Policies reflect collaboration between

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Distribution ▪ Administration	food service, dietetic service, patient care services, and pharmacy, as applicable.
24.01.03 Policy requirements: Food preparation and storage in patient care areas Processes are in place relative to food storage centers located in the patient care areas. Minimally, policies must address: 1. Rotation of stock and supplies. 2. Checking for outdated supplies. 3. Cleaning frequency and procedures for all food preparation work areas and equipment. 4. Measuring and recording temperatures of refrigerators and freezers. 5. Storage, refrigeration, preparation, and heating of nutrition supplements, infant formulas, breast milk, and patient food brought from home. 6. Labeling of food items with patient name, room number, and expiration date. 7. A separate and designated refrigerator for each of the following: ▪ Patient food. ▪ Employee food.	☐ Compliant ☐ Not Compliant Food products must be maintained in a manner that ensures an acceptable level of safety and quality. The food service department collaborates with patient care services in development of policies relative food and nutrition supplements stored on the patient care units. The Infection Control Committee reviews policies relative to the food product safety and the cleaning of food centers and refrigerators in all patient care areas. A process is in place to communicate food product expiration / discard dates; this process is consistently practiced throughout the facility. A process is in place to monitor and remove supplies prior to expiration. Food and products are stored at least six inches off the floor. Cleaning products and paper products are stored away from food. Horizontal surfaces are clean and free of crumbs. **CLEANING** Policies are in place that describe the frequency, procedure, and persons responsible for cleaning food preparation work areas and equipment including floors, counter tops, refrigerators and freezer units, microwave ovens, coffee pots, and toasters. **REFRIGERATOR TEMPERATURES** ▪ Check and record food refrigerator temperatures at least daily. (Checking and recording temperatures is not required for employee food	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify that: ▪ Required policies are in place and current. ▪ Food safety policies have been approved by the Infection Control Committee. ▪ Policies reflect collaboration between Food Service and patient care services. ▪ Food products and supplements are maintained in a safe manner. Food items are stored properly and labeled. ▪ There are no medications stored in food refrigerators. ▪ The food preparation work area and equipment are clean. ▪ Separate refrigerators are provided, as required. ▪ Refrigerator temperatures are maintained within safety guidelines. (Standard requirement does not apply

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ Breast milk, as applicable. ▪ Medications that must be stored at a cool temperature.	refrigerators.) ▪ Desired temperatures: □ Refrigerator temperature range: Between 32° - 40° Fahrenheit (0° – 5° Celsius). □ Freezer temperature range: Between minus 10° and minus 0.4° Fahrenheit (minus 23° to minus 18° Celsius). ▪ The refrigerator log provides space to document the date, time, temperature, and person recording the temperature. The desired refrigerator temperature is indicated on the log. ▪ A process is in place to repair the refrigerator in a timely manner if the temperature should fall out of range. Thirty minutes following the repair, recheck the temperature to ensure the proper temperature has been achieved.	to employee refrigerators.) ▪ Processes for food preparation and storage are consistently followed in all areas of hospital, e.g., the main hospital kitchen, Occupational Therapy, and nursing units.
24.01.04 Preparation and storage of formula and breastmilk Processes are in place that ensures infant formula and breastmilk are properly stored and prepared in accordance with nationally accepted guidelines. Policies are in place to ensure infant safety, including: 1. Guidelines for ordering infant formulas. 2. Guidelines that govern acceptable ingredients that may be added to infant formulas. 3. Guidelines for aseptic infant formula	☐ Compliant ☐ Not Compliant For facilities with an infant patient population, the organization adopts nationally accepted and recognized clinical practice standards such as the Academy of Nutrition and Dietetics "Guidelines for Preparation of Formula and Breastmilk in Health Care Facilities." Aseptic technique is used for all infant formula preparations. Preferably, a separate room is used exclusively for the preparation of infant formula, breastmilk, and infant enteral feedings. When there is no formula room, a dedicated clean space with handwashing facilities must be available to allow for the aseptic preparation of infant formulas. **REFRIGERATORS AND FREEZERS** ▪ As breast milk is both a food and a body fluid it cannot be stored in refrigerators designated for food or medication storage.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ The required policies are in place. ▪ There is a dedicated clean space with handwashing facilities for preparation of infant formulas. ▪ Infant formula and breastmilk is stored and prepared in a safe manner.

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preparation techniques.

4. Storage, preparation, and temperature control of breastmilk and infant formula products.
5. Patient safety with heating breast milk and infant formula.
6. Personnel responsible and qualified to prepare infant formula.
7. Cleaning/autoclaving of equipment used in formula preparation.
8. Indications, use, and sanitation of enteral feeding pump equipment.

- A separate refrigerator is dedicated for storage of infant feedings. Unless prohibited by state law, it is acceptable to store breastmilk and formula in the same refrigerator.
- Refrigeration must be able to chill ingredient water and cool prepared formula to 4° C (40° F).

INFANT FORMULA STORAGE

Prepared infant formula must not be frozen. Refrigerator temperatures for storing infant formula are maintained at:

- 40° Fahrenheit or lower/4° Celsius or lower

BREAST MILK STORAGE

- Refrigerator temperatures for storing breast milk are maintained between:
  - □ 35 ° to 40 ° Fahrenheit/2 ° and 4 ° Celsius
- Freezer temperatures for storing breast milk are maintained:
  - □ At minus 4 ° Fahrenheit or lower/At minus 20 ° Celsius or lower
- Human milk must be stored in food-grade plastic or glass containers.
- Containers must be labeled with the names of the infant and mother, medical record number, and date and time of pumping.
- The breastmilk expressed by each mother is stored in a separate bin to discourage misadministration and cross-contamination.
- Breastmilk shall be warmed or thawed under warm running water. Microwaves and hot water should never be used to warm breastmilk.
- Thawed breast milk must be used within 24 hours. Do not refreeze thawed or fortified breast milk.
- Fortified breast milk should be used within 24 hours.

INFANT FORMULA PREPARATION

- Written formulations are developed and maintained in the infant formula

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preparation room. The written formulations shall be verified for accuracy, preferably by a registered dietitian trained in infant formulation preparation.

- Medications and electrolytes should not be added to formulas in the formula preparation area.
- Single use bottles and nipples should be used for infant feedings.
- When available and appropriate, commercially prepared sterile ready-to-feed and liquid concentrate formulas should be used for infant feedings.
- Processes are in place to sanitize utensils used with infant formula preparation. Measuring cups, spoons, and blenders are sanitized. When oil is added to infant formula for additional fat calories, per physician order, the use of a disposable spoon is acceptable.

USE OF POWDERED FORMULA

- Powdered formula should only be used when commercially prepared sterile liquid formula is not available.
- Powdered formula must be measured by weight.
- Commercially prepared sterile water should be used for infant formula preparation.

STORAGE OF INFANT FORMULA PRODUCTS

- All opened formula products, including liquid concentrate, powders, and additives, should be labeled with expiration date and time.
- Opened, ready-to-feed formula and house-prepared formula may be stored in bulk containers and refrigerated for up to 24-hours.
- Prepared infant formula must not be frozen.

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24.01.05 For future use

24.01.06 For future use

24.01.07 Trash disposal

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Policies are in place for the following processes:

1. Storage and disposal of grease, food waste, and biohazardous waste.
2. Containment, handling, transporting, and removal of trash.
3. Covering, labeling, frequency of emptying, and securing trashcans and lids.
4. Daily washing of trashcans.

The term "trash" refers to common garbage as well as biohazardous waste.

In the Food Service department, typically this includes grease, food waste, and paper/packaging materials. On occasion, a patient tray may return to the department with biohazardous wastes such as soiled dressings, dentures, needles, and syringes.

The facility has policies established relative to containing, covering, labeling, securing, storing, and transporting trashcans in accordance with state and local regulations (see Chapter 11 of this manual).

This practice is consistently implemented throughout the Food Service department.

OBSERVATION AND DOCUMENT REVIEW

Verify that:

- Required policies are in place.
- Staff adhere to the policies relative to trash disposal and removal. Ensure that garbage does not present a health hazard.
- Trash is contained, covered, and labeled consistent with hospital policy.

24.01.08 Physical environment

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Processes are in place for the following:

1. Food and non-food items are stored separately.
2. All food containers are covered.
3. Food containers are labeled with the contents and the date prepared.
4. Foods are within their expiration

Chemicals, cleaning products, mops and brooms are to be stored separately from foods, utensils, pots/pans, plates/bowls, serving trays, or paper products.

Paper products including napkins, plates, cups must not be stored in food preparation areas.

All food packages that are not currently being used are to be covered and/or sealed to protect from contamination and/or evaporation.

OBSERVATION AND DOCUMENT REVIEW

- Verify that food service policies and employee orientation both cover the listed issues.

During the kitchen walk-through, observe for adherence to these principles.

Verify that:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
dates. 5. Loose scoops are not stored in the bulk food containers. 6. Supplies are off the floor. 7. Refrigerator/freezer door seals and water pipes are in good working order. Humidity is controlled to prevent/reduce mold growth. 8. Soap, paper towels, and a sink for hand washing are readily available for staff working in the food preparation area. 9. Food transport vehicles are clean and in good working order. 10. Ceiling tiles are intact and stain-free.	All food containers are to be labeled with the name of the product stored in it. All opened food containers are labeled to indicate the "date opened/date prepared" or "expiration/discard date" consistent with hospital policy. All perishable foods that have passed their expiration date are removed from availability. All expired foods are discarded promptly. Scoop handles become contaminated when handled; thus, storage of scoops in bins may contaminate the stored food. The scoops may be kept in the bin if arranged so the handles hang above the food, or in accordance with state and local health department requirements. Staff working in the food preparation area have sinks for hand washing, soap, and paper towels readily available. The location of the sink does not allow splashing onto food, the preparation table, or utensils. Foot operated sinks are preferred. The Food Service department environment avoids sources of infection: ▪ Walls and floors are clean and kept free of cracks and holes. ▪ Ceiling tiles are in place and secure. ▪ Supplies are stored at least six inches off the floor, per FDA requirement. ▪ Floors in all areas of food storage and preparation are clean. Floors under the storage shelves are free of dust and crumbs. ▪ Refrigerator and freezer doors, walls, and floors are free of cracks and holes. □ Door seals and water pipes are in good working order. □ Humidity is controlled. □ Ceiling fans in refrigerators/freezers are dust free.	▪ Food products and supplements are maintained in a safe manner. Food items are stored properly and labeled with contents and either "date opened /date prepared" or "expiration/discard date." Staff is knowledgeable of labeling practices. ▪ Refrigerators and freezers are in good working order. Humidity is controlled. ▪ Hand washing facilities are in the immediate proximity of the food preparation area. ▪ Food transport vehicles are clean and in good working order. ▪ Ceiling tiles are intact and stain free.

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FOOD TRANSPORT VEHICLES
Food transport vehicles are clean and functioning. The hot food section heats properly; the cold food section is chilled.

FLAMMABLES
Flammables, such as containers of propane gas used for outdoor grilling, are not stored in the kitchen area.

24.01.09 Lighting, ventilation, and temperature control

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Observe for the following:

1. Food products are stored under appropriate conditions (e.g., time, temperature, packaging, location), consistent with nationally accepted guidelines (i.e., Food and Drug Administration (FDA), United States Department of Agriculture (USDA), Hazard Analysis and Critical Control Point (HACCP), etc.).
2. The air supply should flow from clean (food preparation) to dirty (cleanup/ garbage).
3. Daily temperatures are consistent with USDA guidelines and recorded for refrigerator and freezer units.
4. Hot foods are maintained at appropriate temperatures.
5. If dish machines are used, dish machine temperatures are recorded

VENTILATION HOOD SYSTEMS AND FILTERS

- Processes are in place to ensure proper ventilation throughout the food preparation area. Usually, the hospital maintenance department provides oversight for these processes.
- Ventilation of sufficient capacity is provided to keep the area free of excessive heat, steam, condensation, vapors, obnoxious odors, smoke, and fumes.
- Ventilation hood systems or other grease extracting equipment shall be designed to prevent grease or condensation from dripping onto food, equipment, and utensils. Ventilation hoods should be readily removable for cleaning and replacement if not designed to be cleaned in place.
- Intake and exhaust air ducts shall be cleaned and filters changed so they are not a source of contamination by dust, dirt, and other materials.
- The air supply flows from clean to dirty areas of the kitchen.
- Dust is not permitted to accumulate around the ventilation grills.

FOOD TEMPERATURE DANGER ZONE
The food temperature danger zone is between 41° F and 135° F. To avoid bacterial growth:

1. Store cold foods at 40° Fahrenheit (5° Celsius) or less.

OBSERVATION AND INTERVIEW

- Verify that food service policies and employee orientation both cover the listed issues.
- During the kitchen walk through, observe for adherence to these principles. Observe the receiving, food preparation, cooking, cooling, and reheating flow of food, if possible.

Verify:

- Proper ventilation and air flow is provided throughout the food service area. Ventilation hoods and filters are clean and free of dust and grease.
- Refrigerator and freezer temperatures are maintained according to guidelines. Daily records are in place.
- Dishwasher temperatures are maintained per guidelines. Temperature recordings are in place for

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for each cycle.

6. Food preparation areas have adequate lighting.
7. Ceiling light bulbs are shielded.

2. Hot foods should be held and stored at 135 ° Fahrenheit (60° Celsius) or greater.

MAINTAIN PROPER REFRIGERATOR/FREEZER TEMPERATURES

1. There are daily records of food refrigerator and freezer temperatures. Such records are to be maintained for all patient food regardless of the location of the equipment or the department/service distributing the product.
2. The log provides space to document the date, time, and person recording the temperature. The desired refrigerator/freezer temperature is indicated on the log.
3. The internal temperature for refrigerators/freezers are checked and recorded consistent with State and public health rules and regulations, but at least daily.
4. A process is in place for adjusting refrigerators in a timely manner when the temperature is out of range. The temperature is rechecked following adjustments.
5. If food is above 45 degrees, discard it. If frozen food has thawed, do not refreeze.

REFRIGERATOR TEMPERATURES

Refrigerator temperatures should be maintained:

1. Between 32° – 40° Fahrenheit (0° to 5° Celsius) for all refrigerated goods.
2. For fresh meat, poultry, and seafood: 30° – 34° Fahrenheit (minus 1° to 1° Celsius).

FREEZER TEMPERATURES

Freezer temperatures should be maintained:

1. Between minus 10° to minus 0.4° Fahrenheit (minus 23° to minus 18° Celsius) for dairy, ice cream, frozen vegetables, meat, poultry and seafood.
2. For ice cream in scooping cabinets: Between minus 0.4° to 10°

the wash and rinse cycles. Dishes, glassware, and utensils are free of water spots.

- Federal, state, and local regulations are followed.
- **Interview nutritional services personnel about proper dishwashing temperatures.**
- **Interview food services personnel about proper dishwashing temperatures.**
- There is adequate lighting in the food preparation area. Ceiling light bulbs are shielded.

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Fahrenheit (minus 18° to minus 12° Celsius).

DISHWASHING TEMPERATURES
Records are kept of the dishwater temperatures at each cycle.

Setting the right temperature for the commercial dishwasher is critical to ensure properly sanitized cookware, dishes and utensils to prevent foodborne illnesses.

- **Dishwasher temperatures are maintained per manufacturer's guidelines and in accordance with nationally recognized standards of practice (e.g., ANSI, FDA) for both:**
  - □ **High temperature settings with hot water sanitation.**
  - □ **Low temperature setting with chemical sanitation.**
- **The hospital is in compliance with any relevant federal, state and local regulations.**

LIGHTING
There is sufficient lighting in the food handling area to ensure safety.

LIGHT BULBS
1. The FDA (Food and Drug Administration) requires ceiling light bulbs to be shielded, coated, or otherwise shatter-resistant in areas where there is food, clean equipment, and utensils.
2. Shielding of light bulbs is not required in areas that are used only for storing food in unopened packages if:
   - □ The integrity of the packages cannot be affected by broken glass falling onto them.
   - □ The packages are capable of being cleaned of debris from broken bulbs before the packages are opened.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
24.01.10 Staff education	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Food service personnel are trained and function within the scope of the respective job description.	Job descriptions for food service personnel list the full scope of responsibilities. Food service personnel, including contract staff and volunteers, receive an orientation and monthly training consistent with state and local public health regulations. The orientation and training, as appropriate to the job description, addresses relevant policies, including: ▪ Employee health policies: □ Mandatory self-reporting procedures related to hazardous health issues. □ Personnel with hazardous health issues, e.g., open skin lesions, respiratory infections, or gastroenteritis, are prohibited from handling food. ▪ Personal hygiene and handwashing ▪ Sanitation, food safety (food preparation and storage), physical environment, prevention of cross contamination, and infection control practices.	**INTERVIEW, OBSERVATION AND DOCUMENT REVIEW** ▪ Review orientation and ongoing training curricula, schedules, attendance, and competency assessments to verify: □ Appropriateness of orientation/ training material. □ Training is provided on an ongoing basis consistent with state and local regulations. Through observation and interviewing, determine staff have received proper training, e.g., sanitation techniques, employee health policies.
24.01.11 Staff hygiene and health	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
There are policies and procedures regarding the personal hygiene and health of food service employees.	Food service policies are in place and provide guidelines. These include but are not limited to: 1. Hairnets/bonnets, gloves, hand-washing facilities, aprons, and other devices are utilized on an ongoing basis. 2. Employees with open skin lesions and respiratory infections are not	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The employee health program has met these specific food service

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	assigned to food preparation.	requirements. ▪ Personal hygiene practices are consistent with policies.
24.01.12 China and utensils China, glassware, and utensils must be of an acceptable level of safety and quality.	☐ Compliant ☐ Not Compliant Policies describe the actions to be taken by staff to discard chipped and damaged utensils. Damaged dishes, glassware, utensils, and pitted cookware are discarded. Water spots on dishes and utensils indicate improper drying temperatures or methods.	This standard is not met as evidenced by: **OBSERVATION** Verify: ▪ There are no chipped or damaged china, glassware, utensils, or pitted cookware. ▪ Unglazed china is not used. ▪ Dishes and utensils are clean and without water spots.
24.01.13 Traffic control Traffic through the food preparation area is limited to authorized personnel wearing appropriate sanitation garb.	☐ Compliant ☐ Not Compliant Policies and practices prohibit non-departmental staff from entering food preparation areas during production without measures taken to reduce potential contamination of food products. These measures are the same requirements as for nutrition staff. Non-dietary service individuals shall receive prior authorization before entering a food preparation area. Policies are in place to control traffic through the food preparation area. These include: ▪ Identification of authorized and non-authorized personnel. ▪ Use of hairnets/bonnets and other protective clothing to be worn by all	This standard is not met as evidenced by: **OBSERVATION** Verify that practice conforms with policy: ▪ Traffic through the food preparation area is limited. ▪ All individuals in the food preparation area have proper identification and protective gear, per hospital policy. (This includes surveyors who may be requested to wear a hair net, etc.)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	individuals entering the area.	
24.01.14 For future use		
24.01.15 Local health standards The food service is in compliance with state and local health standards.	☐ Compliant ☐ Not Compliant The Food Service Department meets all applicable codes and guidelines relating to the health and safety of the patients, staff, and visitors. Copies of the state/local food codes are available in the department. All state and local health department inspection reports are available for review. There is evidence the identified deficiencies have been corrected and improvement sustained.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify that state/local food preparation codes are available in the department. ▪ Review current health department inspection report. Deficiencies have been corrected and improvements sustained.
24.01.16 Infection control Policies must address the following: 1. Provision of a safe environment consistent with nationally recognized infection control precautions for the prevention of food-borne pathogens/illness, including care of utensils, use of cutting boards, temperature control, etc. 2. Isolation procedures and requirements for delivery of and disposal of food products. 3. Methods for monitoring and	☐ Compliant ☐ Not Compliant This regulation requires the hospital to develop, implement and maintain an infection control program for the prevention, control, and investigation of infections and communicable diseases of patients and personnel. Food preparation equipment and utensils are cleaned, sanitized, and stored in a manner that prevents cross-contamination. To avoid cross-contamination, a separate cutting board is used for each of the following. Boards are sanitized following use. Preferably, cutting boards are color coded to denote the exclusive use for: ▪ Dairy products. ▪ Fruit and vegetables. ▪ Raw poultry and meats.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review Infection Control Committee minutes to verify that food service issues are included in evaluation of compliance issues. ▪ Observe for implementation of the policies. ▪ Verify: □ The food preparation and serving area is a safe and clean environment. □ A process is in place for monitoring

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
evaluating practices of sanitation. 4. Employee health policies regarding infectious diseases and specifically those infected or ill employees, including contract workers and volunteers, must not render food service and/or must not report to work. 5. Recalls of food products. 6. Identifying, investigating, and reporting infections and outbreaks of disease related to food consumption in both employees and patients.	A process is in place to ensure can openers are clean. The cutting or piercing parts of electric can openers are removable to facilitate cleaning and replacement. A process is in place for cleaning ice cream machines. There is an ongoing pest extermination process within the hospital. This can be by hospital employees or by a contracted outside service. The facility has a process for monitoring and evaluating sanitation practices in the food preparation area. Employee health policies are in place relative to food handlers including a process for self-reporting illness. The facility has policies established that outline procedures for: ▪ Prevention of cross-contamination ▪ Cafeteria self-serve buffets ▪ Money handling ▪ Proper glove use, e.g., Food preparation and handling, tray setup and distribution, food serving, tray clean-up and disposal, indications for changing gloves (such as after touching skin, hair, money). References: The U.S. Food and Drug Administration, "2017 Food Code" is available at: https://www.fda.gov/food/fda-food-code/food-code-2017.	and evaluating sanitation practices.

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PHARMACY SERVICES/ MEDICATION USE

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

25.00.00 CONDITION OF PARTICIPATION: Pharmaceutical Services

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must have pharmaceutical services that meet the needs of the patients.

The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision.

The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized pharmaceutical service.

§482.25

A hospital must provide pharmaceutical services that meet the needs of its patients. The services must include either a pharmacy that is directed by a pharmacist, or, when appropriate, a drug storage area that is competently supervised.

The hospital's medical staff is responsible for developing pharmaceutical policies and procedures that minimize the potential for medication errors but may delegate this function to the pharmaceutical service.

The manner or degree of noncompliance with the requirements of this Condition and its component standards must be evaluated to determine whether there is substantial noncompliance with the Condition, warranting a Condition-level citation.

Provision of pharmaceutical services must meet the needs of the patients' therapeutic goal by promoting a safe medication use process that ensures optimal selection of medications, dose, dosage form, frequency, route, duration of therapy and that substantially reduces or eliminates adverse drug events and duplication of treatment.

The hospital's pharmacy must be directed by a registered pharmacist. If a drug storage area is used instead of a pharmacy at any location providing pharmacy services that storage area must be under competent supervision in accordance with state and federal law.

Pharmaceutical services would include:

- The procuring, manufacturing, compounding, packaging, dispensing, ordering, distributing, disposition, use, and administering of all medications, biologicals, chemicals, and the use of medication-related devices.
- Provision of medication-related information to hospital health care professionals and patients necessary to optimize therapeutic outcomes.

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

Note: Score based on the aggregate results of scoring of the §482.25 standards and sub-standards in this chapter. The manner or degree of noncompliance with the requirements of this Condition and its component standards must be evaluated to determine whether noncompliance warrants a Condition-level citation.

Do NOT include HFAP-standard deficiencies with this decision.

- Interview the Chief Pharmacist or the individual delegated to fulfill the functions to verify that either the medical staff has developed policies and procedures regarding the management of pharmaceuticals or that this function is fulfilled by the pharmacy service.
- Does a multidisciplinary committee composed of representatives from nursing, pharmacy, administration, and medicine develop policies and procedures?
- Verify that the purpose of pharmaceutical policies and procedures is to minimize drug errors.

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- Provision of pharmaceutical care. Pharmaceutical care is defined as the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life while minimizing patient risk.

Functions of pharmaceutical care are the:

- Collection and organization of patient-specific information.
- Determination of the presence of medication-therapy problems both potential and actual.
- Summary of the patient's medication related health care needs.
- Identification and specification of pharmaco-therapeutic goals.
- Development of a pharmaco-therapeutic regimen.
- Implementation of a monitoring plan in collaboration with the patient, if applicable, and other health care professionals.
- Monitoring the effects of the pharmaco-therapeutic regimen.
- Redesigning the regimen and monitoring plan as indicated.

POLICIES AND PROCEDURES

Medication errors are a substantial source of morbidity and mortality in the hospitalized setting. Therefore, the development of policies and procedures to minimize medication errors should be based on accepted professional principles; external alerts and proactive review of facility reported and reviewed adverse drug events. It is important to flag new types of mistakes and continually improve and refine things, based on what went wrong.

The hospital's medical staff must develop policies and procedures to minimize drug errors but may delegate this function to the hospital's organized pharmaceutical service.

Policies and procedures to minimize drug errors should include:

1. High-alert medications: dosing limits, administration guidelines,

□ Review the pharmaceutical policies and procedures, the hospital's formulary and, if there is a pharmacy and therapeutic committee, the minutes of the committee meetings.

- Are policies and procedures reviewed and amended based on:
  - □ Facility-generated reports of adverse drug events?
  - □ Facility QAPI activities pertaining to pharmaceutical care?
  - □ Evaluation of external alerts and/or recommendations from national associations?
  - □ Evaluation of literature for new technologies or successful practices that have demonstrated enhanced medication safety in other organizations?
- Is the staff familiar with the medication-related policies and procedures?
- Is there a method to periodically review and evaluate the actual implementation of pharmaceutical policies and procedures by staff?
- Upon review of patient clinical record are issues with regard to provision of pharmaceutical services identified? Is the facility aware of the issues? Was

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

packaging, labeling and storage.

2. Limiting the variety of medication-related devices and equipment. For example, limit the types of general-purpose infusion pumps to one or two.
3. Availability of up-to-date medication information.
4. Availability of pharmacy expertise. Pharmacist available on-call when pharmacy does not operate 24 hours a day.
5. Standardization of prescribing and communication practices to include:
   - □ Avoidance of dangerous abbreviations.
   - □ All elements of the order – dose, strength, units (metric), route, frequency, and rate.
   - □ Alert systems for look-like and sound-alike drug names.
   - □ Use of facility approved pre-printed order sheets whenever possible.
6. That orders to "resume previous orders" are prohibited.
7. A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions).
8. The preparation, distribution, administration, and proper disposal of hazardous medications.
9. Drug recalls.
10. That patient-specific information is readily accessible to all individuals involved in provision of pharmaceutical care. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate.
11. Identification of when weight-based dosing for pediatric populations is required.
12. Requirements for review and revision based on facility-generated reports

there a failure to implement a policy and procedure?

- Are pharmacists an integral component of pharmaceutical care?
- Verify that the hospital's pharmacy service is integrated into its hospital-wide QAPI program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	of adverse drug events and QAPI activities. The hospital should have policies and procedures to actively identify potential and actual adverse drug events. Proactive identification could include; direct observation of medication administration, review of patient's clinical records, identification of patient signals that would warrant immediate review of patient's medication therapy and implementation of medication use evaluation studies. The hospital should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include: ▪ Institute for Safe Medications Practice. ▪ National Coordination Council for Medication Error Reporting and Prevention. Governmental agencies may include: ▪ Food and Drug Administration. ▪ Med Watch Program. ▪ Agency for Health Care Research and Quality. ▪ The hospital's pharmacy services must be integrated into its hospital-wide QAPI program.	
25.00.01 STANDARD: Pharmacy services *The hospital must have pharmaceutical services that meet the needs of the patients.* *§482.25*	☐ Compliant ☐ Not Compliant **WHAT IS INCLUDED IN PHARMACEUTICAL SERVICES?** Pharmaceutical services encompass the functions of procuring, storing, compounding, re-packaging, and dispensing all medications, biologicals, chemicals, and medication-related devices within the hospital. They also include providing medication-related information to care professionals within	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Ask the hospital for evidence of the scope and complexity of its pharmaceutical services.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	the hospital, as well as direct provision of medication-related care. **MEETING PATIENT NEEDS** Hospitals must provide pharmaceutical services that meet the needs of their patients. ▪ The scope and complexity of pharmaceutical services available in the hospital must be consistent with the volume and types of patients the hospital serves. ▪ Except in unusual circumstances, the pharmaceutical service is expected to make available in a timely manner the volume and types of medications typically needed. ▪ These would be those medications typically prescribed by the hospital's practitioners for hospital patients receiving inpatient services, surgical services, diagnostic services involving medications as a component of testing, and outpatient drug therapies administered while the patient is in the hospital. Not every hospital is expected to offer the same level of pharmaceutical services. For example: ▪ It would not be uncommon for a psychiatric hospital to maintain a relatively limited pharmaceutical service, due to minimal need for compounding, and/or dispensing multiple types and forms of medications and biologicals. On the other hand, a short-term acute care hospital with a busy oncology outpatient service and other complex medical and surgical departments would be expected to provide a wider range of pharmaceutical services that are ready to be furnished when needed.	▪ Ask how the hospital has determined that the services meet the needs of its patients. ▪ Ask unit nursing staff if prescribed medications are routinely available and timely. If there are reports of frequent delays or other problems, probe further with the director of pharmaceutical services.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
25.00.02 Licensure	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Each pharmacy location is licensed as required by state law. If the pharmacy provides retail outpatient dispensing it is also licensed for this activity, if required.	Most states require hospital pharmacies to be licensed separately from the facility. Some states require retail pharmacy licenses for outpatient dispensing even if this is limited to employee prescriptions.	**OBSERVATION** ▪ Verify that the license(s) is/are current and prominently posted. Note: States often require reissue in the event of a change in pharmacy director. If required by the state, verify that the license(s) posted is current.
25.00.03 Permits and certifications	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Permits and certifications required by law are current for all pharmacy locations. These are located within the pharmacy area and posted, if required by law.	Permits may include but are not limited to: ▪ Drug Enforcement Agency. ▪ State controlled substance. ▪ Tax free alcohol. ▪ Pharmacist preceptor for intern practitioners.	**OBSERVATION** Verify that: ▪ Permits and certifications are current and posted for all pharmacy locations. ▪ Permits exist for all required activities. ▪ If required by the state, permits are posted.
25.00.04 Pharmacy management and administration	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the hospital's organized	The hospital may utilize a unit dose system, individual prescription, floor stock system or a combination of these systems, properly stored. Pharmaceutical services must be administered in accordance with accepted	**DOCUMENT REVIEW** ▪ Are the policies and procedures consistent with accepted professional

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

pharmaceutical service.

The pharmacy or drug storage area must be administered in accordance with accepted professional principles.

§482.25(a)

professional principles. Accepted professional principles includes compliance with applicable federal and state laws, regulations, and guidelines governing pharmaceutical services, as well as, standards or recommendations promoted by nationally recognized professional organizations**,** such as those found in the U.S. Pharmacopeia/National Formulary (USP/NF).

The hospital's pharmacy service must ensure safe and appropriate procurement, storage, preparation, dispensing, use, tracking and control, and disposal of medications and medication-related devices throughout the hospital, for both inpatient and outpatient services.

Hospitals may choose how to set up the pharmaceutical services utilizing various methods including, but not limited to:

- A unit dose system (i.e., single unit package, dispensed in most ready to administer form possible),
- Individual prescription (i.e., instruction for a single patient, written by a medical practitioner for a medication or treatment),
- Floor stock system (i.e., storage of pharmaceutical and over-the-counter drugs on the patient care unit), or
- A combination of these systems, as long as they are properly stored.

HOSPITALS WITH ONLY A DRUG STORAGE AREA

Hospitals with only a drug storage area must only use drugs that are pre-packaged and need no further preparation beyond that required at the point of care.

POLICIES AND PROCEDURES

The hospital must develop, implement, and periodically review and revise as needed policies and procedures governing provision of pharmaceutical services.

The regulation makes the hospital's medical staff responsible for the policies and procedures, but also permits the medical staff to delegate this function to

principles?

- Does the hospital have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration?
- Is the hospital's organized pharmaceutical services responsible for the procurement, distribution and control of all medication products used in the hospital (including medication-related devices) for inpatient and outpatient care?
- If the hospital has a drug storage area instead of a pharmacy, does it use only drugs that are pre-packaged and need no further preparation beyond that required at the point of care?
- Is there evidence that the hospital's medical staff has either adopted pharmaceutical services policies and procedures, or has delegated this task to the pharmaceutical services?
- Can the pharmacy director provide evidence that the policies and procedures are consistent with accepted professional principles?
- Can the pharmacy director provide evidence that policies and procedures

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

the hospital's pharmaceutical services.

The policies and procedures must reflect accepted professional pharmacy principles, and the pharmacy director must be able to identify the source(s) used when developing and adopting the policies and procedures.

There must also be a process to train staff on the applicable policies and procedures and to monitor their adherence.

POLICIES AND PROCEDURES FOR MINIMIZING DRUG ERRORS

Medication errors are a substantial source of morbidity and mortality risk in the hospitalized setting. Therefore, hospitals must take steps to prevent, identify, and minimize these errors. These steps must be based on accepted professional principles. This includes not only ensuring that the pharmacy processes conform to of accepted standards of pharmacy practice but also proactively identifying and reviewing Adverse Drug Events (ADE) that occur.

Pharmacies also need to be aware of external alerts to real or potential pharmacy-related problems in hospitals.

The pharmaceutical services policies and procedures must be designed to minimize drug errors and are expected to address:

HIGH-ALERT MEDICATIONS

High-alert medications are considered inherently high risk for adverse drug events. High alert drugs may include controlled medications, medications not on the approved FDA list, medications with a narrow therapeutic range, psychotherapeutic medications, look-alike/sound-alike medications and those new to the market or new to the hospital. Although mistakes may or may not be more common with these drugs, the consequences of errors are often harmful, sometimes fatal to patients. Examples of ways to minimize high alert medication errors include, but are not limited to, the following: dosing limits, administration guidelines, packaging, labeling and storage.

INVESTIGATIONAL MEDICATIONS (RESEARCH)

Hospitals that conduct research involving investigational medications must address key areas to prevent medication errors?

- Is there evidence of training staff on applicable pharmaceutical policies and procedures?
- Is there a process in place to monitor adherence to policies and procedures?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

have a policy and procedure in place to ensure that investigational medications are safely controlled and administered.

Procedures for the use of investigational medications include, but are not limited to, the following:

A written process for reviewing, approving, supervising, and monitoring investigational medications specifying that when pharmacy services are provided, the pharmacy controls the storage, dispensing, labeling, and distribution of the investigational medication.

1. Adherence to professional standards of practice for all compounding, packaging dispensing and drug disposal activities;
2. Standardizing medication-related devices and equipment where feasible. For example, limit the types of general-purpose infusion pumps to one or two;
3. Availability of up-to-date medication information and pharmacy expertise on-call when pharmacy does not operate 24 hours a day;
4. Standardization of prescribing and communication practices to include:
   - □ Avoidance of dangerous abbreviations.
   - □ All elements of the order – dose, strength, units (metric), route, frequency, and rate.
   - □ Alert systems for look-like and sound-alike drug names.
   - □ Use of facility approved pre-printed order sheets whenever possible.
   - □ Prohibition of orders to “resume previous orders.”
   - □ Availability of patient-specific information to all individuals involved in provision of pharmaceutical services. The patient information must be sufficient to properly order, prepare, dispense, administer and monitor medications as appropriate.
   - □ Identification of when weight-based dosing for pediatric populations is required.

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	□ A voluntary, non-punitive, reporting system to monitor and report adverse drug events (including medication errors and adverse drug reactions). □ Monitoring drug alerts and/or recalls. The hospital should have a means to incorporate external alerts and/or recommendations from national associations and governmental agencies for review and facility policy and procedure revision consideration. National associations could include Institute for Safe Medications Practice and National Coordinating Council for Medication Error Reporting and Prevention. Governmental agencies may include Food and Drug Administration, Med Watch Program. □ The hospital's pharmacy services must be integrated into its hospital-wide QAPI program and therefore, it is important to flag new types of mistakes and continually improve and refine policies and procedures as a result of analyses of errors and adverse events.	
25.00.05 Management *The institution must have a pharmacy directed by a registered pharmacist or a drug storage area under competent supervision.* *A full time, part time, or consulting pharmacist must be responsible for developing, supervising, and coordinating all of the activities of the pharmacy services.* *§482.25* *§482.25(a)(1)*	☐ Compliant ☐ Not Compliant Pharmaceutical services offered throughout the hospital must be under the direction of a pharmacist, who may be full-time, part-time, or consulting. This is required even in the case of a hospital that has a drug storage area instead of a pharmacy. The director must have documented training or expertise in hospital pharmacy practice and management. The hospital must have written criteria for the qualifications of the pharmacy director in accordance with the scope of services provided. The extent of pharmaceutical services provided by the hospital determines whether a part-time director of the services is sufficient.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Does the hospital have a pharmacist who has been appointed to direct the pharmaceutical services? ▪ Are there written criteria for the qualifications of the pharmacy director? □ Is there evidence in the pharmacist's file that he/she satisfies the criteria? ▪ If the hospital has a drug storage area in lieu of a pharmacy, is there evidence

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- Depending on the volume and complexity of the hospital's services, oversight may not require full-time on-site management at the hospital's pharmacy, but may be accomplished through regularly scheduled visits, and/or use of telecommunications in accordance with federal and state law and accepted professional principles.
- If the hospital does not have a full-time pharmacist, it must be able to provide evidence of how a part-time or consulting pharmacist is able to perform all functions relating to developing, supervising, and coordinating all pharmacy services activities.

In general, hospital pharmacies are staffed with registered pharmacists and pharmacy technicians who perform various functions, including, but not limited to, compounding, labeling, and dispensing of various drugs and biologicals.

There may be instances of small hospitals that do not have a pharmacy but utilize a drug storage area for dispensing pre-packaged drugs only.

- If the hospital has a drug storage area in lieu of a pharmacy, the day-to-day operations of pharmaceutical services must be under the supervision of an individual who, if not a pharmacist, nevertheless has documented competency to oversee compliance with all the pharmaceutical services regulatory requirements (e.g., security, access to locked areas, etc.).
- The hospital must establish in writing the qualifications of the drug storage area supervisor.

Likewise, if a hospital has remote locations or satellites that rely on the pharmacy of the main campus and maintain only drug storage area(s) on-site, there must be competent day-to-day supervision of those storage area(s), under the overall direction of the pharmacist who manages the hospital's pharmaceutical services.

The job description or the written agreement for the responsibilities of the pharmacist director should be clearly defined and include development,

the storage area is under competent supervision?

- If the Director is a part-time employee or consultant, ask him/her how much time/week is spent on developing, supervising and coordinating pharmaceutical services.
- Determine there is current state licensure for all pharmacists serving the facility, including the director.
- Review the implementation of the Pharmacy Director's responsibilities by:
  - □ Reviewing minutes of meetings (if any) with facility staff regarding pharmaceutical services.
  - □ Reviewing the job description or the written agreement to see that the responsibilities of the pharmacist are clearly defined and include development supervision and coordination of all the activities of pharmacy services.
  - □ Determining whether the Pharmacy Director/Manager routinely evaluates the performance and competency of pharmacy personnel.
- Ask the pharmacy director to describe how policies and procedures related to pharmaceutical services are developed, approved, and implemented. What is

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	supervision and coordination of all the activities of pharmacy services, including active leadership of those committees responsible for establishing medication-related policies and procedures.	his/her role in this process? ▪ Is there any evidence of problems within the pharmaceutical services that suggest lack of supervision?
25.00.06 Staffing *The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services, including emergency services.* §482.25(a)(2)	☐ Compliant ☐ Not Compliant Professional criteria, federal and state regulations (and licensing acts) guide the facility requirements for staff. There must be sufficient personnel to respond to the pharmaceutical needs of the patient population being served. The pharmaceutical services staff must be sufficient in types, numbers, and training to provide quality services, including 24-hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff. The number of pharmacists and/or the number of hours of services provided by pharmacists at the hospital, or at each location of the hospital that provides pharmaceutical services, must meet and be in accordance with the needs of its patients and accepted professional principles (as previously defined), and reflect the scope and complexity of the hospital's pharmaceutical services. There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ The pharmaceutical services staff is sufficient in number and training to provide quality services, including 24-hour, 7-day emergency coverage, or there is an arrangement for emergency services, as determined by the needs of the patients and as specified by the medical staff. ▪ There are sufficient personnel to provide accurate and timely medication delivery, ensure accurate and safe medication administration and to provide appropriate clinical services as well as the participation in continuous quality improvement programs that meet the needs of the patient population being served.

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25.00.07 Scheduled drugs *Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.* §482.25(a)(3)	☐ Compliant ☐ Not Compliant A "perpetual" inventory is maintained. Distribution and movement of scheduled drugs throughout the facility is controlled and records are maintained and reconciled. Destruction and waste records are maintained and monitored. Components of a record system to maintain current and accurate records of the receipt and disposition of scheduled drugs include: 1. Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs. 2. Records of the receipt and disposition of all scheduled drugs must be current and must be accurate. 3. Records trace the movement of scheduled drugs throughout the service. 4. The pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and reconciled. 5. The record system, delineated in policies and procedures, tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer. This system provides documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs. 6. All drug records are in order and an account of all scheduled drugs is maintained and any discrepancies in count are reconciled promptly. 7. The hospital system is capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual loss or diversion to the time of detection and	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Review a sample of six narcotic balance sheets representative of anesthesia, ER, GI lab, pharmacy, and from nursing care units. Observe for witnessed waste/destruction and balanced inventory. ▪ Select two drugs from the inventory and complete a drug count with a registered nurse or pharmacist. ▪ Verify that there is a record system in place that provides information on controlled substances in a readily retrievable manner. ▪ Review the records to determine that they trace the movement of scheduled drugs throughout the service. ▪ Verify that there is a system, delineated in policies and procedures, that tracks movement of all scheduled drugs from the point of entry into the hospital to the point of departure either through administration to the patient, destruction or return to the manufacturer. Verify that this system provides documentation on scheduled

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	determination of the extent of loss or diversion. 8. Facility policies and procedures should minimize scheduled drug diversion.	drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs. ▪ Verify that the pharmacist is responsible for determining that all drug records are in order and that an account of all scheduled drugs is maintained and periodically reconciled. ▪ Is the hospital system capable of readily identifying loss or diversion of all controlled substances in such a manner as to minimize the time frame between the actual losses or diversion to the time of detection and determination of the extent of loss or diversion? ▪ Determine if facility policy and procedures minimize scheduled drug diversion.
25.00.08 Space requirements There is adequate space allocated to enhance the security of inventories.	☐ Compliant ☐ Not Compliant Sufficient space permits the orderly storage of inventories. Separate storage for Schedule II drugs exists.	This standard is not met as evidenced by: **OBSERVATION** ▪ Interview staff to determine their familiarity with pharmacy-related policies and procedures. ▪ Verify: □ Space allocation allows for orderly storage of inventory. □ Schedule II inventory is stored

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		separately and double locked.
25.00.09 Scope of service The hospital provides pharmaceutical services appropriate to the scope of service of the facility.	☐ Compliant ☐ Not Compliant The patient mix and acuity drive the scope of services.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Observe physical space, equipment. Review the scope of service statement to verify: □ The scope of service statement identifies the needs of the patients served. □ Pharmaceutical services are appropriate to meet the needs of patients.
25.01.01 Medication control and distribution *In order to provide patient safety, drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice consistent with Federal and State law.* *§482.25(b)*	☐ Compliant ☐ Not Compliant Applicable standards of practice include compliance with all federal and state laws, regulations, and guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations that apply to pharmaceutical care and the control and distribution of drugs and biologicals. The procedures established to prevent unauthorized usage and distribution must provide for an accounting of the receipt and disposition of drugs subject to the Comprehensive Drug Abuse Prevention and Control Act of 1970. Other sources of additional guidelines could include, but are not limited to: American Society of Health-System Pharmacists, American College of Clinical Pharmacy, American Pharmacists Association, United States Pharmacopeia,	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Are questions regarding medication orders resolved with the prescriber and a written notation of these discussions documented in the patient's medical record or pharmacy copy of the prescriber's order? ▪ Does the hospital retrieve and remove medications available for patient use when the hospital has been informed of a drug recall?

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etc.

Note: US Pharmacopeia/National Formulary (USP/NF)

According to the Federal Food, Drug and Cosmetic Act (FD&C Act), the official compendia of the United States for excipients, drug substances, and drug products is the USP/NF. It is published every year in November by the United States Pharmacopeial Convention (http://www.usp.org/) and includes two supplements published in February and June.

The USP is a not-for-profit, non-governmental organization that since 1820 has established quality standards for, among other things, drug substances, drug products and compounded preparations. Congress established a role for USP standards in the adulteration provision of the 1906 Food and Drug Act. That role was expanded in the modern FD&C Act beginning in 1938, with a role for USP compendial standards for naming and identity; strength, quality, and purity; and packaging and labeling, in both the adulteration and misbranding provisions of the Act. (See, for example, §501(b) of the FD&C Act regarding compendial standards for strength, quality, and purity, §502(g) for compendial standards for packaging and labeling). Under the Act, a drug with a name recognized in the USP/NF must comply with compendial identity standards, or be deemed adulterated, or misbranded, or both. To avoid being deemed adulterated, such drugs must also comply with compendial standards for strength, quality, and purity, unless labeled to show all respects in which the drug differs.

The hospital must have a process in place for medication orders to be received in the pharmacy and dispensed in a safe and timely manner.

Safe dispensing of medications must be in accordance with accepted standards of practice and includes, but is not limited to, the following:

1. Implementing systems such as dose limits, pre-printed orders, special labeling, or double checks to minimize adverse drug events, especially for high alert medications.
2. Reviewing all medication orders (except in emergency situations) for

- Are medication orders routinely reviewed by the pharmacy before the first dose?
  - □ What evidence can the hospital present that such reviews take place?
- Does the hospital pharmacy have a system for monitoring the effects of medication therapies for cases specified per hospital policy?

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appropriateness by a pharmacist before the first dose is dispensed. A process is established for resolving questions with the prescribing practitioner and the discussion and outcome are documented in the patient's medical record or pharmacy copy of the prescriber's order.

This review should include:

□ Therapeutic appropriateness of a patient's medication regimen.

□ Therapeutic duplication in the patient's medication regimen.

□ Appropriateness of the drug, dose, frequency, and route of administration.

□ Real or potential medication-medication, medication-food, medication-laboratory test and medication-disease interactions.

□ Real or potential allergies or sensitivities.

□ Other contraindications.

RECALLED OR DISCONTINUED MEDICATIONS

Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons.

- Policies and procedures that address the use of medications brought into the hospital by patients or their families when self-administration of medications is permitted by hospital policy; and
- Having a system in place to reconcile medications that are not administered (e.g., left in the patient's medication drawer) when the pharmacy inventories patient medications or restocks patient medications. For example, did the patient refuse the medication, was there a clinical or treatment reason the medication was not used, or was the medication not used due to an error?

MONITORING THE EFFECTS OF MEDICATIONS

The pharmaceutical service may be responsible for monitoring the effects of

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	medication(s) specified per hospital policy to assure medication therapy is appropriate and minimizes the occurrence of adverse events. Typically, this occurs with anticoagulant therapy and antibiotics prescribed for the pharmacy to establish or adjust the dosage (i.e.; "pharmacy to dose" order). In such cases, the pharmacy's monitoring process includes: ▪ Clinical and laboratory data to evaluate the efficacy of medication therapy to anticipate or evaluate toxicity and adverse effects. ▪ Physical signs and clinical symptoms relevant to the patient's medication therapy. ▪ Assessing the patient's own perceptions about side effects, and, when appropriate, perceived efficacy. Note: See also the Nursing CoP discussion regarding monitoring of patients at standard 16.01.06 [42 CFR §482.23(c)(4)].	
25.01.02 Supervision of pharmacy activities *All compounding, packaging, and dispensing of drugs and biologicals must be under the supervision of a pharmacist and performed consistent with State and Federal laws.* *§482.25(b)(1)*	☐ Compliant ☐ Not Compliant All pharmaceutical services involving compounding, packaging, or dispensing of drugs and biologicals must be conducted by or under the supervision of a registered pharmacist and performed consistent with federal and state laws. The hospital must adopt and implement written policies and procedures to ensure all medications are prepared by authorized personnel. **COMPOUNDED PREPARATIONS** Hospitals use many medications that need to be reconstituted, mixed or which otherwise may be considered "compounded" preparations. Some may be compounded in the hospital pharmacy and/or the hospital may obtain some or all from external sources. The external sources could include: ▪ Manufacturers.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Determine that only pharmacists or pharmacist-supervised personnel compound, package and dispense drugs or biologicals in accordance with State and federal laws and regulations and as accepted standards of practice by: □ Interviewing pharmacy and hospital staff to determine who prepares and dispenses drugs and biologicals. □ Observing onsite preparation and

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- Registered outsourcing facilities.
- Compounding pharmacies.

Regardless of the source, if accepted standards for safe compounding are not met, compounded medications may contain less or more than the intended dose and/or may be chemically or microbiologically contaminated, with potentially devastating or even lethal consequences for the patients who receive them.

USE OF REGISTERED OUTSOURCING FACILITIES

The Drug Quality and Security Act (DQSA), signed into law on November 27, 2013, contains provisions relating to the oversight of compounding of human drugs. The DQSA created a new section 503B in the FDCA under which a compounder may elect to become an "outsourcing facility."

The law defines an "outsourcing facility" as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B of the FDCA.

REGISTERED 503B OUTSOURCING FACILITIES

Facilities that elect to register as outsourcing facilities, per section 503B:

1. Must comply with the FDA's Current Good Manufacturing Practice (CGMP) requirements, which contain minimum requirements for the methods, facilities, and controls used in manufacturing, processing, and packing of a drug product. The CGMP requirements make sure that a product is safe for use, and that it has the ingredients and strength it claims to have. The FDA's publishes the most current versions of its draft and final regulations and guidance related to compounding on its website: fda.gov/drugs/pharmaceutical-quality-resources/current-good-manufacturing-practice-cgmp-regulations.
2. Will be inspected by FDA according to a risk-based schedule.
3. Must meet certain other conditions, such as reporting adverse events

dispensing operations (if applicable).

□ Inspecting drug storage areas.

- Can the hospital demonstrate that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures and quality assurance practices equivalent to or more stringent than the standards described in USP <795> and <797>?
  - □ Can the pharmacy director provide evidence that compounded medications used and/or dispensed by the hospital are being compounded consistent with standard operating procedures and quality assurance practices equivalent to or more stringent than the standards described in USP <795> and <797>?
  - □ If the hospital obtains compounded products from external compounding sources, are the external source(s) registered with the FDA as outsourcing facilities? If not, can the hospital demonstrate that it systematically evaluates and monitors whether the outside compounding pharmacy adheres to accepted standards for safe compounding? For example, does

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and providing FDA with certain information about the products they compound.

The Commissioner of the FDA encouraged the use of registered outsourcing facilities and noted that,
"[a]s a purchaser of compounded drugs, you can play an important role in improving the quality of compounded drugs by requiring compounding pharmacies that supply drugs to your facility to register as outsourcing facilities. Once they register, you and the patients you serve can be assured that FDA will inspect these facilities on a risk-based schedule, hold them to CGMP requirements, monitor the adverse event reports they are required to submit to the agency, and require appropriate labeling."

FDA has posted a list of Registered Human Drug Compounding Outsourcing Facilities, including the end date of the last FDA inspection related to compounding, whether investigators observed any significant objectionable conditions, and whether other FDA actions were taken based on the last inspection, at: fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities.

Note that these registered outsourcing facilities are also popularly referred to as "503B pharmacies."

USE OF 503A COMPOUNDING PHARMACIES
Compounding pharmacies, not registered as an outsourcing facility with the FDA, are popularly referred to as "503A pharmacies" and generally are subject to oversight only by their state pharmacy board.

If a hospital obtains compounded medications from a compounding pharmacy rather than a manufacturer or a registered outsourcing facility, then the hospital must demonstrate how it assures that the compounded medications it receives under this arrangement have been prepared in accordance with accepted professional principles for compounded drugs as well as applicable federal or state laws or regulations.

For example, does the contract with the vendor include provisions:

the contract include provisions ensuring that the hospital has access to quality assurance data verifying that the vendor is adhering to current USP <795> and <797> requirements, and can the hospital document that it obtains and reviews such data?

- Can the pharmacy director explain the risk level(s) of the CSPs being produced in-house and/or obtained from external sources? Can he or she demonstrate that the assigned risk levels are consistent with USP <797> or equivalent/more stringent standards?
- If any CSPs are produced in the hospital:
  - □ Ask for one or more examples of situations in which a BUD had to be determined for a compounded sterile medication (CSP) based on the policy. Interview pharmacy personnel assigned to carry out this function within the hospital and/or to assess how this is done by external source(s) of CSPs.
  - □ Is there evidence that the BUDs are determined consistent with the hospital's policies and procedures?
  - □ Interview staff who engage in sterile and non-sterile compounding. Are

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1. Ensuring that the hospital has access to quality assurance data verifying that the vendor is adhering to current USP <795> and <797> requirements, and can the hospital document that it obtains and reviews such data?
2. Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products?

MEDICATIONS COMPOUNDED BY THE HOSPITAL'S PHARMACY

- Only the pharmacy compounds or admixes all sterile medications, intravenous admixtures, or other drugs except in emergencies or when not feasible (for example, when there is a need for emergency or immediate patient administration of a compounded sterile preparation).
- In addition, all compounding of medications used or dispensed by the hospital must be performed consistent with standards of practice equivalent to or more stringent than those described in the compounding-related chapters in the United States Pharmacopeia and the National Formulary (USP) published by the U.S. Pharmacopeial Convention, which are recognized as authoritative guidance regarding minimum standards of safe practice applicable to both sterile and non-sterile compounding.

COMPOUNDING DEFINITION

- The definition of compounding as that term is used in the USP is found in USP Chapter <795> (USP <795>):

  "The preparation, mixing, assembling, altering, packaging and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order or initiative based on the practitioner/ patient/pharmacist/compounder relationship in the course of professional practice.

- Compounding includes the following:

  1. Preparation of drug dosage forms for both human and animal

they knowledgeable about applicable levels of aseptic practices?

□ Ask the pharmacy director to demonstrate how the following are accomplished to ensure that sterile compounding practices are consistent with USP <797> or equivalent/more stringent standards for the risk level(s) of CSPs being produced for/dispensed to hospital patients:

1) Verification of compounding accuracy and sterility.
2) Environmental quality and controls, including environmental sampling; testing and monitoring; and cleaning and disinfection;
3) Personnel training and competency assessment, including but not limited to accuracy/precision in identifying and measuring ingredients; cleansing and garbing; aseptic manipulation skills; environmental quality and disinfection; appropriate work practices within and adjacent to the direct compounding area; verification/calibration of equipment; sterilization; and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

patients

2. Preparation of drugs or devices in anticipation of prescription drug orders based on routine, regularly observed prescribing patterns
3. Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients
4. Preparation of drugs or devices for the purposes of, or as incident to, research (clinical or academic), teaching or chemical analysis
5. Preparation of drugs and devices for prescriber's office use where permitted by federal and state law."

Compounded medications, whether non-sterile or sterile, may be subject to physical and chemical contamination and unintended variations in strength. Microbial contamination and bacterial endotoxins are particularly hazardous with respect to compounded medications that are intended to be sterile.

MINIMUM STANDARDS OF PRACTICE

USP <797> outlines minimum standards of practice to be followed by all health care personnel in any setting when preparing, storing and transporting "compounded sterile preparations" (CSPs).

Its stated objective is "to describe conditions and practices to prevent harm, including death, to patients that could result from…microbial contamination…excessive bacterial endotoxins…variability of intended strength of correct ingredients…unintended chemical and physical contaminants…and ingredients of inappropriate quality…."

Contaminated CSPs are especially hazardous if administered into body cavities, the central nervous system, vascular system, eyes, joints, and/or used as baths for live organs and tissues.

"All compounded dosage forms that must be sterile when they are administered to patients" are considered by USP <797> to be CSPs, including but not limited to:

post-production quality checks.

- Review the hospital's procedures for maintaining the quality of CSPs during storage, transport and dispensing.
  - □ Are CSPs packaged in a manner to protect package integrity and sterility? How are CSP-specific requirements with respect to motion, light exposure, temperature and potentially hazardous contents addressed?
  - □ How does the hospital ensure that such information is effectively conveyed to non-pharmacy health care personnel and/or to patients/caregivers, if applicable?
- Can the hospital document that it is systematically monitoring and tracking adherence to all the quality assurance and personnel training and competency standards described above?
  - □ Have any problems or risks been identified? If so, did the hospital take effective action to protect patients, if relevant, and to effectively remedy the problem/risk?

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- Aqueous bronchial and nasal inhalations.
- Baths and soaks for live organs and tissues.
- Injections [and infusions].
- Irrigations for wounds and body cavities.
- Ophthalmic drops and ointments.
- Tissue implants."

PHYSICAL LAYOUT AND STRUCTURE

USP <797> specifies differing standards for the physical layout and structure of the locations in which compounding takes place as well as processes, precautions, and quality assurance practices to be implemented during the preparation, transport and storage of CSPs.

The standards differ in part based on the level of risk of microbial contamination of the CSP, and the risk level has implications for whether a CSP must be terminally sterilized before being dispensed and for how long a CSP may be stored before use.

RISK CATEGORIES

The risk categories and accompanying standards are based on specific criteria, including but not limited to, factors such as:

1. The structural design, environmental controls, air quality levels (based on International Organization for Standardization (ISO) standards for particulate matter in air) and air flow patterns in and surrounding the environment to which the contents of the CSP as well as the surfaces of devices and containers for the preparation, transfer, sterilization and packaging of CSPs are exposed.
2. The sterility of the original ingredients and/or device(s) used in compounding, the number of containers that need to be entered, how many times they need to be entered, the nature and complexity of the manipulations and length of time required to prepare the CSP.

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3. Whether compounding personnel are appropriately garbed and gloved.
4. Whether multiple doses of sterile products are pooled to produce a CSP that will be administered on more than one occasion or to more than one patient.

GOAL OF THE USP <797> STANDARDS

The goal of the USP <797> standards is to prevent and/or minimize the risk of microbial contamination of CSPs, whether by direct contact, exposure to particles in air generated by personnel or objects, or other mechanisms.

A major concern is preventing contamination of "critical sites," which include "any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampules, needle hubs) exposed or at risk of direct contact with air…moisture…or touch contamination."

USP <797> describes two basic structural designs for the physical layout and environmental controls intended to minimize airborne contamination of critical sites during preparation of CSPs.

The risk level of the CSPs a facility can produce depends, in part, on which USP <797> environmental quality and control/facility design standards the hospital (or its vendor) is able to meet (low-risk level, medium-risk level and high-risk level are discussed here; see 42 CFR §482.23(c) for a discussion of "immediate-use" CSPs):

1. Some facilities may only prepare low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient, and administration must commence within the lesser of 12 hours of preparation or as recommended in the manufacturer's package insert. Such a facility would have a designated, demarcated room or space that is the "segregated compounding area (SCA)," which contains a device that provides unidirectional airflow of International Standards Organization (ISO) Class 5 air quality (quality class ranges from class 0, the most stringent, to class 9, the most relaxed). The SCA may not be in an area with unsealed openings/potential openings to high traffic

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locations, the outdoors and other proscribed environmental conditions, and the SCA area may not contain any materials or be the site of any activities unrelated to preparing low-risk CSPs.

2. If a facility is preparing high- or medium-level risk CSPs or low-risk CSPs with a beyond-use date of greater than 12 hours, it must meet additional environmental design and monitoring/testing standards in the buffer and ante-areas.
3. USP<797> contains separate standards for the safe compounding of hazardous medications (defined as "...if studies in animals or humans indicate that exposures to them have a potential for causing cancer, development or reproductive toxicity, or harm to organs…"), radiopharmaceuticals and allergen extracts.

In addition, USP <797> includes standards for various processes, precautions and quality assurance practices required and recommended for the safe preparation of all risk levels of CSPs. These address issues such as:

1. The responsibilities of compounding personnel and their supervisors to implement and maintain proper procedures and quality assurance checks.
2. Issues specific to "immediate use" CSPs; single- and multiple-dose containers; CSPs containing hazardous drugs; radiopharmaceuticals; allergen extracts; and automated compounding devices used for parenteral nutrition compounding.
3. Methods for sterilization, depyrogenation, and for verifying compounding accuracy and sterility.
4. Specifications for environmental quality and control, including but not limited to:
5. Specifications and related personnel training, including competency assessment and evaluation of skill in aseptically preparing CSPs using visual observation as well as bacterial sampling of glove fingertips and "media-fill testing" at specified intervals.

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6. Evaluation and monitoring/testing of the environment in which compounding takes place and, if applicable, the adjacent "ante-" and "buffer" areas, including facility layout, design, environmental controls, restricted access, air quality standards and testing, surface characteristics, furnishings, cleaning and disinfection procedures, and standards for personnel health, attire/cosmetics, cleansing/garbing/gloving, aseptic work practices, etc.
7. Suggested standard operating procedures to protect the quality of the environment in which CSPs are prepared.
8. Quality control related to ingredients, devices and equipment used in relation to CSPs.
9. Quality checks to be performed before CSPs are dispensed or administered.
10. Issues related to beyond-use dating and packaging, storage and transportation conditions for CSPs.
11. Protecting dispensed and distributed CSPs.
12. Patient education issues.
13. Monitoring for and reporting adverse patient events related to CSPs.
14. Requirements for a formal quality assurance program to be maintained by providers of CSPs.

Note: For information only – Not Required/Not to be Cited

USP<797> Appendices I and III-V contain summaries and assessment tools that hospitals may find helpful. However, there is no requirement to use specific forms or materials as long as the hospital and/or its external sources of CSPs are implementing plans, procedures, testing and documentation consistent with applicable standards for safe compounding.

PACKAGING AND LABELING OF MEDICATIONS

Safe medication use includes proper packaging and labeling to reduce the risk

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

of error.

For individual drug containers:

1. Each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date.
2. Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a beyond-use date (BUD).
3. It should be noted that, for multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., needle-punctured), the USP standard is that the BUD is 28 days, unless otherwise specified by the manufacturer.
4. In addition, where applicable, each patient's individual drug container is expected to be labeled with the patient's full name and quantity of the drug dispensed.

If the unit dose system is used, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD.

Note: For information only
Certain provisions of the FDCA address the labeling of prescription drugs generally (e.g., section 503(b)(2) of the FDCA). Section 503B of the FDCA includes labeling requirements for drugs compounded by registered outsourcing facilities (see section 503B(a)(10)).

Although hospitals are expected to comply with these requirements, surveyors conducting a Medicare survey do not assess compliance with other Federal laws.

DISPENSING OF MEDICATIONS

Medications must be dispensed in a manner that is safe and meets the needs of the patient.

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- Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of patients.
- Medications are dispensed in a timely manner. The hospital must have a system that ensures that medication orders get to the pharmacy and medications get back to patients promptly.
- Whenever possible, medications are dispensed in the most ready-to-administer form available from the manufacturer or, if feasible, in unit dose that have been repackaged by the pharmacy.
- The hospital consistently uses the same dose packing system, or, if a different system is used, provides education about the use of the dose packaging system.
- All concerns, issues or questions are clarified with the individual prescriber before dispensing; and
- Medications dispensed by the hospital are retrieved when recalled or discontinued by the manufacturer or the Food and Drug Administration (FDA) for safety reasons.

AVAILABILITY OF MEDICATIONS

Medications must be available for administration to patients when needed, including when the pharmacy is not open.

Methods to accomplish this when the pharmacy is not open could include, but are not limited to, one or more of the following:

- Automated dispensing units outside the pharmacy, night cabinets, contracted services after hours via telepharmacy contracting, on-call pharmacists, etc.
- Automated Dispensing Cabinets (ADCs) for medications are a secure option for medication storage since they ensure locked storage of medications and allow for electronic tracking of controlled substances and other drugs. These cabinets often have embedded security features, such as login and password or biometric identification so that they can

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

only by accessed by authorized personnel.

- Policies and procedures must address who can access medications during after-hours.

Note: For information only - Not required/Not to be cited

When using automated dispensing cabinets (ADCs), the Institute for Safe Medication Practices recommendations include the following:

- Security processes are established to ensure adequate control of medications outside of the pharmacy and to reduce the potential for medication diversion from ADCs.
- Utilize biometric user identification or, at a minimum, change user passwords quarterly.
- Link the ADC to the pharmacy computer to allow for patient "profiling," so that a pharmacist can review each medication order and screen it for safety before the drug is dispensed or accessed by the nurse or other healthcare professional.
- Limiting the availability of overrides to the ADC system.
- Limiting access to drugs based on the patients profile so to decrease medication selection errors.
- Store each medication and strength in an individual lidded ADC compartment that opens only when the specific medication is selected.
- Document the destruction of medication waste at the time of removal of medication whenever possible. Record this waste via the ADC, and match the administered dose with ordered dose. Have a process to routinely review/ reconcile the documented medication waste.
- Return all medications to a common secure one-way bin that is maintained by pharmacy, not to an individual pocket or bin within the ADC.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
25.01.03 Security of medications	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Consistent with state and federal requirements, in the pharmacy and throughout the facility: ▪ *All drugs and biologicals must be kept in a secure area, and locked when appropriate.* §482.25(b)(2)(i)	A secure area means that drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. **An area in which staff are actively providing care to patients or preparing to receive patients, i.e., setting up for procedures before the arrival of a patient, would generally be considered a secure area. When a patient care area is not staffed, both controlled and non-controlled substances are locked.** **RESTRICTED AREAS** Areas restricted to authorized personnel would generally be considered "secure areas." If there is evidence of tampering or diversion, or if medication security otherwise becomes a problem, the hospital must evaluate its current medication control policies and procedures and implement changes to ensure that the problem is corrected, and that patient health and safety are maintained. **CONTROLLED SUBSTANCES** All controlled substances must be locked. When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked. **LABOR AND DELIVERY, CRITICAL CARE, AND SURGERY** Generally, labor and delivery suites and critical care units are considered secure if they are staffed and actively providing patient care. However, hospital policies and procedures are expected to ensure that these areas are secure, with entry and exit limited to appropriate staff, patients, and visitors **after patient care hours or when the unit is closed or not in use.** A hospital may choose to lock the entire suite, lock non-mobile carts containing drugs and biologicals, place mobile carts in a locked room, or otherwise lock drugs and biologicals in a secure area. If an individual	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Review hospital policies and procedures governing the security of drugs and biologicals to determine whether they provide for securing and locking as appropriate. ▪ Observe whether medications in various areas of the hospital are stored in a secure area and locked when appropriate. Are medication storage areas periodically inspected by pharmacy staff to make sure medications are properly stored? ▪ Verify that security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc. ▪ Review hospital policies and procedures governing patient self-administration of drugs and biologicals. ▪ Interview staff to determine whether policies and procedures regarding patient self-administration of drugs and biologicals are implemented and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

operating room is not in use, the hospital is expected to lock non-mobile carts, and ensure mobile carts are in a locked room.

This regulation gives the hospital the flexibility to integrate patient self-administration of non-controlled drugs and biologicals into their practices as appropriate.

SELF-ADMINISTRATION

When the hospital allows a patient to self-administer selected drugs and biologicals, the hospital authorizes the patient to have access to these medications. This regulation is consistent with the current practice of giving patients access at the bedside to urgently needed medications, such as nitroglycerine tablets and inhalers. It supports the current practice of placing selected nonprescription medications at the bedside for the patient's use, such as lotions and creams, and rewetting eye drops.

Hospitals are expected to address patient self-administration of non-controlled drugs and biologicals in their policies and procedures (see 42 CFR §§482.23(c)(6)(i) and 482.23(c)(6)(ii)). This regulation supports hospital development, in collaboration with the medical staff and the nursing and pharmacy departments, of formal patient medication self-administration programs for select populations of patients, including hospital policies and procedures necessary to ensure patient safety and security of medications.

The policies and procedures are expected to include measures to ensure the security of bedside drugs and biologicals. They are also expected to address both the competence of the patient to self-administer drugs and biologicals as well as patient education regarding self-administration of drugs and biologicals.

MEDICATION CARTS

Due to their mobility, mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing drugs or biologicals (hereafter, all referred to as "carts") must be locked in a secure area when not in use. Hospital policies and procedures are expected to address the

effective.

- If patient self-administration of drugs and biologicals is permitted, interview patients and staff to determine whether policies and procedures to restrict access to authorized personnel are implemented and effective.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	security and monitoring of carts, locked or unlocked, containing drugs and biologicals in all patient care areas to ensure their safe storage and to ensure patient safety. **AUTOMATED DISTRIBUTION UNITS** Medication automated distribution units with security features, such as logon and password or biometric identification, are considered to be locked, since they can only be accessed by authorized personnel who are permitted access to the medications. Such units must be stored in a secure area.	
25.01.04 Controlled substances *Drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 must be kept locked within a secure area.* §482.25(b)(2)(ii)	☐ Compliant ☐ Not Compliant A secure area means the drugs and biologicals are stored in a manner to prevent unmonitored access by unauthorized individuals. Medication automated distribution units with logon and password/biometric identification are considered to be locked, since they can only be accessed by authorized personnel who are permitted access to Schedule II – V medications. Mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing Schedule II, III, IV, and V drugs must be locked within a secure area.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Verify that hospital policy and procedure requires Schedule II, III, IV, and V drugs to be kept in a locked storage area. ▪ Observe in various parts of the hospital whether Schedule II, III, IV and V drugs are locked and stored in a secure area. ▪ Determine whether security features in automated medication distribution units are implemented and actively maintained, e.g., that access authorizations are regularly updated to reflect changes in personnel, assignments, etc. ▪ Interview staff to determine whether policies and procedures to restrict

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

access to authorized personnel are implemented and effective.

25.01.05 Access to controlled substances

Only authorized personnel may have access to locked areas.

§482.25(b)(2)(iii)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital must assure that only authorized personnel may have access to locked areas where drugs and biologicals are stored.

A hospital has the flexibility to define which personnel have access to locked areas, based on the hospital's needs as well as State and local law. For example, a hospital could include within its definition of "authorized personnel" ancillary support personnel, such as engineering, housekeeping staff, orderlies, and security personnel as necessary to perform their assigned duties.

The hospital's policies and procedures must specifically address how "authorized personnel" are defined for purposes of this section. It is not necessary for the policy to name specific authorized individuals, but the policy should be clear in describing the categories of personnel who have authorized access, as well as whether there are different levels of access authorized in different areas of the hospital, or at different times of day, or for different classes of drugs and biologicals, etc.

The hospital's policies and procedures must also address how it prevents unauthorized personnel from gaining access to locked areas where drugs and biologicals are stored. Whenever unauthorized personnel have access, or could gain access, to those locked areas, the hospital is not in compliance with this requirement and is expected to re-evaluate and tighten its security measures.

INTERVIEW AND DOCUMENT REVIEW

- Verify that there is a hospital policy and procedure for limiting access to locked storage areas to authorized personnel only.
- Verify that there is a hospital policy and procedure defining authorized personnel permitted access to locked areas where drugs and biologicals are stored.
- Observe whether access to locked storage areas is limited to personnel authorized by the hospital's policy.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
25.01.06 Pharmacy security	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
At a minimum, the pharmacy is equipped with locking entries.	The pharmacy is locked when not staffed. Key inventories or access codes are strictly controlled. If "unusual" risk is perceived, measures are taken to respond.	**OBSERVATION AND INTERVIEW** ▪ Evaluate the security of the pharmacy. □ The area is secure from unauthorized entry. □ Keys, security codes, and carts are secure.
25.01.07 Inventory management system	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use. §482.25(b)(3)	The hospital must have a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patent use. This would include drugs that are the subject of a manufacturer's recall. A drug or biological is outdated after its expiration date, which is set by the manufacturer based on stability testing under specified conditions as part of the FDA approval process. It should be noted that a drug or biological may become unusable prior to its expiration date if it has been subjected to conditions that are inconsistent with the manufacturer's approved labeling. **BEYOND-USE DATE** A drug or biological is also outdated after its "beyond-use date" (BUD), which may be reached before the expiration date, but never later. The BUD takes into account the specific conditions and potential for deterioration and microbial growth that may occur during or after the original container is opened, while preparing the medication for dispensing and administration, and/or during the compounding process if it is a compounded	**OBSERVATION** ▪ Interview staff to determine their familiarity with pharmacy-related policies and procedures. ▪ Verify that: □ Space allocation allows for orderly storage of inventory. □ Schedule II inventory is stored separately and double locked.

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medication.

The BUD is to be based on information provided by the manufacturer, whenever such information is available.

- The hospital must maintain and implement policies and procedures that provide clear and consistent direction to pharmacy staff regarding how to determine a BUD when complete BUD information is not available from the manufacturer.
- The policies and procedures must be based on accepted professional principles which are equivalent to, or more stringent than, those described in the United States Pharmacopeia-National Formulary (USP).

According to Chapters <795> and <797> of the USP, the BUD must be safe for patients, and determined conservatively.

- The section in USP <797> entitled "Determining Beyond-Use Dates," which addresses sterile compounding, notes that "the truly valid evidence for predicting beyond-use dating can be obtained only through product-specific experimental studies."
- It provides an example of testing considered more appropriate for certain types of compounded sterile preparations (CSPs) such as "CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity…."
- It also provides examples of important issues that a pharmacist must be able to critically interpret and evaluate when consulting literature sources in the process of determining a BUD; and distinguishes between reviewing literature specific to a particular drug, composition, concentration of ingredients, fill volume, container, storage conditions and duration of use, etc., versus merely reviewing available publications or tables.
- The former is the preferred approach, while the latter results in a "theoretical BUD," which has an inherent likelihood of inaccuracy or

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	error. **FOR INDIVIDUAL DRUG CONTAINERS** ▪ Each floor stock drug container is expected to be labeled with the name and strength of the drug, lot and control number equivalent, and expiration date. ▪ Appropriate accessory and cautionary statements are included as well as the expiration date and/or, if applicable, a BUD. ▪ It should be noted that, for multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., needle-punctured), the USP standard is that the BUD is 28 days, unless otherwise specified by the manufacturer. ▪ In addition, where applicable, each patient's individual drug container is expected to be labeled with the patient's full name and quantity of the drug dispensed. If the unit dose system is used, each single unit dose package is expected to be labeled with the name and strength of the drug, lot and control number equivalent, expiration date and/or, if applicable, a BUD.	
25.01.08 Pharmacy access *When a pharmacist is not available, drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and State law.* §482.25(b)(4)	☐ Compliant ☐ Not Compliant Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be minimized and eliminated as much as possible. The use of well-designed night cabinets, after-hours medication carts, and other methods may preclude the need for non-pharmacist staff to enter the pharmacy. If an urgent or emergent patient need occurs, the hospital must be able to provide medications to the patients in its facility. The hospital must have a process for providing medications to meet patient	This standard is not met as evidenced by: **OBSERVATION** ▪ Interview staff to determine their familiarity with pharmacy-related policies and procedures. ▪ Verify that: □ Space allocation allows for orderly storage of inventory. □ Schedule II inventory is stored

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

needs when the pharmacy is closed.

Policies and procedures must be consistent with federal and state law.

When non-pharmacist healthcare professionals are allowed by law and regulation to obtain medications after the pharmacy is closed, the following safeguards are applied:

1. Access is limited to those medications approved by the hospital. These medications can be stored in a night cabinet, automated storage and distribution device, or a limited section of the pharmacy.
2. Only trained, designated prescribers and nurses are permitted access to medications.
3. Quality control procedures (such as an independent second check by another individual or a secondary verification built into the system, such a bar coding) are in place to prevent medication retrieval errors.
4. The hospital arranges for a qualified pharmacist to be available either on-call or at another location (for example, at another organization that has 24-hour pharmacy service) to answer questions or provide medications beyond those accessible to non-pharmacy staff.
5. The process is evaluated on an on-going basis to determine the medications accessed routinely and the causes of accessing the pharmacy after hours.
6. Changes are implemented as appropriate to reduce the amount of times non-pharmacist health care professionals are obtaining medications after the pharmacy is closed.

Medication removals from the pharmacy or drug cabinet:

1. Are recorded.
2. Are in quantities sufficient only to dose until a pharmacist can review the order and the removal record. (This activity is to be in "preparation for immediate dosing only"; dispensing by non-pharmacists is not permitted.) Some states prohibit entry into the pharmacy proper unless separately and double locked.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	a pharmacist is present thus requiring use of "night" closets or drug cupboards for afterhours supply. 3. All after-hour withdrawals are logged.	
25.01.09 Automatic stop medication orders *Drugs and biologicals not specifically prescribed as to time and/or number of doses must automatically be stopped after a reasonable time that is predetermined by the medical staff.* §482.25(b)(5)	☐ Compliant ☐ Not Compliant In accordance with accepted standards of practice, the medical staff, in coordination and consultation with the pharmacy service, determines and establishes the reasonable time to automatically stop orders for drugs and biologicals not specifically prescribed as to time or number of doses. Hospitals with an electronic health record (EHR) system may have time and dose parameters automatically built into computerized provider order entry (CPOE) screens. These may be part of the hospital's plan for addressing automatic stop orders.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review policies and procedures to determine that there is a protocol established by the medical staff to discontinue and review patients' medical records to determine compliance with stop-order policy. ▪ Ask unit staff what happens in the case of drugs with no stop date or prescribed number of doses. □ Are they aware of the automatic stop policy? Can they describe how it is enforced?
25.01.10 Drug reactions and administration errors and incompatibilities *Drug administration errors, adverse drug reactions and incompatibilities must be immediately reported to the attending physician and if appropriate, to the hospital's quality assurance and* performance improvement *program.*	☐ Compliant ☐ Not Compliant Hospitals are required to ensure that the attending physician is made immediately aware of drug administration errors, adverse drug reactions, and incompatibilities. When the attending physician is unavailable, the covering physician must be notified. When the covering physician must be notified, the patient's	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the hospital has an effective procedure that ensures drug administration errors, adverse drug reactions, and drug incompatibilities are immediately reported to the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

§482.25(b)(6)

attending physician must be notified as soon as he/she is available.

REPORT TO QAPI

In addition, when appropriate, such events must also be reported to the hospital-wide Quality Assessment and Performance Improvement (QAPI) program.

The hospital must adopt policies and procedures that identify the types of events that must be reported immediately to the attending physician, as well as those to be reported to the QAPI program.

DRUG ADMINISTRATION ERROR

The National Coordinating Council Medication Error Reporting and Prevention definition of a medication error is:

Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

In the context of this regulation, however, "drug administration error" is limited to those errors in administration that actually reach the patient, i.e., a medication actually is administered to a patient when it should not be, or the wrong dose is administered, or the wrong root of administration is used, etc., or a medication that should have been administered to the patient has not been administered in a timely manner, as discussed in the medication administration standard at 42 CFR 482.23(c).

ADVERSE DRUG REACTION

The American Society of Health-System Pharmacists (ASHP) defines an adverse drug reaction (ADR) as "Any unexpected, unintended, undesired, or excessive response to a drug that:

attending physician.

- Verify that medication error reporting includes all areas where medication is prepared and administered, e.g., pharmacy, radiology, anesthesia, respiratory therapy, and etc.
- Does the hospital have policies and procedures that define medications errors, ADRs, and drug incompatibilities?
  - □ Is the facility's definition of an adverse drug reaction and medication error based on established benchmarks or studies on report rates published in peer-review journals? Is it identifying as many medication errors and adverse drug reactions as would be expected for the size and scope of services provided by the hospital?
  - □ Do they address the circumstances under which they must be reported immediately to the attending physician, as well as to the hospital's QAPI program?
  - □ Do they address how reporting is to occur?
- Are all medication errors and suspected ADRs promptly recorded in the patient's medical record, including

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1. Requires discontinuing the drug (therapeutic or diagnostic);
2. Requires changing the drug therapy;
3. Requires modifying the dose (except for minor dosage adjustments);
4. Necessitates admission to a hospital;
5. Prolongs stay in a health care facility;
6. Necessitates supportive treatment;
7. Significantly complicates diagnosis;
8. Negatively affects prognosis; or
9. Results in temporary or permanent harm, disability, or death.

Consistent with the definition, an allergic reaction (an immunologic hypersensitivity occurring as the result of unusual sensitivity to a drug) and an idiosyncratic reaction (an abnormal susceptibility to a drug that is peculiar to the individual) are also considered ADRs."

DRUG INCOMPATIBILITIES

A drug incompatibility occurs when drugs interfere with one another chemically or physiologically. Drugs known to be incompatible must not be mixed, administered together, or administered within a timeframe where they will interfere with each other.

When IV medications are administered with known incompatibilities, an error has occurred and it needs to be reported to the attending physician immediately. Any unexpected reaction that occurs between IV medications not previously identified as incompatible also needs to be reported.

Hospitals can minimize the risk of administering incompatible medications by making available pertinent resources, such as drug incompatibility charts and online incompatibility references. The incompatibility information needs to be readily available to staff administering medications. The information needs to be kept up-to-date as the information is frequently updated by drug

those not subject to immediate reporting?

- If upon review of a sample of records, a suspected ADR or medication error is identified, determine if it was reported immediately to the attending or covering physician, in accordance with the hospital's written policies and procedures.
- If it is reported to a covering physician, determine if it was also reported to the attending physician when he/she became available.
- Ask hospital staff what they do when they become aware of a medication error, ADR, or drug incompatibility. Are staff aware of and do they follow the hospital's policy and procedures?
- Ask hospital staff how they manage drug incompatibilities.
  - □ What tools do they use in the clinical setting to minimize the risk of incompatibilities?
  - □ How is the information related to drug incompatibilities made available to the clinical staff administering IV medications (posters, online tools, etc.)?
  - □ How often is the information updated to ensure accuracy?

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manufacturers.

The immediate reporting requirement applies to drug administration errors, adverse drug reactions or incompatibilities that have harmed or have the potential to harm the patient. If the outcome of the drug administration error is unknown, the physician must also be notified without delay.

Drug administration errors that result in no or insignificant harm to the patient must also be documented in the medical record but do not require immediate reporting to the attending physician. For example, if an analgesic dose is missed during the night shift, it can be reported first thing in the morning. Hospital staff are expected to use their clinical judgment, based on patient presentation and assessment in accordance with hospital policy and procedures, to determine whether immediate reporting is required.

On the other hand, for purposes of reporting to the hospital's QAPI program, hospitals must, in accordance with the requirements of the QAPI CoP at 42 CFR §482.21(c)(2), track and report not only the errors that cause or risk harm to the patient, but also those which do not. Such "near misses" and suspected ADRs may reveal important information about systems vulnerabilities that the hospital should address to avoid events that result in harm.

Hospitals must establish policies and procedures for reporting of medication errors, ADRs, and incompatibilities, and ensure that staff are aware of the reporting process. For those events that require immediate reporting, the hospital's policies must establish timeframes for reporting that are based on the clinical effect of the error on the patient.

To improve staff willingness to report medication error incidents, hospitals are encouraged to adopt a non-punitive approach that focuses on system issues rather than individual health care professionals. A non-punitive approach is likely to encourage reporting by those who otherwise may fear retribution or hospital disciplinary action.

In addition to employing broad definitions of medication errors and ADRs for QAPI tracking purposes and encouraging reporting of medication errors, ADRs

- Interview hospital staff to verify awareness of the hospital's policy on reporting and documentation of medication errors and adverse drug reactions.
- How does information regarding medication errors, adverse drug reactions, and incompatibilities get reported to the hospital QAPI program? Ask staff to speak to the process.
- Review QAPI activities for medication errors and adverse reaction reports to determine if upon analyses of the reports that potential corrective actions are identified and implemented, if appropriate.

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	and drug incompatibilities, the hospital must take additional steps to identify these events as part of its QAPI program. Reliance solely on incident reporting fails to identify the majority of errors and adverse reactions. Proactive identification includes observation of medication passes, concurrent and retrospective review of a patient's clinical records, ADR surveillance team, implementation of medication usage evaluations for high-alert drugs, and identification of indicator drugs that, when ordered, automatically generate a drug regimen review for a potential adverse drug event. The hospital must have a method by which to measure the effectiveness of its systems for identifying and reporting to the QAPI program medication errors and ADRs. Such methods could include use of established benchmarks for the size and scope of services provided by the hospital, or studies on reporting rates published in peer-reviewed journals. Hospitals are encouraged, and may be required by State law, to participate in statewide and national reporting of drug administration errors, adverse drug reactions, and incompatibilities. National organizations include, but are not limited to, the Food and Drug Administration's (FDA) MedWatch Reporting Program and the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program.	
25.01.11 <u>Reporting of controlled drug loss and/or abuse</u> *Abuses and losses of controlled substances must be reported, in accordance with applicable Federal and State laws, to the individual responsible for the pharmaceutical service, and to the chief executive officer, as appropriate.* §482.25(b)(7)	☐ Compliant ☐ Not Compliant The tracking system for scheduled drugs is capable of detecting and reporting such abuses and losses.	This standard is not met as evidenced by: **<u>OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW</u>** ▪ Review the policy/procedure regarding abuse or loss of controlled substances to verify that it addresses the reporting of abuse and losses to the CEO, DEA (Drug Enforcement Agency), and appropriate State Boards in accordance with state and federal laws.

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		▪ Interview the pharmacists or pharmacy employees to determine their understanding of the controlled drug policies. ▪ Review reports of pharmaceutical services to determine if there are reported problems with controlled drugs and what actions have been taken to correct the situation. ▪ Conduct a spot check of drug use and other inventory records to ensure that drugs are properly accounted for. ▪ Interview the Pharmacy Director, pharmacist and pharmacy employees to determine their understanding of the controlled drug policies. □ Is there a policy and procedure for handling controlled drug discrepancies? □ Have problems with controlled drugs, if any, been reported to the authorities, according to policy?
25.01.12 Informational resources *Information relating to drug interactions and information of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration must be*	☐ Compliant ☐ Not Compliant The pharmacy must be a resource for medication-related information to the hospital's health-care practitioners and other health care personnel to optimize therapeutic outcomes and minimize adverse drug events. Information must be available concerning drug interactions and information	This standard is not met as evidenced by: **OBSERVATION AND INTERVIEW** ▪ Is drug information readily available to nurses and practitioners, whether in hard copy or electronic format?

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available to the professional staff. §482.25(b)(8)	of drug therapy, side effects, toxicology, dosage, indications for use, and routes of administration. The pharmacy may also assist other health care professionals with the following medication-related functions: 1. Collection and organization of patient-specific information (height, weight, allergies). 2. Identification of the presence of medication-therapy problems, both potential and actual, such as drug-drug interactions, excessive doses. 3. Identification and specification of pharmaco-therapeutic goals. 4. Implementation of a monitoring plan in collaboration with the patient, if applicable, and other health-care professionals. 5. Monitoring the effects of the pharmaco-therapeutic regimen – could include adjusting doses based on lab values (i.e.: Coumadin dosing). 6. Redesigning the regimen and monitoring plan as indicated. For example, practitioners may write an order for "pharmacy to dose" an antibiotic. The pharmacist would then take patient-specific information, review the patient's current medication therapies for any problems, and then calculate the dose required to meet therapeutic goals. Increasingly, as hospitals move to computerized physician-order entry (CPOE) of medication orders, much of this consultation function (e.g.; dosage, path of administration, drug-drug interactions and other contraindications, etc.) is built in to the electronic health record (EHR) system. ▪ However, the pharmacy service remains responsible for the provision of accurate, up-to-date information to meet the needs of the hospital's practitioners, nursing staff and patients. The hospital must also have immediately available sufficient up-to-date reference material on drug therapy, whether in electronic or hard copy format.	▪ If drug information is built in to the hospital's EHR system, ask the pharmacy director how the hospital ensures that the information is accurate and up-to-date. ▪ Ask practitioners whether needed reference information is available to them when prescribing drugs. ▪ Ask nursing staff whether needed reference information is available to them when administering drugs or biologicals and when monitoring patients for effects of medication therapies.

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	A pharmacist also should be readily available by telephone or other means to respond to questions from practitioners and nursing personnel.	
25.01.13 Formulary system *A formulary system must be established by the medical staff to assure quality pharmaceuticals at reasonable costs.* §482.25(b)(9)	☐ Compliant ☐ Not Compliant The medical staff must establish a formulary system. The formulary is reviewed at least annually to ensure the contents are current. The formulary lists medications for dispensing or administration that the hospital maintains or that are readily available. In accordance with accepted standards of practice, the medical staff, in consultation with the pharmacy service, should develop written criteria for determining what medications are available for dispensing or administration. ▪ At a minimum, the criteria include the indication for use, effectiveness, risks (including propensity for medication errors, abuse potential, and sentinel events), and costs. Processes and mechanisms should be established to monitor patient responses to a newly added medication before the medication is made available for dispensing or administration within the hospital. Medications designated as available for dispensing or administration are reviewed periodically based on emerging safety and efficacy information. The hospital should have processes to approve and procure medications that are not on the hospital's medication list. The hospital should have processes to address medication shortages and outages including the following: ▪ Communicating with appropriate prescribers and staff. ▪ Developing approved substitution protocols. ▪ Educating appropriate Licensed Independent Practitioners (LIPs),	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Interview the pharmacist to verify that the medical staff has established a formulary that lists drugs that are available in the hospital. ▪ Interview the Pharmacy Director to determine the process for periodic review of the formulary. ▪ Verify that the formulary lists drugs that are available. ▪ Verify that the formulary is current by reviewing the date of approval by the Medical Staff. ▪ Observe for availability of the formulary in the clinical areas. ▪ Interview clinical staff regarding the availability of the formulary. ▪ The formulary/drug list is more than a pharmacy charge - master; it includes remotely purchased/stored drugs/ biological/diagnostic testing agents.

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	appropriate health care professionals, and staff about these protocols. ▪ Obtaining medications in the event of a disaster. Processes and mechanisms should be established to: ▪ Monitor patient responses to newly added medication before the medication is made available for dispensing or administration within the hospital. ▪ Approve and procure medications that are not on the hospital's formulary/drug list.	
25.01.14 Integrity of medication	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Drugs and biologicals are stored at proper temperatures to maintain strength/ potency. Records are maintained of drug refrigerator and freezer temperatures.	Daily temperature records, from accurate thermometers, are maintained for each drug refrigerator/freezer. Thermometer accuracy is verified against a known standard on a semiannual basis. Recommended guidelines* for consideration are: ▪ Refrigerator temperature range: □ Between 2° – 8° centigrade/ (36° and 46° Fahrenheit). ▪ Freezer temperature range: □ Between minus 25 degrees and minus 10 degrees centigrade (-25° and -10° centigrade) / (-13° and 14° Fahrenheit). *Reference USP 797	**OBSERVATION** ▪ Interview staff to determine their familiarity with pharmacy-related policies and procedures. ▪ Verify that: □ Space allocation allows for orderly storage of inventory. □ Schedule II inventory is stored separately and double locked.
25.01.15 Consultations/resource availability	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:

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Pharmaceutical consultation is made available to prescribers of drugs, to staff administering drugs, and as appropriate to patients and families.	There must be sufficient pharmacist time to provide for consultations, even if there is only a part time or consulting pharmacist. In all instances, a pharmacist serves on the professional medical staff committee(s) which discusses drug therapy. A pharmacist provides in-service programs for nursing staff and serves as a resource to clinical staff.	**INTERVIEW** Verify: ▪ A pharmacist serves on appropriate medical staff committees. ▪ There is sufficient staffing to provide such consultations and educational services for: □ Clinical staff □ Nursing staff □ Patients and families
25.01.16 Medication protocols	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
"Standing," routine, or protocol orders are reviewed and revised by the prescribing practitioner and the professional medical staff at least annually.	When protocol orders are used, the practitioner individualizes the orders for each patient. The order is dated, timed, and signed by the ordering practitioner. Annually, protocol orders are reviewed, updated as indicated, and approved by the Medical Staff. The sponsoring practitioner authenticates the "master" copy as evidenced by his/her signature.	**INTERVIEW AND DOCUMENT REVIEW** Verify: □ All standing or routine orders have been subject to annual review and/or revision. □ Standing orders/protocols have been reviewed by the Professional medical staff via its committee structure. ▪ Interview the Pharmacy Director to ask if there are protocols which have not been so reviewed.

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25.01.17 Home medications	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The professional medical staff, via policy and/or rules and regulations, establishes standards regarding the use of medications brought into the facility by patients.	The facility has a process to identify medications brought into the facility from home. If such drugs are to be given to patients there shall be positive identification of the drug, including manufacturer's lot number. Administration of drugs not supplied by the facility requires a specific policy and procedure.	**INTERVIEW** Verify: ▪ Medical staff-approved policies and procedures and/or medical staff rules/regulations address medications obtained from sources other than the facility pharmacy service. ▪ The pharmacy policy applies to all areas where medication is administered.
25.01.18 Labeling	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Drugs and biologicals leaving the pharmacy service, for other than "par" level storage are labeled with: ▪ the full name of the patient, ▪ the prescriber's name, ▪ the name - strength - quantity - expiration date of the drug, and appropriate accessory/cautionary statements.	State and federal requirements regarding labeling of repackaged drugs are to be enforced. Mechanisms exist to track the manufacturer's lot number; this may be on the label or via logs for in-facility use. Outpatient dispensing requires the lot number on the label.	**OBSERVATION** ▪ Inspect unit dose drawers or patient medication cupboards for the labeling of repackaged drugs. If outpatient dispensing exists, ask to see a drug prepared to ensure the required label information is present. Verify: □ The facility has an effective system for tracking lot numbers. □ Medications are labeled with the required information including lot number and expiration date.

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25.01.19 Standardization of labeling The methods for labeling, packaging, and storing medication have been standardized throughout the facility to reduce adverse events resulting from improper labeling, packaging and or storage of medications.	☐ Compliant ☐ Not Compliant Improper labeling and packaging of medications are well-known causes of serious medication errors. The evidence shows that there are effective methods for simplifying pharmacy and non-pharmacy dispensing by standardizing the labeling of medication containers and drawn-up syringes and the packaging of medications.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENTATION** ▪ Review medication administration policies. Observe medication preparation and storage areas as well as administration to validate compliance. ▪ Review method for ensuring compliance with policies and procedures on medication labeling, packaging, and storage throughout the organization. ▪ Verify that the medication administration labeling policy addresses: □ Labeling of all medications until they are administered to the patient. □ Validation of compliance for all areas. □ An institution-wide approach. □ Storage of look alike, sound alike and varied strengths of medications in physically separate locations. ▪ Verify that compliance with the medication labeling policy is evident throughout the facility.

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25.01.20 High-alert medications	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The safe use of "high-alert" drugs will be facilitated by implementation of the following: 1. Identification of "high-alert" drugs available to workers in the facility. 2. Implementation of a process to identify new medications for addition to the "high-alert" list. 3. Development of protocols, guidelines, dosing scales, and/or checklist for each "high-alert" drug; make these available to relevant caregivers. 4. Implementation of a process to audit compliance with the protocols and guidelines. 5. Utilization of a multidisciplinary team to identify and regularly review safeguards for all "high-alert" drugs.	Certain classes of medications have been repeatedly shown to cause adverse drug events and should be viewed as particularly serious threats to patient safety. Examples of high-alert drugs are: ▪ Intravenous adrenergic agonists and antagonists. ▪ Chemotherapy agents. ▪ Anticoagulants and antithrombotics. ▪ Concentrated parenteral electrolytes. ▪ General anesthetics. ▪ Neuromuscular blockers. ▪ Insulin and oral hypoglycemic. ▪ Narcotics and opiates.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Review policies and procedures to validate that all five requirements are being addressed in the organization. ▪ Review audit materials for ongoing compliance. ▪ Observe storage and use of high alert medications on the units to validate compliance.
25.01.21 Dispensing methods	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Medications will be dispensed in unit-dose or unit-of-use form whenever possible to reduce adverse events resulting from bulk packaging of medications. This is evidenced by:	Hospitals purchase oral dosage medications in two forms - bulk or commercially prepared, prepackaged dosages referred to as unit-of-use or unit dose. When purchased in bulk, the medications must be repackaged into unit-dose aliquots.	**OBSERVATION AND INTERVIEW** ▪ Interview the pharmacy director to validate that the process being utilized is compliant with the standard. ▪ Observe medication dispensing areas to

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1. Unit-dose packaging for medications whenever possible. 2. Dispensing in ready-to-administer form. 3. Unit dose package labeling containing product name, strength, manufacturer, expiration date, and lot number produced in machine-readable code. 4. Preparation and supply of daily unit doses of medications for individual patients under the purview of pharmacists when prepackaged unit dose is not commercially available. 5. Limiting of available supply in patient areas to 24 hours or less at any one time. 6. A defined system for monitoring and improving the performance of the drug distribution system.	Evidence shows that unit-dose packaging reduces the number of medication errors and appears to be widely used in most general medical and surgical wards. However, it is not used as much as it could be in other locations such as intensive care units, operating rooms, and emergency departments.	validate that the standard is being met in all locations.
25.01.22 Preparation of intravenous drugs and fluids Intravenous drugs and admixed fluids are prepared in accordance with standards of pharmacy practice, congruent with State and federal regulations, in a manner to reduce the potential for bacterial or drug/ drug contamination.	☐ Compliant ☐ Not Compliant The expiration date of reconstituted drugs or admixed fluids is prominently printed on the solution label. The use of horizontal and vertical flow hoods is consistent with state and local regulations. Horizontal and vertical flow hoods are inspected and cleaned according to manufacturer instructions and state and local regulations. Cytotoxics are not to be prepared under a horizontal hood. Some states	This standard is not met as evidenced by: **OBSERVATION** ▪ Review the admixture procedure and quality controls for congruence with current practice. ▪ Verify that the pharmacy procedure for cleaning chemical spills, spill kits, and

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	require certification for personnel who are responsible for admixing cytotoxics and other dangerous admixtures. Chemical/hazardous material "spill" kits are readily available to the IV preparation area. Staff is knowledgeable as to using spill kits. Personal protective equipment (PPE) is used consistently and appropriately in the preparation of IV drugs and solutions.	PPE are immediately available where cytotoxics are prepared. ▪ Horizontal and vertical hoods are used for their intended purposes. Horizontal hoods are inspected and changed every six months; the external or vertical hood should be cleaned or changed by maintenance personnel quarterly, consistent with state and local regulations and manufacturer's instructions.
25.01.23 Sample drugs The use of "sample" drugs, if permitted, is controlled by the pharmacy director and is in conformance with federal and state laws.	☐ Compliant ☐ Not Compliant The use of sample drugs is discouraged. The repackaging and/or resale of sample drugs is prohibited. If samples are allowed, hospital policy describes the use, storage, and distribution of sample drugs. Sample drugs are labeled according to hospital policy including lot number, patient name, prescriber's name, dose, and expiration date. If samples are allowed, the director of pharmacy has full accountability for storage, distribution, and use. The director of pharmacy is responsible for maintaining a log of all sample drugs in the event of a product recall. The log includes lot numbers and patient distribution information.	This standard is not met as evidenced by: **OBSERVATION AND INTERVIEW** ▪ Review the policy regarding samples. **Note:** Samples are often located in employee lounges, obstetrics, and the ER. If these are the physician's personal property, sample medications should be secured. ▪ Verify: □ There is an effective, accurate recall process, consistent with the pharmacy recall process. □ If used for patients, the pharmacist has control of sample drugs.

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25.01.24 Patient medication profile	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
There is a medication profile created for each inpatient and serial outpatient receiving drugs and biologicals. This profile includes data designed to assure safe and accurate administration of drugs and biologicals.	The profile may be manual or electronic and may be utilized as a charge document. The patient and drug data entered in medication profiles (or the ability to access via electronic means) include, at least: 1. Height, weight, age, and diagnosis. 2. Food and drug sensitivities. 3. Allergies. 4. Diet order(s). 5. History of prescribed/nonprescribed drug use including legend, over the counter, home remedy, and street drugs. 6. Drugs (administered from floor stock and/or) dispensed for administration based upon direct review of current orders. 7. Drug data indicate the route, schedule, start and stop dates including automatic stop dates, and form dispensed.	**DOCUMENT REVIEW** ▪ Review the medication profiles for five active inpatient records and one active serial outpatient record (such as chemo) to determine the database. ▪ Verify that the medication profiles consistently document each of the seven required elements or that the pharmacy has access via electronic means to all required information.
25.01.25 Profile review	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The profile is reviewed with every order change by an RPh. The review will occur before medication is dispensed or made available for administration except in those instances when review would cause a medically unacceptable delay. The review includes cognitive focus for potential drug and food-drug interactions,	Nearly half of preventable adverse drug events (ADEs) result from a problem in medication ordering. It has been demonstrated in inpatient settings that having a pharmacist review medication orders before administration is associated with a significant decrease in preventable ADEs. Similar findings have been found in ambulatory settings. Including pharmacists on clinical rounds also can reduce medication errors. Methods are established to assure the profile review by a pharmacist.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Review the policy that defines what would be considered a medically acceptable delay in pharmacist review of new orders. ▪ Review a minimum of 10 patient records.

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interferences, or incompatibilities. The review of orders will be documented in the patient record. The pharmacists will maintain a log documenting interventions stemming from the profile review. Compliance with the medication profile review will be audited to determine compliance with the process so that ongoing improvement in medication safety will be achieved.	A log is maintained of pharmacist interventions resulting from the profile review. The pharmacist/prescriber interface, as appropriate, for notification of food service for potential food -drug interactions.	□ Interview the pharmacist and nursing staff to determine staff knowledge of the profile review process. ▪ Verify that: □ A log is maintained for pharmacist interventions stemming from the review for potential interactions, interferences or incompatibilities □ The profiles are reviewed upon order changes. The pharmacist and nursing staff are knowledgeable of the medication profile review process.
25.01.26 Drug administration Mechanisms exist so that drugs and biologicals are administered in a safe, accurate, and effective manner.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Check charts on units to compare physician orders against the medication administration records for accuracy. ▪ Verify that medications administered are consistent with the physician order. □ Medications are administered safely and accurately.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

25.01.27 Label medications and solutions on the sterile field

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The facility must develop and implement policies for safe labeling of medications and solutions used on and off the sterile field in the perioperative settings.

The facility must have policies and processes in place including, but not limited to:

1. The required labeling of medications and solutions, regardless of container, used on and off the sterile field throughout the perioperative experience.
2. The methods used to differentiate and label look-alike products and solutions with similar names.
3. The process used to verify and confirm each medication/solution and the respective matching label.

All surgery settings and procedure rooms are expected to handle chemicals, reagents, specimen preservation agents, and diluents with the same caution as medications.

A process must be in place to label all solutions used in the surgical area including, but not limited to intravenous fluids, medications, body fluids, hydrogen peroxide, formalin, Lugol's solution, radiopaque dyes, sterile saline, sterile water, isopropyl alcohol, skin preparation solutions, chlorhexidine, glutaraldehyde, and the like. Many of the above "look alike" as they are clear/colorless solutions.

Labels must be applied to solutions stored in all types of container used on and off the surgical field in the perioperative area including, but not limited to medicine cups, solution basins, syringes, and specimen cups.

A label is required even if only one solution is involved with the procedure.

It would be unacceptable to write onto plastic containers such as IV bags with marking pens, as there is evidence that the ink may penetrate into the solution.

Sterile medications/solutions that are placed onto the sterile field in the original packaging with the manufacturer's original label on the container that indicates the name and strength of the medication do not require additional labeling.

Use sterile markers and labels that can be opened onto the sterile field. Commercially prepared products are available for this purpose, but labels prepared by the facility are acceptable if sterilization is maintained. Labels are to clearly state the medication/solution and strength. When feasible, include these labels and markers in pre-made surgical packs.

Many medications and solutions have similar names. A process must be

DOCUMENT REVIEW

Review policies and practices relative to medication preparation to verify that systems are in place relating to:

- Required labeling of solutions and medications on and off the sterile field.
- Procedure for differentiating look-alike and sound-alike medications/ solutions.
- Procedure for individually verifying and labeling medications/ solutions and respective labels.

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	identified and implemented when preparing labels to differentiate these. A process must be in place to verify each medication or solution and complete its preparation, labeling, and delivery to the sterile field before preparing the next solution. Label only one medication/solution at a time. Use two staff to confirm each medication/solution and respective label verbally and visually; one of these staff must be a licensed professional involved with the procedure. A process must be in place to discard any unlabeled solution or medication found in the perioperative area. Unlabeled solutions should be considered a hazardous condition and reported using the facility incident reporting protocol. At shift change or relief for breaks, required the entering and exiting staff to concurrently read container labels and verify all medications on the sterile field. Keep original medication/solution containers in the surgical room until completion of the procedure for follow-up reference, if indicated.	
25.01.28 Investigational drugs In order to protect the rights of patient and the professional medical staff, the facility policies shall address the administration of drugs which are: 1. Used for other than their FDA approved use. 2. Experimental. 3. Investigational, when the primary investigator(s) is a member of the	☐ Compliant ☐ Not Compliant The pharmacy director collaborates with the professional medical staff in defining these circumstances. At a minimum, these policies address the following concepts: 1. Patient knowledge of the non-approved use of an FDA approved drug. 2. Patient informed consent in experimental or on-site investigational drug studies. 3. Mechanisms for presenting study protocols and data to an Institutional Review Board or equivalent. 4. The roles of pharmacists, nursing and other non-practitioner staff in	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review policies related to investigational drugs to verify: □ The facility policy addresses non-approved, experimental and investigational uses of drugs. Each of the seven required concepts is addressed. □ The actual use of investigational

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
facility's professional medical staff. 4. Investigational, when the facility patient brings in the drug as a prescription from a practitioner who is not a member of the facility's professional medical staff.	study protocols and data management. 5. The acquisition and storage of investigational drugs. 6. The need for the RN administering investigational drugs and/or planning and supervising the care of a patient receiving investigational drugs to document knowledge of the drug(s). 7. Notification and input from any off-site investigators when their study population is admitted.	drugs is consistent with the investigational drugs policy. ▪ Review patient records if available.
25.01.29 Documentation The effects of therapy are noted in clinical records. The patient's clinical record accurately reflects all doses given as well as the effects of these agents as indicated by: 1. The prescribing practitioner, and any other medical consultants, via progress notations. 2. The nursing staff via the medication administration record in progress notation for the effects of "Pro Re Nata" (PRN) dosing and for clinical outcome dosing. 3. Clinical outcomes. 4. The recording of testing (laboratory, imaging, cardiogram, other objective) to determine the therapeutic effect.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review five recently closed inpatient records for physician progress notes, diagnostic testing data, and other clinical notations to verify that medical records provide evidence that all doses have been administered; appropriate observations are documented.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
25.01.30 Antithrombotic therapy	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The facility ensures that anti-thrombotic (anticoagulation) therapy is effective and safe. The organization utilizes dedicated anti-thrombotic services that facilitate coordinated care management. Explicit organizational policies and procedures are in place regarding anti-thrombotic services.	Anti-thrombotic (anticoagulation) therapy is a complex and labor-intensive intervention for which success depends upon correct dosing decisions, close attention to many details, and good communication among all parties involved. A process is in place to identify and train staff to coordinate the management of patients receiving anti-thrombotic therapy. The process addresses: ▪ Staff training requirements ▪ Dose scheduling ▪ Patient tracking ▪ Patient education Optimal anticoagulation management occurs when a systematic and coordinated process is used. This process includes dedicated management by a qualified healthcare professional that ensures: ▪ Reliable patient scheduling and tracking. ▪ Accessible, accurate, and frequent Prothrombin Time (PT)/International Normalized Ratio (INR) testing. ▪ Patient-specific decision support and interaction. ▪ Ongoing patient education.	**DOCUMENT REVIEW** ▪ Review facility policies and procedures in regard to antithrombotic services to verify that policy is explicit with regard to staff training requirements, dose scheduling and tracking mechanisms, and patient education materials and mechanisms for training. ▪ Review the medical records of patients receiving antithrombotic therapy to verify that anti-thrombotic services are being coordinated per policy and standard.
25.02.01 Preparation and administration of drugs	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Facility policies regarding medication preparation and administration are approved by the professional medical staff	Medication administration policies are based upon principles of sound nursing and pharmacy practice with a focus on patient safety. Policies are collaboratively developed by the pharmacy and the disciplines,	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Interview the pharmacy director and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

and Pharmacy and Therapeutics Committee/function.

Policies address at least the following:

1. Pharmacist review of medication orders/profiles including documentation of review; defined exceptions to pharmacist review.
2. Role of the pharmacist in the medication use process.
3. When a full-time pharmacist is not available onsite, a pharmacist is available by telephone or accessible at another location that has 24-hour pharmacy services.
4. Order verification by the dispensing pharmacist (if the item is not stock in the patient care area).
5. Order verification by the staff administering the product.
6. Mechanisms to assure that the patient is positively identified prior to administering products;
7. Mechanisms to assure that the drug, route, dose, time(s), are accurately recorded for the correct patient;
8. Mechanisms for bedside supply for patient self-administration and for patient-controlled dosing. (Note: bedside medication storage must comply with storage requirements. See e.g., nursing, respiratory, imaging, etc., administering drug products. Collaboratively developed policies are then reviewed and approved by the Professional Medical Staff for review, comment, and approval.

All required subject areas are to be addressed by the facility in policy.

the nurse executive to verify:

- □ Their respective medication administration policies are congruent and have been collaboratively developed. Similarly, verify these issues with other disciplines such as, imaging, respiratory therapy, etc.
- □ The collaboratively developed medication administration policies have been presented to the professional medical staff for review, comment and approval.

- Observe the preparation of drugs and their administration to patients. Observe at least three staff administering a drug or biological product to verify:
  - □ Patient identification procedures are consistently followed. Patients are addressed by name and/or identification checked. The nurse remains with the patient until medication is taken.
  - □ If personnel other than nursing personnel administer drugs or biologicals, this is in accordance with federal and state laws and regulations.
  - □ The drug is identifiable up to the point of administration. The patient

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
25.01.03.) 9. Mechanisms to teach the patient (or his/her family) about the medications; and 10. Mechanisms for identifying and responding to medication variances.		was positively identified. □ If bedside patient self-administration of medication is permitted, verify: ▪ All storage and administration standards are in compliance (e.g., secure storage, documentation of administration). ▪ Verify that nursing or other personnel authorized by medial staff policy to administer drugs have completed appropriate training courses, or, are licensed or authorized to do so by State law and function under supervision as necessary.
25.02.02 Medication preparation environment The facility provides a work environment that facilitates attention to detail and promotes the accurate filling and dispensing of medication orders. Organizational policies and procedures are in place for the pharmacy and nursing work environments that include specific implementation guidelines that address safety in medication preparation areas, including the mechanism for ongoing monitoring of compliance.	☐ Compliant ☐ Not Compliant Although many medication errors have no or minor consequences for patients, others may cause serious morbidity or even death. Errors related to dispensing medications are common, occurring at rates ranging up to 24% of medications dispensed. A number of environmental factors in the medication preparation and dispensing area are known to increase the occurrence of errors. These include: ▪ heavy workload. ▪ cluttered workspace. ▪ noise. ▪ poor lighting.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review organizational policies to verify that policy addresses the required work environment safety elements and applies to all medication preparation areas. ▪ Inspect medication preparation areas in all locations where medication is prepared to verify that they are clean, orderly, well lit, and free of clutter, distraction, and noise.

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Having an organized and well-lit workspace has been shown to both decrease errors and increase efficiency.

25.02.03 Medication reconciliation

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The organization has a formal and systematic approach to the reconciliation of medications across the continuum of care. A process is in place to reconcile current medications at each key transitional point of healthcare, specifically:

1. Upon admission, prepare a complete list of pre-admission medications the patient takes at home.
2. The patient or family member validates the list, when possible.
3. Admission orders are compared against the pre-admission medication list; any variances are reconciled.
4. The complete list of current medications is readily available to prescribers as a reference when writing medication orders.
5. The complete list of medications is provided to the next unit, service, or care setting when the patient is transferred and discharged.
6. The complete list of medications is

Preventable adverse drug events are associated with as many as one out of five patient injuries or deaths. The inadvertent omission of a preadmission medication or failure to order a drug upon discharge can have deleterious outcomes. Through the formal process of medication reconciliation, errors can be prevented and/or reduced throughout the continuum of care.

According to the Institute for Healthcare Improvement (IHI), numerous studies indicate that poor communication of medical information at key transition points is responsible for up 50% of all medication errors. A 30 – 70% disparity rate was found between medications taken at home and those listed in hospital admission orders, in one study. The key transition points where errors with writing medication orders tend to occur are:

- Upon admission.
- Upon transfer to a new unit/service/practitioner.
- At time of discharge.

The goal of medication reconciliation is to ensure that every hospitalized patient continues with the same medications taken prior to admission, unless there is a specified need for change. Admission orders should actually be considered a modification of the patient's medication regimen.

The patient or family member is involved with the reconciliation process to validate the list of preadmission medications. This list includes prescribed and regularly taken over-the-counter drugs, vitamins, herbals, homeopathic, and nutritional supplements. As the intent is to develop the most accurate list of medications possible, the dose and frequency for each drug should be

DOCUMENT REVIEW

Verify:

- A complete list of home medications is obtained upon admission. A process is in place to generate a list of medications in the ambulatory setting.
- A medication reconciliation process is in place upon admission, transfer to the next level of care, and at discharge.
- The patient/family participates with the reconciliation process, when possible.
- The patient receives a copy of the complete medication list upon discharge.
- A process is in place to measure the effectiveness of this initiative with reducing adverse drug events.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
given to the patient upon discharge.	included in the complete list of home medications. The list of preadmission medications is readily available for prescribers to review when writing/changing medication orders. Policy outlines the process, responsible persons, and time frame for completing the initial reconciliation process. The initial medication reconciliation shall be completed within 24 hours of hospital admission. Discrepancies between home medications and those ordered upon admission are discussed and reconciled with the prescriber. Preferably, a brief note is written for any medication that is not continued during the course of hospitalization. The following notes are not acceptable: ▪ "Resume previous orders." ▪ "Resume preoperative orders." ▪ "Resume all home medications." **TRANSFER TO ANOTHER UNIT/SERVICE** The list of current medications accompanies the patient when transferred to another unit or service. A process for the reconciliation of medications at this transitional point is in place. Discrepancies between the list of medications from the previous unit and those ordered following transfer are discussed and reconciled with the prescriber. **DISCHARGE** As part of the discharge planning, there is a reconciliation process to ensure all appropriate medications (including preadmission medications) are continued following discharge. In anticipation of discharge, the list of preadmission medications should be compared against the current medication administration record. The patient/family is informed of medications that will be discontinued or changed upon discharge.	

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

At time of discharge, a copy of the final medication list is provided to:

- The patient/family.
- The next level of care such as home health agency, skilled nursing facility, or transfer to a higher level of care.

MONITORING EFFECTIVENESS

A process is in place to evaluate the effectiveness of this patient safety initiative with reducing adverse drug events. For example, random review of patient records.

EMERGENCY DEPARTMENT

A complete list of current medications is to be obtained for Emergency Department patients.

AMBULATORY CARE

A complete list of current medications is to be obtained for ambulatory care patients. The list will be updated as medications are added or discontinued.

AMBULATORY SERVICES

1. A complete list of medications must be in place for those outpatient services in which medications will be administered, such as:
   - □ Ambulatory surgery.
   - □ Radiological procedures requiring IV contrast, etc.
2. For those outpatient services in which no medications will be administered, such as outpatient radiology, obtaining a current list of medications is preferred, but not required.

25.03.01 Performance Improvement

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

A facility-wide quality assessment performance improvement program is in place, which incorporates adverse drug

The greatest benefit to the facility accrues when QAPI efforts give priority to reviews, which focus on high volume (cost or frequency), high risk, or

DOCUMENT REVIEW

Review the medication use review plan to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
response (ADR) findings and monitors the desired outcomes of medication use. This program shall be utilized to reduce risk in order to maintain and improve clinical outcome. Annually, the facility prepares a medication use review plan.	problem prone areas. The medication use review plan, or a drug utilization evaluation (DUE) plan, should indicate the rationale for selection, and actions taken to achieve improvement should be documented.	verify: ▪ The facility prepares an annual Medication Use Review or Drug Utilization Effectiveness Plan. ▪ The findings from adverse responses and medication variances have been studied and included in QAPI. Monitors are in place. Actions have been taken to achieve improvement.
25.03.02 Data collection and monitoring	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The medication use monitoring is established to assess: ▪ Prescribing (appropriateness) ▪ Preparing/dispensing ▪ Administering ▪ Outcomes	Medication use is an interdisciplinary process in providing patient care. Although review indicators may focus more heavily on one, all four aspects of the process are to be reviewed.	**DOCUMENT REVIEW** Verify: ▪ The medication use review plan is an interdisciplinary process. ▪ Data is collected on all four required functions.
25.03.03 Medication use review	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The pharmacy conducts a medication use review to monitor drugs used in all principal populations served by the facility.	Over the course of a year, the populations should include the age span (pediatric - geriatric) and service location (inpatient, outpatient, and emergency care). Antibiogram studies should be published and distributed to appropriate professionals at least annually.	**DOCUMENT REVIEW** ▪ Verify that life span and service setting populations have been incorporated in medication usage review. ▪ The outcome of the medication use review has been communicated to the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		medical staff. ▪ An annual antibiogram report been prepared and distributed.
25.03.04 Data Reporting Findings from the medication use review are reported quarterly to appropriate medical staff committees and/or departments, and considered by the QAPI program, in impacting improvements in the facility service areas. Such reports are shared, as appropriate, with other disciplines to utilize in their QAPI.	☐ Compliant ☐ Not Compliant Because medication use is interdisciplinary, the findings of medication use review are shared with various disciplines.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Medication use reviews are prepared quarterly. ▪ The information has been reported to appropriate medical staff committees and the QAPI program.
25.03.05 Annual report on medication use The facility documents improvement, as a result of medication use review as reported, in an annual summary.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ An annual summary of medication use review is prepared and submitted to QAPI. ▪ The summary addresses actual improvements, as applicable. **Note:** Reviews may not always (and legitimately) result in improvements. The

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		process of study should yield worthy results.
25.03.06 Performance improvement in medication use The organization uses information obtained from review of medication processes and outcomes to continuously improve the safety of medication administration for patients. The organization will consider technological advances available to them in improving these processes. If technological advances are not an option, the organization will implement alternatives that will resolve identified issues and reduce medication events.	☐ Compliant ☐ Not Compliant Medication errors are common. The literature indicates that between 28-56% of adverse drug events are preventable. Illegible handwriting, unknown or undetected allergies, drug interactions, incorrect dose, and many other factors can cause adverse drug events. Studies have demonstrated that a significant decrease in medication errors and adverse drug events can be achieved by using computerized prescriber order entry technology. Additional technologies are continuously being developed, and it is the responsibility of the organization to examine the feasibility of implementation of these technologies to achieve a safer patient environment. It is clear that some organizations will be unable to afford these technologies. However, that does not negate their responsibility to resolve identified issues by alternative means.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review medication event data. Review minutes where improvement of the medication system and processes are discussed. ▪ Verify: □ The organization has considered implementation of new technologies to reduce medication events. □ If technology is not feasible, alternative strategies to reduce medication events have been implemented.

26

PHYSICAL REHABILITATION SERVICES: PHYSICAL THERAPY, OCCUPATIONAL THERAPY, SPEECH THERAPY, AND AUDIOLOGY

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Note: This chapter is scored if the hospital offers one or more rehabilitation services to patients who are NOT located in a PPS exempt unit.

26.00.00 CONDITION OF PARTICIPATION: Rehabilitation Services

If the hospital provides rehabilitation, physical therapy, occupational therapy, audiology, or speech pathology services, the services must be organized and staffed to ensure the health and safety of patients.

§482.56

☐ Compliant ☐ Not Compliant

This is an optional hospital service but if a hospital provides any degree of rehabilitative services to its patients, the hospital must comply with the requirements of the Condition of Participation.

If rehabilitative services are provided, they must be organized and staffed to ensure the health and safety of patients. This includes providing rehabilitative services in accordance with practitioner orders and acceptable standards of practice.

Acceptable standards of practice include compliance with any applicable Federal or State laws, regulations, or guidelines, as well as standards and recommendations promoted by nationally recognized professional organizations (e.g., American Physical Therapy Association, American Speech and Hearing Association, American Occupational Therapy Association, American College of Physicians, American Medical Association, etc.).

The hospital's rehabilitation services must be integrated into the hospital-wide QAPI program.

This standard is not met as evidenced by:

DOCUMENT REVIEW

Note: Determine whether the hospital provides any degree of rehabilitation services. If yes, Condition-level scoring is based on compliance with standards 26.00.01 through 26.00. and 26.00.06 through 26.00.08

- Verify that the hospital's rehabilitation services are integrated into its hospital-wide QAPI program.

26.00.01 Organization and staffing

The organization of the service must be appropriate to the scope of the services offered.

§482.56(a)

☐ Compliant ☐ Not Compliant

The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the rehabilitation services offered by the hospital in accordance with acceptable standards of practice.

The scope of rehabilitation services offered by the hospital should be defined in written policies and procedures and approved by the Medical staff.

This standard is not met as evidenced by:

DOCUMENT REVIEW

Review organization charts and hospital policies to verify:

- The scope of rehabilitation services offered is defined in writing and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Each service, whether provided through a single discipline department or within a multi-discipline department, must function with established lines of authority and responsibility to ensure the health and safety of patients. There must be an adequate number of qualified staff available when needed to evaluate each patient, initiate the plan of treatment, and supervise supportive personnel when they furnish rehabilitation services. The number of qualified staff is based on the type of patients treated and the frequency, duration, and complexity of the treatment required.	approved by the medical staff. ▪ If the services are provided under an agreement, review policies and contracts to determine responsibilities and delegations of authority relative to the service provided. ▪ Responsibilities and delegations of authority relative to the service are provided. ▪ Services are provided in accordance with acceptable standards of practice. ▪ Therapy is planned and initiated by a licensed therapist. ▪ If services are provided under an arrangement, review policies and contracts. ▪ For each service, determine that adequate types and numbers of qualified staff are available to ensure safe and efficient provision of treatment. ▪ Medical records verify that a qualified professional evaluates the patient and initiates each treatment episode. ▪ A sample of personnel files verify current licensure, certifications, and ongoing training, consistent with applicable state laws.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

26.00.02 Leadership

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The director of services must have the necessary knowledge, experience and capabilities to properly supervise and administer the services.

§482.56(a)(1)

The director must be accountable for the overall operation of the therapy services.

An individual(s) may serve as director for more than one service either as the director of a multi-service department or single service departments.

Each service must be accountable to an individual that directs the overall hospital-wide operation of that service.

The service director must demonstrate through education, experience, and/or specialized training that he/she has the necessary knowledge, experience, and capabilities to properly supervise and administer the service(s).

The director may be part-time or full time. In all situations the director retains professional and administrative responsibility for personnel providing the service. If the director is part-time, the time spent directing the service should be appropriate to the scope of the services provided.

INTERVIEW AND DOCUMENT REVIEW

- Verify that each service is accountable to an individual who directs the overall operation of that service.
- Review the service director's position description to verify that he/she has been granted the authority and responsibility for operation of the service, consistent with hospital policies, State law, and accepted standards of practice.
- If the directors do not work full-time, verify that the number of hours (review timesheets) spent working is appropriate to the scope of services provided.
- Review personnel file(s) to verify that the director has the necessary education, experience, and specialized training to properly supervise and administer the service. This includes maintaining current licensure and certifications as required by State law.
- Interview the director to verify that he/she has the necessary knowledge, experience, and capabilities to properly supervise and administer the service.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
26.00.03 Staff qualifications	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Physical therapy, occupational therapy, or speech-language pathology or audiology services, if provided, must be provided by qualified physical therapists, physical therapist assistants, occupational therapists, occupational therapy assistants, speech-language pathologists, or audiologists as defined in 42 CFR 484. §482.56(a)(2)	The medical staff must define in writing the required qualifications and competencies for the therapy staff, consistent with State law. A policy describes the levels of personnel and qualifications necessary for each service provided. A therapist is a person licensed by the State in which they are practicing and has graduated from a recognized, certified program.	**DOCUMENT REVIEW** Verify that: ▪ The medical staff have defined the qualifications and competencies for all therapy staff, consistent with State law. This document describes the services provided and various levels of personnel permitted to provide each service. ▪ There is a procedure for the periodic review of the written staff qualifications to ensure these are compliant with changes in state law. ▪ Therapy is planned and initiated by a licensed therapist. ▪ Each employee file reflects the qualifications and competencies consistent with the written medical staff specifications. ▪ Therapists have the qualifications and competencies that meet medical staff specifications.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
26.00.04 Minimum staffing requirements Therapy shall be provided by a core team that includes but is not necessarily limited to a qualified licensed therapist.	☐ Compliant ☐ Not Compliant This requirement depends on the mission of the facility and of the physical therapy program. Staff such as therapy aides, therapy assistants and other health care workers may be included as staff members as appropriate.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the organizational chart and staffing plan for the therapy department(s) to verify that it meets the requirement.
26.00.05 Therapy orders Policies govern who can refer/order therapy. Referrals/orders for therapy must indicate the reason(s) for referral/order.	☐ Compliant ☐ Not Compliant These policies are congruent with the Medical Staff Bylaws and Rules and Regulations. They must address referrals/orders for therapy and, if verbal orders are permitted, the policy must address who is qualified to receive a verbal order. **VERBAL ORDERS** Verbal orders for the provision of treatment may be accepted and must be authenticated in accordance with the requirement in §482.56(b), consistent with Federal and State laws, the medical staff, and hospital policy. Verbal orders regarding treatment are acceptable if documented and signed by the person accepting the order. The time, date, and contents of the verbal order and the name of the ordering practitioner must be entered in the record at the time of the order and be countersigned by the practitioner consistent with State laws and facility policy. (See standard 10.01.04 for requirements.)	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review policies and procedures and medical records of therapy patients to verify: ▪ A policy (or bylaws or rules and regulations) describing those who are allowed to refer and order therapy is in place, current, and approved by the Medical Staff. ▪ Only qualified individuals, as approved by the Medical Staff, provide referrals and orders for therapy. ▪ Referrals and orders for therapy include the reason for the referral.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

26.00.06 Delivery of services

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Services must only be provided under the orders of a qualified and licensed practitioner who is responsible for the care of the patient, acting within his or her scope of practice under State law, and who is authorized by the hospital's medical staff to order the services in accordance with hospital policies and procedures and State laws.

§482.56(b)

Rehabilitation services must be ordered by a qualified and licensed practitioner who is responsible for the care of the patient.

The practitioner must have medical staff privileges to write orders for these services or, for outpatient services, if hospital policy permits acceptance of orders from outside practitioners, the practitioner's order must meet the requirements at §482.54(c).

For practitioners who have medical staff privileges, such privileges must be granted in a manner consistent with the State's scope of practice law, as well as with hospital policies and procedures governing rehabilitation services developed by the medical staff and approved by the governing body.

Practitioners who may be granted privileges to order rehabilitation services include physicians, and may also, in accordance with hospital policy, include:

- Nurse Practitioners
- Physicians' Assistants
- Clinical Nurse Specialists as long as they meet the parameters of this requirement.

Although the following licensed professionals are also considered "practitioners" in accordance with Section 1842(b)(18)(C) of the Social Security Act, they generally would not be considered responsible for the care of the patient or qualified to order rehabilitation services:

- Certified registered nurse anesthetist (Section 1861(bb)(2) of the Act).
- Certified nurse-midwife (Section 1861(gg)(2) of the Act).
- Clinical social worker (Section 1861(hh)(1) of the Act).
- Clinical psychologist (for purposes of Section 1861(ii) of the Act and as

DOCUMENT REVIEW

- Does the hospital accept orders from outside practitioners who do not practice at the hospital?
  - ☐ If so, evaluate for compliance with 42 CFR §482.54(c) (standard 31.00.11).
- Review the medical staff policies and procedures for rehabilitation services privileging. Do they identify the types of eligible practitioners and their qualification criteria?
- Review medical records of patients receiving rehabilitation services.
  - ☐ Determine who wrote the orders for the rehabilitation services.
  - ☐ Verify that the practitioner is responsible for the care of the patient and privileged to write orders for rehabilitation services.
  - ☐ Verify the practitioner meets hospital medical staff policy criteria to order services as well as State law for ordering rehabilitation services.
  - ☐ Physical Therapy services are provided only in accordance with

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	defined at 42 CFR 410.71). ▪ Registered dietitian or nutrition professional.	practitioner orders and that those orders are incorporated into the medical record. □ The treatment plan is established by the practitioner ordering the service in collaboration with an individual qualified to provide the service.
26.00.07 Rehabilitation orders *All rehabilitation services orders must be documented in the patient's medical record in accordance with the requirements at 42 CFR §482.24.* §482.56(b)(1)	☐ Compliant ☐ Not Compliant The patient's medical record must contain documentation of all rehabilitation services ordered. The medical record entries must comply with regulations at 42 CFR §482.24.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of patient medical records who received rehabilitation services to verify that the rehabilitation service orders are legible, complete, dated, timed, authenticated, and meet all other medical record requirements specified at 42 CFR §482.24.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

26.00.08 Standards of practice

The provision of care and the personnel qualifications must be in accordance with national acceptable standards of practice and must also meet the requirements of 42 CFR 409.17.

§482.56(b)(2)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The provision of rehabilitation services care and development of the plan of care for rehabilitation services can be initiated only after the order is written for services by a qualified licensed practitioner responsible for the care of the patient.

Physical therapy, occupational therapy, or speech-language pathology must be furnished under a plan of care.

The regulation at 42 CFR §409.17 specifies the following rehabilitation services plan of care requirements:

ESTABLISHMENT OF THE PLAN
The plan must be established before treatment begins by one of the following:

(1) A physician.

(2) A nurse practitioner, a clinical nurse specialist or a physician assistant.

(3) The physical therapist furnishing the physical therapy services.

(4) A speech-language pathologist furnishing the speech-language pathology services.

(5) An occupational therapist furnishing the occupational therapy services.

CONTENT OF THE PLAN
The plan:

(1) Prescribes the type, amount, frequency, and duration of the physical therapy, occupational therapy, or speech-language pathology services to be furnished to the individual; and

(2) Indicates the diagnosis and anticipated goals.

DOCUMENT REVIEW

- Review medical records of patients who received rehabilitation services to verify whether the required care plan was developed and implemented.
- The plan should include:
  - □ Treatment goals and type.
  - □ Amount.
  - □ Frequency.
  - □ Duration of services.
  - □ Goals reflect patient and family input (as appropriate).
- Review employee personnel files to verify the rehabilitation service providers (i.e., physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists) have the necessary education, experience, training, and documented competencies to provide rehabilitation services.
- Ask what national standards of rehabilitation practice provide the basis for its rehabilitation services. Is there

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	CHANGES IN THE PLAN Any changes in the plan are implemented in accordance with hospital policies and procedures. In accordance with 42 CFR §409.17, rehabilitation services must be provided by qualified physical therapists, physical therapy assistants, occupational therapists, occupational therapy assistants, and/or speech-language pathologists who meet the personnel qualifications defined in 42 CFR §484.4. Hospitals must have policies and procedures consistent with State law. Rehabilitation services must be provided according to national standards of practice as established by professional organizations such as, but not limited to, the American Physical Therapy Association, the American Occupational Therapy Association, and the American Speech-Language-Hearing Association.	supporting documentation?
26.00.09 Organizational plan	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
There shall be a written description of the program which includes, at least: 1. The scope of services provided; 2. Services specific to inpatients or outpatients including: □ Admission criteria. □ Assessment and evaluation process. A program evaluation system including outcome measures, e.g., functional index	The scope and complexity of the hospital rehabilitation service must be adequate to meet the needs of its patients. The written scope of service document describes the inpatient and outpatient services provided, in accordance with Federal and State law, regulations, and acceptable standards of practice.	**DOCUMENT REVIEW** Review department policies to verify: ▪ The scope of services for all therapies is available. ▪ The scope of services includes all required components: □ Services provided (e.g., inpatients and/or outpatients). □ Admission criteria. □ Assessment and reassessment.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
measurement (FIM), etc.		□ A program evaluation of outcome measures.
26.00.10 Initial assessments Therapy patients shall have assessments completed promptly before treatment by certified/licensed staff.	☐ Compliant ☐ Not Compliant Initial assessments must be completed prior to any treatments are initiated. Ordinarily, the initial assessment is completed within 24 hours of receipt of the inpatient order and on the initial visit for outpatients. The assessment should include an evaluation of pain as well as the effectiveness of pain management using a quantifiable tool such as: ▪ A visual scale of zero to ten. ▪ The "FACES" tool for children.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review a sample of closed records. Select volumes as appropriate to evaluate both inpatient and outpatient records to verify: ▪ The initial patient assessment was made within 24 hours of receiving the physician's order, per policy. ▪ An initial assessment was completed prior to start of therapy. ▪ Pain is assessed using a quantifiable tool.
26.00.11 Treatment plan/Plan of care Patient assessments shall result in the development of a plan. This treatment plan/plan of care plan identifies goals, services and interventions to assist the patient in regaining independence, reducing pain, and/or adapting to limitations in activities of daily living.	☐ Compliant ☐ Not Compliant The patient plan of care (treatment plan) includes: 1. Measurable short-term and long-term goals with estimated timeframes for achievement, 2. Services and interventions for achieving goals, 3. Incorporates the patient and family goals, as appropriate, and 4. Updates, as necessary, to reflect changes in the patient's condition and response to therapy.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review a sample of closed records. Select volumes as appropriate to evaluate both inpatient and outpatient records to verify: ▪ All patients have a treatment plan/plan of care in the medical record. This plan identifies goals, services, and interventions to assist the patient with

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		regaining independence, reducing pain, and/or adapting to limitations. ▪ The physician and other professional personnel participate in the establishment, review, and revision of the plan of treatment. (This could be a signature, a record of a conference, or record of consultation.)
26.00.12 Treatment goals The treatment goals shall be developed in collaboration with the patient and/or family, as appropriate. These goals include monitoring and treatment for pain management.	☐ Compliant ☐ Not Compliant The patient, and/or family, assists with treatment planning to reflect their understanding of lifestyle and activities.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review a sample of closed records. Select volumes appropriate to evaluate both inpatient and outpatient records to verify: ▪ Patients/family (as appropriate) participate in development of treatment goals. ▪ Treatment goals include pain management utilizing a visual scale from 0 – 10 or the "FACES" tool for children.
26.00.13 Patient/Family education The patient and/or family is informed of all aspects of the nature of the problem, injury(ies), disability, alternative	☐ Compliant ☐ Not Compliant Education of patients and families is documented in the record. Such education includes, but is not limited to, methods to reduce the potential for re-injury.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of closed records. Select volumes as appropriate to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
treatments and devices, and methods of achieving and maintaining progress in the identified goals.		evaluate both inpatient and outpatient records to verify that each patient record demonstrates the delivery of patient/family education.
26.00.14 For future use		
26.00.15 Quality Assessment Performance Improvement (QAPI) Therapy services shall be integrated into the facility-wide QAPI plan.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review the QAPI plan and minutes to verify that: ▪ Therapy services are integrated into the hospital-wide QAPI program. ▪ Data collected is utilized to improve the quality of patient care and patient safety. ▪ Improvements are monitored to insure improvement in outcomes/results.

27

PSYCHIATRIC UNITS (NOT PPS EXCLUDED)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Note: This chapter is used to determine compliance of an acute care hospital with an inpatient psychiatric unit that is reimbursed by CMS according to the Inpatient Prospective Payment System (PPS). As a PPS inpatient unit, all Conditions of Participation for an acute care hospital are applicable.

For an inpatient psychiatric unit that is EXCLUDED from PPS, refer to Chapter 34.

27.00.01 Clinical focus

Psychiatric units within an acute care hospital must:

Be primarily engaged in providing, by or under the supervision of a doctor of medicine or osteopathic medicine, psychiatric services for the diagnosis and treatment of mentally ill persons.

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Psychiatric Services must be under the supervision of an MD or DO.

Services and treatment prescribed to patients must be in accordance with appropriate and acceptable standards of practice.

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

Verify that:

- The unit is primarily engaged in providing psychiatric services for the diagnosis and treatment of mentally ill persons.
- Verify that psychiatric services are under the supervision of an MD/DO.

27.00.02 Scope and description of services

There is a written program description which includes, but is not limited to:

1. The scope of services provided specific to inpatient, partial day, residential and outpatient and aftercare programs
2. How these programs relate to each other.
3. Admission criteria, including limitations.

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The plan for the provision of psychiatric care and services is a component of the facility-wide written plan.

DOCUMENT REVIEW

Verify that:

- The plan for the provision of services effectively outlines the areas listed.
- The plan addresses the ages of patients and the conditions accepted for service.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

4. Assessment/evaluation processes.
5. Treatment planning processes.
6. Therapeutic modalities utilized.
7. Provisions for children, adolescents, young adults, adults, geriatric, and mentally/developmentally disabled patients.
8. Staffing, including the roles, responsibilities, and supervisory relationships of professional staff as part of the treatment team.
9. The quality assessment performance improvement processes.

27.00.03 Confidentiality of information

There shall be policies and practices to protect clinical data and information, which may be described as "unusually sensitive" for psychiatric, and substance abuse patient populations.

☐ Compliant ☐ Not Compliant

The facility protects the clinical data and information found in the medical records of psychiatric and substance abuse patients.

Release of information policies address specific components that may require additional patient consent.

This standard is not met as evidenced by:

OBSERVATION AND DOCUMENT REVIEW

- Verify that the facility has policies that ensure the security and confidentiality of patient information.
- Observe clinical areas for breeches in security and confidentiality of patient information.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

27.01.01 Special medical records requirements for psychiatric units

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The medical records maintained by a psychiatric unit must permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the institution.

The facility has written policies that identify the required elements of the medical record for patients admitted to the psychiatric unit including:

1. Medical history
2. Legal status category
3. Admitting diagnosis
4. Onset of illness
5. Mental status
6. Behavioral assessment
7. Cognitive assessment
8. Psychosocial history
9. Family interview
10. Neurological examination
11. Treatment plan
12. Progress notes
13. Discharge planning
14. Discharge summary

The hospital maintains clinical records on all patients, including records sufficient to permit CMS to determine the degree and intensity of treatment furnished to Medicare beneficiaries.

The clinical record should provide information that indicates:

- need for admission and treatment, treatment goals.
- changes in status of treatment and discharge planning.
- follow-up and the outcomes experienced by patients.

DOCUMENT REVIEW

- Verify that the unit has policies, procedures, and practices to ensure the requirements are met.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
27.01.02 Development of assessment/ diagnostic data Medical records must stress the psychiatric components of the record, including: ▪ A history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.	☐ Compliant ☐ Not Compliant No additional information	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed medical records to verify the medical record includes a history of findings and treatment provided for the psychiatric condition for which the patient is hospitalized.
27.01.03 Patient legal status Medical records must stress the psychiatric components of the record, including: ▪ The identification data must include the patient's legal status.	☐ Compliant ☐ Not Compliant Legal status is defined in the State statutes and dictates the circumstances under which the patient was admitted and/or is being treated – i.e., voluntary, involuntary, committed by court, evaluation and recertification are in accordance with state requirements.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review open and closed medical records to verify that: ▪ The medical record includes identification data regarding the patient's legal status. ▪ Changes in legal status are recorded with the date of change.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

27.01.04 Admitting diagnosis

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Medical records must stress the psychiatric components of the record, including:

- A provisional or admitting diagnosis must be made on every patient at the time of admission and must include the diagnosis of intercurrent diseases as well as the psychiatric diagnosis.

The admission or working psychiatric diagnosis (including rule-out diagnoses) is consistent with the most current edition of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) or the approved International Classification of Diseases (ICD) nomenclature.

- This diagnosis is made and entered into the chart of each patient at the time of the admission examination.
- The final diagnosis may differ from the initial diagnosis if subsequent evaluation and observation support a change. Diagnosis should include physical illness when present.
- If a diagnosis is absent, there must b**e** justification for its absence. For example, if a patient was psychotic on admission and was not accompanied by family or significant others.
- Intercurrent (other than psychiatric) diagnoses must be documented when they are made.
- Attention should be paid to physical examination notes, including known medical conditions, even allergies and recent exposure to infections, illness, or substance abuse, and to available laboratory or test reports which identify abnormal findings to see that these are reflected by appropriate diagnosis.

These diagnoses may be found in a variety of locations in the medical record, e.g., the identification/face sheet, the finding of admission physical examination, the psychiatric evaluation, the "admission work up," or the physician's progress notes.

Diagnostic categories should include physical illness when present.

DOCUMENT REVIEW

- Review open and closed medical records to verify that the requirement was met. The admitting diagnosis may be found on the face sheet, in the history and physical, or in the physician progress notes.
- Are abnormal physical examination findings and/or laboratory findings justified by further diagnostic testing and/or development of an intercurrent diagnosis?

  If yes, was this done?

  - ☐ If an identified physical illness requires immediate treatment, is the treatment being given?
  - ☐ How will an identified physical illness be likely to impact on the patient's eventual outcome?
  - ☐ To what extent has this potential impact been addressed by the team?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

27.01.05 Patient reason for admission: Family perspective

Medical records must stress the psychiatric components of the record, including:

- The reasons for admission must be clearly documented as stated by the patient and or others significantly involved.

☐ Compliant ☐ Not Compliant

The purpose of this regulation is to provide an understanding of what caused the patient to come to the hospital, and the patient's response to admission.

The hospital records the statements and reason for admission given by family and by others, as well as the patient (preferably verbatim), with informant identified, in a variety of locations, e.g., in transfer and admission notes from the physician, nurses and social workers.

This standard is not met as evidenced by:

DOCUMENT REVIEW

- Review open and closed medical records to determine the requirement was met.
- Did the informant witness the patient's behavior?
  - □ If not, on what basis has the informant come to know the patient's behavior?
- Has staff elicited whether the patient has exhibited similar behavior previously?
  - □ If so, what was different this time to make hospitalization necessary?
- Were there other changes/events in the patient's environment (death, separations of significant others) which contributed to the need for hospitalization?
  - □ If so, has staff explored how these will impact in the patient's treatment?
  - □ Has this been addressed by the treatment team?
- Has there been an interruption or change in the patient's medication

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

which may have been a factor in the patient's hospitalization?

27.01.06 Psychosocial history/ assessment

Medical records must stress the psychiatric components of the record, including:

- The social service records, including reports of interviews with patients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The purpose of the social work assessment is to determine the current baseline social functioning (strengths and deficits) of the patient, from which treatment interventions and discharge plans are to be formulated.

Patient length of stay is a key factor influencing hospital documentation policy, i.e., establishing timeframes for completion, documentation, and filing of the psychosocial assessment, and treatment planning in the medical record.

A psychosocial history/assessment must be completed on all patients.

The three key components to be addressed include:

1. Factual and historical information
   - □ Specific reasons for the patient's admission or readmission.
   - □ A description of the patient's past and present bio-psychosocial functioning.
   - □ Family and marital history, dynamics, and patient's relationships with family and significant others.
   - □ Pertinent religious and cultural factors.
   - □ History of physical, sexual, and emotional abuse.
   - □ Significant aspects of psychiatric, medical, and substance abuse history and treatment as presented by family members and significant others.
   - □ Educational, vocational, employment, and military service history.
   - □ Identification of community resources including previously used treatment sources.

DOCUMENT REVIEW

- Review open and closed medical records for the psychosocial history/assessment to verify that the patient participated to the extent possible.
- Verify that family members or others provided information.
- Verify that all three key components are included in the assessment.
- Does the psychosocial history/ assessment indicate:
  - □ Clear identification of the informants(s) and sources of information?
  - □ Whether information is considered reliable?
  - □ Patient participation to the extent possible in provision of data relative to treatment and discharge planning?
  - □ Integration of significant data including identified high risk psychosocial issues (problems) into

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	□ Identification of present environmental and financial needs. 2. Social Evaluation □ Patient strength and deficits. □ High risk psychosocial issues requiring early treatment planning and intervention - i.e., unattended child/children in home; prior noncompliance to specific treatment and/ or discharge interventions; and potential obstacles to present treatment and discharge planning. 3. Conclusions and Recommendations Assessment of Sections 1 and 2 shall result in the development of three recommendations related to the following areas. □ Anticipated necessary steps for discharge to occur. □ High risk patient and/or family psychosocial issues requiring early treatment planning and immediate intervention regardless of the patient's length of stay. □ Specific community resources/support systems for utilization in discharge planning - i.e., housing, living arrangements, financial aid, and aftercare treatment sources. □ Anticipated social work role(s) in treatment and discharge planning.	the treatment plan? □ How does the hospital insure the information is reliable?
27.01.07 Neurological examination Medical records must stress the psychiatric components of the record, including: ▪ When indicated, a complete neurological examination must be recorded at the time of the admission	☐ Compliant ☐ Not Compliant Upon admission the patient should receive a thorough history and physical examination with all indicated laboratory examinations. These investigations must be sufficient to discover all structural, functional, systemic, and metabolic disorders. A thorough history of the patient's past physical disorders, head trauma, accidents, substance dependence/abuse, exposure to toxic agents, tumors,	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed medical records to verify that the requirement was met. **Note:** Positive neurological symptomatology found in the systems

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
physical examination.	infections, seizures or temporary loss of consciousness, and headaches, will alert the physician to look for the presence of continuing pathology or possible sequelae any of which may turn out to be significant and pertinent to the present mental illness. Equally important is a thorough physical examination to look for signs of any current illness since psychotic symptoms may be due to a general medical condition or substance related disorder. In addition to the required history and physical, when indicated, a complete neurological exam must be conducted and recorded. **THE SCREENING NEUROLOGICAL EXAMINATION** As part of the physical examination, the physician will perform a "screening" neurological examination. ▪ While there is no precise definition of a screening neurological examination in medical practice, such examination is expected to assess gross function of the various divisions of the central nervous system as opposite to detained, fine testing of each division. ▪ Gross testing of Cranial Nerves **I** through XII should be included. Cranial Nerve I, the olfactory nerve, is to be included with the patient examination. ▪ Statements such as "Cranial Nerves II to XII intact" are not acceptable. ▪ These areas may be found in various parts of the physical examination and not just grouped specifically under the neurological. In any case where a system review indicates positive neurological symptomatology, a more detailed examination would be necessary, with neurological work-up or consultation ordered as appropriate after the screening neurological examination was completed. **COMPLETE NEUROLOGICAL EXAMINATION** A complete, comprehensive neurological examination includes a review of the patient's history, physical examination and for psychiatric patients, a review	review (history, physical, and the "neurological screening") should result in a neurologic workup or consultation. ▪ Did the presence of an abnormal physical finding or laboratory finding justify the need for further diagnostic testing, or for the development of an intercurrent diagnosis? □ If the finding justified further follow-up in either situation, was such follow-up done? ▪ Is there evidence that a screening neurological examination was done and recorded at the time of the physical examination? ▪ Was the screening neurological or history indicative of possible involvement (tremors, paralysis, motor weakness or muscle atrophy, severe headaches, seizures, head trauma? If indicated, was a complete, comprehensive neurological exam ordered, completed and recorded in the medical record in a timely manner?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	of the psychiatric evaluation. The neurologist/psychiatrist himself/herself also takes a history to obtain the necessary information not already available in the medical record or referral form. The neurological examination is a detailed, orderly survey of the various sections of the nervous system. ▪ As an example, whereas a simple reading of a printed page will be sufficient to assess grossly the patient's sight (cranial nerve II) in a complete neurological examination, the neurologist may test visual acuity with a Snellen chart, perform a fundoscopic examination of both eyes (sometimes after dilating the pupils) and he/she will examine the patient's visual fields. In the examination of the motor system, the power of muscle groups of the extremities, the neck and trunk are tested. Where an indication of diminished strength is noted, testing of smaller muscle groups and even individual muscles are tested. In a complete neurological examination, all the systems are examined, but the physician will emphasize even more the areas pertinent to the problem for which the examination was requested.	
27.01.08 <u>Psychiatric evaluation</u> Each patient must receive a psychiatric evaluation.	☐ Compliant ☐ Not Compliant The psychiatric evaluation is done for the purpose of determining the patient's diagnosis and treatment and, therefore, it must contain the necessary information to justify the diagnosis and planned treatment. The psychiatric evaluation is a total appraisal or assessment of the patient's illness. It is the physician's assessment of the contributing factors and forces in the evolution of the patient's illness including the patient's perception of his or her illness.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review medical records to satisfy the requirements of this standard, and to meet the standards of medical practice. ▪ Verify that the psychiatric evaluation includes the following component parts:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Through the psychiatric evaluation the physician seeks to secure a biographical-historical perspective of the patient's personality, with a clear psychological picture of the patient as a specific human being with his or her individual problems.

While performing the psychiatric evaluation, the physician reaches an understanding of the patient's basic personality structure, of the patient's developmental period, of his or her value systems, of his or her past medical history including surgical procedures and other treatments, his or her past psychological traumatic experiences, his or her defense mechanisms, his or her supporting systems, any precipitating factors and how all these may have impacted and interplayed with each other to result in the present illness.

In the psychiatric evaluation the patient should emerge as a dynamic human being with a past, a present and a potential future with a thread of logical continuity.

The psychiatric evaluation includes all the requirements described in this standard and the information necessary to justify the diagnosis and treatment.

- A physician signature is necessary.

NON-PHYSICIANS

In cases where the mental status portion of the psychiatric evaluation is performed by a non-physician, there should be evidence that the person is:

1. Credentialed by the hospital.
2. Legally authorized by the state to perform the function.
3. A physician review and countersignature is present, where required by hospital policy or state law.

- □ The patient's chief complaints and/or reaction to hospitalization, recorded in the patient's own words when possible.
  - Why is the patient in the hospital?
  - Was it his/her idea? (Does he/she feel ill/disturbed/frightened?)
  - Is the patient in the hospital against his/her will? Who decided to hospitalize? Why?
- Past history of any psychiatric problems or treatment, including prior precipitating factors, diagnosis, course and treatment.
  - □ Has the patient been chronically ill? Continuously? Repeatedly?
  - □ How severely has the past illness/treatment interfered with the patient's development and/or adjustment?
  - □ Are there persistent symptoms/ signs/behaviors that must be addressed and treated in order to favorably impact on the future psychiatric course?
  - □ What medications or supports helped him/her improve in the past? Are the same resources available to impact on the patient's treatment

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		during this episode? ▪ Past family, educational, vocational, occupational, and social history. □ To what extent, if any, is there a presence or absence of familial predisposition? □ What is the patient's education level? Was he/she a good student? Is he/she still interested in learning? □ What jobs has the patient held? For how long? Is he/she now employed/ unemployed? For how long? Has he/she ever worked? □ How does the patient get along with people? As a child, did he/she have friends? Does he/she have friends now? ▪ Within the psychiatric evaluation does one find the specific signs and symptoms, and other factors that justify the diagnosis?
27.01.09 Timeframe for completion Each patient must receive a psychiatric evaluation that must: ▪ Be completed within 24 hours of admission.	☐ Compliant ☐ Not Compliant Facility policy establishes the timeline for completion of the psychiatric evaluation. Practice is consistent with policy.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of open and closed medical records to verify that the assessment met the requirement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
27.01.10 Medical history Each patient must receive a psychiatric evaluation that must: ▪ Include a medical history.	☐ Compliant ☐ Not Compliant The psychiatric evaluation includes the non-psychiatric medical history including: ▪ Physical disabilities. ▪ Intellectual disabilities. ▪ Treatment.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of open and closed medical records to verify that the psychiatric evaluation met the requirement. ▪ Does the psychiatric evaluation include: □ Relevant past surgery? Past medical conditions and disabilities especially those of a chronic nature? ▪ Have these contributed to the patient's psychiatric condition? How? ▪ Are any of these conditions still present to any significant degree? ▪ Are they likely to impact on the patient's recovery remission? ▪ Should they be addressed immediately? ▪ Does the facility have the capability to intervene? If not, how is the need to be met?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
27.01.11 Mental status	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Each patient must receive a psychiatric evaluation that must: ▪ Contain a record of mental status.	The mental status must describe the appearance and behavior, emotional response, verbalization, thought content, and cognition of the patient as reported by the patient and observed by the examiner at the time of the examination. ▪ This description is appropriate to the patient's condition.	**DOCUMENT REVIEW** ▪ Review a sample of open and closed medical records to verify that the psychiatric evaluation met the requirement. ▪ Explore the mental status for descriptions of the patient's presentation during the examination that are relevant to the diagnosis and treatment.
27.01.12 Reason for admission	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Each patient must receive a psychiatric evaluation that must: ▪ Note the onset of illness and the circumstances leading to admission.	In a hospitalized patient, the identified problem should be related to the patient's need for hospital admission. The psychiatric evaluation includes a history of present illness, including onset, precipitating factors and reason for the current admission, signs and symptoms, course, and the results of any treatment received.	**DOCUMENT REVIEW** ▪ Review a sample of open and closed medical records to verify that the psychiatric evaluation met the requirement. □ How long has the patient been ill? Was it a gradual or sudden onset? □ Is this a recurrence? □ What were the precipitating factors? □ What happened? ▪ What symptoms, signs, behaviors made this hospitalization necessary?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		□ What treatment has the patient already received before coming to the hospital? □ Is any medication received listed?
27.01.13 Behavioral assessment Each patient must receive a psychiatric evaluation that must: ▪ Describe attitudes and behavior (those requiring change for the patient to function in a less restrictive environment).	☐ Compliant ☐ Not Compliant The problem statement should describe behavior(s) which require change in order for the patient to function in a less restrictive setting. The identified problems may also include behavioral or relationship difficulties with significant others which require active treatment to facilitate a successful discharge.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of open and closed medical records to verify that the psychiatric evaluation met the requirement. ▪ The evaluation includes a problem statement that includes behavioral or relationship difficulties that require active treatment to facilitate a successful discharge.
27.01.14 Cognitive assessment Each patient must receive a psychiatric evaluation that must: ▪ Estimate intellectual functioning, memory functioning and orientation.	☐ Compliant ☐ Not Compliant The psychiatric evaluation must estimate the intellectual functioning, memory, and orientation of the patient.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of open and closed medical records to verify that the psychiatric evaluation includes an estimate of intellectual functioning, memory, and orientation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
27.01.15 Inventory of strengths Each patient must receive a psychiatric evaluation that must: ▪ Include an inventory of the patient's asset (strengths) in descriptive, not interpretive fashion.	☐ Compliant ☐ Not Compliant Although the term strength is often used interchangeably with assets, only the assets that describe personal factors on which to base the treatment plan or which are useful in therapy represent personal strengths. Strengths are personal attributes i.e., knowledge, interests, skills, aptitudes, personal experiences, education, talents, and employment status, which may be useful in developing a meaningful treatment plan.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of open and closed medical records to verify that the psychiatric evaluation met the requirement. ▪ The evaluation includes an inventory of the patient's strengths (assets) in a descriptive manner.
27.01.16 Treatment plan: Individualized Each patient must have an individual comprehensive treatment plan. The individualized treatment plan provides evidence of: 1. A substantiated diagnosis that serves as the basis for the treatment interventions. 2. Short-term and long-range goals. 3. The date it was developed and the schedule for update. 4. The treatment modalities/ approaches to be used. 5. Responsibilities of each member of the treatment team.	☐ Compliant ☐ Not Compliant The patient and treatment team collaboratively develop the patient's treatment plan. The treatment plan is the outline of what the hospital has committed to do for the patient, based on an assessment of the patient's needs. Documentation justifies the diagnosis and treatment activities. The substantiated diagnosis serves as the basis for treatment interventions. A substantiated diagnosis is the diagnosis identified by the treatment team to be the primary focus upon which treatment planning will be based. It evolves from the synthesis of data from various disciplines.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** 1. Review a sample of closed, open and outpatient records. Determine compliance to all required elements. 2. Has the information gained from assessing / evaluating the patient been utilized to create an individualized treatment plan? ▪ How do treatment plan goals relate to the problems being treated? ▪ Do goals indicate the outcomes to be achieved by the patient? ▪ Are the goals written in a way that

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
6. The outcome goal, mechanism, and time frame for achievement. 7. Discharge and follow up plan. 8. Reassessment per planned schedule and upon significant changes in the patient's response and progress. 9. The names of the participants in the planning process. 10. Evidence of patient (surrogate) involvement/congruence with the plan.		allows changes in the patient's behavior to be measured?
27.01.17 Progress notes The medical record must provide adequate documentation to justify the diagnosis and treatment activities of the patient. Progress notes are dated, timed and signed by the author. Minimally, progress notes are authored by: ▪ Physicians, at least daily; ▪ Nurses, with a change of shift; and ▪ Others significantly involved in active treatment modalities.	☐ Compliant ☐ Not Compliant The recording of progress is evidence of individual patient performance. Notes should be dated and signed (signature and title or discipline). ▪ Specifically, the progress notes recorded by the professional staff, or others responsible for the patient's treatment, must give a chronological picture of the patient's progress or lack of progress towards attaining short and long-range goals outlined in the individual treatment plan. ▪ Progress notes should relate to the goals of the treatment plan.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed patient records. Review progress notations for patient progress. ☐ Select two or more identified problems and goal statements to trace the documentation of progress. ☐ Entries must be dated and signed with the discipline identified. ☐ The progress notes recorded by the professional staff, or others responsible for the patient's treatment, must give a chronological

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

picture of the patient's progress or lack of progress towards attaining short and long-range goals of the treatment plan.

□ Expect to see greater frequency when patients are more acutely ill and/or in a crisis of some kind.

- Are the physicians, nurses, social workers and other disciplines, i.e., rehabilitative therapy and psychology who are significantly involved in active treatment modalities/interventions actually documenting progress?
- Do the progress notes relate to the goals of the treatment plan? Do they include precise statements of progress?

27.01.18 Discharge summary

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The medical record must document:

- A discharge summary with outcome of hospitalization, disposition of case and provisions for follow-up care.

The discharge summary should contain a recapitulation of the patient's hospitalization, which is a summary of the circumstances and rationale for admission, and a synopsis of accomplishments achieved as reflected through the treatment plan.

RECOMMENDATIONS FOR FOLLOW-UP OR AFTERCARE
The patient's discharge summary should describe the services and supports that are appropriate to the patient's needs and that will be effective on the day of discharge.

Examples include:

- A complete description of arrangements with treatment and other

DOCUMENT REVIEW

- Verify that closed patient records have a discharge plan and discharge summary.
- Is there an indication that the discharge planning process included the participation of multidisciplinary staff and the patient? Have the results been communicated to the post-hospital treatment entity?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

community resources for the provision of follow-up services. Reference should be made to prior verbal and written communication and exchange of information.

- A plan outlining psychiatric, medical/physical treatment and the medication regimen as applicable.
- Specific appointment date(s) and names and addresses of the service provider(s).
- Description of community housing/living arrangement.
- Economic/financial status or plan, i.e., supplemental security income benefits.
- Recreational and leisure resources.
- A complete description of the involvement of family and significant others with the patient after discharge.

SUMMARY OF PATIENT'S CONDITION AT DISCHARGE
The patient's discharge planning process should address anticipated problems after discharge and suggested means for intervention, i.e., accessibility and availability of community resources and support systems including transportation, special problems related to the patient's functional ability to participate in aftercare planning.

The discharge summary and/or plan should contain information about the status of the patient on the day of discharge, including psychiatric, physical and functional condition.

27.02.01 Special staffing requirements for psychiatric units in acute care hospitals
The psychiatric unit must have adequate numbers of qualified professional and supportive staff to:

☐ Compliant ☐ Not Compliant

The purpose of this standard is to ensure that the psychiatric hospital is adequately staffed with qualified mental health professionals and supportive staff to carry out an intensive and comprehensive active treatment program

This standard is not met as evidenced by:

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ evaluate patients, formulate written individualized comprehensive treatment plans, provide active treatment measures and engage in discharge planning.	and to protect and promote the physical and mental health of the patients.	▪ Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. Review incident reports, medication error reports, patient and staff injury reports for indications that staffing is an issue. ▪ Assess staffing by: □ Observing sampled patients and others during structured sessions and in unstructured settings. You should be able to observe behavioral evidence of a rational organization of resources. □ Interview patients and staff to determine whether or not necessary treatment modalities and other services are being provided in a timely manner. □ Review the medical records of patients in the sample to ascertain if necessary active treatment assessments, treatments, evaluations, and activities have been conducted and documented. □ Review other records such as restraint and seclusion records, incident reports, medication error reports, reports of patient/staff injuries, etc., to determine the extent to which staffing levels or

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

deployment contributed to negative patient outcomes.

- Evaluate all outcome data in light of the success or failure observed during the survey relevant to each patient receiving active treatment and achieving desired outcomes of care. This is the primary basis for evaluating the adequacy of the hospital's staffing.

27.02.02 Medical director of inpatient psychiatric services

Inpatient psychiatric services must be under the supervision of a clinical director, service chief or equivalent who is qualified to provide the leadership required for an intensive treatment program.

The clinical director, service chief or equivalent must meet the training and experience requirements for examination by the American Osteopathic Board of Neurology and Psychiatry or the American Board of Psychiatry and Neurology.

The Medical Director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.

☐ Compliant ☐ Not Compliant

The Clinical Director is a physician who has completed an approved residency program and has been certified or is eligible for examination to become certified by the American Board of Psychiatry and Neurology, or the American Osteopathic Board of Neurology and Psychiatry.

To be admitted to the American Board Examinations the following conditions must be met:

1. License without restrictions
2. Graduation from a medical school approved by either the Medical Osteopathic Association or the American Medical Association.
3. A successful completion of an approved residency-training program for at least 3 years before 1988 that the America Council on Graduate Medical Education (ACGME) approves. After 1988, it must be a four-year accredited program.

Of the members of the organized medical staff, one is named as clinical director (medical director).

- The clinical director is ultimately responsible for the medical and

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

- Verify that there is a member of the medical staff named as the Clinical Director.
  - □ Review the job description to determine that quality improvement program development is a responsibility of the clinical director, as well as implementation of educational programs for all levels of staff.
- Verify that the Clinical Director meets the residency requirements of a psychiatry/neurology program, approved by the American Board of Psychiatry and Neurology (ABPN) or the American Osteopathic Board of Neurology and Psychiatry (AOBNP).

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	psychiatric care that is provided to patients. ▪ The clinical director should ascertain that quality improvement programs are in place to monitor all areas of patient care and should implement educational programs for all levels of staff. The medical director is accountable for the oversight of the QAPI program of services provided by the professional staff. Inpatient psychiatric services include the following functions: ▪ admission interviews, assessments, and evaluations. ▪ psychiatric and medical workups. ▪ treatment team leadership. ▪ medication management. ▪ on-call provision of emergency psychiatric and medical treatment. ▪ provision of individual, group and family therapies. ▪ provision of clinical supervision to other professionals and paraprofessionals. ▪ provision of medical and psychiatric educational workshops and conferences for all staff. ▪ provision of consultation to staff for clinical and/or administrative matters. In states that allow psychologists to have admitting privileges, it is still the responsibility of the clinical director to oversee the quality of the patient's treatment.	▪ Review the clinical director's personnel folder or ask the clinical director if he/she has one of the following: □ Certification of the American Board of Psychiatry and Neurology and/or certification of the American Osteopathic Board of Neurology and Psychiatry. □ If no certification, evidence that the person took the Boards would satisfy that the person had the training and equivalency to be admitted to the board examination. □ If indicated, medical school and residency training.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

27.02.03 Director of nursing qualifications

The Director/Manager of Psychiatric Nursing Services must be a registered nurse who has a master's degree in psychiatric or mental health nursing or its equivalent from a school of nursing accredited by the National League for Nursing or be qualified by education and experience in the care of the mentally ill.

The director must demonstrate competence:

- to participate in interdisciplinary formulation of individual treatment plans;
- to give skilled nursing care and therapy; and
- to direct, monitor, and evaluate the nursing care furnished.

☐ Compliant ☐ Not Compliant

During the interview with the Director/Manager of Psychiatric Nursing Services, assess his/her educational background and psychiatric nursing and leadership skills.

- If the Director/Manager of Psychiatric Nursing Services has less than a master's degree in Psychiatric Nursing, expect to see evidence of experience and on-going training in psychiatric nursing. Documented consultation from a nurse with a Master's in Psychiatric Nursing constitutes on-going training.

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

- Based on structured observations of the patients in the psychiatric unit, patient and staff interviews and medical record review, ascertain that nursing services are provided in accordance with safe, acceptable standards of nursing practice under the leadership of the Director/Manager of psychiatric services.
- Information obtained during interview with the Director/Manager of Psychiatric Nursing Services should verify:
  - □ implementation of continuous quality improvement programs;
  - □ provision of orientation, in-service and continuing education programs for nursing personnel especially in the areas of psychiatric nursing, nursing process, prevention, and management of violence,
  - □ CPR training and
  - □ Universal Precautions training for staff.
- Verify the Director/Manager of Psychiatric Nursing Services has the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

required education/ experience in the care of the mentally ill as evidenced by either:

- □ A master's degree in psychiatric/mental health nursing

  OR

- □ An RN with a related master's, such as psychology or nursing education, with 2 years of psychiatric inpatient nursing care

  OR

- □ A BSN, ADN, or diploma in nursing with at least two years of psychiatric inpatient nursing care and documented educational programs (ANA Psychiatric Nurse certification, psychiatric specific CEU's e.g., American Psychiatric Nurses Association) focused on psychiatric nursing, occurring at sufficient intervals to keep the Director of Psychiatric Nursing current;
- □ Documented clinical consultation/ supervision from a master's-prepared psychiatric nurse.

- Are nursing assessments completed on all patients?
- Do the multidisciplinary treatment plans reflect nursing input which include specific nursing interventions

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		for nursing problems (e.g., violence toward self/others, physical/medical crises)? ▪ Is nursing care evaluated by an RN, with changes in the care based on the patient's progress or lack thereof? ▪ Are intrusive techniques (e.g., seclusion, restraint, electroconvulsive therapy (ECT), and/or medical procedures) and patient incidents (e.g., medication errors, patient falls, patient-to-patient and patient-to-staff injuries) monitored in accordance with hospital policy, State statutes and safe nursing practice? ▪ Are nursing personnel observed relating to patients in a therapeutic manner?
27.02.04 Psychological services The facility must provide or have available psychological services to meet the needs of the patients.	☐ Compliant ☐ Not Compliant Psychological services may include the following: ▪ Diagnostic testing and diagnostic formulations on request from physicians ▪ Provision of individual, group and family therapies ▪ Participation in multidisciplinary treatment conferences ▪ Program development and evaluation. Psychologist personnel are available to provide essential diagnostic formulations upon request. Psychologist personnel are available to provide	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Determine the number of full-time, part-time, and consulting psychologists. If contractual services are used, verify their availability to provide needed services to patients. ▪ Determine the extent that psychological testing is requested, the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

program development, interdisciplinary planning, and intervention, and evaluate program effectiveness as needed to implement the program philosophy.

The number of full-time, part-time, and consulting psychologists must be adequate to provide necessary services to patients. Arrangements with outside resources must assure that necessary patient services will be provided.

response time and the availability of the results.

- Did the patients in the sample have a need for psychological services or testing?
  - □ Were they provided in a timely manner and with sufficient intensity?
  - □ Did any of the patients in the sample indicate a need for psychological services, but none were requested?
- What types of psychological services are offered (e.g., assessments, therapy)?
- Do certain groups of patients receive testing routinely? Dementia? Children? Adolescents? Why?
- Once tests are performed, are results reported in sufficient time to be integrated in the patient's active treatment and treatment plan?
- How does the hospital or psychological services department determine whether or not:
  - □ it meets the needs of patients?
  - □ Its services are underutilized or over-utilized?
- Why have psychological services staff been deployed as they have?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
27.02.05 Therapeutic activities program The psychiatric unit must provide a therapeutic activities program. The program must be appropriate to the needs and interests of the patients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.	☐ Compliant ☐ Not Compliant There are sufficient resources to provide physical and psychosocial therapeutic activities to meet the needs of the patient populations. Therapeutic activities are provided within the program schedule on the day and evening shifts each day of the week, including weekends. Activities do not present undue hazard to the therapeutic milieu. Activities may be planned/directed by: ▪ An occupational therapist. ▪ A recreational therapist with a BS degree. ▪ A music therapist with a bachelor's degree. ▪ Other related therapist. A variety of therapeutic and rehabilitative activities are selectively used as therapeutic tools in providing active treatment to the psychiatric patients. Therapeutic activities focus upon the development and maintenance of adaptive skills that will improve the patient's functioning. In contrast, leisure activities provide the patient with individualized opportunities to acquire knowledge, skills and attitudes about meaningful leisure involvement and experiences. A patient may need treatment and/or remediation of functional behavior(s) prior to leisure involvement. However, for some psychiatric patients the priority need may be for leisure education and activities.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify therapeutic activities are provided that meet the needs of the patient population. ▪ Verify the program provides adequate variety and availability of activities that are focused on restoring and maintaining physical and psychosocial function.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
27.03.01 Privacy and safety: Identify patients at risk *The patient has the right to receive care in a safe setting.* §482.13(c)(2)	**Score at 15.03.01.** Refer to standard 15.03.01 for requirements.	
27.03.02 Privacy and safety: Environmental Risk Assessment *The patient has the right to receive care in a safe setting.* §482.13(c)(2)	**Score at 15.03.02.** Refer to standard 15.03.02 for requirements.	
27.03.03 Patient Bedrooms: Safety and Security The facility must provide a safe environment to ensure patient safety, quality of care, and to prevent self-harm. Patient bedrooms have closable doors; door locks and other structural restraints are kept to a minimum. Doors are constructed to prevent barricading; staff must be allowed to enter patient rooms, baths, toilet, and shower rooms. Mirrors are as distortion free as possible.	☐ Compliant ☐ Not Compliant Privacy for sleeping and personal activities is afforded to the extent possible while maintaining access by staff to protect patients who may accidentally or intentionally be involved in harmful behaviors. The hospital conducts period ongoing assessments and reassessments to identify and determine any "at risk" behaviors that may result in patient self-harm.	This standard is not met as evidenced by: **OBSERVATION** ▪ Observe doors in the unit to determine staff access. ▪ Doors for rooms where patients at high risk for self-harm are housed may be specially fitted (piano hinge or other devices) to reduce risk of suicidal hanging gestures. ▪ Are barricading possibilities considered and mechanisms to reduce or deal with such behavior in place? ▪ Are mirrors shatter resistant?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

27.03.04 Sleeping accommodations

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Sleeping areas meet the program goals and the (age, developmental and clinical) needs of the patients.

- Multi-person bedrooms are restricted to same sex patients and do not exceed State requirements for maximum number of patients per room.

BEDROOMS
Programs often use "dormitory" style beds. Provisions for "Gatch" facility beds exist for those patients who may require elevations of the upper or lower body such as for hiatal hernia, etc., and for the attachment of side rails. Some beds may be specially equipped for restraint application. All mattresses and pillows meet facility requirements for fluid barrier resistance and fire resistance.

PERSONAL PROPERTY
Lockers may be provided; access to property is not unreasonably restricted. Closets are provided to hang garments; breakaway devices may be utilized in closets. Patient personal property which does not represent a unit safety or fire hazard may be kept by the patient for use or display in his / her bedroom.

PRIVACY AND SECURITY
Privacy for sleeping and personal activities is afforded to the extent possible while maintaining access by staff to protect patients who may accidentally or intentionally be involved in harmful behaviors. Provision of a lockable door protects vulnerable patients from unwanted/ harmful contact with other patients.

OBSERVATION AND INTERVIEW

- Interview program staff to identify the variations in needs of patients who are typically served.
  - □ Are some clinical needs not met due to non-availability of equipment/ furnishings?
  - □ When "Gatch" beds are utilized are they non-electric or has the lock out mechanism been placed to prevent accidental injury?
  - □ Do coverings for mattresses and pillows adequately provide fluid barrier and fire protection?
  - □ Are safe provisions made for hanging of garments?
  - □ Is there a locker for each available bed?
  - □ Are potentially hazardous belongings secured?
  - □ Do sleeping areas reflect "personalization" by patients?
- Observe doors in the unit to determine staff accesses.

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FOR FUTURE USE

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FOR FUTURE USE

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SURGICAL SERVICES

INTRODUCTION

If the hospital provides any surgical procedures, then it must comply with all requirements of this Condition of Participation. In addition to surgical procedures performed in a main operating room, these requirements apply to surgical procedures including, but not limited to, those performed as outpatient surgical services, and in departments such as Interventional Radiology, Invasive Cardiology/Cardiac Catheterization Lab, and Endoscopy Services whether at the main hospital facility or at remote locations.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
30.00.00 CONDITION OF PARTICIPATION: Surgical Services	☐ Compliant ☐ Not Compliant ☐ Not Applicable	This standard is not met as evidenced by:
If the hospital provides surgical services, the services must be well organized and provided in accordance with acceptable Standards of Practice. *If outpatient surgical services are offered, the services must be consistent in quality with inpatient care in accordance with the complexity of services offered.* §482.51	The provision of surgical services is an optional hospital service. However, if a hospital provides any degree of surgical services to its patients, the hospital must comply with all the requirements of this Condition of Participation (CoP). If surgical services are provided, they must be organized and staffed in such a manner to ensure the health and safety of patients. Acceptable standards of practice include maintaining compliance with applicable Federal and State laws, regulations, and guidelines governing surgical services or surgical service locations, as well as with any standards and recommendations promoted by or established by nationally recognized professional organizations (e.g., the American Medical Association, American College of Surgeons, Association of Operating Room Nurses, Association for Professionals in Infection Control and Epidemiology, etc.). **OUTPATIENT SURGICAL SERVICES** Outpatient surgical services must comply with all hospital CoPs including the surgical services CoP. Outpatient surgical services must be provided in accordance with acceptable standards of practice. Additionally, outpatient surgical services must be consistent in quality with the hospital's inpatient surgical services. Post-operative care planning, coordination of needed post-operative care and appropriate follow-up care of outpatient surgery patients	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ View all operative rooms and suites. [Request the use of proper attire for inspection.] Assess through observation whether services are provided in accordance with acceptable standards of practice. Verify that: ☐ Access to the operative and recovery area is limited to authorized personnel and that the traffic flow pattern adheres to accepted standards of practice. ☐ Aseptic and sterile technique is used by all individuals in the surgical area. ☐ There is appropriate cleaning between surgical cases and appropriate terminal cleaning. ☐ Operating room attire is suitable for the kind of surgical case performed;

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	must be consistent in quality with inpatient care in accordance with the complexity of the services offered and the needs of the patient. A process is in place for surgery, anesthesia, and post-anesthesia recovery services to collect and analyze data. Data is collected from all surgical/ invasive procedure areas of the facility, including remote locations. These data are integrated with the hospital-wide QAPI program.	that persons working in the operating suite wear only clean surgical costumes; that surgical costumes are designed for maximum skin and hair coverage. □ Equipment is available for rapid and routine sterilization of operating room materials. □ Equipment is monitored, inspected, tested, and maintained by the hospital's biomedical equipment program and in accordance with Federal and State law, regulations and guidelines and following manufacturer's recommendations. □ Sterilized materials are packaged, handled, labeled, and stored in a manner that ensures sterility e.g., in a moisture and dust-controlled environment and policies and procedures for expiration dates have been developed and are followed in accordance with accepted standards of practice. □ Temperature and humidity are monitored and maintained within accepted standards of practice. □ Medical/surgical devices and equipment are checked and maintained routinely by clinical/biomedical engineers.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		□ All surgical service activities and in all locations are integrated into the hospital-wide QAPI program.
30.00.01 Organizational structure *The organization of the surgical services must be appropriate to the scope of the services offered.* §482.51(a)	☐ Compliant ☐ Not Compliant The hospital must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish the surgical services offered by the hospital in accordance with acceptable standards of practice. The scope of surgical services provided by the hospital should be defined in writing and approved by the medical staff.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the hospital's organizational chart displaying the relationship of the operating room service to other services. □ Confirm that the operating room's organization chart indicates lines of authority and delegation of responsibility within the department or service.
30.00.02 Leadership *The operating rooms must be supervised by an experienced registered nurse or a Doctor of Medicine or* Doctor of Osteopathic Medicine*.* §482.51(a)(1)	☐ Compliant ☐ Not Compliant Inpatient and outpatient ORs must be supervised by an experienced RN or MD/DO. The RN or MD/DO supervising the operating room must demonstrate appropriate education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The hospital should address its required qualifications for the supervisor of the hospital's operating rooms in its policies and the supervisor's personnel	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that an RN, MD or DO is assigned responsibility for supervision of the operating rooms. ▪ Request a copy of the supervisor's position description to determine that it specifies qualifications, duties, and responsibilities of the position.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	file should contain information demonstrating compliance with the hospital's established qualifications.	▪ Verify that the supervisor is experienced and competent in the management of surgical services.
30.00.03 Scrub nurses	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
A Registered Nurse plans and supervises the care of each operative patient. *Licensed Practical Nurses (LPNs) and surgical technologists (operating room technicians) may serve as "scrub" nurses under the supervision of a registered nurse.* §482.51(a)(2)	If the hospital uses LPNs or operating room technicians (ORTs) as "scrub nurses," those personnel must be under the supervision of a RN who is immediately available to physically intervene and provide care. Operative records will indicate which RN assessed and planned the perioperative care for each surgical/invasive procedure patient. Assisting staff, including private employees of surgeons, will be identified in the medical record.	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Review patient charts to verify: ▪ The perioperative/invasive procedure documents provide space for identification of personnel present. ▪ An RN planned and supervised the perioperative care. ▪ An RN is available for supervision in the department or service. ▪ An RN is immediately available to all LPN and ORT scrub nurses. □ Validate the availability by requesting and reviewing a staffing schedule for the OR.
30.00.04 Circulating nurse	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Qualified registered nurses may perform circulating duties in the operating room. *In accordance with applicable State laws and approved medical staff policies and*	The circulating nurse must be a registered nurse. An LPN or surgical technologist may assist an RN with carrying out circulatory duties (in accordance with applicable state laws and medical-staff approved hospital policy) but the LPN or surgical technologist must be under the	**INTERVIEW AND DOCUMENT REVIEW** ▪ If LPNs and surgical technologists are assisting with circulating duties, verify that they do so in accordance with

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
procedures, LPNs and surgical technologists may assist in circulatory duties under the supervision of a qualified registered nurse who is immediately available to respond to emergencies. §482.51(a)(3)	supervision of the circulating RN who is in the operating suite and who is available to immediately and physically respond/intervene to provide necessary interventions in emergencies. The supervising RN would not be considered immediately available if the RN were located outside the operating suite or engaged in other activities/duties which prevent the RN from immediately intervening and assuming whatever circulating activities/duties that were being provided by the LPN or surgical technologist. The hospital, in accordance with State law and acceptable standards of practice, must establish the qualifications required for RNs who perform circulating duties and LPNs and surgical technologists who assist with circulating duties. If a case is circulated by other than an RN, the operative record will be co-authored by the RN who was immediately available. The term "immediate availability" precludes simultaneous primary circulating duties.	applicable state laws and medical staff approved policies and procedures. ▪ In situations where LPNs and surgical technologists are permitted to assist with circulating duties, verify that a qualified RN supervisor is immediately available to respond to emergencies. □ Is the medical record is co-authored by the supervising RN? ▪ Verify that RNs working as circulating nurses are working in accordance with applicable State laws and medical staff approved policies and procedures.
30.00.05 <u>Surgical privileges</u>	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Surgical privileges must be delineated for all practitioners performing surgery in accordance with the competencies of each practitioner. *The surgical service must maintain a roster of practitioners specifying the surgical privileges of each practitioner.* §482.51(a)(4)	Surgery and all surgical procedures must be conducted by a practitioner who meets the medical staff criteria and procedures for the privileges granted, who has been granted specific surgical privileges by the governing body in accordance with those criteria, and who is working within the scope of those granted and documented privileges. Surgical privileges must be reviewed and updated at least every two years. A current roster listing each practitioner's specific surgical privileges must be available in the surgical suite and area/location where the scheduling of surgical procedures is done.	**<u>DOCUMENT REVIEW</u>** ▪ Review the hospital's method for reviewing the surgical privileges of practitioners. This method should require a written assessment of the practitioner's training, experience, health status, and performance. ▪ Verify that a current roster listing each practitioner's specific surgical privileges is current, complete, and available in the surgical suite and the area where

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must also be retained in these areas/locations.

SURGICAL PRIVILEGES
See standard 03.01.09 for additional information regarding the granting of privileges.

Surgical privileges are granted in accordance with the competencies of each practitioner.

The hospital must specify the surgical privileges for each practitioner that performs surgical tasks. This would include practitioners such as:

- Doctor of Medicine/Doctor of Osteopathic Medicine
- Dentists
- Oral surgeons
- Podiatrists
- RN first assistants
- Nurse practitioners
- Surgical physician assistants
- Surgical technicians, etc.

When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures, and the degree of supervision (to include whether the supervising practitioner must be physically present in the same or in line of sight of the practitioner being supervised) are delineated in that practitioner's surgical privileges and included on the surgical roster.

If the hospital uses RN First Assistants, surgical PA, or other non-MD/DO surgical assistants, the hospital must establish criteria, qualifications, and a credentialing process to grant specific privileges to individual practitioners based on each individual practitioner's compliance with the privileging/credentialing criteria and in accordance with federal and state

the scheduling of surgical procedures is done.

- Determine that a current list of surgeons suspended from surgical privileges or who have restricted surgical privileges is retained in these areas/locations.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	laws and regulations. This would include surgical services tasks conducted by these practitioners while under the supervision of an MD/DO. When practitioners whose scope of practice for conducting surgical procedures requires the direct supervision of an MD/DO surgeon, the term "supervision" would mean the supervising MD/DO surgeon is present in the same room, working with the same patient.	
30.00.06 For future use		
30.00.07 First assistants	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The Medical Staff Rules and Regulations and/or policies identify: 1. Hazardous cases which require a physician first assistant to be scrubbed. 2. The types of cases wherein a qualified non-physician first assistant may be scrubbed.	The facility has a policy that: 1. Defines the hazardous procedures performed at the facility. The definition of "hazardous" procedures may vary from one facility to another. As an example, open cranial and thoracic procedures are noted as those requiring a physician first assistant. 2. Defines cases that require: □ A scrubbed physician first assistant □ A scrubbed non-physician first assistant 3. The Medical Staff Rules should delineate the "qualification" process for non-physician first assistants.	**DOCUMENT REVIEW** Verify that: ▪ Rules and Regulations or policy identify the hazardous cases that require a physician first assistant. ▪ The policy regarding use of first assistants is available; practice is compliant with policy.
30.00.08 Physician availability	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The Medical Staff Rules and Regulations and/or policies require that when the entire surgical team is non-physician that	When the surgeon is a dental or podiatric (non-physician) practitioner, and the anesthesia provider is a non-physician:	**INTERVIEW AND DOCUMENT REVIEW** Verify that:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
a physician be immediately available to the procedure.	▪ There shall be evidence that a physician responsible for management of medical crises has been notified of the case start and is immediately available to provide intervention (within three to five minutes). When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision must be delineated in that practitioner's surgical privileges and included on the surgical roster.	▪ If a case is entirely non-physician, the medical record reflects that a physician is notified, accepts accountability, and is immediately available. ▪ Rules and Regulations describe this scenario for ensuring physician availability. ▪ Staff is knowledgeable of this process.
30.00.09 Standards of practice *Surgical services must be consistent with needs and resources.* *Policies governing surgical care must be designed to assure the achievement and maintenance of high standards of medical practice and patient care.* §482.51(b)	☐ Compliant ☐ Not Compliant There is a policy manual governing activity in all operative/invasive procedure locations. This includes the "main" operating room and all remote surgical suites, including cesarean and general delivery rooms, endoscopy, and invasive vascular labs. Policies governing surgical care contain: 1. Aseptic and sterile surveillance and practice, including scrub techniques. 2. Identification of infected and non-infected cases. 3. Housekeeping requirements/procedures. 4. Patient care requirements, including: a. preoperative work-up. b. patient consents and releases. c. clinical procedures. d. safety practices. e. patient identification procedures. 5. Duties of scrub and circulating nurse.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Review the Surgical Services policy manual to verify: □ All required policies are in place and reflect current practice. □ The Surgical Services policies reflect current practice and has been reviewed and approved within the last three years by all appropriate individuals/groups. □ Practices in remote locations are consistent with the surgical service Standards for Practice, (i.e., draping, setting up "back table, etc.) □ Policies and procedures address the elements specified. If the hospital uses alcohol-based skin preparations

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

6. Safety practices, including patient identification, site identification, procedure verification, and surgical counts.
7. The requirement to conduct surgical counts in accordance with accepted standards of practice.
8. Scheduling of patients for surgery.
9. Personnel policies unique to the OR.
10. Resuscitative techniques.
11. DNR status.
12. Care of surgical specimens, including collection, labeling, handling, and processing methods.
13. Malignant hyperthermia.
14. Appropriate protocols for all surgical procedures performed. These may be procedure-specific or general in nature and will include a list of equipment, materials, and supplies necessary to properly carry out job assignment.
15. Sterilization and disinfection procedures.
16. Acceptable operating room attire.
17. Handling infectious, biomedical, and medical waste.
18. Outpatient surgery postoperative care planning and coordination, and provisions for follow-up care.

POLICY APPROVAL

Principles of care are consistent in all locations.

The policies are developed, or are approved, by the Surgical Services Supervisor, Chief of Surgery, administration, Infection Control committee, and the Pharmacy Therapeutics Committees, as appropriate, and the professional medical staff.

in anesthetizing locations, determine whether it has adopted policies and procedures to minimize the risk of surgical fires.

- Interview surgical services staff to determine whether they are aware of and follow hospital policies and procedures.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Policies and procedures must be written, implemented, and enforced. Surgical services' policies must be in accordance with acceptable standards of medical practice and surgical patient care.

Policies and procedures are developed relating to changes or new technology and procedures. Policies are reviewed and revised as necessary, consistent with state regulations and facility policy, but no less often than every three years.

USE OF ALCOHOL-BASED SKIN PREPARATIONS IN ANESTHETIZING LOCATIONS

Alcohol-based skin preparations are considered the most effective and rapid-acting skin antiseptic, but they are also flammable and contribute to the risk of fire.

The use of an alcohol-based skin preparation in inpatient or outpatient anesthetizing locations is not considered safe, unless appropriate fire risk-reduction measures are taken, preferably as part of a systematic approach by the hospital to preventing surgery-related fires.

A review of recommendations produced by various expert organizations concerning use of alcohol-based skin preparations in anesthetizing locations indicates there is general consensus that the following risk reduction measures are appropriate:

- Using skin prep solutions that are:
  1) packaged to ensure controlled delivery to the patient in unit dose applicators, swabs, or other similar applicators; and
  2) provide clear and explicit manufacturer/ supplier instructions and warnings. These instructions for use should be carefully followed.
- Ensuring that the alcohol-based skin prep solution does not soak into the patient's hair or linens. Sterile towels should be placed to absorb drips and runs during application and should then be removed from the anesthetizing location prior to draping the patient.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Ensuring that the alcohol-based skin prep solution is completely dry prior to draping. This may take a few minutes or more, depending on the amount and location of the solution. The prepped area should be inspected to confirm it is dry prior to draping.
- Verifying that all of the above has occurred prior to initiating the surgical procedure. This can be done, for example, as part of a standardized pre-operative "time out" used to verify other essential information to minimize the risk of medical errors during the procedure.

Hospitals that employ alcohol-based skin preparations in anesthetizing locations should establish appropriate policies and procedures to reduce the associated risk of fire. They should also document the implementation of these policies and procedures in the patient's medical record.

Failure by a hospital to develop and implement appropriate measures to reduce the risk of fires associated with the use of alcohol-based skin preparations in anesthetizing locations should be cited as condition-level noncompliance.

30.00.10 History and Physical and Update to the History and Physical

Prior to surgery or a procedure requiring anesthesia services and except in the case of emergencies:

(i) A medical history and physical examination must be completed and documented no more than 30 days before or 24 hours after admission or registration, and except as provided under item (iii) below.

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

There must be a complete history and physical examination (H&P), and an update, if applicable, in the medical record of every patient prior to surgery, or a procedure requiring anesthesia services, except in emergencies.

1. The H&P must be conducted in accordance with the requirements of standards 03.01.07-.08 [42 CFR 482.22(c)(5)].
2. The history and physical must be completed and documented no more than 30 days before or 24 hours after hospital admission or registration. In all cases, except for emergencies, the H&P must be completed and documented before the surgery or procedure takes place, even if that

DOCUMENT REVIEW

Review a sample of open and closed medical records of patients (both inpatient and outpatient) who have had surgery or a procedure requiring anesthesia to verify:

- An H&P was conducted and documented in a timely manner, i.e.:
  - □ A history and physical has been completed according to the required timeline and is placed in the medical

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(ii) An updated examination of the patient, including any changes in the patient's condition, must be completed and documented within 24 hours after admission or registration when the medical history and physical examination are completed within 30 days before admission or registration, and except as provided under item (iii) below.

(iii) Or, An assessment of the patient must be completed and documented after registration (in lieu of the requirements of paragraphs (i) and (ii) above) when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies, in accordance with the requirements at §482.22(c)(5)(v), specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services.

§482.51(b)(1)
§482.51(b)(1)(i-iii)

surgery or procedure occurs less than 24 hours after admission or registration.

3. If the H&P was completed within 30 days before of admission or registration, then an updated examination must be completed and documented within 24 hours after admission or registration. In all cases, except for emergencies, the update must be completed and documented before the surgery or procedure takes place, even if that surgery or procedure occurs less than 24 hours after admission or registration.

The documented history and physical is placed in the patient's medical record within 24 hours of admission or registration and prior to any surgery or procedure requiring anesthesia services.

Any history and physical conducted more than 30 days prior to admission is not acceptable and must be repeated.

1. A physician, oral and maxillofacial surgeon, or other qualified individual is expected to review the history and physical that was completed prior to admission and conduct an assessment and include any changes since the initial examination.
2. If there are no changes to the history and physical, the practitioner is expected to prepare a medical record entry update indicating that the history and physical was reviewed, the patient examined, and that the physician concurs with the findings of the history and physical completed on the specified date.
3. The updated medical history and physical is attached to the original history and physical within 24 hours of admission or registration and prior to any surgery or a procedure requiring anesthesia services.
4. If patient changes are identified during the updated evaluation, the practitioner documents the changes in the updated note.

record within 24 hours of admission or registration and in all cases prior to surgery or a procedure requiring anesthesia services. (In emergent cases a brief admission note with the critical patient information and vital signs is documented in the medical record.)

□ A history and physical completed within 30 days of admission is acceptable if an updated medical history and physical examination is completed including any changes; the update is documented and placed in the medical record within 24 hours of admission or registration and before surgery or a procedure requiring anesthesia services. This update must be attached to the original history and physical.

□ The H&P was conducted in accordance with the requirements of standards 03.01.07-.08 **[**42 CFR 482.22(c)(5)**].**

□ The records of patients who did not have a timely H&P or update indicate that the surgery or procedure was conducted on an emergency basis.

▪ Determine if the hospital has elected to establish a policy for a presurgical or

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	USE OF ASSESSMENT IN LIEU OF THE HISTORY AND PHYSICAL AND UPDATE TO THE HISTORY AND PHYSICAL An assessment of the patient in lieu of the requirements of a History and Physical and Update to the History and Physical is permissible under conditions identified in the standard [per § 482.51(b)(1)(i) and (ii)]*when the patient is receiving specific outpatient surgical or procedural services and when the medical staff has chosen to develop and maintain a policy that identifies,* in accordance with the requirements at standards 10.01.07 and 10.01.08 [42 CFR 482.22(c)(5)(v)], specific patients as not requiring a comprehensive medical history and physical examination, or any update to it, prior to specific outpatient surgical or procedural services. To ensure patient health and safety, these specific patient policies are to be supported by nationally recognized evidence and guidelines for best practices as well as the clinical judgement of the medical staff.	pre-procedural assessment of the patient (in lieu of the requirements for a comprehensive pre-surgical or preprocedural H&P and its update). If so, confirm that: □ the patient assessment is completed and documented after registration, but prior to surgery or a procedure requiring anesthesia services and □ the patient is receiving specific outpatient surgical or procedural services as outlined in the policy and □ the policy is supported by nationally recognized evidence and guidelines for best practices.
30.00.11 Surgical informed consent *A properly executed Informed Consent Form for the operative procedure must be in the patient's chart prior to the procedure, except in emergencies.* §482.51(b)(2)	**This standard is scored at 10.01.16.** The medical record contains a properly executed informed consent form for procedures and treatments in accordance with standard 10.01.16 [42 CFR §482.24(c)(4)(v)]. ▪ Informed consents will be written in simple sentences (4th grade comprehension level) and in the primary language of the patient. ▪ Interpreter services will be provided as need is identified. ▪ After the informed consent discussion has occurred, the patient or legal representative will be asked to recount what he or she has been told.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Review the medical records of post-surgical inpatients and outpatients and department policies to verify: ▪ The medical staff has specified which procedures are considered surgery and therefore require a properly executed informed consent form. ▪ The medical record contains a properly executed informed consent form for

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

See also standard 15.01.09 [42 CFR §482.13(b)(2)] under Patients' Rights and standard 10.01.16 [42 CFR §482.24(c)(4)(v)] under Medical Records to understand all requirements related to informed consent.

The primary purpose of the informed consent process for surgical services is to ensure that the patient, or the patient's representative, is provided information necessary to enable him/her to evaluate a proposed surgery before agreeing to the surgery. Typically, this information would include potential short- and longer-term risks and benefits to the patient of the proposed intervention, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's professional judgment. Informed consent must be obtained, and the informed consent form must be placed in the patient's medical record, prior to surgery, except in the case of emergency surgery.

Hospitals must assure that the practitioner(s) responsible for the surgery obtain informed consent from patients in a manner consistent with the hospital's policies governing the informed consent process.

SURGICAL INFORMED CONSENT POLICY

Hospitals must assure that the practitioner(s) responsible for the surgery obtains informed consent from patients in a manner consistent with hospital policy. See standard 10.01.16 Informed Consent for the required elements of the policy.

If there are additional requirements under State law for informed consent, the hospital must comply with those requirements.

SURGICAL INFORMED CONSENT PROCESS

A well-designed informed consent process would include discussion of the following:

1. Description of the proposed surgery, including the anesthesia to be used.
2. Indications for the proposed surgery.

each procedure or treatment performed, per hospital policy.

- The informed consent form is in the language that the patient can understand. The informed consent contains the required components as identified in 10.01.16.
  - □ Determine that the informed consent contains the information in the explanation is a way that a layperson can understand.
- Verify that the hospital's informed consent policies identify the circumstances when a surgery would be considered an emergency and thus not require an informed consent form be placed in the medical record prior to surgery.
- Review a minimum of six medical records of surgical patients and verify that they did not involve emergency surgery and that they contain informed consent forms that were executed prior to the surgery. When possible, review medical records of patients who are about to undergo surgery, or who are located in a surgical recovery area.
- Interview two or three post-surgical patients, as appropriate based on their ability to provide a cogent response, or the patients' representatives, to see

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	3. Material risks and benefits for the patient related to the surgery and anesthesia, including the likelihood of each, based on the available clinical evidence, as informed by the responsible practitioner's clinical judgment. Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but a high degree of severity. 4. Treatment alternatives, including the attendant material risks and benefits. 5. The probable consequences of declining recommended or alternative therapies. 6. Who will conduct the surgical intervention and administer anesthesia. 7. Whether physicians other than the operating practitioner, including but not limited to residents, will be performing important tasks related to the surgery, in accordance with the hospital's policies. Important tasks include: □ opening and closing. □ dissecting tissue. □ removing tissue. □ harvesting grafts. □ transplanting tissue. □ administering anesthesia. □ implanting devices. □ placing invasive lines. **NOTE ON USE OF SURGICAL RESIDENTS** For surgeries in which residents will perform important parts of the procedure, discussion with the patient should disclose any/all of the following, if relevant:	how satisfied they are with the informed consent discussion prior to their surgery.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

1. Physicians who are in approved post-graduate residency training programs are expected to perform portions of the surgery, based on their availability and level of competence.
3. Decisions that may be made at the time of the surgery regarding resident participation and their manner of participation will depend on the availability of residents with the necessary competence, knowledge the operating practitioner/teaching surgeon has of the resident's skill set, and the patient's condition.
4. Residents performing surgical tasks will be under the supervision of the operating practitioner/teaching surgeon.
5. Whether, based on the resident's level of competence, the operating practitioner/teaching surgeon will not be physically present in the same operating room for some or all the surgical tasks performed by residents.

   Note: A "moonlighting" resident or fellow is a post-graduate medical trainee who is practicing independently, outside the scope of his/her residency training program and would be treated as a physician within the scope of the privileges granted by the hospital.
6. Whether, as permitted by state law, qualified medical practitioners who are not physicians will perform important parts of the surgery or administer the anesthesia, and if so, the types of tasks each type of practitioner will carry out; and that such practitioners will be performing only tasks within their scope of practice for which they have been granted privileges by the hospital.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

30.00.12 Required OR equipment

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The Surgical Services maintains an adequate inventory of instrumentation, supplies and equipment. *The following equipment must be available to the operating room suites:*

- *Call-in system (intercom or equivalent)*
- *Cardiac monitor*
- *Defibrillator*
- *Aspirator (suction equipment/ vacuum)*
- *Resuscitator (ventilator)*
- *Tracheotomy set*

§482.51(b)(3)

Systems and processes shall be in working order and available for emergency communication and for patient care crises. The availability of oxygen is essential. The use of pulse oximetry and immediate availability of blood gas analysis should be considered as "standard."

Note: A cricothyroidotomy set is not a substitute for a tracheotomy set.

The term "resuscitator" refers to a hand-held bag type of device; a mechanical ventilator is not required.

Adequate equipment must be available to respond to emergencies in more than one location simultaneously. The call-in system must have the capability of summoning help internally as well as externally to the department, as needed.

Age-specific resuscitation equipment is required to meet the emergency needs of the patient. If the facility treats **neonatal/**pediatric patients, pediatric sized resuscitation equipment is immediately available.

The organization has a policy that defines:

- **Supplies and equipment required for emergencies.**
- **The process and frequency of checking for outdated supplies in carts.**
- **How all types of emergency carts are managed after use and during transport to be restocked to ensure security of supplies and medications. Emergency carts may include, but are not limited to:**
  - □ **Resuscitation Carts**
  - □ **Medication Carts**
  - □ **Anesthesia Carts**
  - □ **OB Hemorrhage Carts**

OBSERVATION

Verify:

- All required systems in surgical and invasive procedure rooms are working.
- All required equipment is readily available with adequate inventory for patient care.
- All equipment is working and, as applicable, in compliance with the hospital's biomedical inspection, testing, and maintenance program.
- Age-specific resuscitation equipment is readily available. If the facility treats **neonatal/**pediatric patients, **neonatal/**pediatric size endotracheal tubes/tracheostomy sets are immediately available.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	□ **Malignant Hyperthermia Carts** ▪ **Individuals authorized to transport carts.** ▪ **Secure locations in which carts may be stored prior to use by floors/departments.** ▪ **Frequency of cart lock check.** ▪ **Management of carts when a unit is closed. Carts must be stored in a secure location.**	
30.00.13 <u>Supply and instrumentation availability and sterilization</u> Instrumentation, supplies, and equipment are sufficient in quantity so that movement in and out of the area is minimized during cases. Processed instruments are protected from surface/airborne contamination. "IUSS" (Immediate Use Steam Sterilization formerly known as "Flash" sterilization) is limited to rare circumstances. The facility follows IUSS criteria and guidelines for sterilization. Shipping cartons are not permitted in the "clean" environment.	☐ Compliant ☐ Not Compliant The design of operating and invasive procedure rooms is such that personnel and supply movement provides for the protection of "clean" supplies. Signage, or "red" lines, may be used to denote "clean" from general traffic areas. Clean linen and sterile packages are not subject to dust accumulation, moisture, or other potential sources of contamination. "IUSS" (flash sterilization) is not to be used in lieu of adequate instrument inventories. The facility adopts criteria and practices in accordance with manufacturer's instructions and national guidelines such as CDC, CDC-HICPAC, AORN, AAMI, etc.	This standard is not met as evidenced by: **<u>OBSERVATION AND DOCUMENT REVIEW</u>** Verify: ▪ General and "clean" areas are clearly identified. ▪ Staff adhere to traffic rules. Movement in and out of the area is minimized. ▪ Shipping cartons are neither stored in the clean storage area nor on the floor. ▪ Sterile packages are intact and protected from dust, moisture, and other sources of contamination. ▪ The sterilization log demonstrates that IUSS (flash sterilization) is only used for emergency purposes. ▪ The facility uses IUSS guidelines. ▪ Staff uses safety measures with the chemical disinfectants/cold sterilant

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

products. These products are labeled and reflect current dates.

30.00.14 Operative site verification

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The facility shall have a policy and procedure that requires documented verification of the operative site before surgery occurs. The operative site verification policy and procedure must define:

1. Patient involvement in the process.
2. Types of cases requiring marking, but at minimum, cases involving laterality, multiple structures (fingers/toes) or multiple levels (spine) and the process to support completion.
3. Documents/information required in the verification process (i.e., patient interview, consent, H&P, surgery schedule, x-rays/test results).
4. How discrepancies are handled.
5. Use of a procedural "time out" prior to the start of the procedure which includes verification of:
   - □ Patient identity.
   - □ Correct side and site.
   - □ Agreement on procedure.

The surgeon shall clearly document the intended intervention site in the patient's records; these records should accompany the patient to the operating room.

The operative site must be identified prior to surgery.

The non-surgical site must never be marked.

Standardization is necessary; often medical staff perform procedures in more than one location. Lack of standardization has caused confusion and surgical errors as a result.

OBSERVATION AND DOCUMENT REVIEW

- Review the policy and procedure as well as closed medical records to verify that the requirement was met.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

□ Availability of implants/special equipment/requirements.

7. Required documentation for each element.

30.00.15 For future use

30.00.16 Pneumatic tourniquets

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Whenever a pneumatic tourniquet is used, the patient is evaluated for risk of an ischemic and/or thrombotic complication. Prophylactic measures are instituted, as appropriate.

The requirements to demonstrate standards compliance are as follows:

1. Explicit organizational policies and procedures for the proper use and maintenance of pneumatic tourniquets, including a risk assessment protocol and the plan to prevent complications.
2. Documentation in the patient record of the risk assessment and the complication prevention plan.

Pneumatic tourniquets are sometimes used to create a bloodless surgical field (e.g., to improve visualization for orthopedic and plastic surgery on the extremities) or for the instillation of regional anesthesia to the limb.

Ischemic neuromuscular injury may occur if the tourniquet remains inflated too long. Direct pressure injury to nerves may also occur. Additionally, tourniquet inflation and deflation may depress cardio-respiratory function in the perioperative period, including causing "showers" of embolic debris to the heart, which may in turn cause a pulmonary embolism.

Examples of approaches for implementation include:

1. Training in the proper use of the pneumatic tourniquet device for all perioperative staff.
2. Regular inspection and maintenance of the device according to the manufacturer's written instructions.
3. Proper fit of the device by selecting the proper size and appropriate positioning of the tourniquet cuff.
4. Keep tourniquet inflation time to a minimum.
5. Keep tourniquet inflation pressure to a minimum.
6. Follow inflation and deflation procedures as recommended by the manufacturer.

DOCUMENT REVIEW

- Review organizational policy on use of the pneumatic tourniquet.
- Review patient records to verify:
  - □ A policy on the use of the pneumatic tourniquet is in place; all required content is included.
  - □ The medical record provides evidence of care consistent with the pneumatic tourniquet policy, including a risk assessment and plan for prevention of complications.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

7. Perform continuous monitoring of the tourniquet inflation time and pressure display.

30.00.17 Postoperative care

There must be adequate provisions for immediate postoperative care.

§482.51(b)(4)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Adequate provisions for immediate post-operative care include:

1. Post-operative care must be provided to all surgical patients, including same-day surgery patients, in accordance with acceptable standards of practice.
2. A post-operative care area, usually referred to as the post-anesthesia care unit (PACU), is a separate area of the hospital. Access is limited to authorized personnel.
3. Policies and procedures specify transfer requirements to and from the PACU.
4. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the PACU includes, but is not limited to:
   a. Level of activity
   b. Respirations
   c. Blood pressure
   d. Level of consciousness
   e. Level of pain
   f. Patient color
   g. Cardiac status
5. If a patient is not transferred to the PACU, determine that provisions are made for close observation until the patient has regained

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

Verify:

- The hospital has provisions for postoperative care. Patient assessments are consistent with policy.
- There are policies and procedures that govern the recovery room area and they are used consistently throughout the organization.
- Patients in a PACU are monitored and assessed appropriately prior to transfer or discharge (in the case of same-day surgery patients) from the PACU.
- The hospital has a system for identifying and addressing the monitoring needs of post-operative patients transferred from the PACU to other areas of the hospital.
- Ask staff in the PACU and in units that receive patients from the PACU how the needs of post-operative patients for vigilant monitoring are addressed when

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	consciousness, e.g., direct observation by a qualified RN in the patient's room. **POST-OPERATIVE MONITORING** Hospitals are expected to develop and implement policies and procedures addressing the minimum scope and frequency of patient monitoring in post-PACU care settings, consistent with accepted standards of practice. Patients receiving post-operative intravenous (IV) opioid medications are of particular concern, due to the higher risk for over-sedation and respiratory depression. Once out of the PACU, patients receiving IV opioid medication may be placed on units where vital signs and other monitoring traditionally has not been done as frequently as in the PACU or intensive care units, increasing the risk that patients may develop respiratory compromise that is not immediately recognized and treated. See additional information at standard 16.01.06 [§482.23(c)(4)]. When post-surgical patients are transferred out of the PACU to another area of the hospital but continued on IV opioid medications, they need vigilant monitoring, even if post-PACU care is not typically referred to as "immediate" post-operative care.	the patients are transferred from the PACU to other areas of the hospital.
30.00.18 <u>Operating room register</u> *The operating room register(s) must be complete and up to date.* §482.51(b)(5)	☐ Compliant ☐ Not Compliant Registers may separately exist for operative/invasive procedures accomplished in remote locations such as cesarean delivery rooms, endoscopy, cardiac catheterization labs, etc. Whether these are manual journals, or electronic logs, the data are consistent. The register includes, at least: 1. Patient's name.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** Examine the OR register or equivalent record which lists all surgery performed by the surgery service to verify: ▪ The register includes all items specified. ▪ The register is current.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	2. Patient's hospital identification number. 3. Date of the operation. 4. Inclusive or total time of the operation. 5. Identity of the surgeon and any assistant(s). 6. Name of nursing personnel (scrub and circulating). 7. Type of anesthesia used and name of person administering it. 8. Operation performed. 9. Pre- and post-op diagnosis. 10. Age of patient.	▪ The register is used in <u>all</u> operative/ invasive procedure areas.
30.00.19 <u>Operative report</u> *An operative report describing-* ▪ *Techniques* ▪ *Findings* ▪ *Tissues removed or altered must be written or dictated immediately following surgery and signed by the surgeon.* §482.51(b)(6)	☐ Compliant ☐ Not Compliant The operative/procedure report is made <u>immediately</u> available so that care of the patient is "transferable" if the surgeon is unable to attend to the immediate needs of the patient. If handwritten, the operative report is legible. If dictated, the operative report is printed and in the medical record no more than 24 hours after the procedure. The operative report includes, at least: 1. Name and hospital identification number of the patient. 2. Date and times of the surgery. 3. Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks. 4. Pre-operative and post-operative diagnosis. 5. Name of the specific surgical procedure(s) performed.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review a minimum of six medical records of patients who had a surgical encounter to verify that an operative/procedure report is immediately available in the medical record. □ The surgical report is dated and signed by the responsible surgeon and includes the required elements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	6. Type of anesthesia administered. 7. Complications, if any. 8. A description of techniques, findings, and tissues removed or altered. 9. Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any. 10. Surgeon(s) or practitioner's names and a description of specific significant surgical tasks that were conducted by practitioners other than the primary surgeon/practitioner (significant surgical procedures include: Opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues).	
30.00.20 Pathology review exemptions All tissues and foreign bodies not submitted for pathologic review shall be described and recorded in the medical record by the operating surgeon or physician removing the tissue or foreign body.	☐ Compliant ☐ Not Compliant The hospital has a policy, approved by the medical staff, that specifies the required documentation and description relative to removal of tissues/foreign bodies. At a minimum, the policy addresses: 1. The detailed descriptions and photographs that are to be included in the medical record for all foreign bodies of potential medico-legal significance. 2. Recording the model number or serial numbers of orthopedic appliances. 3. An accurate count of teeth from partial or full mouth extractions. The process to ensure that strict chain-of-custody is maintained on all foreign bodies or other specimens of potential medico-legal importance.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review five medical records of patients who have had foreign bodies removed or foreign bodies implanted (e.g., orthopedic appliances) to verify: □ The required policy, approved by the Medical Staff, is in place. □ Medical record documentation includes a description of tissue or foreign bodies removed and model numbers of appliances, as relevant.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
30.00.21 Label medications and solutions on and off the sterile field	**This standard is scored at 25.01.27.**	This standard is not met as evidenced by:
The facility must develop and implement policies for safe labeling of medications and solutions used on and off the sterile field in the perioperative settings. The facility must have policies and processes in place including, but not limited to: 1. The required labeling of medications and solutions, regardless of container, used on and off the sterile field throughout the perioperative experience. 2. The methods used to differentiate and label look-alike products and solutions with similar names. 3. The process used to verify and confirm each medication/solution and the respective matching label.	All surgery settings and procedure rooms are expected to handle chemicals, reagents, specimen preservation agents, and diluents with the same caution as medications. A process must be in place to label all solutions used in the surgical area including, but not limited to intravenous fluids, medications, body fluids, hydrogen peroxide, formalin, Lugol's solution, radiopaque dyes, sterile saline, sterile water, isopropyl alcohol, skin preparation solutions, chlorhexidine, glutaraldehyde, etc. Many of these look alike as they are clear/colorless solutions. Labels must be applied to solutions stored in all types of containers used on and off the surgical field in the perioperative area including, but not limited to medicine cups, solution basins, syringes, and specimen cups. A label is required even if only one solution is involved with the procedure. It would be unacceptable to write onto plastic containers such as IV bags with marking pens, as there is evidence that the ink may penetrate into the solution. Sterile medications/solutions that are placed onto the sterile field in the original packaging with the manufacturer's original label on the container that indicates the name and strength of the medication do not require additional labeling. Use sterile markers and labels that can be opened onto the sterile field. Commercially prepared products are available for this purpose, but labels prepared by the facility are acceptable if sterilization is maintained. Labels are to clearly state the medication/solution and strength. When feasible, include these labels and markers in pre-made surgical packs.	**DOCUMENT REVIEW** Review policies and practices relative to medication preparation. Determine that systems are in place relating to: ▪ Required labeling of solutions and medications on and off the sterile field. ▪ Procedure for differentiating look-alike and sound-alike medications/solutions. ▪ Procedure for individually verifying medications/solutions and respective labels.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Many medications and solutions have similar names. A process must be identified and implemented when preparing labels to differentiate these. A process must be in place to verify each medication or solution and complete its preparation, labeling, and delivery to the sterile field before preparing the next solution. Label only one medication/solution at a time. Use two staff to confirm each medication/solution and respective label verbally and visually; one of these staff must be a licensed professional involved with the procedure. A process must be in place to discard any unlabeled solution or medication found in the perioperative area. Unlabeled solutions should be considered a hazardous condition and reported using the facility incident reporting protocol. At shift change or relief for breaks, the entering and exiting staff must concurrently read container labels and verify all medications on the sterile field. Keep original medication/solution containers in the surgical room until completion of the procedure for follow-up reference, if indicated.	
30.01.01 **For future use**		
30.02.01 **For future use**		
30.02.02 **For future use**		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
30.02.03 Nursing care: Post-anesthesia	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
A Registered Nurse plans and supervises the care of each post-anesthesia patient. Licensed practical/vocational nurses and technologists may provide services under the supervision of a Registered Nurse.	PACU records will indicate which RN assessed and planned post-anesthesia care for each surgical/invasive procedure patient. Assisting staff are identified in the medical record. A qualified RN provides immediate post-anesthesia care for any surgical or invasive procedure patient. If permitted by state law, Medical Staff policies may be formulated to permit LPNs/LVNs/or technologists to assist in these duties, under the supervision of a qualified RN who is immediately available to respond to emergencies.	**DOCUMENT REVIEW** Review policies and patient records to verify: ▪ The post-anesthesia care (PACU) documents provide space for identification of personnel that provided patient care. ▪ An RN planned and supervised the PACU care. ▪ A process is in place describing the supervision of LPNs/LVNs, if permitted by state law and hospital policy. ▪ If care is provided by staff other than a RN, both staff names are identified on the medical record as evidence of the immediate supervision and availability of a RN (within the suite).
30.02.04 For future use		
30.02.05 For future use		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
30.02.06 PACU required equipment *The post-anesthesia recovery services maintains an adequate inventory of instrumentation, supplies and equipment. At a minimum the following equipment must be available:* ▪ *Call-in-system (intercom or equivalent)* ▪ *Cardiac monitor* ▪ *Defibrillator* ▪ *Aspirator (suction equipment/ vacuum)* ▪ *Resuscitator (ventilator)* ▪ *Tracheotomy set* §482.51(b)(3)	☐ Compliant ☐ Not Compliant Systems and processes are in working order and available for emergency communication and for patient care crises. The availability of oxygen is essential. A cricothyroidotomy set is not a substitute for a tracheotomy set. The term "resuscitator" refers to a hand-held bag type of device; a mechanical ventilator is not required. **The organization has a policy that defines:** ▪ **Supplies and equipment required for emergencies.** ▪ **The process and frequency of checking for outdated supplies in carts.** ▪ **How all types of emergency carts contents are managed after use and during transport to be restocked to ensure security of supplies and medications. Emergency carts may include, but are not limited to:** □ **Resuscitation Carts** □ **Medication Carts** □ **Anesthesia Carts** □ **OB Hemorrhage Carts** □ **Malignant Hyperthermia Carts** ▪ **Individuals authorized to transport carts.** ▪ **Secure locations in which carts may be stored prior to use by floors/departments.** ▪ **Frequency of cart lock check.** ▪ **Management of carts when a unit is closed. Carts must be stored in a secure location.**	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ Surgical and invasive procedure post-anesthesia recovery rooms have working systems and an adequate inventory of equipment available for patient care. □ All required equipment is readily available. ▪ All equipment is working and, as applicable, in compliance with the hospital's biomedical inspection, testing, and maintenance program. ▪ Age-specific resuscitation equipment is readily available. ▪ If the facility treats **neonatal/**pediatric patients, **neonatal/**pediatric size endotracheal tubes/tracheostomy set are immediately available.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Adequate equipment must be available to respond to emergencies in more than one location simultaneously.

The call-in system must have the capability of summoning help internally as well as externally to the department, as needed.

The following should be available to meet the assessed needs of patients:

1. Oxygen, humidified
2. Pulse oximetry and immediate availability of blood gas analysis
3. Patient temperature monitoring
4. Re-warming mechanisms
5. Immediate access to supplies to manage a malignant hyperthermia crisis.
6. Age-specific resuscitation equipment is required to meet the emergency needs of the patient. If the facility treats pediatric patients, pediatric sized resuscitation equipment is immediately available.

30.02.07 **For future use**

30.02.08 **For future use**

30.02.09 **For future use**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
30.02.10 Required policies	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Post-anesthesia care service standards of practice (policies) provide for the achievement and maintenance of high standards of medical practice and patient care. Minimally, the following standards are in place: 1. Disinfection/sterilization of reusable equipment. 2. Traffic control. 3. Housekeeping. 4. Control of pharmaceuticals. 5. Management of pain including assessment and treatment utilizing a visual scale of zero to ten or the "FACES" tool for children.	There is a policy manual governing activity and available in all PACU locations that includes: ▪ The "main" PACU ▪ All remote surgical suites, cesarean and general delivery rooms, endoscopy and invasive vascular labs. Standards of Care are consistent in all locations. The policies are developed or approved by the PACU services supervisor, Chief of Anesthesia, administration, the Infection Control Committee, and the Pharmacy Therapeutics Committees, as appropriate, and the Professional Medical Staff. Policies are developed relating to changes or new technology and procedures. Policies are reviewed and revised as necessary in accordance with State regulation and facility policy but no less often than triennially.	**OBSERVATION AND DOCUMENT REVIEW** Review the PACU Service Policy Manual to verify: ▪ All required policies are in place. ▪ The PACU policy manual reflects current practice and has been reviewed and approved within the last three years by all appropriate individuals/groups. ▪ Practice is consistent with policy. Practices in remote locations are consistent with the PACU Services policy manual. ▪ If separate PACU service policies exist in remote locations (i.e., modifications in determining acuity, etc.), these have been authored or co-authored and approved by the PACU services supervisor prior to other approvals.
30.02.11 Policy: Bypass of post-anesthesia recovery service	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
There is a system to determine which patients require the PACU services and which patients may "bypass" this service.	There shall be one level of care provided to patients recovering from anesthesia regardless of whether the recovery is in the PACU, the ICU, or another location. This requirement also applies to patients that require post-anesthesia recovery after usual business hours.	**DOCUMENT REVIEW** Review medical records for patients that bypassed the PACU to verify that: ▪ A PACU "bypass" policy in place.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
If a patient is transferred directly to an ICU following anesthesia, there is a post anesthesia recovery period in that ICU. All post anesthesia patients (exception: local/topical) shall be considered as PACU candidates. Provisions are made to provide patients with the same standard of post anesthesia care when the regular PACU mechanism is not available.	The facility has a policy, approved by the Medical Staff, which lists patients that may bypass the PACU following anesthesia. Patients that might be excluded from PACU include those who received: ▪ Local/topical anesthesia. ▪ Acupuncture or hypnosis. ▪ Anxiolytic drugs therapy used as "anesthesia." The medical record shall contain an assessment of the patient's condition at the conclusion of the surgical/invasive procedure that justifies bypassing PACU care, consistent with hospital policy criteria. Qualified personnel of ample numbers shall provide post-anesthesia care. When patients are recovered in a location other than the PACU or after usual business hours, these personnel have received an orientation and ongoing training relative to the care of patients following all types of anesthesia provided at the facility. Staff training includes the PACU related policies and standards of practice. There is evidence that the staff who provide afterhours care meet the orientation/competency requirements for regular PACU staff.	▪ The PACU bypass criteria were consistently met. ▪ The medical records contain documentation of an appropriate post- procedure assessment at the conclusion of the procedure and upon arrival in the ICU. ▪ Processes are in place to provide orientation and ongoing training to ensure competent staff care for patients that are recovered in locations other than PACU or after-hours.

30.02.12 For future use

30.02.13 PACU discharge criteria

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The Medical Staff Rules and Regulations or policies and procedures define the PACU discharge criteria. These criteria, if used in lieu of a practitioner assessment/order, are consistently

The post-anesthesia criteria provide consistent and quantifiable data to make the discharge decisions.

DOCUMENT REVIEW

▪ Review of charts of patients discharged from PACU to verify that the medical record reflects the consistent and appropriate use of

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
applied whenever post anesthesia recovery occurs.		approved discharge criteria when determining discharge readiness from the PACU.
30.02.14 Documentation requirements A post-anesthesia care record is prepared for each patient and documents the following: 1. Nature of surgical/invasive/ manipulative procedure. 2. Date/time of arrival and transported by whom. 3. Level of consciousness and vital signs at time of arrival. 4. Name of anesthesia provider and anesthesia technique employed. 5. Condition of patient on arrival to the PACU as jointly assessed by the anesthesia provider and PACU RN. 6. "Key" observations at intervals specified in the PACU standards of practice to include vital signs, reactivity, sensorium, fluid intake/ output/balance, pain management, medications given with appropriate observations, and according to patient need, EKG, SAO2 and other monitoring results.	☐ Compliant ☐ Not Compliant Post-anesthesia care records document the required information regardless of location where the care is provided. These are made a permanent part of the patient's medical record. Close observation of the patient is essential during transportation and the period of emergence from anesthesia. Emotional and physiological responses to surgery, manipulation or invasion are to be monitored to the point that a patient can be determined to be safely transferred to another level of care. Transfer/discharge from the PACU is only by physician order or Medical Staff approved criteria.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review medical records of patients that received post-anesthesia care to verify: ▪ The medical record contains a post-anesthesia care report. ▪ The required information is consistently documented.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

7. Name of the nurse receiving the patient from PACU.
8. Name of the licensed independent practitioner discharging the patient from PACU care.

30.03.01 Outpatient discharge requirement

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Outpatient surgical/invasive procedure patients, who have had other than local or topical anesthesia, shall have a responsible person to provide transportation following the procedure, except those exempted by the practitioner who performed the surgical procedure.

Arrangements for transportation by a responsible person shall be clarified by staff, prior to initiation of the procedure.

The outpatient who has had anesthesia may have delayed responses to these agents which impact judgment and personal safety. For patient safety, it is essential that provisions for the patient's discharge are made prior to the procedure.

Transportation may be provided by someone known to the patient or through other arrangements, as deemed appropriate by the facility. These arrangements are documented in the medical record.

INTERVIEW AND DOCUMENT REVIEW

- Verify that staff can articulate the facility's discharge practices.
- Review medical records for patients discharged following outpatient surgery/procedure.
- Verify documentation that a responsible person transported the patient following the procedure, or the exemption to this requirement is documented by the physician performing the procedure.

30.03.02 Outpatient discharge instructions

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Outpatient surgical/invasive procedure patients, and their families/companions as appropriate, are provided with instructions regarding post procedure

Post procedure instructions include, at least:

1. Signs/symptoms of post-procedure feelings that are "normal."
2. Signs/symptoms of post-procedure problems that require immediate attention and/or notification of the physician.

DOCUMENT REVIEW

- Review medical records for patients discharged following outpatient surgery/procedure to verify that it

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
management in language that the patient or accompanying responsible person can understand.	3. The mechanism to use in the event of post-procedure problems when the physician cannot be notified. 4. The date and time to next see a health care provider for follow-up care. 5. Changes in diet/medication. 6. Pain management and treatment using a visual scale of zero to ten or the "FACES" tool for children. 7. Alterations in activity. 8. Management of wounds or devices.	contains documentation that post procedure care instructions were provided to the patient/responsible adult.
30.03.03 Post-procedure follow-up call Outpatient surgical/invasive procedure patients are contacted by the facility within 24 to 72 hours post procedure, when possible, to determine their status.	☐ Compliant ☐ Not Compliant The hospital policy identifies patients to be "at risk" that should receive a follow-up call to assess the clinical well-being post-surgery. Mechanisms are established to determine patient status following discharge. 1. A process is in place to document these follow-up calls. The clinical evaluation information obtained from post-discharge follow-up telephone calls is recorded in the medical record. 2. Information obtained from these calls is tracked and reported to the QAPI program to identify opportunities for improving the outpatient program. Adverse events may include, but are not limited to: ▪ Pain management issues. ▪ Bleeding. ▪ Returns to the Emergency Department. 3. Patient satisfaction with the facilities and the service can also be assessed; however, this information is not ordinarily recorded in the medical record.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview staff to identify the process used. ▪ Verify that medical records contain documentation of these follow-up calls. ▪ Verify that there is a mechanism to review and trend outcome or process issues as a result of the follow-up calls. □ Determine if the findings are reported to the QAPI Committee.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Facilities may determine the time frame, which is "best" for their population. (Some patients return to school or work so rapidly that contact may not be possible.)	

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31

OUTPATIENT SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
31.00.00 CONDITION OF PARTICIPATION: Outpatient Services *If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice.* §482.54	☐ Compliant ☐ Not Compliant This is an optional hospital service; however, if a hospital provides any degree of outpatient care to its patients, the hospital must comply with the requirements of this Condition of Participation (CoP). The Medicare Hospital CoP applies to both inpatient and outpatient services of the hospital. The hospital must be in compliance with the CoP in 42 CFR §482 in all on-campus and off-campus outpatient service locations. The hospital's outpatient services must be integrated into its hospital-wide QAPI program. Tag 1080 provides more detailed guidance on the overall requirements for outpatient services and permits standard-level citations for identified deficiencies. The manner and degree of noncompliance identified in relation to Tags 1077 – 1080 may result in substantial noncompliance with this CoP, requiring citation at the condition level. (31.00.01; 31.00.02; 31.00.12) All outpatient services provided by the hospital, both on campus and at any provider-based clinics, must meet the needs of the patients, in accordance with acceptable standards of practice. The hospital must ensure that the services, equipment, staff and facilities are adequate to provide the outpatient services offered at each location in accordance with acceptable standards of practice. If the hospital offers outpatient surgical services, the surgical services Condition of Participation requires that the offered services must be consistent in quality with inpatient care in accordance with the services offered. Acceptable standards of practice include standards that are set forth in federal or state laws, regulations or guidelines, as well as standards and	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Determine locations and type(s) of outpatient services provided and verify: ▪ All outpatient services at all locations are in compliance with the hospital CoP. ▪ Equipment, staff, and facilities are adequate to provide the outpatient services offered at each location are in accordance with acceptable standards of practice. ▪ The hospital's outpatient services are integrated into its hospital-wide QAPI program. ▪ Ask the individual(s) directing outpatient services whether the hospital orders for that type of outpatient service from referring physicians who are not members of the hospital's medical staff. If yes: ▪ Ask for evidence that the medical staff has approved the policy. ▪ Ask how the hospital verifies that the order comes from a referring practitioner who is appropriately licensed in the jurisdiction where

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	recommendations promoted by nationally recognized professional organizations (e.g., the American Medical Association, American College of Radiology, American College of Surgeons, etc.	he/she sees the patient to prescribe such orders. Ask for documentation of such verification efforts. □ Score compliance with this Condition of Participation based on the scoring throughout the requirements cited in this chapter. **Note:** If non-compliance does not rise to the Condition Level, score at standard 31.00.12.
31.00.01 Integration of services *Outpatient services must be appropriately organized and integrated with inpatient services.* §482.54(a)	☐ Compliant ☐ Not Compliant The facility has a written plan for outpatient services. The hospital's outpatient services at all locations must be integrated with inpatient services (e.g., radiology, laboratory, surgical services, anesthesia (including pain management) services, other diagnostic services, etc.) as appropriate to the outpatient services offered. The hospital must have written policies in place to assure the integration of outpatient services, including an established method of communication between outpatient service departments to corresponding inpatient services. The hospital must coordinate the care, treatment, and services to a patient. In order to provide continuity of care, it should have an established method of communication between inpatient services and outpatient care in order to provide continuity of care to its patients.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the outpatient organization plan to verify: □ The outpatient organization plan is integrated with the inpatient services in accordance with the needs of the patient care provided at each of those locations. □ That the hospital has an established method of communication and established procedures to assure integration with inpatient services to provide continuity of care. ▪ Review medical records of outpatients who were later admitted to the hospital to determine that pertinent

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

information from the outpatient record has been included in the inpatient record.

- Verify that the outpatient services are organized in a manner appropriate to the scope and complexity of services offered.

31.00.02 Personnel

1. *The hospital must assign one or more individuals to be responsible for outpatient services.*
2. *The hospital must have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.*

§482.54(b)(1)
§482.54(b)(2)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital's outpatient services may be directed by one or more individuals.

Hospitals have the flexibility to determine how best to organize their outpatient services, including how direction will be provided. As services offered in outpatient departments become more varied, complex and technologically advanced, hospitals may find it better to have individuals with more specialized expertise providing direction for a specific type of outpatient services.

Hospitals should define in writing the qualifications and competencies necessary for their outpatient services department leader(s). These qualifications should include items such as education, experience, and specialized training consistent with State law and acceptable standards of practice. The qualifications for the department leader demonstrate education and experience in physical therapy, occupational therapy, speech language pathology.

The hospital should define in writing the qualifications and competencies necessary to direct each outpatient service for which there is a separate director.

Qualifications include necessary education, experience, and specialized training consistent with state law and acceptable standards of practice.

DOCUMENT REVIEW

- Ask how the hospital has organized its outpatient services and to identify the individual(s) responsible for providing direction for outpatient services.
- Review the organizations policies and procedures to determine the person's responsibility.
- Review the position description and personnel file of the individual(s) responsible for a selection of outpatient services to ensure they are qualified, in accordance with State law, acceptable standards of practice and hospital policy to direct the service for which they are responsible.
- Visit several on- and off-campus locations where hospital outpatient services are provided. Given the scope

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Adequate types and numbers of qualified licensed healthcare professionals and other personnel must be available to provide patients with the appropriate level of care for the outpatient services offered by the hospital. The types and number of qualified personnel required for each area of the hospital's main campus or for each provider-based off-site location must be based on the scope and complexity of outpatient services offered and the number and types of patients treated as outpatients at each.	and complexity of the services being offered, are there sufficient personnel with the appropriate education, experience, certifications, current licensure where appropriate, and competencies for assigned responsibilities? ▪ Verify: □ All outpatient services are assigned to one (1) or more persons to manage the overall operation of hospital outpatient services. ▪ Review policies and contracts if services are provided under an arrangement. ▪ Review the staffing plan and the weekly /monthly schedule. Verify: □ There is sufficient staff available by classification and volume to care for the patients served. □ The staff qualifications including education, experience, certifications, current licensure where appropriate and competencies are appropriate for assigned responsibilities. ▪ Review personnel files to verify that the staff qualifications including education, experience, certifications, current licensure where appropriate and competencies are appropriate for assigned responsibilities.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ Compare duty rosters to patient log to verify that sufficient MD/DO, nurses and other staff are available to provide care to verify that the types and number of qualified personnel are appropriate for the types and numbers of patients receiving care, and the frequency, duration, and complexity of services offered.
31.00.03 Documentation in patient records All consultation reports, laboratory reports, radiology reports, etc., shall be reviewed with appropriate follow-up action noted in the outpatient record.	☐ Compliant ☐ Not Compliant Appropriate follow up shall be defined in the outpatient services policies and procedures.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review policy and procedures. ▪ Review medical records for determination of appropriate follow-up action. Verify: □ Follow-up expectations are defined in facility policy. □ Outpatient medical records demonstrate appropriate follow-up action, consistent with policy.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
31.00.04 Patient satisfaction Patient satisfaction questionnaires/ comment cards shall be available for patients.	☐ Compliant ☐ Not Compliant No additional information	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review data to verify that patient satisfaction is measured for outpatient services.
31.00.05 Activity Logs The facility shall have appointment/ encounter/recall and phone logs in use that are up to date.	☐ Compliant ☐ Not Compliant No additional information	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review the appointment recall and phone logs to verify that documentation is current and consistent with policy.
31.00.06 After-Hours Resources The facility shall have after-hours care arrangements in place with call schedules available for the patients.	☐ Compliant ☐ Not Compliant No additional information	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Review after-hours arrangements and, if possible, interview a patient to verify: ▪ Processes are in place to meet this requirement. ▪ The after-hours care arrangements are clearly communicated to patients.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
31.00.07 Referrals The facility shall have arrangements in place for referring patients that require higher level of appropriate care (i.e., hospitalizations, consults, procedures, and diagnostics).	☐ Compliant ☐ Not Compliant No additional information	This standard is not met as evidenced by: **INTERVIEW** ▪ Interview the person responsible for outpatient service to verify that arrangements for these levels of care are in place.
31.00.08 For future use		
31.00.09 For future use		
31.00.10 Storage The commodities supplied to patient care and support services are stored in such a manner so as to protect them from damage, or loss, such as from moisture, thermal change, rodents, vermin, or theft.	☐ Compliant ☐ Not Compliant No additional information	This standard is not met as evidenced by: **OBSERVATION** ▪ Observe supply carts, cabinets, and storeroom(s) to verify that supplies are appropriately stored and protected from damage due to moisture, temperature changes, theft, etc.
31.00.11 Orders for outpatient services *Outpatient services must be ordered by a practitioner who meets the following conditions:* 1. *Is responsible for the care of the*	☐ Compliant ☐ Not Compliant This regulation allows hospitals to accept orders for outpatient services both from practitioners who hold hospital privileges as well as practitioners who do not, including those who are not located in the hospital's close geographic area.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine whether the facility allows outpatient services to be ordered by non-physician practitioners or

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

patient.

2. *Is licensed in the State where he or she provides care to the patient.*
3. *Is acting within his or her scope of practice under State law.*
4. *Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:*
   (i) All practitioners who are appointed to the hospital's medical staff and who have been granted privileges to order the applicable outpatient services.
   (ii) All practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the medical staff and the hospital for ordering the applicable outpatient services for their patients.

§482.54(c)
§482.54(c)(1)
§482.54(c)(2)
§482.54(c)(3)
§482.54(c)(4)
§482.54(c)(4)(i)
§482.54(c)(4)(ii)

- It is not uncommon for individuals to obtain health care services in a variety of locations from a variety of practitioners. Sometimes an individual elects to seek services from a specialist in a tertiary setting removed from the area where the individual lives, but prefers to get follow-up care, such as physical therapy after a surgery, closer to home. Sometimes an individual may have multiple residences in different areas and may need to continue care locally when moving between residences. Sometimes individuals receive urgent or even emergent care while traveling.
- Accepting orders and referrals for outpatient services from practitioners not on the medical staff or not holding privileges enables a hospital to promote ready access to care for patients in the area it serves.
- Finally, sometimes a practitioner who does not practice in a local hospital may nevertheless refer patients to that hospital for outpatient services, such as diagnostic imaging, physical and occupational therapy, etc.

AUTHORITY

The authority to write orders for outpatient services is covered under the hospital's medical staff privileging process for members of the hospital's medical staff and for practitioners who have been granted privileges by the hospital without being appointment to the medical staff.

For practitioners who do not hold hospital privileges the hospital's medical staff policy may permit them to refer patients to the hospital with orders for specific outpatient services so long as all the above criteria are met.

1. The policy must address how the hospital verifies the referring/ordering practitioner is appropriately licensed and acting within his/her scope of practice. The regulation does not prescribe the details of the licensure and scope of practice verification process but instead provides a hospital the flexibility to accomplish this in the manner it finds efficient and effective.
2. The hospital is expected to ensure the verification process is followed for physicians who are not members of the medical staff.

- Determine whether the facility has medical staff-approved policies that address the professionals that are eligible to order outpatient services.
- Survey a variety of settings that offer outpatient services. Ask department staff whether orders or referrals for that type of outpatient service are accepted from practitioners who do not hold hospital privileges. If yes:
  - □ Ask for evidence that the medical staff has adopted the policy.
  - □ Ask how the hospital verifies that the order or referral comes from a referring practitioner who is appropriately licensed in the jurisdiction where he/she provides care to the patient and is practicing within his/her scope of practice under State law to prescribe such orders. Ask for documentation of such verification efforts.
  - □ Ensure the same verification process is followed consistently in all outpatient settings.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

all outpatient services in all hospital locations.

3. The policy must also make clear whether the policy applies to all hospital outpatient services, or whether there are specific services for which orders may only be accepted from practitioners with medical staff privileges. For example, a hospital may prefer not to accept orders for a regimen of outpatient chemotherapy or outpatient therapeutic nuclear medicine services from a referring physician who does not hold medical staff privileges. In such cases, the hospital's policy must make these exceptions clear to the general authorization for accepting orders from referring practitioners.

A hospital is required to comply with this requirement only if it chooses to allow practitioners who are not members of the medical staff to order outpatient services.

Hospitals have the flexibility to determine whether they will allow a practitioner who is not a member of the medical staff to order outpatient services as well as the ability to establish through medical staff bylaws and hospital policy other parameters for who will and who will not be authorized to order outpatient services.

If a hospital is unable or unwilling to verify the respective State scope of practice, licensure, etc., for a practitioner, the hospital is not required to authorize the practitioner to order outpatient services in its facility.

If a hospital allows practitioners who are not on the hospital's medical staff to order hospital outpatient services, the hospital must be able to demonstrate compliance with the regulatory requirement.

If the facility chooses to allow outpatient services to be ordered by non-physician practitioners or physicians that are not members of the medical staff, the hospital has medical staff approved policies and procedures that establish:

1. Whether to allow non-physician practitioners, such as Physical Therapists,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Occupational Therapists, Speech Language Pathologists, qualified Dietitians, and qualified nutrition professionals to write orders, consistent with State law and regulations. 2. Whether to allow practitioners with a professional license from another State to write outpatient orders, consistent with State law and regulations. 3. When presented with a referral or order for outpatient services from a practitioner who does not have privileges at the hospital, prior to performing the test or procedure, staff perform verification that practitioner who does not have privileges at the hospital: □ Is licensed in the State where he or she provides care to the patient. □ Is acting within his or her scope of practice under State law. □ Is authorized in accordance with State law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. These medical staff policies are approved by the governing body at least every three years and more often as changes are implemented.	
31.00.12 STANDARD: Outpatient services If the hospital provides outpatient services, the services must meet the needs of the patients in accordance with acceptable standards of practice. §482.54	☐ Compliant ☐ Not Compliant No additional information	This standard is not met as evidenced by: **DOCUMENT REVIEW** **Note**: After reviewing all CMS requirements, CMS standard-level deficiencies within the CoP should be cited here if non-compliance does not rise to the Condition level. Do NOT include ACHC standard deficiencies.

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SWING BEDS

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
32.00.00 <u>CONDITION OF PARTICIPATION: Special requirements for hospital providers of long-term care services ("Swing-Beds")</u> *A hospital that has a Medicare provider agreement must meet the following requirements in order to be granted an approval from CMS to provide post-hospital extended care services, as specified in 42 CFR §409.30, and be reimbursed as a swing-bed hospital, as specified in 42 CFR §413.114.* §482.58	☐ Compliant ☐ Not Compliant ☐ Not Applicable, Hospital has no swing-beds Swing-bed services are an optional service. The swing-bed concept allows a hospital to use their beds interchangeably for either acute-care or post-acute care. A "swing-bed" is a change in reimbursement status. The patient swings from receiving acute-care hospital inpatient services and reimbursement to receiving post-acute care services and reimbursement. A psychiatric hospital is not allowed to have swing bed approval. Allowing a hospital to operate swing-beds is done by issuing a "swing-bed approval." If the hospital fails to meet the swing-bed requirements (not the same as the hospital Conditions of Participation) and the hospital does not implement a plan of correction, they lose the approval to operate swing-beds and receive swing-bed reimbursement. However, in such a situation, the hospital does not go on a termination track. If the hospital continues to meet all other applicable hospital CoPs, it continues to participate in Medicare, but loses its swing-bed approval. Swing-beds do not have to be located in a special section of the hospital although a hospital may choose to do so. The patient does not have to change locations in the hospital merely because their admission status changes unless the hospital requires it. The change in status from acute care to swing-bed status can occur within the same part of the hospital or the patient can be moved to another part of the hospital for swing-bed admission. Likewise, a patient may be discharged from one hospital and admitted in swing bed status to another hospital that has swing bed approval. Beds in a hospital IPPS-excluded rehabilitation or psychiatric unit, or a separately certified, co-located Medicare participating entity (e.g., a distinct part SNF/NF, another hospital, or an inpatient hospice) cannot be used by the	This standard is not met as evidenced by: **Note:** If the hospital provides swing-bed services, score this Condition based on the results of scoring the standards from the remainder of the chapter.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

hospital for providing swing-bed services.

There must be discharge orders from acute care hospital inpatient services and subsequent admission orders for swing-bed services, the same as if the patient had been transferred to a separately certified skilled nursing facility.

The same clinical record may be used for a swing-bed patient, but it must include discharge orders from acute care hospital inpatient services and admission orders to swing-bed services. When the same clinical record is used, the swing-bed services must be clearly delineated.

There is no length of stay restriction for any hospital swing-bed patient.

There is no Medicare requirement to place a swing-bed patient in a nursing home and there are no requirements for transfer agreements between hospitals and nursing homes.

While there is no length of stay limit for patients in swing-bed status, the intended use for swing beds is for a transitional time period to allow the patient to fully recover to return home or while awaiting placement into a nursing facility.

The Medicare statute and regulations require that, in order to be eligible for Medicare coverage of post-hospital skilled nursing facility (SNF) or swing-bed care, a beneficiary must have a qualifying 3-day inpatient stay in a participating or qualified hospital or participating CAH prior to admission to a swing bed in a hospital, or admission to a SNF. *This requirement applies only to patients who are Medicare beneficiaries who seek Medicare coverage of their SNF services.* It is not evaluated or enforced through the survey and certification process, since it is a coverage requirement.

Note: Swing-beds must not be confused with beds in a skilled nursing facility (SNF) or nursing facility (NF), including a distinct part SNF/NF, that shares the same building/campus as the hospital but is a separately certified provider with its own Medicare provider agreement.

An onsite survey must be conducted and the hospital must meet all the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	requirements of 42 CFR 482.58 before the hospital can obtain swing bed approval. Surveyors assess the manner and degree of non-compliance with the swing bed standards in determining whether there is condition-level compliance or non-compliance.	
32.00.01 Eligibility *A hospital must meet the following eligibility requirements:* 1. *The facility has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care type inpatient units (for eligibility of hospitals with distinct parts electing the optional reimbursement method, see 42 CFR §413.24(d)(5).* 2. *The hospital is located in a rural area. This includes all areas not delineated as "urbanized" areas by the Census Bureau, based on the most recent census.* 3. *The hospital does not have in effect a 24-hour nursing waiver granted under 42 CFR §488.54(c).* 4. *The hospital has not had a swing-bed approval terminated within the two years previous to application.* §482.58(a)	☐ Compliant ☐ Not Compliant Hospitals seeking swing-bed approval are screened prior to survey for their eligibility for swing-beds. CMS determines whether the hospital has satisfied the eligibility criteria. The eligibility criteria require: **MEDICARE PROVIDER AGREEMENT** ▪ An initial applicant hospital may seek swing-bed approval. If the applicant hospital meets all Federal requirements for participation, including those for swing-bed approval, the applicant hospital's approval for swing-bed services will be effective with the effective date of the hospital's Medicare participation agreement. **FEWER THAN 100 MAINTAINED BEDS** The bed-count is not based on the number of licensed or certified beds, but on maintained beds. ▪ "Maintained beds" are those patient beds within the Medicare certified hospital that are present for use in providing inpatient services, observation services, and/or swing-bed services. ▪ Maintained beds would include: □ Patient beds that are that located within nursing units of the hospital; □ Established bed locations in patient rooms where the bed is temporarily out of service or temporarily absent from the location it	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify that: ▪ The hospital has fewer than 100 hospital beds, excluding beds for newborns and beds in intensive care units. Note: A hospital licensed for more than 100 beds may be eligible for swing-bed approval if it utilizes and staffs for fewer than 100 beds. Surveyors are to count the beds in each nursing unit. Do not count beds in recovery rooms, intensive care units, operating rooms, newborn nurseries, or stretchers in emergency departments. However, do count the beds within IPPS-excluded Rehabilitation and Psychiatric Units. ▪ The hospital meets criteria as a rural facility. ▪ The hospital does NOT have a nursing waiver in place.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.58(a)(1) §482.58(a)(2) §482.58(a)(3) §482.58(a)(4)	routinely occupies; and □ Those beds that are located within nursing units that are temporarily closed but are still included on the hospital's license and which can be brought into service when the hospital chooses. □ Beds within a hospital's IPPS-excluded psychiatric or rehabilitation unit may not be used for the provision of swing bed services, the beds maintained within those units are included with the number of maintained beds within the hospital (that is because the §482.58(a)(1) does not exclude those beds from the count). ▪ If a Medicare certified hospital has multiple inpatient locations such as remote locations or satellites, all maintained beds at each location must be combined into a single bed-count. The total count of maintained beds for the Medicare certified hospital must be less than 100. **RURAL LOCATION** ▪ CMS is responsible for conducting the evaluation as to whether the hospital is located outside of an urbanized area. ▪ The hospital must be located outside an urbanized area but may be located in an urban cluster (the terms "urbanized area" and "urban cluster" are two distinct classifications of population size used by the U.S. Census Bureau. ▪ In a situation where a hospital has multiple inpatient locations, such as a multi-campus hospital or a hospital with satellites, each inpatient location must be individually evaluated to determine if it is located outside an urbanized area. When any inpatient location of the Medicare certified hospital is located within an urbanized area the hospital does not qualify for swing-bed approval. ▪ A hospital's swing-bed approval must be terminated if the U.S. Census Bureau delineates the hospital, or any inpatient location of the hospital, as being located within an urbanized area. **NO 24-HOUR NURSING WAIVER**	▪ The hospital has not had a termination of swing bed approval within the 2 years prior to application.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ CMS will determine if the hospital has a 24-hour nursing waiver in effect. ▪ A hospital that currently has swing-bed approval that seeks and is granted a 24-hour nursing waiver under 42 CFR 488.54(c) must have its swing-bed approval terminated. **PRIOR SWING BED APPROVAL TERMINATED** ▪ When a hospital is seeking initial swing-bed approval, CMS will verify that the hospital did not previously hold swing-bed approval that was terminated within the prior two years. It does not matter whether the termination was voluntary or involuntary.	
32.00.02 Skilled nursing facility services *The facility must be in substantial compliance with the following skilled nursing facility requirements which are scored individually.* 1. *Resident rights* §483.10(b)(7), (c)(1), (c)(2)(iii), (c)(6), (d), (e)(2), (e)(4), (f)(4)(ii), (f)(4)(iii), (h), (g)(8), (g)(17), and (g)(18) introductory text 2. *Admission, transfer, and discharge rights* §483.5 definition of transfer and discharge, §483.15(c)(1), (c)(2)(i), (c)(2)(ii), (c)(3), (c)(4), (c)(5), and (c)(7) 3. *Freedom from abuse, neglect, and exploitation* (§483.12(a)(1), (a)(2), (a)(3)(i),	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **Note**: This requirement is scored individually throughout the chapter.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(a)(3)(ii), (a)(4), (b)(1), (b)(2), (c)) 4. *Social services* §483.40(d) 5. Discharge Planning §483.21(c)(2) 6. Specialized rehabilitative services §483.65 7. Dental services §483.55(a)(2), (a)(3), (a)(4), and (a)(5) and §483.55(b) §482.58(b)		
32.01.01 Resident rights *The resident has the right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility.* §483.10(a) *The facility must provide the resident or resident's representative a written list of rights afforded to the swing-bed resident, including the right:* 1. *To request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive.* §483.10(c)(6)	☐ Compliant ☐ Not Compliant Long-term residents have rights guaranteed to them under federal and state law.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that there is a process to provide a written list of the resident rights to the swing-bed resident. ▪ Verify that the list of resident rights includes all required elements. ▪ Review medical records to verify the resident rights have been provided to the resident/resident's representative.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

2. *To choose his or her attending physician.*

§483.10(d)

3. *To be informed of and participate in his or her treatment.*

§483.10(c)(1)

4. *To be fully informed in language that he or she can understand of his or her total health status, including his or her medical condition.*

§483.10(c)(1)

5. *To be informed, in advance, of changes to the plan of care.*

§483.10(c)(2)(iii)

6. *To personal privacy and confidentiality of his or her personal and medical records.*

§483.10(h)

7. *To refuse the release of personal and medical records, except* as provided by *state law.*

8. *To send and receive mail, packages and other materials delivered to the facility for the resident through a means other than the postal services. To have privacy of communications. To have access to stationery, postage, and writing implements at the resident's own expense.*

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§483.10(g)(8) §483.10(g)(8)(i) §483.10(g)(8)(ii) *9. To have immediate access to the resident's immediate family and other relatives, subject to the resident's right to deny or withdraw consent at any time.* §483.10(f)(ii) *10. To retain and use personal possessions, including furnishings, clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents.* §483.10(e)(2) *11. To share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.* §483.10**(e)**(4) *12. To be free from abuse, neglect, misappropriation of property, and exploitation.* §483.12		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

32.01.02 Right to request, refuse, and/or discontinue treatment

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The resident has the right to:

- *Request, refuse, and/or discontinue treatment, to participate in or refuse to participate in experimental research, and to formulate an advance directive.*

§483.10(c)(6)

"Treatment" is defined as care provided for purposes of maintaining/ restoring health, improving functional level, or relieving symptoms.

"Experimental research" is defined as development and testing of clinical treatments, such as an investigational drug or therapy that involves treatment and/or control groups. For example, a clinical trial of an investigational drug would be experimental research.

The resident has the right to refuse to participate in experimental research. A resident being considered for participation in experimental research must be fully informed of the nature of the experiment and understand the possible consequences of participating. The opportunity to refuse to participate in experimental research must occur prior to the start of the research. Aggregated resident statistics that do not identify individual residents may be used for studies without obtaining resident permission.

"Advance directive" means a written instruction, such as living will or durable power of attorney for health care, recognized under state law, relating to the provisions of health care when the individual is incapacitated.

A resident who has the capacity to make a health care decision and who withholds consent to treatment or makes an explicit refusal of treatment either directly or through an advance directive, may not be treated against his/her wishes.

This provision applies to residents admitted on or after December 1, 1991. The regulation at 42 CFR §489.102 specifies that at the time of admission of an adult resident, the facility must:

- Maintain written policies and procedures concerning advance directives with respect to all adult individuals receiving medical care.
- Provide written information concerning his or her rights under State law

INTERVIEW AND DOCUMENT REVIEW

- Review the hospital's policies to determine the requirement is met.
- Review medical records to determine that advance directives were requested on all patients and copies are available.
- Review the records of sampled residents for facility compliance with advance directive notice requirements.
- Determine to what extent the facility educates its staff regarding advance directives.
- Determine to what extent the facility provides education for the community regarding individual rights under State law to formulate advance directives.
- Is there evidence in the medical record that the patient was informed of his rights, including the right to accept or refuse medical or surgical treatment?
- If the facility participates in any experimental research involving residents, does it have an Institutional Review Board or other committee that reviews and approves research protocols?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	(whether statutory or recognized by the courts of the State) to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment, and the right to formulate advance directives. ▪ Document in the resident's medical record whether or not the individual has executed an advance directive. ▪ Note condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive. ▪ Ensure compliance with requirements of State law regarding advance directives. ▪ Provide for educating staff regarding the facility's policies and procedures on advance directives. ▪ Provide for community education regarding issues concerning advance directives. The facility is not required to provide care that conflicts with an advance directive. In addition, the facility is also not required to implement an advance directive if, as a matter of conscience, the provider cannot implement an advance directive, and state law allows the provider to conscientiously object. The sum total of the community education efforts must include a summary of the state law, the rights of residents to formulate advance directives, and the facility's implementation policies regarding advance directives. Video and audio tapes may be used in conducting the community education effort. Individual education programs do not have to address all the requirements if it would be inappropriate for a particular audience.	**Note**: The requirement at §483.75(c) "Relationship to Other HHC Regulations may apply," see 45 CFR Part 46, Protection of Human Subjects of Research. "Although these regulations at §483.75(c) are not in themselves considered requirements under this part, their violation may result in the termination or suspension of, or the refusal to grant or continue payment with Federal funds."

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

32.01.03 Choice of attending physician

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The resident has the right to choose his or her attending physician.

1. *The physician must be licensed to practice.*
2. If the physician chosen by the resident refuses to or does not meet requirements specified in this part, the facility may seek alternate physician participation as specified in [items] (4) and (5) of this section to assure provision of appropriate and adequate care and treatment.
3. *The facility must ensure that each resident remains informed of the name, specialty, and way of contacting the physician and other primary care professionals responsible for his or her care.*
4. *The facility must inform the resident if the facility determines that the physician chosen by the resident is unable or unwilling to meet requirements specified in this part and the facility seeks alternate physician participation to assure provision of appropriate and adequate care and treatment. The facility must discuss the alternative physician participation*

A resident in a swing-bed of a general acute care hospital can choose his/her own physician, unless the hospital requires that physicians of residents in hospital swing-beds have hospital admitting privileges. If this is so, the resident can choose his/her own physician from those with appropriate privileges.

- The right to choose a personal physician does not mean that the physician must serve the resident.
- If the physician of the resident's choosing fails to fulfill a given requirement, such as frequency of physician visits, the facility will have the right, after informing the resident, to seek alternate physician participation to assure provision of appropriate and adequate care and treatment.

A facility may not place barriers in the way of residents choosing their own physician. If a resident does not have a physician, or if the resident's physician becomes unable or unwilling to continue providing care to the resident, the facility must assist the resident in exercising his/her choice in finding another physician.

A resident can choose his/her own physician but cannot have a physician who does not have swing bed admitting privileges.

The requirement for free choice is met if a resident is allowed to choose a personal physician from among those who have practice privileges.

INTERVIEW AND DOCUMENT REVIEW

- Review the facility's policies to determine the requirement is met.
- Interview patients to verify they were given the opportunity to select their own personal physician.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

with the resident and honor the resident's preferences, if any, among options.

5. *If the resident subsequently selects another attending physician who meets the requirements specified in this part, the facility must honor that choice.*

§483.10(d)
§483.10(d)(1-5)

32.01.04 Planning and implementing care

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The resident has the right to be informed of, and participate in, his or her treatment, including:

- *The right to be fully informed in language that he or she can understand of his or her total health status, including but not limited to, his or her medical condition.*

§483.10(c)
§483.10(c)(1)

The intent of this requirement is to assure that each resident knows his or her rights and responsibilities and that the facility communicates this information prior to or upon admission, during the resident's stay, and when the facility's rules changes.

"Participates in planning care and treatment," means that the resident is afforded the opportunity to select from alternative treatments to the level of his ability to understand.

This applies both to initial decisions about care and treatment and to decisions about changes in care and treatment.

Information on health status must be presented in language that the resident can understand. Communicating with the resident in language that the resident can understand includes minimizing the use of technical words, providing interpreters for non-English speaking residents, using sign language when needed, or other interventions, as appropriate.

"Total health status" includes:

INTERVIEW AND DOCUMENT REVIEW

- Look for on-going efforts on the part of facility staff to keep residents informed.
- Look for evidence that information is communicated in a manner that is understandable to residents.
- Is information available when it is most useful to the residents such as when they are expressing concerns, raising questions, and on an on-going basis?
- Review medical records for evidence that the resident has participated in planning and treatment care changes. There should be a notation in the multidisciplinary care meetings of patient participation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ functional status. ▪ medical care. ▪ nursing care. ▪ nutritional status. ▪ rehabilitation and restorative potential. ▪ activities potential. ▪ cognitive status. ▪ oral health status. ▪ psychosocial status. ▪ sensory and physical impairments.	▪ Look for evidence that the resident was afforded the right to participate in care planning or was consulted about care and treatment changes. ▪ If there appears to be a conflict between a resident's right and the resident's health or safety, determine if the facility attempted to accommodate both the exercise of the resident's rights and the resident's health, including exploration of care alternatives through a thorough care planning process in which the resident may participate. ▪ If a resident whose ability to make decisions about care and treatment is impaired, was he kept informed and consulted on personal preferences to the level of his ability to understand?
32.01.05 Informed of care and treatment *The resident has the right to participate in the development and implementation of his or her person-centered plan of care, including but not limited to:* ▪ *The right to be fully informed, in advance, of changes to the plan of care.*	☐ Compliant ☐ Not Compliant "Informed in advance," means that the resident receives information necessary to make a health care decision. The information should include his/her medical condition, changes in his/her medical condition, the benefits and reasonable risks of the recommended treatment, and reasonable alternatives. If there are any financial costs to the resident in the treatment options, they should be disclosed in advance and in writing to the resident prior to his/her	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview the person responsible for the swing-bed services to determine how the standards are met. ▪ Review medical records for evidence that the resident has been notified in advance of care and treatment and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§483.10(c)(2)(iii)	decision.	changes in care.
32.01.06 Personal privacy and confidentiality *The resident has the right to personal privacy and confidentiality of his/her personal and medical records.* 1. *Personal privacy includes accommodations, medical treatment, written and telephone communications, personal care, visits, and meetings of family and resident groups but this does not require the facility to provide a private room for each resident.* 2. *The facility must respect the residents right to personal privacy, including the right to privacy in his or her oral (that is, spoken), written, and electronic communications, including the right to send and promptly receive unopened mail and other letters, packages and other materials delivered to the facility for the resident, including those delivered through a means other than a postal service.* 3. *The resident has a right to secure and confidential personal and medical records.*	☐ Compliant ☐ Not Compliant "Right to privacy" means the resident has the right to privacy with whomever the resident wishes to be private and this privacy should include full visual, and to the extent desired, for visits and other activities, auditory privacy. Private space may be created flexibly and need not be dedicated solely for visitation purposes. ▪ For example, privacy for visitation or meetings might be arranged by using a dining area between meals, a vacant chapel, office or room; or an activities area when activities are not in progress. Arrangements for private space could be accomplished through cooperation between the facility's administration and resident or family groups so that private space is provided for those requesting it without infringement on the rights of other residents. Facility staff must examine and treat residents in a manner that maintains the privacy of their bodies. A resident must be granted privacy when going to the bathroom and in other activities of personal hygiene. If an individual requires assistance, authorized staff should respect the individual's need for privacy. Only authorized staff directly involved in treatment should be present when treatments are given. People not involved in the care of the individual should not be present without the individual's consent while he/she is being examined or treated. Staff should pull privacy curtains, close doors, or otherwise remove residents from public view and provide clothing or draping to prevent unnecessary exposure of body parts during the provision of personal care and services.	This standard is not met as evidenced by: **OBSERVATION AND INTERVIEW** ▪ Interview residents to determine if the staff respect the resident's privacy relating to communication, mail, and packages. ▪ Document any instances where you observe a resident's privacy being violated. Completely document how the resident's privacy was violated. Example: "Resident #12 left without gown or bed covers and unattended on 2B Corridor at 3:30 p.m. February 25, 2020." Identify the responsible party, if possible.

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(i) *The resident has the right to refuse the release of personal and medical records except as provided* by *state law.*

(ii) *The facility must allow representatives of the Office of the State Long-Term Care Ombudsman to examine a resident's medical, social, and administrative records in accordance with State law.*

§483.10(h)

32.01.07 For future use

32.01.08 Mail

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The resident has the right to send and receive mail, and to receive letters, packages and other materials delivered to the facility for the resident through a means other than a postal service, including the right to:

(i) *Privacy of such communications,*

(ii) *Have access to stationery, postage, and writing implements at the resident's own expense.*

§483.10(g)(8)
§483.10(g)(8)(i-ii)

"Promptly" means delivery of mail or other materials to the resident within 24 hours of delivery by the postal service (including a post office box) and delivery of outgoing mail to the postal service within 24 hours of regularly scheduled postal delivery and pickup service.

INTERVIEW

- Interview the person responsible for the Swing bed unit to determine how the requirement was met.
- Interview a resident to verify that the requirement was met.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
32.01.09 Access and visitation rights ▪ *The facility must provide immediate access to a resident by immediate family and other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time.* ▪ *The facility must provide immediate access to a resident by others who are visiting with the consent of the resident, subject to reasonable clinical and safety restrictions and the resident's right to deny or withdraw consent at any time.* §483.10(f)(4)(ii-iii)	☐ Compliant ☐ Not Compliant The facility may set reasonable hours for visitation. If it would violate the rights of a roommate to have visitors in the resident's room, the facility must establish alternate areas in the facility for visiting. These areas could include the chapel, a suitable office area, a dining room, or a porch or patio area.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the policy or process for visitation in the facility to ensure that reasonable guidelines are in place and that there is a clear patient consent process for visitors defined. ▪ Interview patients to verify that the process is in force.
32.01.10 Personal property *The resident has the right to retain and use personal possessions, including furnishings, and clothing, as space permits, unless to do so would infringe upon the rights or health and safety of other residents*. §483.10(e)(2)	☐ Compliant ☐ Not Compliant The intent of this regulation is to encourage residents to bring personal possessions into the facility, as space, safety considerations and fire code permits. All residents' possessions must be treated with respect and safeguarded. The facility has the right to limit personal property due to space limitations in the facility or for safety considerations.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review the facility's policies to determine that the requirement is met. ▪ Observe patient rooms to confirm that residents have personal possessions. If residents' rooms have few personal possessions, ask residents and families if: □ They are encouraged to have and to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		use personal items. □ Their personal property is safe in the facility.
32.01.11 Married couples *The resident has the right to share a room with his or her spouse when married residents live in the same facility and both spouses consent to the arrangement.* §483.10(e)(4)	☐ Compliant ☐ Not Compliant The requirement means that when a room is available for a married couple to share, the facility must permit them to share it, if they choose.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review the facilities policies to determine that the requirement is met. ▪ Observe the residents' area to determine that if married residents are patients, they have the arrangement if they request it.
32.01.12 Freedom from abuse, neglect, and exploitation *The resident has the right to be free from abuse neglect, misappropriation of resident property, and exploitation.* *This includes but is not limited to freedom from corporal punishment, involuntary seclusion and any physical or chemical restraint not required to treat the resident's medical symptoms.* §483.12 §482.58(b)(3)	☐ Compliant ☐ Not Compliant The intent of this regulation is to assure that each resident is free from abuse, corporal punishment, and involuntary seclusion. The facility is responsible for preventing abuse, but also for those practices and omissions, neglect, and misappropriation of property, which if left unchecked, lead to abuse. Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals. "Abuse" is defined as the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm or pain or mental anguish, or deprivation by an individual, including a caretaker, of goods or services that are necessary to attain or maintain physical, mental,	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Review the policy on abuse to determine it addresses the 6 types of abuse identified in the standard. ▪ Request a select group of accident/ incident reports in the last three months to determine if there have been predisposing factors for abuse or neglect. **Note**: Offsite, pre-survey review of complaints can focus the survey team's on-

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	and psychosocial well-being. This presumes that instances of abuse of all residents, even those in a coma, cause physical harm, or pain or mental anguish. "Verbal abuse" is defined as any use of oral, written or gestured language that willfully includes disparaging and derogatory terms to residents or their families, or within their hearing distance, regardless of their age, ability to comprehend, or disability. Examples of verbal abuse include but are not limited to: threats of harm; and saying things to frighten a resident, such as telling a resident that she will never be able to see her family again. "Sexual abuse" includes, but is not limited to, sexual harassment, sexual coercion, or sexual assault. "Physical abuse" includes hitting, slapping, pinching, and kicking. It also includes controlling behavior through corporal punishment and restraints. "Mental abuse" includes, but is not limited to, humiliation, harassment, and threats of punishment or deprivation. "Involuntary seclusion" is defined as separation of a resident from other residents or from his or her room or confinement to his or her room (with or without roommates) against the resident's will, or the will of the resident's legal representative. Emergency or short term monitored separation from other residents will not be considered involuntary seclusion and may be permitted if used for a limited period as a therapeutic intervention to reduce agitation until professional staff can develop a plan of care to meet the resident's needs. "Misappropriation of resident's property" is defined as the patterned or deliberate misplacement, exploitation, or wrongful, temporary, or permanent use of a resident's belongings or money without the resident's consent.	site review of actual incidents and predisposing factors to abuse or neglect and misappropriation of property. ▪ Report and record any instances where the survey team observes an abusive incident. Completely document who committed the abusive act, the nature of the abuse, and where and when it occurred. Ensure that the facility addresses that incident immediately. ▪ If the survey team's observations and resident's responses signal the presence of abuse, determine how the facility prevents and reports abusive behavior. ▪ If a resident is being temporarily separated from other residents, for less than 24 hours, as an emergency short-term intervention, answer these questions-- □ What are the symptoms that led to the consideration of the separation? □ Are these symptoms caused by failure to: ▪ Meet individual needs? ▪ Provide meaningful activities? ▪ Adjust the resident's environment? a. Can the cause(s) be removed? b. If the cause(s) cannot be

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removed, has the facility attempted to use alternatives short of separation?

c. Does the facility use the separation for the least amount of time?

f. To what extent has the resident, surrogate or representative participated in care planning and made an informed choice about separation?

g. Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives?

h. If residents are temporarily separated in secured units, staff should carry keys to these units at all times.

i. If the purpose of the unit is to provide specialized care for residents who are cognitively impaired (through a program of therapeutic activities designed to enable residents to attain and maintain the highest practicable physical, mental or psychosocial well-being) then placement in the unit is not in violation of

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resident rights, as long as the resident's individual care plan indicates the need for the stated purpose and services provided in the unit and the resident, surrogate, or representative has participated in the placement decision.

32.02.01 Medicaid and Medicare notification

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare/Medicaid or by the facility's per diem rate.

The facility must--

(i) *Inform each Medicaid-eligible resident, in writing, at the time of admission to the nursing facility and when the resident becomes eligible for Medicaid of-*

(A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;

If Medicare or Medicaid does not make payment for services, the provider must fully inform the resident of any related charges both at the time of admission and prior to the time that changes will occur in their bills.

Listed below are general categories and examples of items and services that the facility may charge to resident funds if they are requested and agreed to by a resident.

- Telephone
- Television/radio for personal use.
- Personal comfort items including smoking materials, notions, novelties, and confections.
- Cosmetic and grooming items and services in excess of those for which payment is made.
- Personal clothing.
- Personal reading matter.
- Gifts purchased on behalf of a resident.
- Flowers and plants.

INTERVIEW AND DOCUMENT REVIEW

- Review facility policies, documents, and patient medical records. Verify that notification of covered services and charges is enforced.
- Ask the resident about out-of-pocket expenses for items and services.
  - □ Who handles payments?
  - □ How do they know the cost of items and services?
  - □ Do they receive an explanation of charges in their bill?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and *(ii) Inform each Medicaid-eligible resident when changes are made to the items and services specified in* [items (A) and (B)]. §483.10(g)(18) §483.10(g)(17) §483.10(g)(17)(i) §483.10(g)(17)(i)(A) §483.10(g)(17)(i)(B) §483.10(g)(17)(i)(B)(ii)	▪ Social events and entertainment offered outside the scope of the activities program. ▪ Non-covered special care services such as privately hired nurses or aides. ▪ Private room, except when therapeutically required for example, isolation for infection control. ▪ Specially prepared or alternative food requested.	
32.02.02 <u>Resident adjudged incompetent</u> *The resident has the right to exercise his or her rights as a resident of the facility and as a citizen or resident of the United States.* ▪ *In the case of a resident adjudged incompetent under the laws of a State by a court of competent jurisdiction, the rights of the resident devolve to and are exercised by the resident representative appointed under State law to act on the resident's behalf.* ▪ *The court-appointed resident*	☐ Compliant ☐ Not Compliant The facility has written policies that depict the process for ensuring the representative of the incompetent resident acts on behalf of the resident.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review facility policies to verify all required elements are included. ▪ Review the medical record of at least one patient adjudged incompetent by a court to determine these requirements are met.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

representative exercises the resident's rights to the extent judged necessary by a court of competent jurisdiction, in accordance with State law.

§483.10(b)(7)

32.03.01 Facility prohibits and prevents abuse

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The facility must develop and implement written policies and procedures that:

(1) Prohibit and prevent abuse, neglect, and exploitation of residents and misappropriation of resident property.

(2) Establish processes and guidelines to investigate any such allegations.

§483.12(b)
§483.12(b)(1-3)

The facility is responsible for preventing abuse, but also for those practices and omissions, neglect, and misappropriation of property, which if left unchecked, lead to abuse.

Residents must not be subjected to abuse by anyone, including, but not limited to, facility staff, other residents, consultants or volunteers, staff of other agencies serving the individual, family members or legal guardians, friends, or other individuals.

See standards 32.01.12 and 32.03.03 for additional information and definitions.

INTERVIEW AND DOCUMENT REVIEW

- Review the facility's policies to determine all elements of the requirement are met.
- Interview the person responsible for the swing bed unit to determine how the requirement was met.
- Interview a resident to verify that the requirement was met.

32.03.02 Employment restrictions and screening of staff

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The facility must –

A. *Not employ or otherwise engage individuals who*:

(i) *Have been found guilty of abuse, neglect, exploitation, misappropriate of property, or mistreatment by a court of law*

The intent of this regulation is to prevent employment of individuals who have been convicted of abusing, neglecting, or mistreating individuals in a health care related setting.

Any facility staff found guilty of neglect, abuse, or mistreating residents or misappropriation of property by a court of law, must have his or her name entered into the nurse aide registry, or reported to the licensing authority, as appropriate.

DOCUMENT REVIEW

- Review human resource policies and procedures on background and reference checks prior to hire.
- Review employee files to determine that a background and reference check has been done prior to hire for all staff.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
OR (ii) *Have had a finding entered into the State nurse aide registry concerning abuse, neglect, exploitation, mistreatment of residents or misappropriation of their property.* *B. Report to the State nurse aide registry or licensing authorities any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for serve as a nurse aide or other facility staff.* §483.12(a)(3) §483.12(a)(3)(i-ii) §483.12(a)(4) §482.58(b)(3)	The facility has written policies establishing: 1. Unacceptable hiring practices. 2. The procedure for reporting to the State nurse aid registry or licensing authorities any knowledge of court actions that would indicate unfitness to serve as an employee. In addition to inquiry of the State nurse aide registry or other licensing authorities, the facility should check all staff references and make reasonable efforts to uncover information about any past criminal prosecutions. "Found guilty" applies to situations where the defendant pleads guilty, is found guilty, or pleads *nolo contendere*. "Finding" is defined as a determination made by the State that validates allegations of abuse, neglect, mistreatment of residents or misappropriation of their property.	▪ Spot check employment applications for questions about convictions or mistreatment, neglect or abuse of residents, or misappropriation of their property. □ Verify that applicants have answered these questions and if affirmative answers had resulted in rejections of employment candidates. ▪ Contact the State Nurse Aide Registry or Board of Nursing, as appropriate. □ Determine if applicants with a finding concerning mistreatment, neglect, and abuse of residents or misappropriation of their property have been rejected.
32.03.03 Staff treatment of residents *The facility must*: *1. Not use verbal, mental, sexual, or physical abuse, corporal punishment or involuntary seclusion.* *2. Ensure that the resident is free from physical or chemical restraints imposed for purposes of discipline or convenience and that are not required to treat the resident's medical*	☐ Compliant ☐ Not Compliant The facility has written policies establishing the staff treatment of residents including unacceptable behaviors and consequences**.** "Physical restraints" are defined as any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident's body that the individual cannot remove easily and that restricts freedom of movement or normal access to one's body. "Chemical Restraint" is defined as a psychopharmacologic drug that is used for discipline or convenience and **is** not required to treat medical symptoms. "Discipline" is defined as any action taken by the facility for the purpose of	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview the person responsible for the swing bed unit to determine how the requirement was met. ▪ Interview a resident to determine that the requirement was met.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
symptoms. When the use of restraints is indicated, the facility must use the least restrictive alternative for the least amount of time and document ongoing re-evaluation of the need for restraints. §483.12(a)(1) §483.12(a)(2) §482.58(b)(3)	punishing or penalizing residents. "Convenience" is defined as any action taken by the facility to control resident behavior or maintain residents with a lesser amount of effort by the facility and not in the resident's best interest. Medical symptoms that would warrant the use of restraints should be reflected in the comprehensive assessment and care planning. The facility must engage in a systematic and gradual process toward reducing restraints (e.g., gradually increasing the time for ambulation and muscle strengthening activities).	
32.03.04 For future use		
32.03.05 Reporting allegations of patient mistreatment, neglect, or abuse *In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:* ▪ *Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property are reported immediately, but not later than 2 hours after the allegation is made, if the events that cause the allegation involve abuse or result in serious bodily injury, or not later than 24 hours if the events that cause the allegation do not involve abuse and do*	☐ Compliant ☐ Not Compliant The facility has written policies establishing the reporting procedure to be implemented in response to allegations of abuse, neglect, exploitation, or mistreatment of a resident.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the policy and procedure to determine that it meets the requirement. ▪ Interview to determine if the facility has had any of the alleged violations and ask how these were reported and handled. □ Was the administrator notified of the incident allegation and when?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
not result in serious bodily injury, to the administrator of the facility and to other officials (including to the State Survey Agency and adult protective services where state law provides for jurisdiction in long-term care facilities) in accordance with state law through established procedures. §483.12(c) §483.12(c)(1) §482.58(b)(3)		
32.03.06 Investigation of alleged abuse *In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:* ▪ *Have evidence that all alleged violations are thoroughly investigated* *and* ▪ *Prevent further potential abuse, neglect, exploitation, or mistreatment while the investigation is in progress.* §483.12(c)(2-3) §482.58(b)(3)	☐ Compliant ☐ Not Compliant Investigations should occur as close to the time of the incident as possible. **See standard 32.03.07 for additional information.** The chain of evidence should be secured in a safe place.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the policy and procedure to determine it meets the requirement. ▪ Verify that reported cases of abuse have been investigated by review of the documentation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
32.03.07 Reporting on investigations of abuse allegations *In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:* ▪ *Report the results of all investigations to the administrator or his designated representative and to other officials in accordance with State law, including to the State Survey Agency, within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.* §483.12(c)(4) §482.58(b)(3)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the policy and procedure to determine the requirement was met. ▪ Interview the administrator to determine if there have been any allegations that have been investigated and what corrective action was taken. ▪ Ask for the results of any in-house investigations of mistreatment, neglect, or abuse of residents, misappropriation of their property, or injuries of unknown sources. □ Did investigations begin promptly after the report of the problem? □ Is there a record of statements or interviews of the resident, suspect (if one is identified), any eyewitnesses and any circumstantial witnesses? □ Was relevant documentation reviewed and preserved (e.g., dated dressing which was not changed when treatment recorded change)? □ Was the alleged victim examined promptly (if injury was suspected) and the finding documented in the report? □ What steps were taken to protect

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

the alleged victim from further abuse (particularly where no suspect has been identified)?

□ What actions were taken as a result of the investigation?

□ What corrective action was taken, including informing the nurse aide registry, State licensure authorities, and other agencies (e.g., long-term care ombudsman; adult protective services; Medicaid fraud and abuse unit)?

32.04.01 For future use

32.04.02 Coordinate assessments

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

A facility must coordinate assessments with the preadmission screening and resident review (PASARR) program under Medicaid in 42 CFR 483.128 and 483.130 to the maximum extent practicable to avoid duplicative testing and effort.

Coordination includes—

(1) *Incorporating the recommendations from the PASARR level II determination and the PASARR evaluation report into a resident's assessment, care planning, and*

The facility has written policies and procedures that describe the coordination of the pre-admission screening with the PASARR resident review assessment.

THE PRE-ADMISSION SCREENING AND ANNUAL RESIDENT REVIEW (PASARR)

- The Level I is an evaluation to identify individuals with Mental Illness (MI) or Intellectual/Developmental Disability (ID/DD).

  In the case of first-time identifications, for the issuance of written notice to the individual or resident and his or her legal representative that the individual or resident is suspected of having MI or IID and is being referred to the State mental health or intellectual disability authority for Level II screening.

- Level II is the function of evaluating and deterring whether Nursing Facility services and specialized services are needed.

INTERVIEW AND DOCUMENT REVIEW

- Verify that the facility has written policies that outline this coordination.
- Interview the social worker and/or other staff to determine how the PASARR is used to screen and refer these residents.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

transitions of care.

(2) *Referring all level II residents and all residents with newly evident or possible serious mental disorder, intellectual disability, or a related condition for level II resident review upon a significant change in status assessment.*

§483.20(e)
§483.20(e)(1-2)

32.05.01 Social services

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The facility must provide medically-related social services to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

§483.40(d)
§482.58(b)(4)

"Medically-related social services" means services provided by the facility's staff to assist residents in maintaining or improving their ability to manage their everyday physical, mental, and psychosocial needs.

These services could include, for example:

- Making arrangements for adaptive equipment, clothing, and personal items.
- Maintaining contact with family (with resident's permission) to report on changes in health, current goals, discharge planning, and encouragement to participate in care planning.
- Assisting staff to inform residents and those they designate about the resident's health status and health care choice.
- Making referral and obtaining services from outside entities (e.g., talking books, absentee ballots, community wheelchair transportation).
- Assisting residents with financial and legal matters (e.g., applying for pensions, referrals to lawyers, referrals to funeral homes for preplanning

DOCUMENT REVIEW

- Review medical records to find evidence that social service interventions successfully address resident's needs and link social supports, physical care, and physical environment with resident's needs and individuality.
- For residents selected for review—
  - ☐ How do facility staff implement social services interventions to assist the resident in meeting treatment goals?
  - ☐ How do staff that are responsible for social work monitor the resident's progress in improving physical,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	arrangements). ▪ Discharge planning services (e.g., helping to place a resident on a waiting list for community congregate living, arranging intake for home care services for residents returning home, assisting with transfer arrangements to other facilities). ▪ Providing or arranging provision of needed counseling services; ▪ Assisting residents to determine how they would like to make decisions about their health care, and whether they would like anyone else to be involved in those decisions; ▪ Finding options that meet the physical and emotional needs of each resident; ▪ Meeting the needs of residents who are grieving; and ▪ Assisting residents with dental/denture care, podiatric care; eye care; hearing services, and obtaining equipment for mobility or assistive eating devices. Where needed services are not covered by the Medicaid State Plan, nursing facilities are still required to obtain these services.	mental and psychosocial functioning? Has goal attainment been evaluated and the care plan changed accordingly? □ How does the care plan link goals to psychosocial functioning / well-being? □ Has the staff responsible for social work established and maintained relationships with the resident's family or legal representative? □ What attempts does the facility make to access services for Medicaid recipients when those services are not covered by a Medicaid State Plan? □ Look for evidence that social services interventions successfully address residents' needs and link social supports, physical care, and physical environment with residents' needs and individuality.
32.05.02 For future use		
32.06.01 Specialized rehabilitative services: Provision of services *If specialized rehabilitative services such as but not limited to physical therapy,*	☐ Compliant ☐ Not Compliant The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the medical record for

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

speech-language pathology, occupational therapy, respiratory therapy and rehabilitative services for a mental disorder and intellectual disability or services of a lesser intensity as per 42 CFR 483.120(c), are required in the resident's comprehensive plan of care, the facility must:

(1) *Provide the required services*

or

(2) *In accordance with 42 CFR §483.70(g), obtain the required services from an outside resource that is a provider of specialized rehabilitative services and is not excluded from participating in any federal or state health care programs pursuant to section 1128 and 1156 of the Social Security Act.*

§483.65
§483.65(a)
§483.65(a)(1-2)

assessment and care plan, to prevent avoidable physical and mental deterioration and to assist them in obtaining or maintaining their highest practicable level of functional and psychosocial well-being.

Specialized rehabilitative services are considered a facility service and are included within the scope of facility services. They must be provided to residents who need them even when the services are not specifically enumerated in the State plan. No fee can be charged a Medicaid recipient for specialized rehabilitative services because they are covered facility services.

A facility is not obligated to provide specialized rehabilitative services if it does not have residents who require these services.

If a resident develops a need for these services after admission, the facility must either provide the services, or, where appropriate, obtain the service from an outside resource.

For a resident with mental illness (MI) or intellectual disability (ID) to have his or her specialized needs met, the individual must receive all services necessary to assist the individual in maintaining or achieving as much independence and self-determination as possible.

Specialized services for mental illness or intellectual disability refers to those services to be provided by the State which can only be delivered by personnel or programs other than those of the nursing facility (NF) because the overall level of NF services is not as intense as necessary to meet the individual's needs.

"Mental health rehabilitative services for MI and ID" refers to those services of lesser frequency or intensity to be implemented by all levels of nursing facility staff who come into contact with the resident who is mentally ill or who has intellectual disabilities. These services are necessary regardless of whether or not they require additional services to be provided for or arranged by the State as specialized services.

Mental health rehabilitative services for MI and ID may include, but are not rehabilitative services.

- Determine the extent of follow through with the comprehensive care plan. Verify from the chart that the resident is receiving frequency and type of therapy as outlined in the care plan.

Physical Therapy

- □ What did the facility do to improve the resident's muscle strength? The resident's balance?
- □ What did the facility do to determine if an assistive device would enable the resident to reach or maintain his/her highest practicable level of physical function?
- □ If the resident has an assistive device, is he/she encouraged to use it on a regular basis?
- □ What did the facility do to increase the amount of physical activity the resident could do (for example, the number of repetitions of an exercise, the distance walked)?
- □ What did the facility do to prevent or minimize contractures, which could lead to decreased mobility and increased risk of pressure ulcer occurrence?

Occupational Therapy

- □ What did the facility do to decrease

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

limited to:

- Consistent implementation during the resident's daily routine and across settings, of systematic plans which are designed to change inappropriate behavior.
- Drug therapy and monitoring of the effectiveness and side effects of medications which have been prescribed to change inappropriate behavior or to alter manifestations of psychiatric illness.
- Provision of a structured environment for those individuals who are determined to need such structure (e.g., structured socialization activities to diminish tendencies toward isolation and withdrawal).
- Development, maintenance, and consistent implementation across settings of those programs designed to give individuals the daily living skills they need to be more independent and self-determining, including, but not limited to, grooming, personal hygiene, mobility, nutrition, vocational skills, health, drug therapy, and mental health education, money management, and maintenance of the living environment.
- Crisis intervention services.
- Individual, group, and family psychotherapy.
- Development of appropriate personal support networks.
- Formal behavior modification programs.

the amount of assistance needed to perform a task?

- □ What did the facility do to decrease behavioral symptoms?
- □ What did the facility do to improve gross and fine motor coordination?
- □ What did the facility do to improve sensory awareness, visual-spatial awareness, and body integration?
- □ What did the facility do to improve memory, problem solving, attention span, and the ability to recognize safety hazards?

Speech, Language Pathology

- □ What did the facility do to improve auditory comprehension?
- □ What did the facility do to improve speech production?
- □ What did the facility do to improve expressive behavior?
- □ What did the facility do to improve the functional abilities of residents with moderate to severe hearing loss who have received an audiologic evaluation?
- □ For the resident who cannot speak, did the facility assess for a communication board or an alternate means of communication?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Rehabilitative Services for MI and ID

- □ What did the facility do to decrease incidents of inappropriate behaviors, for individuals with ID, or behavioral symptoms for persons with MI? To increase appropriate behavior?
- □ What did the facility do to identify and treat the underlying factors behind tendencies toward isolation and withdrawal?
- □ What did the facility do to develop and maintain necessary daily living skills?
- □ How has the facility modified the training strategies it uses with its residents to account for the special learning needs of its residents with MI or ID?

Questions to ask individuals with MI or ID--

- □ Who do you talk to when you have a problem or need something?
- □ What do you do when you feel happy? Sad? Can't sleep at night?
- □ In what activities are you involved, and how often?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
32.06.02 Rehabilitative service orders: Qualifications *Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.* §483.65(b) §482.58(b)(6)	☐ Compliant ☐ Not Compliant Once the assessment for specialized rehabilitative services is completed, a care plan must be developed, followed, and monitored by a licensed professional. Once a resident has met his or her care plan goals, a licensed professional can either discontinue treatment or initiate a maintenance program which either nursing or restorative aides will follow to maintain functional and physical status. "Qualified personnel," means that professional staff are licensed, certified, or registered to provide specialized therapy/rehabilitative services in accordance with applicable State laws. Health rehabilitative services for MI and ID must be implemented consistently by all staff unless the nature of the services is such that they are designated or required to be implemented only by licensed or credentialed personnel.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review medical records for physician orders and documentation of the services performed. ▪ Determine if there are any problems in quality of care related to maintaining or improving functional abilities. Determine if these problems are attributable in part to the qualifications of specialized rehabilitative services staff. ▪ Determine from the care plan and record that rehabilitative services are provided under the written order of a physician and by qualified personnel. If a problem in a resident's rehabilitative care is identified that is related to the qualifications of the care providers, it may be necessary to validate the care provider's qualifications. ▪ If the facility does not employ professional staff who have experience working directly with or designing training or treatment programs to meet the needs of individuals with MI or ID, how has the facility arranged for the necessary direct or staff training

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		services to be provided?
32.07.01 Dental services *The facility must assist residents in obtaining routine and 24-hour emergency dental care.* §483.55 §482.58(b)(7)	☐ Compliant ☐ Not Compliant This requirement makes the facility directly responsible for the dental care needs of its residents. The facility must ensure that a dentist is available for residents. They can satisfy this requirement by employing a staff dentist or having a contract/ arrangement with a dentist to provide services. For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose an additional charge for the services. Medicaid residents may not be charged. For all residents of the facility, if they are unable to pay for needed dental services, the facility should attempt to find alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well-being.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview the person in charge of the swing bed unit to determine how dental services are provided. ▪ If there are contract services, review the contract.
32.07.02 SKILLED NURSING FACILITY: Patient liability for dental care *A facility –* (1) *May charge a Medicare resident an additional amount for routine and emergency dental services.* (2) *Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's*	☐ Compliant ☐ Not Compliant For Medicare and private pay residents, facilities are responsible for having the services available, but they may impose and additional charge for the services. For Medicaid residents, the facility must provide the resident, without charge, all emergency dental services, as well as those routine dental services that are covered under the state plan. For all residents of the facility, if they are unable to pay for needed dental	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the policies and procedures to determine all elements of the requirement are met.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility. §483.55(a)(2) §483.55(a)(3) §482.58(b)(7)	services, the facility should attempt to find alternative funding sources or alternative service delivery systems so that the resident is able to maintain his/her highest practicable level of well-being. "Routine dental services" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures). "Emergency dental services" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity, appropriately treated by a dentist that requires immediate attention.	
32.07.03 <u>SKILLED NURSING FACILITY</u>: <u>Resident dental appointments</u> The facility *must, if necessary or requested, assist the resident:* ▪ *In making appointments.* ▪ *By arranging for transportation to and from the dental services location.* ▪ *Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating*	☐ Compliant ☐ Not Compliant "Prompt referral" means, within reason, as soon as the dentures are lost or damaged. Referral does not mean the resident must see a dentist at that time but does mean that an appointment (referral) is made, or that the facility is aggressively working at replacing dentures.	This standard is not met as evidenced by: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** ▪ Review the policy and procedure to determine the requirement was met. ▪ Interview staff/patients to verify that the policy defines actual practice. □ Do residents selected for comprehensive or focused reviews, who have dentures, use them? □ Are residents missing teeth and possibly in need of dentures? □ Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
circumstances that led to the delay. §483.55(a)(4) §483.55(a)(4)(i-ii) §483.55(a)(5) §482.58(b)(7)		oral hygiene? □ Are resident's dentures intact? Appear properly fitted?
32.07.04 NURSING FACILITIES: Provision of dental services *The facility-* *(1) Must provide or obtain from an outside resource, in accordance with 42 CFR §483.70(g), the following dental services to meet the needs of each resident:* *(i) Routine dental services (to the extent covered under the State plan).* *(ii) Emergency dental services.* §483.55(b) §483.55(b)(1) §483.55(b)(1)(i-ii) §482.58(b)(7)	☐ Compliant ☐ Not Compliant If the facility does not employ a qualified professional person to furnish a specific service to be provided by the facility, the facility must have that service furnished to residents by a person or agency outside the facility. "Routine dental services" means an annual inspection of the oral cavity for signs of disease, diagnosis of dental disease, dental radiographs as needed, dental cleaning, fillings (new and repairs), minor dental plate adjustments, smoothing of broken teeth, and limited prosthodontic procedures (e.g., taking impressions for dentures and fitting dentures). "Emergency dental services" includes services needed to treat an episode of acute pain in teeth, gums, or palate; broken, or otherwise damaged teeth, or any other problem of the oral cavity, appropriately treated by a dentist that requires immediate attention.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Review the policy to verify that it meets the requirement. ▪ Observe and interview patients to determine if the policy is being followed.
32.07.05 NURSING FACILITIES: Appointments and referrals *The facility must, if necessary or if requested, assist the resident—* ▪ *In making appointments.*	☐ Compliant ☐ Not Compliant "Prompt referral" means within reason as soon as the dentures are lost or damaged. Referral does not mean that the resident must see the dentist at that time but does mean that an appointment (referral) is made, or that the	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ **Review the policy and procedure to**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ *By arranging for transportation to and from the dental services locations.* ▪ *Must promptly, within 3 days, refer residents with lost or damaged dentures for dental services. If a referral does not occur within 3 days, the facility must provide documentation of what they did to* ensure the resident could still eat and drink adequately while awaiting dental services and the extenuating circumstances that led to the delay; ▪ *Must have a policy identifying those circumstances when the loss or damage of dentures is the facility's responsibility and may not charge a resident for the loss or damage of dentures determined in accordance with facility policy to be the facility's responsibility; and* ▪ *Must assist residents who are eligible and wish to participate to apply for reimbursement of dental services as an incurred medical expense under the State plan.* §483.55(b)(2) §483.55(b)(2)(i-ii) §483.55(b)(3-5) §482.58(b)(7)	facility is aggressively working at replacing the dentures.	**determine the requirement was met.** ▪ **Interview staff/patients to verify that the policy** defines actual practice. □ Do residents selected for comprehensive or focused reviews, who have dentures, use them? □ Are residents missing teeth and possibly in need of dentures? □ Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene? □ Are resident's dentures intact? Appear properly fitted?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
32.08.01 Transfer and discharge: Definition *Transfer and discharge include movement of a resident to a bed outside of the certified facility whether that bed is in the same physical plant or not.* *Transfer and discharge do not refer to movement of a resident to a bed within the same certified facility.* §483.5	☐ Compliant ☐ Not Compliant Transfer and discharge are defined to support the intent of the regulation which is to significantly restrict a facility's ability to transfer or discharge a resident once that resident has been admitted to the facility to prevent dumping of high care or difficult residents. This requirement applies to transfer or discharges that are initiated by the facility, not by the resident.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the records of at least 5 swing-bed patients transferred/ discharged from the facility since the last survey in order to determine the reasons documented by the physician.
32.08.02 Transfer and discharge: Facility requirements *(i) The facility must permit each resident to remain in the facility, and not transfer or discharge the resident from the facility unless—* *(A) The transfer or discharge is necessary for the resident's welfare and the resident's needs cannot be met in the facility.* *(B) The transfer or discharge is appropriate because the resident's health has improved sufficiently so the resident no longer needs the services provided by the facility.* *(C) The safety of individuals in the facility is endangered due to the*	☐ Compliant ☐ Not Compliant If transfer is due to a significant change in the resident's condition, the facility must conduct the appropriate assessment prior to any transfer or discharge to determine if a new care plan would allow the facility to meet the resident's needs. If the significant change in the resident's condition is an emergency, immediate transfer should be arranged.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ During closed record review, identify the reasons for transfer/discharge. □ Do records document accurate assessments and attempts through care planning to address the resident's needs through multidisciplinary interventions, accommodation of individual needs, and attention to the resident's customary routine? □ Did the resident's physician document in the record if the resident was transferred/discharged for the sake of the resident's welfare

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

clinical or behavioral status of the resident.

(D) The health of individuals in the facility would otherwise be endangered.

(E) The resident has failed, after reasonable and appropriate notice, to pay for (or to have paid under Medicare or Medicaid) a stay at the facility. Non-payment applies if the resident does not submit the necessary paperwork for third party payment or after the third party, including Medicare or Medicaid, denies the claim and the resident refuses to pay for his or her stay. For a resident who becomes eligible for Medicaid after admission to a facility, the facility may charge resident allowable charges only under Medicaid.

(F) The facility ceases to operate.

(ii) *The facility may not transfer or discharge the resident while the appeal is pending, pursuant to §431.230 of this chapter, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to §431.220(a)(3) of this chapter, unless the failure to discharge or transfer would endanger the health*

and the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization) or if the resident's health improved to the extent that the transferred/ discharged resident no longer needed the services of the facility?

□ Did a physician document in the record if residents were transferred because the health of individuals in the facility is endangered?

□ Do the records of residents transferred /discharged due to safety reasons reflect the process by which the facility concluded that in each instance transfer or discharge was necessary?

□ If the entity to which the resident was discharged is another long-term care facility, evaluate the extent to which the discharge summary and the resident's physician justify why the facility could not meet the needs of this resident.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
or safety of the resident or other individuals in the facility. The facility must document the danger that failure to transfer or discharge would pose. §483.15(c)(1)(i) §483.15(c)(1)(i)(A-F) §482.58(b)(2)		
32.08.03 <u>Transfer and discharge: Documentation requirements</u> *When the facility transfers or discharges a resident under any of the circumstances specified above in 42 CFR §483.15(c)(1)(i)(A), the facility must ensure that the transfer or discharge is documented in the resident's medical record and appropriate information is communicated to the receiving health care institution or provider.* (i) *The documentation in the resident's medical record must include: —* (A) *The basis for the transfer per 42 CFR 483.15 (c)(1)(i) of this section.* (B) *In accordance with 42 CFR 483.15 (c)(1)(i)(A), the specific resident need(s) that cannot be met, facility attempts to meet the resident needs, and the service available at the receiving facility*	☐ Compliant ☐ Not Compliant Documentation of the transfer/discharge may be completed by a physician extender unless prohibited by State law or facility policy.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Verify through medical record review of patients who were transferred or discharged that the reason was documented by a physician.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

to meet the need(s).

(ii) *The documentation required must be made by —*

(A) *The resident's physician when transfer or discharge is necessary as described above in 42 CFR 483.15(c)(1)(A) or (B)*

and

(B) *physician when transfer or discharge is necessary as described above in 42 CFR 483.15(c)(1)(i)(C) or (D).*

§483.15(c)(2)
§483.15(c)(2)(i)
§483.15(c)(2)(i)(A-B)
§483.15(c)(2)(ii)
§483.15(c)(2)(ii)(A-B)
§482.58(b)(2)

32.08.04 Notice before transfer

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Before a facility transfers or discharges a resident, the facility must—

(i) *Notify the resident and if known, the resident's representative of the discharge and the reasons for the move in writing and in a language and manner they understand. The facility must send a copy of the notice to a*

No additional information.

DOCUMENT REVIEW

- Review the policies and procedures to verify all required elements were addressed.
- Review at least five transferred or discharged patient records to determine that the documentation was complete, including all required

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
representative of the Office of the State Long-Term Care Ombudsman. (ii) *Record the reasons for the transfer or discharge in the resident's medical record; and* (iii) *Include in the notice the items described in 42 CFR 482.15(c)(5).* §483.15(c)(3) §483.15(c)(3)(i-iii) §482.58(b)(2)		criteria. □ Was the resident/representative was provided written notification of the transfer/discharge in a language they understood? □ Was a copy of the transfer/discharge notification sent to the Office of the State Long-Term Care Ombudsman?
32.08.05 Timing of the notice *Except when specified in 42 CFR 483.15(c)(4)(ii) and 42 CFR 483.15(c)(8), the notice of transfer or discharge required must be made by the facility at least 30 days before the resident is transferred or discharged.* *Notice **must** be made as soon as practicable before transfer or discharge when—* (A) *The safety of individuals in the facility would be endangered.* (B) *The health of individuals in the facility would be endangered.* (C) *The resident's health improves sufficiently to allow a more immediate transfer or discharge.*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the policy to verify the requirement was met. ▪ Review a minimum of three transfer/ discharge records to assess compliance. □ Verify the notice was made at least 30 days before the transfer/ discharge unless there were other qualifying reasons for transferring sooner to ensure the safety and health of the resident.

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(D) *An immediate transfer or discharge is required by the resident's urgent medical needs.*

(E) *A resident has not resided in the facility for 30 days.*

§483.15(c)(4)
§483.15(c)(4)(i)
§483.15(c)(4)(ii)
§483.15(c)(4)(ii)(A-E)
§482.58(b)(2)

32.08.06 Contents of the notice

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The written notice specified in 42 CFR 483.15(c)(3) must include the following:

(i) *The reason for transfer or discharge.*

(ii) *The effective date of transfer or discharge.*

(iii) *The location to which the resident is transferred or discharged.*

(iv) *A statement of the resident's appeal rights, including the name, address (mailing and email), and telephone number of the entity which receives such requests; and information on how to obtain an appeal form and assistance in completing the form and submitting the appeal hearing request.*

For additional information.

DOCUMENT REVIEW

- Review a minimum of three transfer/ discharge records to determine compliance.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(v) *The name, address (mailing and email) and telephone number of the Office of the State Long-Term Care Ombudsman.*

(vi) *For nursing facility residents with intellectual and developmental disabilities or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with developmental disabilities established under Part C of the Developmental Disabilities Assistance and Bill of Rights Act of 2000; and*

(vii) *For nursing facility residents with a mental disorder or related disabilities, the mailing and email address and telephone number of the agency responsible for the protection and advocacy of individuals with a mental disorder established under the Protection and Advocacy for Mentally Ill Individuals Act.*

§483.15(c)(5)
§483.15(c)(5)(i-vii)
§482.58(b)(2)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
32.08.07 Orientation for transfer or discharge *A facility must provide and document sufficient preparation and orientation to residents to ensure safe and orderly transfer or discharge from the facility.* *This orientation must be provided in a form and manner that the resident can understand.* §483.15(c)(7) §482.58(b)(2)	☐ Compliant ☐ Not Compliant "Sufficient preparation" means the facility informs the resident where he or she is going and takes steps within its control to assure safe transportation. Some examples of orientation may include: ▪ Trial visits, if possible, by the resident to a new location. ▪ Working with family by requesting their assistance to assuring the resident that valued possessions are not left behind or lost. ▪ Orienting staff in the receiving facility to resident's daily patterns. ▪ Reviewing with staff routines for handling transfers and discharges in a manner that minimizes unnecessary and avoidable anxiety or depression and recognizes characteristic resident reactions identified by the care plan. The medical record includes documentation of preparation and orientation.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review social service notes to see if appropriate referrals have been made and, if necessary, resident counseling has occurred.
32.08.08 Discharge summary *When the facility anticipates discharge a resident must have a discharge summary that includes:* (i) *A recapitulation of the resident's stay that includes, but is not limited to, diagnoses, course of illness/treatment or therapy, and pertinent lab, radiology, and consultation results.* (ii) *A final summary of the resident's status to include items in 42 CFR*	☐ Compliant ☐ Not Compliant The intent of this regulation is to ensure appropriate discharge planning and communication of necessary information to the continuing care provider. "Post discharge plan of care" means the discharge planning process, which includes assessing continuing care needs and developing a plan designed to ensure the individual's needs will be met after discharge from the facility into the community. When the facility "anticipates discharge" means that the discharge was not an emergency discharge (e.g., hospitalization for an acute condition), or due to the resident' death.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review a select group of medical records to verify that the requirement was met: ▪ Does the discharge summary have information pertinent to continuing care for the resident? ▪ Is there evidence of discharge planning in the records of discharged residents who had an anticipated discharge or those residents to be discharged

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
483.20, at the time of the discharge that is available for a release to authorized persons and agencies, with the consent of the resident or resident's representative. (iii) *Reconciliation of all pre-discharge medications with the resident's post-discharge medications (both prescribed and over-the-counter).* (iv) *A post-discharge plan of care that is developed with the participation of the resident and, with the resident's consent, the resident representative(s), which will assist the resident to adjust to his or her new living environment. The post-discharge plan of care must indicate where the individual plans to reside, any arrangements that have been made for the resident's follow up care and any post-discharge medical and non-medical services.* §483.21(c)(2) §483.21(c)(2)(i-iv) §482.58(b)(5)	"Adjust to his or her new living environment" means that the post-discharge plan should describe the resident's and family's preferences for care, and how care should be coordinated if continuing treatment involves multiple care givers. It should identify specific resident needs after discharge, such as: ▪ personal care. ▪ sterile dressing. ▪ physical therapy. ▪ describe resident/caregiver education needs to prepare the resident for discharge.	shortly (e.g., in the next 7-14 days)? ▪ Do discharge plans address necessary post discharge care? ▪ Has the facility aided the resident and his/her family in locating and coordinating post discharge services? □ What types of pre-discharge preparation and education has the facility provided the resident and his/her family?

33

PPS EXCLUDED AND DISTINCT PART UNIT: PHYSICAL REHABILITATION UNIT

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Note: DISTINCT PART REHABILITATION UNIT/MEDICARE PROSEPCTIVE PAYMENT SYSTEM EXCLUDED UNIT

Standards in this chapter apply ONLY to Rehabilitation Units that have been designated by Medicare as an excluded PPS unit. Requirements for these units include:
42 CFR 482 - Conditions of Participation for hospitals
42 CFR 412.25 - Excluded hospital units: Common Requirements
42 CFR 412.29 - Excluded Rehabilitation Units: Additional Requirements

33.00.01 PPS excluded hospital units: Basis for exclusion

In order to be excluded from the Prospective Payment Systems (PPS) specified in §412.1(a)(1), a rehabilitation unit must meet the following requirements in addition to all criteria under subpart B of part 412 of 42 CFR 412:

Be part of an institution that-

- *Has in effect an agreement under part 489 (42 CFR 489) to participate as a hospital and*
- *Is not excluded in its entirety from the prospective payment systems and*
- *Has enough beds that are not excluded from the inpatient prospective payment systems to permit the provision of adequate cost information, as required by §413.24(c) of 42 CFR 413.24.*

§412.25(a)
§412.25(a)(1)

☐ Compliant ☐ Not Compliant

The hospital has an agreement to participate in the Medicare program and is not already excluded in its entirety from IPPS, such as a rehabilitation hospital. In other words, the unit seeking exclusion cannot comprise the entire hospital.

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

Verify that:

- The hospital has an agreement to participate in the Medicare PPS Exclusion program.
- The hospital is not already excluded in its entirety from PPS, such as a rehabilitation hospital.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
33.00.02 PPS excluded hospital units: Admission Criteria *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.* §412.25(a)(2)	☐ Compliant ☐ Not Compliant The hospital has written admission criteria. The approved admission criteria are consistently followed for both Medicare and non-Medicare patients.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review policies and open and closed records to verify that: ▪ Written admission criteria are in place. ▪ The approved admission criteria are followed for all patients.
33.00.03 PPS excluded hospital units: Separate medical records *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.* §412.25(a)(3)	☐ Compliant ☐ Not Compliant PPS exempt units have medical records that are separate and not commingled with other hospital records. These records are readily available for review.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the medical records for the exempt unit are separate and are not commingled with other hospital records; these are readily available for review.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
33.00.04 PPS excluded hospital units: Availability of clinical records and information *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.* §412.25(a)(4)	☐ Compliant ☐ Not Compliant The hospital has a written policy that specifies the clinical information that is to accompany the patient when transferred to the exempt rehabilitation unit.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review policies and medical records to verify: ▪ The hospital has a policy detailing the prompt transfer of clinical information for patients transferred to the rehabilitation unit. ▪ The medical record reflects that clinical information is promptly transferred with the record.
33.00.05 PPS excluded hospital units: State licensure requirements *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Meet applicable State licensure laws.* §412.25(a)(5)	☐ Compliant ☐ Not Compliant **HOSPITAL LICENSING** ▪ The hospital demonstrates that all applicable State licensure laws are met. ▪ The hospital provides documentation of any and all unmet State licensure requirements including documentation for deficient practices. ▪ The unit meets special licensing requirements issued by the State, as required. **PROFESSIONAL STAFF** The hospital has current licenses for its professional staff. The professional staff are licensed by the state in which the hospital is located.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ All applicable state licensure laws are met, including any special licensing requirements issued by the state. ▪ All professional staff files have current licenses issued by the state in which the unit is located.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
33.00.06 PPS excluded hospital units: Utilization review requirements *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Have utilization review standards applicable for the type of care offered in the unit.* §412.25(a)(6)	☐ Compliant ☐ Not Compliant The hospital has a utilization review plan that includes the review of rehabilitation services. (No utilization review standards are required if the QIO is conducting review activities.)	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the utilization review plan includes review of rehabilitation services, either internally or through the QIO.
33.00.07 PPS excluded hospital units: Distinct unit structure *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Have beds physically separate from (that is, not commingled with) the hospitals other beds.* §412.25(a)(7)	☐ Compliant ☐ Not Compliant The PPS exempt rehabilitation beds are physically separate from the beds in other units of the hospital	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the PPS exempt rehabilitation beds are physically separate from other units of the hospital.
33.00.08 PPS excluded hospital units: Fiscal intermediary *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** • Verify that the PPS excluded unit uses the same fiscal intermediary as the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ *Be serviced by the same fiscal intermediary as the hospital.* §412.25(a)(8)		hospital.
33.00.09 PPS excluded hospital units: Separate cost center *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Be treated as a separate cost center for cost finding and apportionment purposes.* §412.25(a)(9)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the PPS excluded unit Is treated as a separate cost center for cost finding and apportionment purposes.
33.00.10 PPS excluded hospital units: Allocate costs *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Use an accounting system that properly allocates costs.* §412.25(a)(10)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the PPS excluded unit uses an accounting system that properly allocates costs.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
33.00.11 PPS excluded hospital units: Statistical data *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ Maintain adequate statistical data to support the basis of allocation. §412.25(a)(11)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the PPS excluded unit maintains adequate statistical data to support the basis of allocation.
33.00.12 PPS excluded hospital units: Cost report *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.* §412.25(a)(12)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the PPS excluded unit reports its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.
33.00.13 PPS excluded hospital units: Requirements on the first day of the first cost reporting period *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the PPS excluded unit is fully equipped and staffed and is capable of

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ *As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient…rehabilitation care regardless of whether there are any inpatients in the unit on that date.* §412.25(a)(13)		providing hospital inpatient rehabilitation care, regardless of whether there are any inpatients in the unit.
33.00.14 PPS excluded hospital units: Changes in the size of excluded units *Except in the special cases noted at the end of this paragraph, changes in the number of beds or square footage considered to be part of an excluded unit under this section are allowed one time during a cost reporting period if the hospital notifies its Medicare contractor and the CMS RO in writing of the planned change at least 30 days before the date of the change. The hospital must maintain the information needed to accurately determine costs that are attributable to the excluded unit.* *A change in bed size or a change in square footage may occur at any time during a cost reporting period and must remain in effect for the rest of that cost reporting*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine whether the PPS excluded unit has had a change in the number of beds or a change in square footage during this accreditation cycle. If yes: □ Has the facility notified the Medicare contractor and the CMS Regional Office (RO) in writing at least 30 days prior to the change? □ Did the communication clearly define the unit costs?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

period.

Changes in bed size or square footage may be made at any time if these changes are made necessary by relocation of a unit to permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility or because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

§412.25(b)

33.00.15 PPS excluded hospital units: Change in status of hospital units

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of 42 CFR 412.25.

(1) The status of a hospital unit may be changed from not excluded to exclude only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of a hospital's next cost reporting

No additional information.

INTERVIEW AND DOCUMENT REVIEW

- Determine whether the PPS excluded unit has had a change in status during this accreditation cycle.
  If yes:
  - ☐ Has the facility notified the fiscal intermediary and the CMS Regional Office in writing within 30 days before the change?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

period.

(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.

§412.25(c)
§412.25(c)(1-2)

33.00.16 PPS excluded hospital units: Number of excluded units

Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.

§412.25(d)

☐ Compliant ☐ Not Compliant

The hospital may have one PPS excluded Rehabilitation Unit.

The hospital may also have one PPS excluded Psychiatric Unit.

This standard is not met as evidenced by:

OBSERVATION AND INTERVIEW

- Verify that there is only one PPS excluded rehabilitation unit in this facility.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
33.00.17 Satellite facility: Definition For purposes of paragraphs (e)(2) through (e)(5) of 42 CFR 412.25, a *satellite facility is:* ▪ *A part of a hospital unit that provides inpatient services in a building also used by another hospital, or* ▪ *In one or more entire buildings located on the same campus as buildings used by another hospital.* §412.25(e) §412.25(e)(1)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND OBSERVATION** Verify that the satellite facility: ▪ Provides inpatient services consistent with requirement. ▪ Is located consistent with requirement.
33.00.18 Satellite facility: Criteria *Except as provided in paragraphs (e)(3) and (e)(6) of 42 CFR 412.25, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:* (i) *In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify that the satellite facility: ▪ Meets criteria for exclusion from PPS consistent with requirement. ▪ The unit's number of state-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of state-licensed and Medicare-certified beds on the last day of the unit's last cost

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of state-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October 1, 1997. (ii) *The satellite facility independently complies with—* (A) *For a Rehabilitation Unit, the requirements under §412.29 of this subpart in 42 CFR 412.29.* §412.25(e)(2) §412.25(e)(2)(i) §412.25(e)(2)(ii) §412.25(e)(2)(ii)(A)		reporting period.
33.00.19 Satellite facility: Separate governing body *The satellite facility meets all the following requirements:* ▪ *Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify that: ▪ The governing body/CEO of the satellite facility is different than that for the hospital. ▪ The care provided is not under control

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
located, and it furnishes inpatient care through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located. §412.25(e)(2)(iii)(A)		of the hospital medical staff and chief medical officer.
33.00.20 Satellite facility: Admission and discharge records *The satellite facility meets all the following requirements:* ▪ *It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.* §412.25(e)(2)(iii)(B)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the satellite facility maintains admission and discharge records separate from the hospital. □ These records are readily available.
33.00.21 Satellite facility: Beds are physically separate *The satellite facility meets all the following requirements:* ▪ *It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.* §412.25(e)(2)(iii)(C)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **OBSERVATION AND INTERVIEW** ▪ Verify that the beds of the satellite facility are physically separate from the beds of the hospital.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
33.00.22 Satellite facility: Fiscal intermediary *The satellite facility meets all the following requirements:* ▪ *It is serviced by the same fiscal intermediary as the hospital unit of which it is a part.* §412.25(e)(2)(iii)(D) §483.20(e)(1-2)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the satellite facility uses the same fiscal intermediary as the hospital of which it is a part.
33.00.23 Satellite facility: Separate cost center *The satellite facility meets all the following requirements:* ▪ *It is treated as a separate cost center of the hospital unit of which it is a part.* §412.25(e)(2)(iii)(E)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** • Verify that the satellite facility is a separate cost center of the hospital of which it is a part.
33.00.24 Satellite facility: Accounting system *The satellite facility meets all the following requirements:* ▪ *For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the satellite facility uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
maintains adequate statistical data to support the basis of allocation. §412.25(e)(2)(iii)(F)		allocation.
33.00.25 Satellite facility: Hospital cost report *The satellite facility meets all the following requirements:* ▪ *It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.* §412.25(e)(2)(iii)(G)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the satellite facility reports its costs on the cost report of the hospital of which it is a part, using the same fiscal period and same method of apportionment as the hospital.
33.00.26 Satellite facility: Exception *Except as specified in paragraphs (e)(4) and (e)(5) of 42 CFR 412.25, the provisions of paragraph (e)(2) of 42 CFR 412.25 do not apply to any unit structured as a satellite facility on September 30, 1999, and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documents to verify that the satellite facility meets this requirement. ▪ Determine whether this unit was structured as a satellite facility on September 30, 1999 and excluded from the prospective payment systems on that date.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
the number of beds and square footage considered to be part of the unit at the satellite facility on September 30, 1999. §412.25(e)(3)		If yes, has the unit continued to operate under the same terms and conditions, including the number of beds and square footage considered to be part of the unit at the satellite facility on September 30, 1999?
33.00.27 Satellite facility: Increase/ decrease the square footage or decrease the number of beds *In applying the provisions of paragraph (e)(3) of 42 CFR 412.25, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility—* *(i) To permit construction or renovation necessary for compliance with changes in federal, state, or local law affecting the physical facility* *(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.* §412.25(e)(4) §412.25(e)(4)(i-ii)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine whether the satellite facility increased/decreased its square footage or decreased the number of beds. If yes, were these changes: □ To permit construction or renovation necessary for compliance with federal, state, or local law? □ Due to a catastrophic event?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
33.00.28 Satellite facility: Structure changes after October 1, 2006 *For the cost reporting periods beginning on or after October 1, 2006, in applying the provisions of Medicare paragraph (e)(3) of 42 CFR 412.25—* (i) *Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of 42 CFR 412.25, without affecting the provisions of paragraph (e)(3) of 42 CFR 412.25; and* (ii) *If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of 42 CFR 412.25, it may subsequently increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds considered to be part of the satellite*	☐ Compliant ☐ Not Compliant For any unit that was a structure of satellite facility on September 30, 1999, it is acceptable for the satellite facility to increase/decrease the square footage of the satellite facility or decrease the number of beds.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** • Determine whether the unit was a structure of a satellite facility on September 30, 1999. If yes, determine if the satellite facility increased/ decreased the square footage of the satellite facility or decreased the number of beds, these changes were consistent with the requirement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
facility does not exceed the number of beds at the satellite facility on September 30, 1999. §412.25(e)(5) §412.25(e)(5)(i-ii)		
33.00.29 Satellite facility: Inpatient rehabilitation facility *The provisions of Medicare paragraph (e)(2)(i) of 42 CFR 412.25—* ▪ *Do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of 42 CFR 412.25, effective for cost reporting periods beginning on or after October 1, 2003.* §412.25(e)(6)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documents to verify that the satellite facility is compliant with the requirement.
33.00.30 Changes in classification of hospital units *For purposes of exclusions from the prospective payment system under 42 CFR 412.25—* ▪ *The classification of a hospital unit is effective for the unit's entire cost reporting period. Any changes in the*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documents to determine if the satellite facility made any changes in the classification of a unit. If yes: □ Were these changes only made at the start of a cost reporting period?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
classification of a hospital unit are made only at the start of a cost reporting period. §412.25(f)		
33.01.00 Inpatient rehabilitation facility (IRF) Prospective Payment System: Classification criteria for payment. *To be excluded from the prospective payment systems described in 42 CFR §412(a)(1) and to be paid under the prospective payment system specified in 42 CFR §412.1(a)(3), an inpatient rehabilitation unit of a hospital (otherwise referred to as an IRF) must meet the following requirements*: §412.29	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **Note:** score this standard based on compliance with standards 33.01.01 through 33.01.10.
33.01.01 IRF: Provider agreement ▪ *Have (or be part of a hospital that has) a provider agreement under part 489 of 42 CFR 489 to participate as a hospital.* §412.29(a)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the facility has an agreement to participate in the Medicare program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
33.01.02 IRF: Requirement to serve inpatient population *Except in the case of a "new" IRF or "new" IRF beds, as defined in paragraph (c) of 42 CFR 412.29, an IRF must show that, during its most recent, consecutive, and appropriate 12-month time period (as defined by CMS or the Medicare contractor), it served an inpatient population that meets the following criteria:* *(1) For cost reporting periods beginning on or after July 1, 2004, and before July 1, 2005, the IRF served an inpatient population of whom at least 50 percent, and for cost reporting periods beginning on or after July 1, 2005, the IRF served an inpatient population of whom at least 60 percent required intensive rehabilitation services for treatment of one or more of the conditions specified at paragraph (b)(2) of 42 CFR 412.29.* *A patient with a comorbidity, as defined at §412.602 of 42 CFR 412.602, may be included in the inpatient population that counts toward the required applicable percentage if—*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the facility inpatient population for the most recent consecutive 12-month time period that 60 percent of the patients were admitted for intensive rehabilitation services as defined in the standard.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(i) The patient is admitted for inpatient rehabilitation for a condition that is not one of the conditions specified in paragraph (b)(2) of 42 CFR 412.29;

(ii) The patient has a comorbidity that falls in one of the conditions specified in paragraph (b)(2) of 42 CFR 412.29; and

(iii) The comorbidity has caused significant decline in functional ability in the individual that, even in the absence of the admitting condition, the individual would require the intensive rehabilitation treatment that is unique to inpatient rehabilitation facilities paid under subpart P of 42 CFR 412 and that cannot be appropriately performed in another care setting covered under this title.

(2) List of conditions.

(i) Stroke

(ii) Spinal cord injury

(iii) Congenital deformity

(iv) Amputation

(v) Major multiple trauma

(vi) Fracture of femur (hip fracture)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(vii) Brain injury

(viii) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease

(ix) Burns

(x) Active polyarticular rheumatoid arthritis, psoriatic arthritis, and seronegative arthropathies resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(xi) Systemic vasculidities with joint inflammation, resulting in significant functional impairment of ambulation and other activities of daily living that have not improved after an appropriate, aggressive,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission or that result from a systemic disease activation immediately before admission, but have the potential to improve with more intensive rehabilitation.

(xii) Severe or advanced osteoarthritis (osteoarthrosis or degenerative joint disease) involving two or more major weight bearing joints (elbow, shoulders, hips, or knees, but not counting a joint with a prosthesis) with joint deformity and substantial loss of range of motion, atrophy of muscles surrounding the joint, significant functional impairment of ambulation and other activities of daily living that have not improved after the patient has participated in an appropriate, aggressive, and sustained course of outpatient therapy services or services in other less intensive rehabilitation settings immediately preceding the inpatient rehabilitation admission but have the potential to improve with more intensive rehabilitation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(A joint replaced by a prosthesis no longer is considered to have osteoarthritis, or other arthritis, even though this condition was the reason for the joint replacement.)

(xiii) Knee or hip joint replacement, or both, during an acute hospitalization immediately preceding the inpatient rehabilitation stay and also meet one or more of the following specific criteria:

(A) The patient underwent bilateral knee or bilateral hip joint replacement surgery during the acute hospital admission immediately preceding the IRF admission.

(B) The patient is extremely obese with a Body Mass Index of at least 50 at the time of admission to the IRF.

(C) The patient is age 85 or older at the time of admission to the IRF.

§412.29(b)
§412.29(b)(1)
§412.29(b)(1)(i-ii)
§412.29(b)(2)
§412.29(b)(2)(i- xiii)
§412.29(b)(2)(xiii)(A-C)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
33.01.03 IRF: Written certification for new IRFs *In the case of new IRFs (as defined in paragraph (c)(1) of 42 CFR 412.29) or new IRF beds (as defined in paragraph (c)(2) of 42 CFR 412.29), the IRF must provide a written certification that the inpatient population it intends to serve meets the requirements of paragraph (b) of 42 CFR 412.29.* *This written certification will apply until the end of the IRF's first full 12-month cost reporting period or, in the case of new IRF beds, until the end of the cost reporting period during which the new beds are added to the IRF.* *(1) New IRFs* *An IRF hospital or IRF unit is considered new if it has not been paid under the IRF PPS in subpart P of this part (42 CFR 412.25) for at least five calendar years. A new IRF will be considered new from that point that it first participates in Medicare as an IRF until the end of its first full 12-month cost reporting period.* *(2) New IRF beds* *Any IRF beds that are added to an existing IRF must meet all applicable state Certificate of Need and state*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** For new units, verify that: ▪ The attestation statement and rehabilitation hospital worksheet has been submitted to the state agency. ▪ The rehabilitation unit has not been paid under PPS for at least 5 calendar years. ▪ The added beds, if applicable, were approved by CMS. If the rehabilitation unit or hospital has undergone a change of ownership or a merger: ▪ Ensure that the new owners have accepted assignment of the previous Medicare provider agreement, OR ▪ If assignment was not accepted, the facility cannot request continued participation as a PPS excluded rehab hospital.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

licensure laws. New IRF beds may be added one time at any point during a cost reporting period and will be considered new for the rest of that cost reporting period. A full 12-month cost reporting period must elapse between the delicensing or decertification of IRF beds in an IRF hospital or IRF unit. Before an IRF can add new beds, it must receive written approval from the appropriate CMS RO, so that the CMS RO can verify that a full 12-month cost reporting period has elapsed since the IRF has had beds delicensed or decertified. New IRF beds are included in the compliance review calculations under paragraph (b) of this section from that time that they are added to the IRF.

(3) *Change of ownership or leasing*

An IRF hospital or IRF unit that undergoes a change of ownership or leasing, as defined in §489.18 of 42 CFR 489.18, retains its excluded status and will continue to be paid under the prospective payment system specified in §412.1(a)(3) before and after the change of ownership or leasing if the new owner(s) of the IRF accept assignment of the previous owners' Medicare provider agreement and the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

IRF continues to meet all of the requirements for payment under the IRF prospective payment system. If the new owner(s) do not accept assignment of the previous owners' Medicare provider agreement, the IRF is considered to be voluntarily terminated and the new owner(s) may re-apply to participate in the Medicare program. If the IRF does not continue to meet all of the requirements for payment under the IRF prospective payment system, then the IRF loses its excluded status and is paid according to the prospective payment systems described in §412.1(a)(1).

(4) Mergers

If an IRF hospital (or a hospital with an IRF unit) merges with another hospital and the owner(s) of the merged hospital accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit retains its excluded status and will continue to be paid under the prospective payment system specified in §412.1(a)(3) before and after the merger, as long as the IRF hospital or IRF unit continues to meet all of the requirements for payment under the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
IRF prospective payment system. If the owner(s) of the merged hospital do not accept assignment of the IRF hospital's provider agreement (or the provider agreement of the hospital with the IRF unit), then the IRF hospital or IRF unit is considered voluntarily terminated and the owner(s) of the merged hospital may reapply to the Medicare program to operate a new IRF. §412.29(c) §412.29(c)(1-4)		
33.01.04 IRF: Preadmission screening *An inpatient rehabilitation unit must:* ▪ *Have in effect a preadmission screening procedure under which each prospective patient's condition and medical history are reviewed to determine whether the patient is likely to benefit significantly from an intensive inpatient program.* *This procedure must ensure that the preadmission screening for each Medicare Part A Fee-for-Service patient is reviewed and approved by a rehabilitation physician prior to the patient's admission to the IRF.* §412.29(d)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review five patient records from the unit to verify: ▪ The unit has preadmission screening procedures in place that address whether the patient is likely to benefit significantly from an intensive inpatient program or assessment. ▪ The medical records indicate that the criteria are used and patients would benefit significantly from an intensive inpatient program or assessment.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
33.01.05 Medical supervision *An inpatient rehabilitation unit must:* ▪ *Have in effect a procedure to ensure that patients receive close medical supervision, as evidenced by at least 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation to assess the patient both medically and functionally, as well as to modify the course of treatment as needed to maximize the patient's capacity to benefit from the rehabilitation process.* §412.29(e)	☐ Compliant ☐ Not Compliant Facility policies define: 1. Required medical supervision. 2. Special training and experience requirements for inpatient rehabilitation medical staff.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review five patient records from the unit to verify: • Each record contains documentation of a minimum of 3 face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation. • The facility policy addresses the required elements.
33.01.06 Personnel qualifications *An inpatient rehabilitation unit must:* ▪ *Furnish, through the use of qualified personnel, rehabilitation nursing, physical therapy, and occupational therapy, plus, as needed, speech-language pathology, social services, psychological services (including neuropsychological services), and orthotic and prosthetic services.*	☐ Compliant ☐ Not Compliant All licenses of the professional staff are current and are issued by the State in which the personnel are providing services. The hospital has a means of ensuring that its personnel are qualified and competent, consistent with State law.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ All licenses for the professional staff are current and are issued by the State in which the personnel are providing services. ▪ The hospital has a means of ensuring that its personnel are qualified and competent.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§412.29(f)		▪ The hospital has policies that establish the qualifications of personnel providing rehabilitation services.
33.01.07 Medical director of rehabilitation: Qualifications *An inpatient rehabilitation unit must have a director of rehabilitation who:* ▪ *Provides services to the IRF hospital and its inpatients on a full-time basis or, in the case of a rehabilitation unit, at least 20 hours per week.* ▪ *Is a doctor of medicine or osteopathic medicine.* ▪ *Is licensed under State law to practice medicine or surgery.* ▪ *Has had, after completing a one-year hospital internship, at least two years of training or experience in the medical management of inpatients requiring rehabilitation services.* §412.29(g)	☐ Compliant ☐ Not Compliant The medical director of the rehabilitation unit provides at least 20 service hours per week. The 20 hours may be any combination of patient services and administration. These 20 hours cannot be delegated to a Physician Assistant or any other qualified professional.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review the personnel file of the director as well as personnel time cards/logs, etc. to verify that: ▪ The rehabilitation unit has a medical director of rehabilitation. □ Is s/he an MD or DO? ▪ The medical director provides at least 20 service hours per week. ▪ The license of the director is current and issued by the State in which the service is being provided. ▪ The medical director has met the criteria for internship plus 2 years of training or experience.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
33.01.08 Plan of treatment *The inpatient rehabilitation unit must:* ▪ *Have a plan of treatment for each inpatient that is established, reviewed, and revised as needed by a physician in consultation with other professional personnel who provide services to the patient.* §412.29(h)	☐ Compliant ☐ Not Compliant The treatment plan includes measurable long-term and short-term goals with estimated time frames for achieving these. This treatment plan identifies goals, services and interventions to assist the patient in regaining independence, reducing pain, and/or adapting to limitations in activities of daily living.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review a sample volume of closed records appropriate to evaluate inpatient care. Verify that: ▪ Each patient has a plan of treatment in their medical record. ▪ The physician and other professional personnel participate in the establishment, review and revision of the plan of treatment. (This could be a signature, a record of a conference, or record of consultation.)
33.01.09 Coordinated interdisciplinary team approach *The inpatient rehabilitation unit must:* ▪ *Use a coordinated interdisciplinary team approach in the rehabilitation of each inpatient, as documented by the periodic clinical entries made in the patient's medical record to note the patient's status in relationship to goal attainment and discharge plans, and that team conferences are held at least once per week to determine the*	☐ Compliant ☐ Not Compliant Facility policy addresses the functioning of the interdisciplinary team approach: ▪ Planning patient care. ▪ Establishing goals. ▪ Documentation expectations. ▪ Frequency of team meetings.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review policies to verify that they address the required elements. ▪ Review a sample volume of closed records appropriate to evaluate inpatient care. Verify that: □ An interdisciplinary team approach is used for the rehabilitation of each patient.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
appropriateness of treatment. §412.29(i)		□ Weekly team conferences are held to determine appropriateness of treatment. □ Medical records contain periodic clinical entries related to achievement of goals.
33.01.10 Retroactive adjustments *If a new IRF (or new beds that are added to an existing IRF) are excluded from the prospective payment systems specified in §412.1(a)(1) and paid under the prospective payment system specified in §412.1(a)(3) for a cost reporting period under paragraph (c) of 42 CFR 412.29, but the inpatient population actually treated during that period does not meet the requirements of paragraph (b) of 42 CFR 412.29, we adjust payments to the IRF retroactively in accordance with the provisions in §412.130.* §412.29(j)	☐ Compliant ☐ Not Compliant ☐ Not Applicable New IRFs must meet the requirements of this section to receive retroactive payment.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that facility policies address the required elements.
33.02.01 Multidisciplinary team The rehabilitation program uses an integrated, multidisciplinary approach to	☐ Compliant ☐ Not Compliant The disciplines represented in the core team will vary depending upon the	This standard is not met as evidenced by: **DOCUMENT REVIEW**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
patient care. The rehabilitation program's core team may include, but is not necessarily limited to: 1. Physician 2. Rehabilitation RN 3. Speech Therapist 4. Occupational Therapist 5. Social Worker 6. Physical Therapist 7. Therapeutic Recreational Specialist for inpatient facilities	mission and objective of the facility. Other healthcare workers may be included as appropriate, such as: ▪ Psychologist ▪ Psychiatrist ▪ Neuropsychologist ▪ Orthotist ▪ Prosthetist ▪ Exercise physiologist ▪ Vocational rehabilitation counselor ▪ Audiologist	▪ Review the organizational chart for the integrated, multidisciplinary rehabilitation services program to determine it meets the requirement.
33.02.02 Physician responsibility	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Each patient in the rehabilitation service has a physician member of the Medical Staff responsible for his/her medical condition.	All physical rehabilitation outpatients and inpatients have accessibility to the same level of quality health care. That care may require that a local family physician is responsible for overseeing the management of care for a remotely located specialist.	**DOCUMENT REVIEW** ▪ Review a sample of inpatient and out-patient records to verify that each patient is under the care of a member of the medical staff.
33.02.03 Nursing care	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
A registered nurse must be responsible for supervising the quality of nursing care rendered and be competent to participate in the interdisciplinary formulation of	The registered nurse should be knowledgeable by education and/or experience in the care of rehabilitation patients.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Interview the supervising registered nurse.

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individual rehabilitation plans.		▪ Review the job description of the supervising registered nurse.
33.02.04 Organizational plan There is a written description of the program which includes, but need not be limited to the following: 1. The scope of services provided and how these services relate to each other. 2. Services specific to inpatient or outpatient programs including: a. Admission criteria b. The assessment and evaluation process. c. A program evaluation system including treatment criteria and outcome measures, e.g., functional index measurement (FIM) and referral/discharge procedures.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the program for treatment criteria, assessment and evaluation including outcome measures. ▪ Verify that an organizational plan for the rehabilitation program is available for review. The plan includes all required components..
33.02.05 Collaborative goals The goals are developed in collaboration with the patient, and family, as appropriate.	☐ Compliant ☐ Not Compliant The patient, and family when appropriate, assists with planning the treatment goals. The goals reflect their understanding of lifestyles and activities.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review at least ten recently closed rehabilitation records. Choose the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
The goals include monitoring and treatment of pain using a quantifiable tool such as: ▪ A visual scale of zero to ten. ▪ The "FACES" tool for children.		sample based upon distribution of inpatient and outpatient volumes. ▪ Verify that goals are developed in collaboration with the patient and family, as appropriate.
33.02.06 Patient/family education The patient, and/or family when appropriate, is informed of all aspects of the nature of the problem, injury(ies), alternative treatments and devices, and methods of achieving and maintaining progress in the identified goals.	☐ Compliant ☐ Not Compliant Education of patients and families is documented in the medical record. Such education includes methods to reduce the potential for re-injury.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review at least ten recently closed rehabilitation records. Choose the sample based upon distribution of inpatient and outpatient volumes. ▪ Verify that patient/family education is provided appropriate to the nature of the patient problems and interventions.
33.02.07 Quality assessment and performance improvement (QAPI) Rehabilitation services shall be integrated into the facility-wide QAPI plan.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review the QAPI plan and minutes to verify that: ▪ Rehabilitation Services are integrated into the facility-wide QAPI Plan.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ Rehabilitation services-related data is collected and used to improve the quality of patient care and patient safety. Improvements are monitored to insure improvement in outcomes/results.

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PPS EXCLUDED AND DISTINCT PART UNIT: PSYCHIATRIC UNIT

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Note: Standards in this chapter apply ONLY to Psychiatric Units that have been designated by Medicare as an excluded PPS unit. Requirements for these units include:

42 CFR 482 - Conditions of Participation for hospitals
42 CFR 412.25 - Excluded hospital units: Common Requirements
42 CFR 412.27 - Excluded Psychiatric Units: Additional Requirements

34.00.01 PPS excluded hospital units: Basis for exclusion

In order to be excluded from the Prospective Payment Systems (PPS) specified in §412.1(a)(1), a psychiatric unit must meet the following requirements in addition to all criteria under subpart B of part 412 of 42 CFR 412:

Be part of an institution that-

- *Has in effect an agreement under part 489 (42 CFR 489) to participate as a hospital and*
- *Is not excluded in its entirety from the prospective payment systems and*
- *Has enough beds that are not excluded from the inpatient prospective payment systems to permit the provision of adequate cost information, as required by §413.24(c) of 42 CFR 413.24.*

§412.25(a)
§412.25(a)(1)(i-iii)

☐ Compliant ☐ Not Compliant

The hospital has an agreement to participate in the Medicare program and is not already excluded in its entirety from IPPS, such as a psychiatric hospital. In other words, the unit seeking exclusion cannot comprise the entire hospital.

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

Verify that:

- The hospital has an agreement to participate in the Medicare PPS Exclusion program.
- The hospital is not already excluded in its entirety from PPS, such as a psychiatric hospital.

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34.00.02 PPS excluded hospital units: Admission Criteria *In order to be excluded for the Medicare PPS System, the unit must meet the following criteria:* ▪ *Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.* §412.25(a)(2)	☐ Compliant ☐ Not Compliant The hospital has written admission criteria. The approved admission criteria are consistently followed for both Medicare and non-Medicare patients.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review policies and open and closed records to verify that: ▪ Written admission criteria are in place. ▪ The approved admission criteria are followed for all patients.
34.00.03 PPS excluded hospital units: Separate medical records *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Have admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.* §412.25(a)(3)	☐ Compliant ☐ Not Compliant PPS exempt units have medical records that are separate and not commingled with other hospital records. These records are readily available for review.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the medical records for the exempt unit are separate and are not commingled with other hospital records; these are readily available for review.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
34.00.04 PPS excluded hospital units: Availability of clinical records and information *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Have policies specifying that necessary clinical information is transferred to the unit when a patient of the hospital is transferred to the unit.* §412.25(a)(4)	☐ Compliant ☐ Not Compliant The hospital has a written policy that specifies the clinical information that is to accompany the patient when transferred to the exempt psychiatric unit.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review policies and medical records to verify: ▪ The hospital has a policy detailing the prompt transfer of clinical information for patients transferred to the psychiatric unit. ▪ The medical record reflects that clinical information is promptly transferred with the record.
34.00.05 PPS excluded hospital units: State licensure requirements *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Meet applicable State licensure laws.* §412.25(a)(5)	☐ Compliant ☐ Not Compliant **HOSPITAL LICENSING** ▪ The hospital demonstrates that all applicable state licensure laws are met. ▪ The hospital provides documentation of any and all unmet state licensure requirements including documentation for deficient practices. ▪ The unit meets special licensing requirements issued by the state, as required. **PROFESSIONAL STAFF** The hospital has current licenses for its professional staff. The professional staff are licensed by the state in which the hospital is located.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ All applicable state licensure laws are met, including any special licensing requirements issued by the state. ▪ All professional staff files have current licenses issued by the state in which the unit is located.

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34.00.06 PPS excluded hospital units: Utilization review requirements *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Have utilization review standards applicable for the type of care offered in the unit.* §412.25(a)(6)	☐ Compliant ☐ Not Compliant The hospital has a utilization review plan that includes the review of psychiatric services. (No utilization review standards are required if the QIO is conducting review activities.)	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the utilization review plan includes review of psychiatric services, either internally or through the QIO.
34.00.07 PPS excluded hospital units: Distinct unit structure *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Have beds physically separate from (that is, not commingled with) the hospitals other beds.* §412.25(a)(7)	☐ Compliant ☐ Not Compliant The PPS exempt psychiatric beds are physically separate from the beds in other units of the hospital	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the PPS exempt psychiatric beds are physically separate from other units of the hospital.
34.00.08 PPS excluded hospital units: Fiscal intermediary *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** • Verify that the PPS excluded unit uses the same fiscal intermediary as the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ *Be serviced by the same fiscal intermediary as the hospital.* §412.25(a)(8)		hospital.
34.00.09 PPS excluded hospital units: Separate cost center *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Be treated as a separate cost center for cost finding and apportionment purposes.* §412.25(a)(9)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the PPS excluded unit Is treated as a separate Cost Center for cost finding and apportionment purposes.
34.00.10 PPS excluded hospital units: Allocate costs *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Use an accounting system that properly allocates costs.* §412.25(a)(10)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the PPS excluded unit uses an accounting system that properly allocates costs.

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34.00.11 PPS excluded hospital units: Statistical data *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ Maintain adequate statistical data to support the basis of allocation. §412.25(a)(11)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the PPS excluded unit maintains adequate statistical data to support the basis of allocation.
34.00.12 PPS excluded hospital units: Cost report *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:* ▪ *Report its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.* §412.25(a)(12)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the PPS excluded unit reports its costs in the hospital's cost report covering the same fiscal period and using the same method of apportionment as the hospital.
34.00.13 PPS excluded hospital units: Requirements on the first day of the first cost reporting period *In order to be excluded from the Medicare PPS System, the unit must meet the following criteria:*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the PPS excluded unit is fully equipped and staffed and is capable of

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▪ *As of the first day of the first cost reporting period for which all other exclusion requirements are met, the unit is fully equipped and staffed and is capable of providing hospital inpatient psychiatric…care regardless of whether there are any inpatients in the unit on that date.* §412.25(a)(13)		providing hospital inpatient psychiatric care, regardless of whether there are any inpatients in the unit.
34.00.14 PPS excluded hospital units: Changes in the size of excluded units *Except in the special cases noted at the end of this paragraph, changes in the number of beds or square footage considered to be part of an excluded unit under this section are allowed one time during a cost reporting period if the hospital notifies its Medicare contractor and the CMS RO in writing of the planned change at least 30 days before the date of the change. The hospital must maintain the information needed to accurately determine costs that are attributable to the excluded unit.* *A change in bed size or a change in square footage may occur at any time during a cost reporting period and must remain in effect for the rest of that cost reporting*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine whether the PPS excluded unit has had a change in the number of beds or a change in square footage during this accreditation cycle. If yes: □ Has the facility notified the Medicare contractor and the CMS Regional Office (RO) in writing at least 30 days prior to the change? □ Did the communication clearly define the unit costs?

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period.

Changes in bed size or square footage may be made at any time if these changes are made necessary by relocation of a unit to permit construction or renovation necessary for compliance with changes in Federal, State, or local law affecting the physical facility or because of catastrophic events such as fires, floods, earthquakes, or tornadoes.

§412.25(b)

34.00.15 PPS excluded hospital units: Change in status of hospital units

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

For purposes of exclusions from the prospective payment systems under this section, the status of each hospital unit (excluded or not excluded) is determined as specified in paragraphs (c)(1) and (c)(2) of 42 CFR 412.25.

(1) The status of a hospital unit may be changed from not excluded to exclude only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the prospective payment systems before the start of

No additional information.

INTERVIEW AND DOCUMENT REVIEW

- Determine whether the PPS excluded unit has had a change in status during this accreditation cycle.
  If yes:
  - ☐ Has the facility notified the fiscal intermediary and the CMS Regional Office in writing within 30 days before the change?

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a hospital's next cost reporting period.

(2) The status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.

§412.25(c)
§412.25(c)(1-2)

34.00.16 PPS excluded hospital units: Number of excluded units

Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems.

§412.25(d)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The hospital may have one PPS excluded Psychiatric Unit.

The hospital may also have one PPS excluded Rehabilitation Unit.

OBSERVATION AND INTERVIEW

- Verify that there is only one PPS excluded psychiatric unit in this facility.

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34.00.17 Satellite facility: Definition For purposes of paragraphs (e)(2) through (e)(5) of 42 CFR 412.25, a *satellite facility is:* ▪ *A part of a hospital unit that provides inpatient services in a building also used by another hospital, or* ▪ *In one or more entire buildings located on the same campus as buildings used by another hospital.* §412.25(e) §412.25(e)(1)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND OBSERVATION** Verify that the satellite facility: ▪ Provides inpatient services consistent with requirement. ▪ Is located consistent with requirement.
34.00.18 Satellite facility: Criteria *Except as provided in paragraphs (e)(3) and (e)(6) of 42 CFR 412.25, effective for cost reporting periods beginning on or after October 1, 1999, a hospital that has a satellite facility must meet the following criteria in order to be excluded from the acute care hospital inpatient prospective payment systems for any period:* (i) *In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify that the satellite facility: ▪ Meets criteria for exclusion from PPS consistent with requirement. ▪ The unit's number of state-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of state-licensed and Medicare-certified beds on the last day of the unit's last cost

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
beginning before October 1, 1997, the unit's number of State-licensed and Medicare-certified beds, including those at the satellite facility, does not exceed the unit's number of state-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period beginning before October 1, 1997. (ii) *The satellite facility independently complies with—* (B) *For a psychiatric unit, the requirements under §412.27(a).* §412.25(e)(2) §412.25(e)(2)(i-ii) §412.25(e)(2)(ii)(B)		reporting period.
34.00.19 <u>Satellite facility: Separate governing body</u>	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The satellite facility meets all the following requirements: ▪ *Effective for cost reporting periods beginning on or after October 1, 2002, it is not under the control of the governing body or chief executive officer of the hospital in which it is located, and it furnishes inpatient care*	No additional information.	**<u>INTERVIEW AND DOCUMENT REVIEW</u>** Verify that: ▪ The governing body/CEO of the satellite facility is different than that for the hospital. ▪ The care provided is not under control of the hospital medical staff and chief medical officer.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
through the use of medical personnel who are not under the control of the medical staff or chief medical officer of the hospital in which it is located. §412.25(e)(2)(iii)(A)		
34.00.20 Satellite facility: Admission and discharge records *The satellite facility meets all the following requirements:* ▪ *It maintains admission and discharge records that are separately identified from those of the hospital in which it is located and are readily available.* §412.25(e)(2)(iii)(B)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the satellite facility maintains admission and discharge records separate from the hospital. □ These records are readily available.
34.00.21 Satellite facility: Beds are physically separate *The satellite facility meets all the following requirements:* ▪ *It has beds that are physically separate from (that is, not commingled with) the beds of the hospital in which it is located.* §412.25(e)(2)(iii)(C)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **OBSERVATION AND INTERVIEW** ▪ Verify that the beds of the satellite facility are physically separate from the beds of the hospital.

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34.00.22 Satellite facility: Fiscal intermediary *The satellite facility meets all the following requirements:* ▪ *It is serviced by the same fiscal intermediary as the hospital unit of which it is a part.* §412.25(e)(2)(iii)(D)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the satellite facility uses the same fiscal intermediary as the hospital of which it is a part.
34.00.23 Satellite facility: Separate cost center *The satellite facility meets all the following requirements:* ▪ *It is treated as a separate cost center of the hospital unit of which it is a part.* §412.25(e)(2)(iii)(E)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** • Verify that the satellite facility is a separate cost center of the hospital of which it is a part.
34.00.24 Satellite facility: Accounting system *The satellite facility meets all the following requirements:* ▪ *For cost reporting and apportionment purposes, it uses an accounting system that properly allocates costs and maintains adequate statistical data to*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the satellite facility uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
support the basis of allocation. §412.25(e)(2)(iii)(F)		allocation.
34.00.25 Satellite facility: Hospital cost report *The satellite facility meets all the following requirements:* ▪ *It reports its costs on the cost report of the hospital of which it is a part, covering the same fiscal period and using the same method of apportionment as the hospital of which it is a part.* §412.25(e)(2)(iii)(G)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the satellite facility reports its costs on the cost report of the hospital of which it is a part, using the same fiscal period and same method of apportionment as the hospital.
34.00.26 Satellite facility: Exception *Except as specified in paragraphs (e)(4) and (e)(5) of 42 CFR 412.25, the provisions of paragraph (e)(2) of 42 CFR 412.25 do not apply to any unit structured as a satellite facility on September 30, 1999 and excluded from the prospective payment systems on that date, to the extent the unit continues operating under the same terms and conditions, including the number of beds and square footage*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documents to verify that the satellite facility meets this requirement. ▪ Determine whether this unit was structured as a satellite facility on September 30, 1999 and excluded from the prospective payment systems on that date.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
considered to be part of the unit at the satellite facility on September 30, 1999. §412.25(e)(3)		If yes, has the unit continued to operate under the same terms and conditions, including the number of beds and square footage considered to be part of the unit at the satellite facility on September 30, 1999?
34.00.27 <u>Satellite facility: Increase/ decrease the square footage or decrease the number of beds</u> *In applying the provisions of paragraph (e)(3) of 42 CFR 412.25, any unit structured as a satellite facility on September 30, 1999, may increase or decrease the square footage of the satellite facility or may decrease the number of beds in the satellite facility considered to be part of the satellite facility at any time, if these changes are made by the relocation of a facility—* *(i) To permit construction or renovation necessary for compliance with changes in federal, state, or local law affecting the physical facility* *(ii) Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.* §412.25(e)(4) §412.25(e)(4)(i-ii)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Determine whether the satellite facility increased/decreased its square footage or decreased the number of beds. If yes, were these changes: □ To permit construction or renovation necessary for compliance with federal, state, or local law? □ Due to a catastrophic event?

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34.00.28 Satellite facility: Structure changes after October 1, 2006 *For the cost reporting periods beginning on or after October 1, 2006, in applying the provisions of Medicare paragraph (e)(3) of 42 CFR 412.25—* (i) *Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit only at the beginning of a cost reporting period or decrease the square footage or number of beds considered to be part of the satellite facility subject to the provisions of paragraph (b)(2) of 42 CFR 412.25, without affecting the provisions of paragraph (e)(3) of 42 CFR 412.25; and* (ii) *If the unit structured as a satellite facility decreases its number of beds below the number of beds considered to be part of the satellite facility on September 30, 1999, subject to the provisions of paragraph (b)(2) of 42 CFR 412.25, it may subsequently increase the number of beds at the beginning or a cost reporting period as long as the resulting total number of beds*	☐ Compliant ☐ Not Compliant For any unit that was a structure of satellite facility on September 30, 1999, it is acceptable for the satellite facility to increase/decrease the square footage of the satellite facility or decrease the number of beds.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Determine whether the unit was a structure of a satellite facility on September 30, 1999. If yes, determine if the satellite facility increased/ decreased the square footage of the satellite facility or decreased the number of beds, these changes were consistent with the requirement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
considered to be part of the satellite facility does not exceed the number of beds at the satellite facility on September 30, 1999. §412.25(e)(5) §412.25(e)(5)(i-ii)		
34.00.29 Satellite facility: Inpatient rehabilitation facility *The provisions of Medicare paragraph (e)(2)(i) of 42 CFR 412.25—* ▪ *Do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of 42 CFR 412.25, effective for cost reporting periods beginning on or after October 1, 2003.* §412.25(e)(6)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documents to verify that the satellite facility is compliant with the requirement.
34.00.30 Changes in classification of hospital units *For purposes of exclusions from the prospective payment system under 42 CFR 412.25—* ▪ *The classification of a hospital unit is effective for the unit's entire cost*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documents to determine if the satellite facility made any changes in the classification of a unit. If yes: □ Were these changes only made at

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
reporting period. Any changes in the classification of a hospital unit are made only at the start of a cost reporting period. §412.25(f)		the start of a cost reporting period?
34.01.01 PPS excluded psychiatric unit: Additional Requirements *To be excluded from the prospective payment system, a psychiatric unit must meet the requirements in 34.01.02 through 34.01.17.* §412.27	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **Note:** Score this standard based on compliance with standards 34.01.02 through 34.01.17.
34.01.02 PPS excluded psychiatric unit: Admission criteria The psychiatric unit will: ▪ *Admit only patients whose admission to the unit is required for active treatment, of an intensity that can be provided appropriately only in an inpatient hospital setting, of a psychiatric principal diagnosis that is listed in the International Classification of Diseases, Tenth Revision, Clinical Modification.*	☐ Compliant ☐ Not Compliant Patients admitted to the PPS excluded unit have a principal psychiatric diagnosis that requires active inpatient treatment.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a select group of clinical records to verify that there is a principal diagnosis that meets the requirement.

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§412.27(a)		
34.01.03 PPS excluded psychiatric unit: Scope of service The psychiatric unit will: ▪ *Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, therapeutic activities.* §412.27(b)	☐ Compliant ☐ Not Compliant Personnel may be contracted or on the regular staff. However, there must be an employed registered nurse supervising care at all times the unit is open and providing care.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the scope of service for the unit to determine all required services are provided. ▪ Verify by reviewing staffing sheets that an employed RN is on duty supervising care delivery at all times.
34.01.04 PPS excluded psychiatric unit: Treatment plan The psychiatric unit will: ▪ *Maintain medical records that permit determination of the degree and intensity of the treatment provided to individuals who are furnished services in the unit, and that meet the following requirements.* §412.27(c)	☐ Compliant ☐ Not Compliant Each patient record contains a treatment plan.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review medical records to verify that there is a current diagnosis and treatment plan for each.

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34.01.05 PPS excluded psychiatric units: Development of assessment/ diagnostic data *Medical records must stress the psychiatric components of the record, including history of findings and treatment provided for the psychiatric condition for which the inpatient is treated in the unit.* §412.27(c)(1)	☐ Compliant ☐ Not Compliant Each patient record contains a psychiatric history including treatment provided for the psychiatric condition.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify through medical record review that all medical records reflect a psychiatric history of findings and treatment.
34.01.06 PPS excluded psychiatric units: Legal status *The medical records must include:* ▪ *The identification data of the inpatient's legal status.* §412.27(c)(1)(i)	☐ Compliant ☐ Not Compliant Legal status is defined in state statutes and dictates the circumstances under which the patient was admitted and/or is being treated, i.e., voluntary, involuntary, committed by court. Evaluation and recertification are in accordance with state requirements. Any changes in the legal status of the patient must be recorded with the date of change on the medical record.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview unit staff about the terminology they use in defining "legal status." ▪ If evaluation and recertification of the patient is required by the state, verify that legal documentation supporting this status is present. ▪ Review medical records to verify that any changes in the legal status of the patient are recorded with the date of change on the medical record.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
34.01.07 PPS excluded psychiatric units: Admission diagnosis *The medical records must include:* ▪ *A provisional or admitting diagnosis must be made on every inpatient at the time of admission and must include the diagnoses of intercurrent diseases as well as the psychiatric diagnoses.* §412.27(c)(1)(ii)	☐ Compliant ☐ Not Compliant There is an admission or working psychiatric diagnosis (including rule-out diagnoses) written in accordance with the most current edition of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) or the approved International Classification of Diseases (ICD) nomenclature. The final diagnosis may differ from the initial diagnosis if subsequent evaluation and observation support a change. Diagnosis should include physical illness when present.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a selection of medical records to verify inclusion of the admitting diagnosis. Note: This may be found on the face sheet, in the history and physical, or in the physician progress notes. Verify whether: ▪ Abnormal lab results or H&P findings were followed up and justified? ▪ Acute physical illnesses requiring immediate treatment are managed appropriately. ▪ The diagnosis is written in DSM nomenclature. ▪ If the diagnosis is absent, there is written justification for the omission. For example, the patient was psychotic on admission and not accompanied by family. ▪ There is an evaluation and treatment plan for identified physical illnesses that may impact the patient's psychiatric outcome.

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34.01.08 PPS excluded psychiatric units: Patient reason for admission *The medical records must include:* ▪ *The reasons for admission must be clearly documented as stated by the inpatient or others significantly involved, or both.* §412.27(c)(1)(iii)	☐ Compliant ☐ Not Compliant The purpose of this regulation is to provide an understanding of what caused the patient to come to the hospital, and the patient's response to admission. The hospital records the statements and reasons for admissions given by the family and by others as well as the patient (preferably verbatim) with informant identified. This information may be documented in a variety of locations within the patient record, e.g., in transfer and admission notes from the physician, nurses and social workers.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that all clinical records reviewed reflected the reason for admission as stated by the patient, family, or other interested parties.
34.01.09 PPS excluded psychiatric units: Social history and assessment *The medical records must include:* ▪ *The social service records, including reports of interviews with inpatients, family members, and others must provide an assessment of home plans and family attitudes, and community resource contacts as well as a social history.* §412.27(c)(1)(iv)	☐ Compliant ☐ Not Compliant The purpose of the social work assessment is to determine the current baseline social functioning (strengths and deficits) of the patient, from which treatment interventions and discharge plans are to be formulated. A psychosocial history/assessment shall be completed for all patients. Three key components to be addressed are: **1. FACTUAL AND HISTORICAL INFORMATION** ▪ Specific reasons for the patient's admission or readmission. ▪ A description of the patient's past and present biopsychosocial functioning. ▪ Family and marital history, dynamics, and patient's relationships with family and significant others ▪ Pertinent religious and cultural factors.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review a sample volume of open and closed records to evaluate the social service assessment. Verify that: ▪ The patient participated to the extent possible. □ Did family members or others provide information? ▪ All three key components are included in the assessment. High-risk psychosocial issues should be included in the treatment plan. Verify that each record

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	▪ History of physical, sexual, and emotional abuse. ▪ Significant aspects of psychiatric, medical, and substance abuse history and treatment as presented by family members and significant others. ▪ Educational, vocational, employment, and military service history. ▪ Identification of community resources including previously used treatment sources. ▪ Identification of present environmental and financial needs. **2. SOCIAL EVALUATION** ▪ Patient strength and deficits. ▪ High risk psychosocial issues requiring early treatment planning and intervention, i.e., unattended children in the home; prior noncompliance; potential obstacles to treatment and discharge planning. **3. CONCLUSIONS AND RECOMMENDATIONS RESULTING FROM THE ASSESSMENT** ▪ Anticipated necessary steps for discharge to occur. ▪ High-risk patient and/or family psychosocial issues requiring early treatment planning and immediate intervention regardless of the patient's length of stay. ▪ Specific community resources/support systems for utilization in discharge planning. ▪ Anticipated social work role in treatment and discharge planning.	□ Factual and historical information. □ Social evaluation (baseline social functioning including strengths and weaknesses). □ Conclusions and recommendations (in anticipation of social work's role in treatment and discharge planning).

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34.01.10 PPS excluded psychiatric units: Neurological examination *The medical records must include:* ▪ *When indicated, a complete neurological examination must be recorded at the time of the admission physical examination.* §412.27(c)(1)(v)	☐ Compliant ☐ Not Compliant Upon admission the patient must receive a thorough history and physical examination with all indicated laboratory examinations. A thorough history of the patient's past physical disorders, head trauma, accidents, substance dependence/abuse, exposure to toxic agents, tumors, infections, seizures or temporary loss of consciousness, and headaches, will alert the physician to look for the presence of continuing pathology or possible sequelae any of which may turn out to be significant and pertinent to the present mental illness. In addition to the required history and physical, when indicated, a complete neurological exam must be conducted and recorded.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed medical records to verify that the requirement was met. □ Positive neurological symptomatology found in the systems review (history and physical "screening" neurological exam) should result in a neuralgic workup or consultation. □ At a minimum, the screening neurological exam includes a detailed description of gross testing for cranial nerves II through XII.
34.01.11 PPS excluded psychiatric units: Psychiatric evaluation *Each inpatient must receive a psychiatric evaluation that must:* ▪ Comply with requirements found in 34.01.11 – 34.01.18. §412.27(c)(2)	☐ Compliant ☐ Not Compliant The psychiatric evaluation is done for the purpose of determining the patient's diagnosis and treatment and, therefore, it must contain the necessary information to justify the diagnosis and planned treatment. The psychiatric evaluation must include: ▪ Chief complaints, reaction to hospitalization. ▪ Past history of any psychiatric problems and treatment, including previous precipitating factors, diagnosis, and course of treatment.	This standard is not met as evidenced by: **DOCUMENT REVIEW** **Note:** Score this standard based on the criteria below and the scoring for standards 34.01.12 – 34.01.18. ▪ Review a sample of open and closed medical records to verify that complete psychiatric evaluations were done on

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Past family, educational, vocational, occupational, and social history. The psychiatric evaluation is a total appraisal or assessment of the patient's illness. It is the physician's assessment of the contributing factors and forces in the evolution of the patient's illness including the patient's perception of his or her illness. ▪ A physician signature is necessary. In cases where the mental status portion of the psychiatric evaluation is performed by a nonphysician, there should be evidence that the person is credentialed by the hospital, legally authorized by the state to perform the function, and a physician review and countersignature is present, where required by hospital policy or state law.	all admissions. ▪ The psychiatric exam must include the following components: □ Chief complaint(s). □ Reaction to hospitalization. □ Past history of any psychiatric problems and treatment, including previous precipitating factors, diagnosis, and course of treatment. □ Past family, educational, vocational, occupational and social history.
34.01.12 PPS excluded psychiatric units: Psychiatric evaluation requirements – time frame *Each inpatient must receive a psychiatric evaluation that must:* ▪ *Be completed within 60 hours of admission.* §412.27(c)(2)(i)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed medical records to verify that a complete assessment is completed within the required time frame.
34.01.13 PPS excluded psychiatric units: Psychiatric evaluation requirements – medical history *Each inpatient must receive a psychiatric evaluation that must:* ▪ *Include a medical history.*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed medical records to verify that a medical history

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§412.27(c)(2)(ii)		was completed for all admissions.
34.01.14 PPS excluded psychiatric units: Psychiatric evaluation requirements – mental status *Each inpatient must receive a psychiatric evaluation that must:* ▪ *Contain a record of mental status.* §412.27(c)(2)(iii)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed medical records to verify that the psychiatric evaluation includes a record of mental status. □ Does the mental status record describe the appearance, behavior, emotional response, verbalization, thought content, and cognition of the patient?
34.01.15 PPS excluded psychiatric units: Psychiatric evaluation requirements – onset of illness *Each inpatient must receive a psychiatric evaluation that must:* ▪ *Note the onset of illness and the circumstances leading to admission.* §412.27(c)(2)(iv)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed medical records to verify that the psychiatric evaluation includes documentation of the onset of the illness and the circumstances leading to admission. □ Are the identified problems related to the patient's need for admission?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
34.01.16 PPS excluded psychiatric units: Psychiatric evaluation requirements – Description of attitudes and behaviors *Each inpatient must receive a psychiatric evaluation that must:* ▪ *Describe attitudes and behavior.* §412.27(c)(2)(v)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed medical records to verify that the psychiatric evaluation includes documentation describing patient attitudes and behavior. □ Does the problem statement describe the behavior(s) which require modification in order for the patient to function in a less restrictive environment?
34.01.17 PPS excluded psychiatric units: Psychiatric evaluation requirements – cognition *Each inpatient must receive a psychiatric evaluation that must:* ▪ *Estimate intellectual functioning, memory functioning, and orientation.* §412.27(c)(2)(vi)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed medical records to verify that the psychiatric evaluation includes documentation of intellectual functioning, memory functioning, and orientation.

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34.01.18 PPS excluded psychiatric units: Psychiatric evaluation requirements – assets *Each inpatient must receive a psychiatric evaluation that must:* ▪ *Include an inventory of the inpatient's assets in descriptive, not interpretative fashion.* §412.27(c)(2)(vii)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed medical records to verify that the psychiatric evaluation includes documentation of patient assets. **Note:** For the purposes of this regulation, words such as "youth", "pretty", "social security income" and "has a car" do not represent assets.
34.01.19 PPS excluded psychiatric units: Treatment plan *Each inpatient must have an individual comprehensive treatment plan that shall be based on an inventory of the inpatient's strengths and disabilities.* *The written plan must include:* ▪ *a substantiated diagnosis.* ▪ *short-term and* ▪ *long term goals.* ▪ *the specific treatment modalities utilized.* ▪ *responsibilities of each member of the*	☐ Compliant ☐ Not Compliant The patient and treatment team collaboratively develop the patient's treatment plan. The treatment plan is the outline of what the facility has committed itself to do for the patient based on an assessment of the patient's needs. The facility selects its format for treatment plans and treatment plan updates.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Observe, as available, scheduled treatment program meetings (individual, group, family meetings, therapeutic activities, and therapeutic procedures) and treatment planning meetings to assess: □ Are all disciplines required to meet the patient's needs represented at planning meetings? ▪ Review a selection of treatment plans to verify:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
treatment team. ▪ *adequate documentation to justify the diagnosis and the treatment.* ▪ *rehabilitation activities carried out.* §412.27(c)(3)(i)		□ An individualized treatment plan has been developed for each patient, based on the assessments and evaluations. □ The patient's response toward meeting planned goals is reviewed periodically and modified as necessary. □ The plans must reflect an integrated approach to care planning and delivery, including all disciplines caring for the patient. □ The treatment plan is a result of collaboration between the patient and the treatment team. □ The treatment plan is individualized. □ There is a primary diagnosis upon which the treatment interventions are based. The treatment plan goals are written in a manner that allows for changes in the patient's behavior to be measured. □ The treatment plan goals are relevant to the patient's condition. □ The treatment team encourages the patient's active participation and responsibility for engaging in the treatment regimen. □ For patients who have been secluded or restrained, less restrictive

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		interventions were considered prior to the use of seclusion or restraints. □ There is rationale for use of seclusion and/or restraints. □ If the use of seclusion and/or restraints is a frequent occurrence, does the treatment plan document alternative interventions to address and treat negative patient behavior?
34.01.20 PPS excluded psychiatric units: Documentation of active treatment *The treatment received by the inpatient must be documented in such a way as to assure that all active therapeutic efforts are included.* §412.27(c)(3)(ii)	☐ Compliant ☐ Not Compliant There are sufficient resources to provide physical and psychosocial therapeutic activities to meet the needs of the patient populations. Active treatment is an essential requirement for inpatient psychiatric care. Active treatment is a clinical process involving ongoing assessment, diagnosis, intervention, evaluation of care and treatment, and planning for discharge and aftercare, under the direction of a psychiatrist. The patient is in the hospital because it has been determined that the patient requires intensive, 24-hour, specialized psychiatric intervention that cannot be provided outside the psychiatric unit or hospital.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed medical records. □ Were treatment modalities provided with sufficient frequency and intensity to assure that the patient achieves an optimal level of functioning? □ Does the patient require 24-hour specialized psychiatric care? □ Is the patient receiving all aspects of treatment to which the unit has committed itself, based on the assessment, evaluation, and plan of care?

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		▪ Review policies and procedures on therapeutic use of restrictions, such as visitors, mail, and phone calls to validate patient rights are being protected. □ Do the policies and procedures adequately direct staff on alternatives or less restrictive interventions prior to the use of seclusion and restraints? □ Has the staff documented that less restrictive therapeutic interventions have been reviewed and/or attempted?
34.01.21 PPS excluded psychiatric units: Progress notes requirements *Progress notes must be recorded by the doctor of medicine or osteopathic medicine responsible for the care of the inpatient, a nurse, social worker and, when appropriate others significantly involved in active treatment modalities.* *The frequency of progress notes is determined by the condition of the inpatient but must be recorded at least weekly for the first two months and at least once a month thereafter and must contain recommendations for revisions in*	☐ Compliant ☐ Not Compliant Once developed, the individualized treatment plan guides the formulation of progress notations. Notations formatted by individual disciplines address patient progress in achieving identified behaviors in response to the listed problems and goals. Progress notes of an individual team member may be integrated as long as all participants present are identified by title and discipline. It would be expected to see progress notes in greater frequency when patients are more acutely ill and/or in crisis of some kind. Progress notes must be dated and signed.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review open and closed medical records for progress notations for patient progress. □ Select two or more identified problems and goal statements to trace in the progress notes. □ Entries must be dated and signed with the discipline identified. □ Are the progress note entries reflective of the acuity of the patient

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
the treatment plan as indicated as well as precise assessment of the inpatient's progress in accordance with the original or revised treatment plan. §412.27(c)(4)		and completed within appropriate frequency consistent with patient acuity? □ Does the content of the treatment notes and progress notes support the treatment plan? ▪ What the staff is doing to carry out the treatment plan? ▪ The patient's response?
34.01.22 PPS excluded psychiatric units: Discharge planning and summary *The record of each patient who has been discharged must have a discharge summary that includes a recapitulation of the inpatient's hospitalization in the unit and recommendations from appropriate services concerning follow-up or after care as well as a brief summary of the patient's condition on discharge.* §412.27(c)(5)	☐ Compliant ☐ Not Compliant The discharge summary includes: ▪ The reason for admission. ▪ Treatment achieved during hospitalization. ▪ A baseline of the psychiatric and social functioning of the patient at the time of discharge. ▪ The patient and family response to the intervention. The patient's behavioral condition at discharge is described in relation to the achievement of long and short-term goals identified in the individualized master treatment plan. Concurrent physical problems are identified with treatment and outcomes. All relevant elements of the aftercare plan are listed to include identification of the community resources identified. Many states have a range of services offered through the department of health. Examples include but are not limited to core mental health services	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review closed medical records to verify that required elements are addressed in the discharge summary: □ The patient's behavioral condition in relation to short- and long-term goals in the treatment plan. □ Concurrent physical problems identified with treatment and outcomes. □ Relevant facts about the aftercare plan and community resources. □ Documentation of psych-education provided to the patient and family regarding signs and symptoms of

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	such as counseling, individual and group therapy, medication, and medication monitoring, outpatient residential services, and specialized programs for children and adolescents.	illness, strategies to prevent re-hospitalization, and how to improve their disease management skills. □ Does the discharge planning process include the participation of the multidisciplinary staff and the patient? □ Are the details of the discharge plan communicated to the post-hospital treatment entity?
34.01.23 PPS excluded psychiatric units: Staffing requirements *The unit must meet special staff requirements in that the unit must have adequate numbers of qualified professional and supportive staff to evaluate inpatients, formulate written, individualized, comprehensive treatment plans, provide active treatment measures, and engage in discharge planning.* *The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—* ▪ *Evaluate inpatients* §412.27(d)(1)(i)	☐ Compliant ☐ Not Compliant The facility should be adequately staffed with qualified mental health professionals to carry out an intensive and comprehensive active treatment program to protect and promote the physical and mental health of its patients.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. ▪ Review incident reports, medication error reports, and patient and staff injury reports for indications that staffing is an issue. ▪ Is there adequate staff to ensure that admission work-ups are completed in a timely manner? ▪ Review the planned and actual staffing patterns. Review the treatment

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		calendar. Review admission and discharge logs to identify patterns. □ Correlate these findings with open and closed patient record review, looking at documentation for assessments and treatments as well as restraint and seclusion use to determine if staffing was having a negative impact on outcomes.
34.01.24 PPS excluded psychiatric units: Staffing requirements *The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—* ▪ *Formulate written, individualized comprehensive treatment plans.* §412.27(d)(1)(ii)	☐ Compliant ☐ Not Compliant The facility has adequate number of appropriate staff to formulate written, individualized comprehensive treatment plans in a timely manner.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. ▪ Are all members of the treatment team able to contribute their data and perspectives toward formulation of the treatment plan? ▪ Review the planned and actual staffing patterns. Review the treatment calendar. Review admission and discharge logs to determine patterns. □ Correlate these findings with open and closed patient record review.

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		Look at documentation for assessments and treatments as well as restraint and seclusion utilization to determine if staffing was having a negative impact on outcomes.
34.01.25 PPS excluded psychiatric units: Staffing requirements The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to— ▪ Provide active treatment measures. §412.27(d)(1)(iii)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. ▪ Review incident reports, medication error reports, and patient and staff injury reports for indications that staffing is an issue. ▪ Is the distribution of staff consistent with particular patient needs? ▪ Review the planned and actual staffing patterns. Review the treatment calendar. Review admission and discharge logs to determine patterns. □ Correlate these findings with open and closed patient record review, looking at documentation for assessments and treatments as well

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		as restraint and seclusion utilization to determine if staffing was having a negative impact on outcomes.
34.01.26 PPS excluded psychiatric units: Staffing requirements *The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—* ▪ *Engage in discharge planning.* §412.27(d)(1)(iv)	☐ Compliant ☐ Not Compliant The facility has adequate number of appropriate staff to engage in discharge planning in a timely manner	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Through observation, interview and record review determine if numbers and/or deployment of qualified staff is a concern. ▪ Does the record indicate that staff has participated in discharge planning? ▪ Are staff aware of discharge plans for the patients they are working with? ▪ Review the planned and actual staffing patterns. Review the treatment calendar. Review admission and discharge logs to determine patterns. □ Correlate these findings with open and closed patient record review, looking at documentation for assessments and treatments as well as restraint and seclusion utilization to determine if staffing was having a negative impact on outcomes.

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34.01.27 PPS excluded psychiatric units: Director of inpatient psychiatric services - medical staff *Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent who is qualified to provide the leadership required for an intensive treatment program.* *The number and qualifications of doctors of medicine and osteopathic medicine must be adequate to provide essential psychiatric services.* §412.27(d)(2)	☐ Compliant ☐ Not Compliant Of the members of the organized medical staff, one is named as clinical director. There are sufficient medical staff members to provide services; the number depends upon the size of the facility or unit and the scope of services provided. The clinical (medical) director is ultimately responsible for the medical and psychiatric care that is provided to patients. The education, training, and experience for the medical director are established.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify that: ▪ There is a named clinical (medical) director. ▪ The clinical director meets the qualifications established for the role. ▪ There are enough qualified medical staff to provide the services offered. The services must be provided in a timely manner. ▪ Coverage is adequate to meet the needs of the patients. ▪ There should be at least one qualified physician to provide back- up/relief services for the clinical (medical) director.
34.01.28 PPS excluded psychiatric units: Medical director qualifications *The Clinical Director, service chief, or equivalent must meet the training and experience requirements for examination by:* ▪ *the American Board of Psychiatry and*	☐ Compliant ☐ Not Compliant The Clinical (Medical) Director has completed an approved residency program and has been certified, or is eligible for examination to become certified, by the AOA or the ABMS.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify that: ▪ The Clinical (Medical) Director meets the residency requirements of a psychiatry/neurology program

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Neurology *or* ▪ *the American Osteopathic Board of Neurology and Psychiatry.* §412.27(d)(2)(i)		approved by the ABPN/AOBNP. ▪ He/she is board certified or board eligible.
34.01.29 PPS excluded psychiatric units: Medical director responsibilities *The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff.* §412.27(d)(2)(ii)	☐ Compliant ☐ Not Compliant The director is accountable for the oversight of the QAPI program of service provided by the professional staff. The director should ascertain that quality improvement programs are in place to monitor patient care.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the director is knowledgeable of and accountable for the professional staff QAPI program. ▪ Review the job description to determine that quality improvement program is a responsibility of the director, as well as implementation of educational programs for all levels of staff. □ Are there appropriate professional staff available to provide necessary medical and treatment services? □ Does the unit have policies and procedures to direct medical and direct care staff in situations when patients become agitated and aggressive, posing a potential threat to self or others?

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34.01.30 PPS excluded psychiatric units: Nursing services *The unit must have a qualified director of psychiatric nursing services.* *In addition to the director of nursing, there must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide nursing care necessary under each inpatient's active treatment program and to maintain progress notes on each inpatient.* §412.27(d)(3)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that there is a DON for the psychiatric unit.
34.01.31 PPS excluded psychiatric units: Nursing services leadership *The director of psychiatric nursing services must be:* ▪ *a registered nurse who has a master's degree in psychiatric and mental health nursing, or its equivalent, from a school of nursing accredited by the National League for Nursing, or* ▪ *be qualified by education and experience in the care for the mentally ill.* *The director must demonstrate competence:*	☐ Compliant ☐ Not Compliant The facility has established the education, training, and experience requirements for the Director of Psychiatric Nursing position. The duties, functions, and responsibilities of the Director of Psychiatric Nursing are clearly delineated and include the following: ▪ Supervision and evaluation of nursing and paraprofessional staff. ▪ Participation in the formulation of patient treatment plans. ▪ Medication teaching. ▪ Management of therapeutic milieus. ▪ Provision of mandatory and voluntary in-service training of specialized treatments and therapies, such as individual group and family therapies	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the Director of Psychiatric Nursing's personnel file to verify s/he meets the established qualifications. ▪ Education/experience in the care of the mentally ill may be evidenced by either: □ A master's degree in psychiatric/ mental health nursing. □ RN with a related master's, such as psychology or nursing education, with 2 years of psychiatric inpatient

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▪ *to participate in interdisciplinary formulation of individual treatment plans;* ▪ *to give skilled nursing care and therapy; and* ▪ *to direct, monitor, and evaluate the nursing care furnished.* §412.27(d)(3)(i)	that require the expertise of the professional psychiatric nurse.	nursing care. □ BSN, ADN, or diploma in nursing with at least 2 years of psychiatric inpatient nursing care and documented educational programs focused on psychiatric nursing, occurring at sufficient intervals to keep the Director of Psychiatric Nursing current. ▪ Documented clinical consultation/ supervision from a master's prepared psychiatric nurse.
34.01.32 PPS excluded psychiatric units: Staffing *The staffing pattern shall ensure the availability of a registered nurse 24 hours each day.* *There must be adequate numbers of registered nurses, licensed practical nurses, and mental health workers to provide the nursing care necessary under each inpatient's active treatment program.* §412.27(d)(3)(ii)	☐ Compliant ☐ Not Compliant There is at least one RN for each distinct (program) unit in the facility for each shift of operation. "On call" RNs do not constitute coverage. Additional professional and supportive nursing staff is provided to adequately implement the philosophy of care and to meet identified needs of the patient populations.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** □ Verify the availability of at least one RN per shift for the unit. Request calculations regarding planned and actual staffing in raw numbers and full-time equivalencies. □ Determine if nurse staffing is diluted by performance of non-nursing activities such as housekeeping and escort services. □ Determine if the program uses nurses in group facilitation, 1:1 interventions, etc.

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34.01.33 PPS excluded psychiatric units: Psychological services *The unit must provide or have available psychological services to meet the needs of the inpatients.* *The services must be furnished in accordance with acceptable standards of practice, service objectives, and established policies and procedures.* §412.27(d)(4)	☐ Compliant ☐ Not Compliant There may be a psychologist at the facility or the psychologist services may be provided through a contracted agreement.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Identify the number of full-time, part-time, and consulting psychologists. If contractual services are used, determine their availability to provide needed services to patients. ▪ Determine the extent that psychological testing is requested, the response time and the availability of the results. □ Are the patients in need of psychological therapy or testing receiving those services in a timely manner, and with sufficient intensity?
34.01.34 PPS excluded psychiatric units: Social services *There must be a director of social services who monitors and evaluates the quality and appropriateness of social services furnished.* *The services must be furnished in accordance with accepted standards of practice and established policies and*	☐ Compliant ☐ Not Compliant The duties, functions, and responsibilities of the director of social services should be clearly delineated and documented in the facility's policies and procedures. Social work contact with the patient, family, and significant others should occur during, or as soon as possible, after the admission. High-risk case finding should result in significant data being available for early integration into the treatment plan and subsequent social work action as	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that there is a qualified individual named as the Director of Social Services. ▪ Review the job description and qualifications of the director to verify the requirement is met.

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procedures. *Social service staff responsibilities must include, but are not limited to,* ▪ participating in discharge planning. ▪ arranging for follow-up care. ▪ developing mechanisms for exchange of appropriate information with sources outside the hospital. §412.27(d)(5)	indicated. The treatment team for possible inclusion into the patient's treatment plan should consider the anticipated social work role and expected interventions as recommended in the psychosocial assessment. The role of the social worker must reflect psycho-education of patients and families on signs and symptoms of illness to prevent re-hospitalization and improve their disease management skills.	▪ Interview the social worker to determine how services are provided to patients. ▪ Does the director periodically audit the quality of social work services? ▪ Review a selection of medical records to verify that the requirements are met.
34.01.35 PPS excluded psychiatric units: Therapeutic activities *The unit must provide a therapeutic activities program.* §412.27(d)(6)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that there is a therapeutic activities program that provides a variety of activities throughout the week.
34.01.36 PPS excluded psychiatric units: Program scope *The program must be appropriate to the needs and interests of inpatients and be directed toward restoring and maintaining optimal levels of physical and psychosocial functioning.*	☐ Compliant ☐ Not Compliant The program has sufficient resources to provide physical and psychosocial therapeutic activities, to meet the needs of the patient populations. Therapeutic activities are provided within the program schedule on the day and evening shifts each day of the week, including weekends. Activities do not present undue hazard to the therapeutic milieu.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Determine the adequacy of activities in providing safe and meaningful outlets that correlate to the identified needs of the patient population.

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§412.27(d)(6)(i)		▪ Has the unit ensured consistent availability and provision of individualized therapeutic activities and rehabilitative services based on patient's needs?
34.01.37 PPS excluded psychiatric units: Program staffing *The number of qualified therapists, support personnel, and consultants must be adequate to provide comprehensive therapeutic activities consistent with each inpatient's active treatment program.* §412.27(d)(6)(ii)	☐ Compliant ☐ Not Compliant There are adequate numbers of qualified therapists and support personnel to support the physical and psychosocial therapeutic activities to meet the needs of the patient populations. Therapeutic activities are provided within the program schedule on the day and evening shifts each day of the week, including weekends. Activities do not present undue hazard to the therapeutic milieu. Activities may be planned/directed by: ▪ An occupational therapist. ▪ Bachelor of Science (BS) prepared recreational therapist. ▪ A Bachelor of Science (BS) or Bachelor of Arts (BA) prepared music or other related therapist.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Identify the number of full time, part time and consulting therapeutic activity staff. ▪ Identify their roles and responsibilities in accomplishing the philosophy of the program. ▪ Verify the adequacy of activities in providing safe and meaningful outlets that correlate to the identified needs of the patient population. □ Are there clearly defined monitoring and evaluation mechanisms to conduct consistent and timely review of the quality and appropriateness of therapeutic and rehabilitative services?

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34.02.01 Scope and description of available services There is a written program description which includes, but is not limited to: 1. The scope of services provided specific to inpatient, partial day, residential and outpatient and aftercare programs. 2. How these programs relate to each other. 3. Admission criteria, including limitations 4. Assessment/evaluation process 5. Treatment planning processes 6. Therapeutic modalities utilized 7. Provisions for children, adolescent, young adult, adult, geriatric and mentally/developmentally disabled patients. 8. Staffing, including the roles, responsibilities and supervisory relationships of professional staff as part of the treatment team. 9. The quality assessment and improvement program.	☐ Compliant ☐ Not Compliant The plan for the provision of psychiatric care and services is a component of the facility-wide written plan.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the plan for the provision of services. ▪ Verify the plan addresses: □ The required elements. □ The ages of patients and the conditions accepted for service.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
34.02.02 Physical facilities	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The physical facilities for psychiatric patients provide, to the extent possible, an attractive environment. The environment provides for patient privacy for sleeping, bathing, toileting, and other activities of a personal nature without compromising the safety of the therapeutic milieu.	To the extent possible, the dignity of each patient is preserved and enhanced in the physical space provided for psychiatric and/or substance abuse patient care areas. Shatterproof materials are used for windows, fixture covers, mirrors, etc. Showerheads and other fixtures are designed to reduce the potential of patient injury.	**OBSERVATION** ▪ Observe the physical setting for the elements listed. □ Does it promote reasonable privacy and the dignity of the patient population? □ Is a sense of safety and security present?
34.02.03 Patient bedrooms: Safety and security	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
▪ Patient bedrooms have closable doors, door locks and other structural restraints are kept to a minimum. ▪ Doors are constructed to prevent barricading and allow staff to enter patient rooms, baths, toilet, and shower rooms. ▪ Mirrors are as distortion free as possible.	Privacy for sleeping and personal activities is afforded to the extent possible while maintaining access by staff to protect patients who may accidentally or intentionally be involved in harmful behaviors.	**OBSERVATION** ▪ Observe doors in the unit to verify that the staff has access patients. ▪ Determine if the environment has been assessed for potentially hazardous items that could be used for homicidal or suicidal purposes: □ Doors for rooms where patients at high risk for self-harm are housed may be specially fitted (piano hinge or other devices) to reduce risk of suicidal hanging gestures. □ Are barricading possibilities considered and mechanisms to

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		reduce or deal with such behavior in place? □ Are mirrors and light fixtures shatter-resistant? □ Are light fixtures secured from tampering?
34.02.04 Patient hygiene needs ▪ Patients are provided with clean bath and bed linens on a regularly scheduled basis, and as required to meet basic hygienic needs. ▪ Linen inventories are stored in secured closets; reasonable access by patients is provided. ▪ Patients may be encouraged to take responsibility for maintaining their own living quarters including daily housekeeping activities appropriate with their abilities. ▪ Patients shall be oriented to the unit's expectations concerning housekeeping. Access to hazardous cleaning chemicals is minimal and constantly supervised.	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **OBSERVATION** ▪ Observe linen inventories and schedules for issuing same to patients. □ Does staff assist patients who need help in changing bed linen? □ Are "housekeeping" activities promoted as participating in normal activities of daily living behavior?

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34.02.05 Handicapped accessibility The facility shall be barrier-free to permit handicapped individuals to gain access for visiting and therapy. All toilets are equipped with seats, handicapped grab bars, and patient operated call devices without compromising privacy or safety.	☐ Compliant ☐ Not Compliant The facility shall be barrier-free consistent with the current provisions of the Americans with Disabilities Act (ADA).	This standard is not met as evidenced by: **OBSERVATION** ▪ During tour of the unit, verify that the area is barrier-free.
34.02.06 Confidentiality of information There shall be policies and practices to protect clinical data and information, which may be described as "unusually sensitive" for psychiatric patients.	☐ Compliant ☐ Not Compliant The facility has written policies regarding the release of information. Policies address specific components that may require additional patient consent. In filing closed records, the facility may adhere to unit record principles with parallel files; one for psychiatric/substance abuse and another for general medical-surgical records with a file notation that indicates "other file(s) exist and may be accessed by persons with appropriate need, within the health information service area." Upon subsequent readmission to the facility for non-behavioral treatment, the behavioral record is not routinely forwarded, but is made available on a "need to know" basis. If a patient is admitted to the inpatient psychiatric unit from a medical-surgical unit in the hospital, the patient must first be discharged from the acute unit and readmitted to the psychiatric unit.	This standard is not met as evidenced by: **OBSERVATION** ▪ Review policies to verify that the required security and confidentiality of patient information are addressed. ▪ Observe clinical areas for breeches in security and confidentiality of patient information.

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APPENDIX

INSTRUCTIONS FOR THE FACILITY DEMOGRAPHIC REPORT

FOR PROVIDERS. BY PROVIDERS.

ACUTE CARE HOSPITAL CRITICAL ACCESS HOSPITAL

Introduction and Overview

Each healthcare facility is responsible for providing an environment in which to deliver healthcare services that are safe and hazard-free, as much as possible, for patients, staff, and visitors. Management of the physical environment includes, but is not limited to, having an environment that is in compliance with the National Fire Protection Association (NFPA) *101 Life Safety Code*®, 2012 edition, and NFPA 99 *Health Care Facilities Code*, 2012 edition, and these have mandatory references that are considered the applicable codes.

Accreditation Commission for Health Care (ACHC) monitors the organization's management of the physical environment through the use of the Facility Demographic Report (FDR), accreditation requirements, worksheets, and tools designed to provide pertinent and detailed information concerning the facility. While these worksheets and tools are mandatory, they are designed only to assist in assessing the organization's compliance with the applicable codes and do not by themselves represent or demonstrate complete compliance. Only on-site field review and inspection of the facility and supporting documentation can confirm compliance.

Organizations must still perform their own assessments for compliance with the applicable codes, and they may use whatever tools they wish to perform these assessments. Organizations may even choose to contract with Life Safety professionals to perform these assessments. ACHC Surveyors will assess an organization's level of compliance with the applicable codes based on visual inspections and review of pertinent documentation.

The following pages detail information that must be completed and maintained by your organization at your own facility and made available for review by a Surveyor. ACHC will not accept any other accreditation organization's documents to demonstrate compliance with the applicable codes, nor will ACHC accept any previous version of an ACHC document.

The Facility Demographic Report must be updated when there are changes in the facility and reviewed at least annually.

Required Documentation for Life Safety

Facility Demographic Report (FDR)

The Facility Demographic Report documents specific engineering information to be reviewed. It references detailed information about the facility and should be completed by individuals who have a working knowledge of the applicable codes and standards and an understanding of the buildings being evaluated. The FDR should be completed only by individuals who qualify by meeting these requirements.

Complete one FDR form per facility. Each building that is designated a healthcare occupancy or an ambulatory healthcare occupancy is required to have a completed Facility Demographic Report. Free-standing business occupancies are not required to have a Facility Demographic Report completed. If the organization has more than one location, individual forms should be used for each location. Do not use more than one form per facility location. Additions and wings that are contiguous to healthcare facilities should all be included on the same report even if they are separated by fire-rated barriers. Each question or request for information on this report must be completed. Permission is granted for organizations to make as many photocopies of this report as needed to complete the required documentation.

Definitions of occupancy classifications commonly used in healthcare facilities

Healthcare Occupancy

An occupancy used to provide medical or other treatment or care simultaneously to four (4) or more patients on an inpatient basis, where such patients are mostly incapable of self-preservation because of age, because of physical or mental disability, or because of security measures not under the occupants' control.

The healthcare facilities regulated by this occupancy chapter are those that provide sleeping accommodations for their occupants and are occupied by persons who are mostly incapable of self-preservation because of age, because of physical or mental disability, or because of security measures not under the occupants' control. The requirements established by this chapter apply to all hospitals, nursing homes, and limited care facilities.

Examples of Healthcare Occupancies:

- Hospitals
- Psychiatric hospitals
- Specialty hospitals
- Inpatient hospices
- Nursing homes
- Skilled nursing facilities
- Long-term care facilities
- Inpatient substance abuse facilities

Ambulatory Healthcare Occupancy

An occupancy used to provide services or treatment simultaneously to four (4) or more patients that provides, on an outpatient basis, one or more of the following: (1) treatment for patients that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others; (2) anesthesia that renders the patients incapable of taking action for self-preservation under emergency conditions without the assistance of others; (3) emergency or urgent care for patients who, due to the nature of their injury or illness, are incapable of taking action for self-preservation under emergency conditions without the assistance of others.

Examples of Ambulatory Healthcare Occupancies include:

- Physical rehab outpatient centers
- Ambulatory surgery centers
- Freestanding emergency departments
- Diagnostic centers

Business Occupancy

An occupancy used for the transaction of business other than mercantile.

Examples of Business Occupancies include:

- Administrative offices
- Physicians' offices
- Outpatient clinics (ambulatory)
- Support service centers (i.e., maintenance, laundry, sterile processing, etc.)

Identification and Resolution of a *Life Safety Code* Deficiency

Once a *Life Safety Code* deficiency is identified, it must be resolved. If the deficiency cannot be resolved the same day it is discovered, then it must be documented on the organization's work order system and have a documented assessment for Alternative Life Safety Measures (ALSM). During a survey, the organization will need to be able to demonstrate that the organization is aware of the *Life Safety Code* deficiencies and is adequately managing a resolution.

Requesting a *Life Safety Code* Equivalency

ACHC will accept Fire Safety Evaluation System (FSES) equivalency requests for those *Life Safety Code* deficiencies cited on the Survey Report that would represent an unreasonable hardship to resolve. Only FSES equivalency requests that comply with the current approved edition of the National Fire Protection Association 101A *Guide on Alternative Approaches to Life Safety* will be accepted. After a successful review, ACHC will send the equivalency request to the Centers for Medicare & Medicaid Services (CMS) Regional Office for approval.

Life Safety Code Waiver Request

For Life Safety Code deficiencies that cannot be resolved, or equivalized, waivers will be accepted for review at the ACHC offices. While ACHC does not have authority to approve a waiver to a Life Safety Code requirement, ACHC will review the waiver request; clarifying information may be requested. Following the ACHC review, ACHC will forward the waiver request to the Location/CMS office for approval.

Contact your Account Advisor for instructions on how to submit a waiver.

Instructions for Completing the Facility Demographic Report

Note: This Facility Demographic Report must be reviewed and updated annually by the organization.

Enter all information requested, including the date the form was completed.

For the purpose of this document, the name of the facility may be different from the name of the organization. This document is specific to one facility or campus only. Each facility must have its own FDR completed. The Contact Person will be the individual responsible for Life Safety compliance for this facility. This may or may not be the same individual responsible for item 16.

Items 1 through 3

Enter the total square footage of all occupancies in this facility. Break down the total area and identify the amount of ambulatory care occupancy, the amount of business/other occupancy, and the amount of healthcare occupancy. Enter the current number of inpatient beds that the facility is licensed to have, not the number of actual beds. Enter the current number of operating/procedure rooms that the facility is using.

Items 4 through 6

"Construction Type" is a term used by NFPA 220 *Standard on Types of Building Construction* (2012 edition) to identify the fire-resistant rating of structural members of the building. Enter the NFPA Construction Type on line 4. Construction Type will be limited to one of the following designations:

Type I (442)	Type I (332)	Type II (222)	Type II (111)	Type II (000)
Type III (211)	Type III (200)	Type IV (2HH)	Type V (111)	Type V (000)

It is possible there may be more than one Construction Type used in the facility, depending on the date of original construction and subsequent additions. Identify on line 5 if there is more than one Construction Type used in this facility and the locations where they are.

If there are different occupancies in the facility, they may require fire-rated barrier separation. Identify on line 6 if there is more than one occupancy type, what they are, and where they are located.

Items 7 through 10

Identify the year of construction for the original building and the year of construction for any subsequent major additions or renovations. The year of actual occupancy can be used to identify the year of construction. Note: Based on the CMS adoption of the 2012 Life Safety Code, any building constructed prior to July 5, 2016, must comply with the 2012 Life Safety Code Chapter 21 for existing construction; any building constructed after July 6, 2016, must comply with Chapter 20 for new construction. Construction requiring bringing the building up to "new" would be modification, reconstruction, change of use, change of occupancy classification, or addition of square footage as defined in 2012 Life Safety Code Chapter 43.

Enter the number of stories that are designed to be normally occupied in the facility. This would include any stories that are currently vacant but were designed to be occupied. It would exclude any stories at the top of the facility that are designed to be exclusively mechanical rooms and penthouses for equipment. Identify how many stories are located below the level of exit discharge. The level of exit discharge is the floor where more than 50% of the occupants are expected to exit the building in the event of an emergency.

Not all exit stairwells may actually discharge directly outdoors but may discharge to a lobby or corridor that leads outdoors. Identify any stairwells that do not discharge directly to the outdoors.

Items 11 and 12

On line 11, enter information concerning automatic sprinklers in the facility. Identify which areas, if any, are protected with Quick Response sprinklers. If the facility is protected with a fire pump, enter the year that the pump was installed or replaced.

Enter on line 12 the level of smoke detection in your facility. Smoke detectors are not necessarily required in all the places identified on line 11, but if they are present, it should be indicated.

Items 13 and 14

Emergency power generators may be fueled by fuels other than diesel fuel. Identify the fuel your emergency power generators use. Some organizations have generators that do not serve as emergency power supply systems (EPSS). Do not include information for generators that are not considered EPSS.

Identify any trash and/or linen chutes. Include any chutes that are present but not in operation.

Item 15

Doors in the path of egress are not permitted to be locked unless they comply with one of the exceptions permitted by the Life Safety Code. Identify the locations in your facility where doors in the path of egress are locked and which exception is used for these locks: clinical needs; delayed egress; access control; elevator lobby locks; specialized protective measures for patient safety.

Item 16

Identify the individual who has been designated by leadership to be responsible for the completion of this Facility Demographic Report. This may or may not be the same individual identified as the contact person. This item asks for an explanation of the qualifications for this individual. The individual completing this report must be familiar with the NFPA 101 Life Safety Code (2012 edition) and the details of the facility. The organization may choose one of their own staff members to complete this report, or the organization may choose an outside source to do so. The organization needs to document qualifications the individual possesses in order to be responsible for this document.

Item 17

This line requests information regarding approval of any equivalencies or waivers. Such approvals must be identified as to where they apply in the facility. Hard copies of the approvals must be available for Surveyor review. ACHC will accept only equivalencies or waivers approved by CMS.

Item 18

Certain building systems in healthcare facilities must be designed to meet Category 1 through Category 4 requirements as detailed in Chapter 4 of NFPA 99-2012. Each system must be evaluated for its potential impact should the system fail. Based on worst-outcome scenario of a failure's impact, the system is assigned a category. The chapter on that particular building system then describes the requirements for the selected category. The four levels of system categories as defined by Chapter 4 of NFPA 99-2012 are summarized below. Please refer to the code chapter for complete descriptions.

Category 1	Facility systems in which failure of such equipment or system is likely to cause major injury or death of patients or caregivers.
Category 2	Facility systems in which failure of such equipment is likely to cause minor injury to patients or caregivers.
Category 3	Facility systems in which failure of such equipment is not likely to cause injury to patients or caregivers, but can cause patient discomfort,
Category 4	Facility systems in which failure of such equipment would have no impact on patient care.

Therefore, a risk assessment is required for certain building systems, based on a documented defined procedure. ACHC does not prescribe the format for the risk assessment, but NFPA 99-2012 recommends the following documents:

- ISO/IEC 31010 Risk Management – Risk Assessment Techniques
- NFPA 551 Guide for the Evaluation of Fire Risk Assessments
- SEMI S10-0307E Safety Guidelines for Risk Assessment and Risk Evaluation Process
- Other formal process

The results of the risk assessment procedure must be documented, and the records must be reviewed and approved by the organization's Safety Committee. All risk assessments must be available for review during a survey. The following building systems are required to be evaluated for categories in a risk assessment:

- Gas and Vacuum Systems (Chapter 5: Piped Oxygen, Medical Air, Vacuum, WAGD)
- Electrical Systems (Chapter 6: Distribution, Back-up Power, Transfer Switches)
- HVAC (Chapter 9: Heating, Ventilating and Cooling Equipment)
- Electrical Equipment (Chapter 10: Electrical Safety and Inspection process performed by Clinical Engineering/Biomed)

Enter the category designation for each of the building systems listed above based on the organization's documented risk assessment. The hospital must be prepared to show the documented risk assessment upon request during survey.

Item 19

Item 19 is the place to enter any other information that you believe is relevant to overall compliance with the Life Safety Code at this facility. Also, this can be used to explain answers to other questions, if needed.

FACILITY DEMOGRAPHIC REPORT

ACUTE CARE HOSPITAL CRITICAL ACCESS HOSPITAL

Date: _____

Name of Organization: _____

Address: _____

City: _____ State: _____ Zip Code: _____

ACHC ID Number: _____

Contact Person: _____ Title: _____

Telephone Number: _____ Email: _____

1. Total square footage of all occupancies in this facility: _____
    - » Ambulatory Care Occupancy: _____
    - » Business/Other Occupancy: _____
    - » Healthcare Occupancy: _____
2. Number of Inpatient Beds: _____
3. Number of Operating Rooms / Procedure Rooms: _____

4. Identify the Construction Type(s) used in this facility. Select from the list below: _____

Type I (442)	Type I (332)	Type II (222)	Type II (111)	Type II (000)
Type III (211)	Type III (200)	Type IV (2HH)	Type V (111)	Type V (000)

NOTE: A sprinkler system is required for existing and new construction when the building has two or more stories for the following Construction Types (refer to #20): Type II (000), Type III (200), Type V (000).

5. Is there more than one Construction Type in this facility? ☐ Yes ☐ No

   » If YES, are the different Construction Types separated by fire rated barriers? ☐ Yes ☐ No

   » If YES, identify the different Construction types and their locations:

6. Is there more than one type of occupancy in this facility? ☐ Yes ☐ No

   » If YES, are the different occupancies separated by fire rated barriers? ☐ Yes ☐ No

   » If YES, identify the different types and the locations:

   (Be prepared to show the Surveyor the firewall; for example, provide a 16-foot ladder to see above ceilings.)

7. Date of original construction of this facility: _____

8. Date of subsequent additions to this facility: _____

9. Total number of occupied stories in the building: _____

   » Number of building's occupied stories below the level of exit discharge: _____

10. Total number of exit stairwells that do not discharge directly to the outdoors: _____

11. Is the entire facility protected with automatic sprinklers? ☐ Yes ☐ No

    » If NO, what areas are not protected with automatic sprinklers?

    » List all areas, if any that are protected with Quick Response automatic sprinklers:

    » Is the facility equipped with a fire pump? ☐ Yes ☐ No

        ▪ If YES, what year was the fire pump installed or replaced? _____

12. Which level(s) of smoke detection does this facility have? (Check all that apply.)

    ☐ In corridors
    ☐ In operating/procedure rooms
    ☐ Near doors held open by magnets
    ☐ None
    ☐ In Elevator lobbies
    ☐ Near Fire alarm control panels
    ☐ In Areas open to the corridor
    ☐ Other: _____

13. Emergency power generator fueled by (Must choose one):

    ☐ Diesel
    ☐ Natural gas
    ☐ Other
    ☐ None

14. Facility has linen and/or trash chutes (Must choose one): ☐ Yes ☐ Yes, but not in operation ☐ No

15. Identify below the location(s) in the facility where doors in the path of egress are locked or ☐ None:

    » Clinical Needs Locks: _____

    » Delayed Egress Locks: _____

- Access-Control Locks: _____
- Elevator Lobby Locks: _____
- Specialized Protective Measure Locks: _____

16. Who has been designated by leadership to be responsible for the completion of the Facility Demographic Report (FDR) form?

- Name: _____
- Title: _____
- Organization: _____
- Telephone: _____ Email: _____
- What skills and knowledge does this person possess that qualifies the person to complete the FDR?:

17. Does the facility have any approved equivalencies or approved waivers concerning any Life Safety Code deficiencies?

☐ Yes ☐ No

- If YES, identify what the equivalency and/or waiver is for, and the location where it applies:

18. Based on a documented Risk Assessment conducted by the organization, please identify which NFPA 99-2012 Building System Category has been determined for the respective building services:

Gas and Vacuum Systems:	☐ Category 1	☐ Category 2	☐ Category 3	☐ Category 4
Electrical Systems:	☐ Category 1	☐ Category 2	☐ Category 3	☐ Category 4
HVAC:	☐ Has the organization performed a risk assessment on HVAC equipment and systems related to Chapter 9?			
Electrical Equipment:	☐ Has the organization performed a risk assessment on electrical equipment related to Chapter 10?			

19. Please include any other information that is relevant to the Physical Environment: