2025 EDITION

ACHC®

ACCREDITATION REQUIREMENTS FOR CRITICAL ACCESS HOSPITALS

ACCREDITATION COMMISSION *for* HEALTH CARE

ACHC offers programs for acute care and community-based healthcare providers and suppliers.

Accreditation

Acute Care Hospital[1]
Ambulatory Care[2]
Ambulatory Surgery Center[1]
Assisted Living[2]
Behavioral Health[2]
Clinical Laboratory[1]
Critical Access Hospital[1]
Dentistry
DMEPOS[1]
Home Care[2]
Home Health[1,2]
Home Infusion Therapy[1]
Hospice[1,2]
Office-Based Surgery
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
achc.org
customerservice@achc.org

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 hospitals that meet the criteria for designation as Critical Access Hospitals. The intent of the standards is to help the individual organization and, when applicable, an affiliated group of organizations, maximize the potential to improve outcomes for specific patient populations. We recognize that CAHs 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 establish policies at the corporate level. In contrast, a smaller facility may employ a committee of the whole to create individual policies. Either approach can be fully compliant; our goal is to confirm that required policies are relevant to the CAH, and that patient care and related operational practices follows these as defined.

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

Account Advisors

Each organization 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 organization'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 your hospital's ability to render care 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 1–19 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."

Table of Contents

Table of Contents

01

COMPLIANCE WITH REGULATIONS

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.00.00 CONDITION OF PARTICIPATION: Compliance with federal, state, and local laws and regulations	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH and its staff are in compliancewith applicable Federal, State, and local laws and regulations. §485.608 Tag C-0810	Failure of the CAH to meet a federal, state, or local law may only be cited when the federal, state, or local authority having jurisdiction has made both a determination of noncompliance and has taken a final adverse action as a result. Surveyors will refer or report suspected violations to the appropriate federal, state, or local agency.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Verify whether a federal, state, or local authority has made a determination of noncompliance and has taken a final adverse action. If yes, cite this CoP.
01.00.01 Compliance with federal laws and regulations	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients. §485.608(a) Tag C-0812	Each CAH must be in compliance with applicable federal laws and regulations related to the health and safety of patients. This includes other Medicare regulations and federal laws and regulations not specifically addressed in the CoPs. Specific requirements that ACHC will examine during a survey are identified below. **ADVANCE DIRECTIVES** An advance directive is defined at §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." In accordance with the provisions of §489.102(a), the advance directives regulations apply to CAHs. The CAH patient (inpatient or outpatient) has the right to formulate advance directives, and to have CAH staff implement and comply with the individual's advance directive. The regulation at §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	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** **A. Assessing compliance with Advance Directives Requirements** ▪ Review the advance directive notice. Does it advise inpatients or applicable outpatients, or their representatives, of the patient's right to formulate an advance directive and to have CAH staff comply with the advance directive (in accordance with state law)? □ Does it include a clear, precise, and valid statement of limitation if the CAH cannot implement an advance directive on the basis of conscience? ▪ Review the records of a sample of patients for evidence of CAH compliance with advance directive

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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 specified in §485.614(h), for the purpose 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 CAH must, when presented with the document, provide the designated individual the information required to make informed decisions about the patient's care. The CAH 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, outpatientvisit, unless the patient ceases to be incapacitated and expressly withdraws the designation, either orally or in writing.

§489.102 also requires the CAH to:

- Provide written notice of policies regarding 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 CAH may provide the advance directive information required under §489.100 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 person in accordance with state law." (§489.102(e))
- §489.102(b)(1) requires that notice of the advance directive policy be provided at the time an individual is admitted as an inpatient. However, the CAH should also consider providing the advance directive notice to

notice requirements.

  - □ Does every inpatient or applicable outpatient record contain documentation that notice of the CAH's advance directives policy was provided at the time of admission or registration?
  - □ Is there documentation of whether or not each patient has an advance directive?
  - □ For those patients who have reported an advance directive, has a copy of the patient's advance directive been placed in the medical record?
- What mechanism is in place to allow patients to formulate an advance directive or to update their current advance directive? Is there evidence that the CAH is promoting and protecting each patient's right to formulate an advance directive?
- Determine to what extent the CAH complies, as permitted under state law, with patient advance directives that delegate decisions about the patient's care to a designated individual.
- Determine to what extent the CAH educates its staff regarding advance directives.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

outpatients (or their representatives) at the time of registration in the emergency department, in an observation status, or for same-day surgery.

- □ The notice must include a clear and precise statement of limitation if the CAH 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.

The 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 CAH or an 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.

Issuance of the written notice of the CAH'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.
- The provision of care may not be conditioned on or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive.
- Assure 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.
- Interview staff to determine their knowledge of the advance directives of the patients in their care.
- Determine to what extent the CAH provides education for the patient population regarding one's rights under state law to formulate advance directives.

B. Assessing Required Disclosures

Physician Ownership

- Ask whether the CAH is physician-owned. (Surveyors are not required to make a determination regarding whether a CAH meets the Medicare definition of "physician owned.")
- If the CAH indicates that it is physician-owned but is exempt under §489.20(v) from the disclosure requirement of §489.20(u)(2), ask to see 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. Note: As with any other on-the-spot correction of a deficiency during a survey, creation of an attestation at the time of a survey does not mean that there was no deficiency, and that the CAH would not be cited.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Provide for the education of staff concerning its policies and procedures on advance directives. The right to formulate advance directives includes the right to formulate a psychiatric advance directive (as allowed by state law).
- Provide community education regarding advance directives and the CAH must document its efforts.

PSYCHIATRIC ADVANCE DIRECTIVE

This type of 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. 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 to be 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 CAH, 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 should be accorded the same respect and consideration given to a traditional advance directive for health care. CAHs 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.

Psychiatric advance directives should be considered even if state law has not explicitly addressed their use. When a patient is, for any reason, unable to communicate his/her wishes, the preferences expressed in the psychiatric advance directive can give critical insight as the CAH's professional staff develops a plan of care and treatment for the patient.

- If the CAH is physician-owned but not exempt from the physician-owned disclosure requirements:
  - □ Verify that appropriate policies and procedures are in place to assure that written notices are provided to all patients at the beginning of an inpatient or outpatient stay.
  - □ Review the notice issued to each patient. Confirm that it discloses that a list of owners and investors who are physicians or immediate family members of physicians is available upon request, and that such list is provided at the time the request is made by or on behalf of the patient.
  - □ Determine whether the physician-owned CAH's medical staff membership and admitting privileging requirements include a requirement that physician owners who refer patients to the CAH agree to provide written disclosure of their own or any immediate family member's ownership or investment interest to all patients at time of the referral.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

REQUIRED CAH DISCLOSURES TO PATIENTS

Physician Ownership

- §489.3 defines a "physician-owned hospital" as any participating hospital, including a CAH, in which a physician or immediate family member of a physician (as defined in §411.351) has an ownership or investment interest, except for those satisfying an exception found at §411.356(a) or (b). Surveyors are not required to make an independent determination regarding whether a CAH meets the Medicare definition of "physician-owned," but they must ask whether the CAH is physician-owned.
- §489.20(u)(2) provides that physician-owned CAHs must require each physician owner who is a member of the hospital's medical staff to agree, as a condition of obtaining/retaining CAH medical staff membership or admitting privileges, to disclose in writing, their ownership or investment interest or that of any immediate family member, to all patients they refer to the CAH. This disclosure is 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 notice requirement does not apply to any physician-owned CAH that does not have at least one referring physician (as defined at §411.351 of this chapter) who has an ownership or investment interest in the CAH or who has an immediate family member who has an ownership or investment interest in the CAH. In such cases, the CAH 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 CAH. The CAH must maintain this attestation in its records.
  - □ The CAH may exempt from this disclosure requirement any physician owner who does not refer any patients to the CAH.
- §489.20(u)(1) requires that all physician-owned CAHs provide written notice to their patients at the beginning of each patient's inpatient stay or outpatient visit stating that the CAH is physician-owned, in order to assist

MD/DO 24/7 Onsite Presence

- Determine whether an MD/DO is present in the CAH 24 hours per day, 7 days per week.For each required location where an MD/DO is not present:
  - □ Verify that policies and procedures require written notice at the beginning of a planned or unplanned inpatient stay or outpatient visit to all inpatients and to all outpatients receiving observation services, surgery, or another procedure requiring anesthesia that a physician is not present at all times that a physician is not present at all times.
  - □ Verify that there is a signed acknowledgement of such disclosure by the patient, obtained 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 CAH.
  - □ Verify that the CAH's emergency department has signage with the appropriate disclosure information.
  - □ Review the notice the CAH issues to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

the patient in making an informed decision about his or her care.

- □ 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 CAH 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 CAH.

- §489.12 permits CMS to refuse to enter into a provider agreement with a physician-owned CAH applicant that does not have procedures in place to notify patients of physician ownership in the hospital, as required under §483.20(u).
  - □ §489.53(c) permits CMS to terminate the provider agreement of a physician-owned CAH if the CAH fails to comply with the requirements at §489.20(u).

Content of the Notice

- The notice must disclose, in a manner reasonably designed to be understood by all patients, that the CAH is physician-owned and that a list of owners or investors who are physicians or immediate family members of physicians is available upon request. If the patient (or someone on behalf of the patient) requests this list, the CAH must provide it at the time of the request.

MD/DO 24/7 Onsite Presence

- §489.20(w) mandates that that if there is no physician present in the CAH 24 hours per day, seven days per week, the CAH must provide written notice to all inpatients at the beginning of a planned or unplanned inpatient stay, and to outpatients for certain types of outpatient visits. The purpose of the requirement is to assist the patient in making an informed decision about his/her care. CAHs that have an MD/DO (including residents who are MDs or DOs) on-site 24/7 do not need to issue any disclosure notice about emergency services capability.

verify that it indicates how it will meet the medical needs of any patient who develops an emergency medical condition at a time when no physician is present at that CAH, including any remote location.

C. Other Federal Requirements

- Refer suspected noncompliance with federal laws and regulations to the appropriate agency having jurisdiction (e.g., hazardous chemical and waste issues to EPA, blood-borne pathogens, and TB control to OSHA, etc.)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- ☐ 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 applicable outpatient visit.
- ☐ A planned inpatient stay or outpatient visit subject to the notice requirement begins with the provision of a package of information regarding scheduled preadmission testing and registration for a planned CAH 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 CAH.
- ☐ Individual notices are not required in the CAH's dedicated emergency department (DED) (as that term is defined in §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 department. The posted notice must state that the CAH does not have a physician (MD or DO) present in the hospital 24 hours per day, 7 days per week, and must indicate how the CAH will meet the medical needs of any patient with an emergency medical condition, as defined in §489.24(b) [the EMTALA definition], at a time when there is no MD or DO present. If the medical needs of an emergency department patient require admission, then the individual notice provisions of §489.20(w) would apply to that patient.
- ☐ Before admitting an inpatient or providing outpatient services requiring notice, the CAH must obtain a signed acknowledgement from the patient stating that he/she understands that a physician may not be present during all hours that services are furnished to him/her.
- ☐ In the event of an unplanned surgery or inpatient admission to treat an emergency medical condition, it may 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

circumstances the CAH must provide notice and obtain acknowledgement as soon as possible after the patient's stay or visit begins.

- □ For a Medicare-participating CAH with multiple campuses for inpatient services (e.g., a main provider campus and a separate remote location for a psychiatric or rehabilitation distinct part unit (DPU) under one CMS Certification Number), a separate determination is made for each campus/location as to whether the disclosure notice is required.

  For example, if a CAH has a main campus with 25 inpatient beds and a remote location with 10 psychiatric DPU beds and 10 rehabilitation DPU beds, and a physician is present 24/7 on the main campus, but not at the DPU remote location, the CAH is required to provide the disclosure notice at the DPU location. No notice is required for patients coming to the main provider campus. In this same example, if the CAH also has a provider-based, off-campus ambulatory surgery department, no notice is required at that off-campus surgery site, since the CAH's main campus does have an MD/DO present 24/7.

- □ §489.53(c) permits CMS to terminate a provider agreement with a CAH if the CAH fails to comply with the requirements at §489.20(w) whenit does not have an MD or DO on-site 24/7.

OTHER FEDERAL REQUIREMENTS

Other federal requirements apply to patient health and safety in the CAH. For example, federal laws and regulations govern both the disposal of medical waste and occupational health. Surveyors assess compliance with CMS regulations and ACHC standards. A surveyor who suspects a CAH may not be in compliance with other federal requirements may refer the matter to the appropriate federal agency.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.00.02 Compliance with state and local laws and regulations *All patient care services are furnished in accordance with applicable State and local laws and regulations.* §485.608(b) Tag C-0814	☐ Compliant ☐ Not Compliant State practice acts vary widely relative to the extent to which MD/DOs may delegate responsibilities to nurse practitioners, clinical nurse specialists, and physician assistants. Some states have updated their practice acts to include definitions and specific references to permitted/prohibited activities, supervision/guidance required by a MD/DO, and local situations in which nurse practitioners, clinical nurse specialists, and physician assistants may function.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Prior to the onsite survey, determine what professional specialists provide patient care services at the CAH and review state practice act requirements.
01.00.03 Licensure of the CAH *The CAH is licensed in accordance with applicable Federal, State, and local laws and regulations.* §485.608(c) Tag C-0816	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Prior to the onsite survey, determine whether the CAH is subject to licensure requirements and if so, verify that the CAH is licensed.
01.00.04 Licensure, certification, or registration of personnel *Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.* §485.608(d) Tag C-0818	☐ Compliant ☐ Not Compliant The CAH must ensure that 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 could include nurses, MD/DOs, physician assistants, dietitians, x-ray technologists, dentists, physical therapists, occupational therapists, respiratory technicians, and facility administrators. All CAH staff must meet all applicable standards required by state or local law. This would include at a minimum:	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Policies regarding personnel certification, licensure, and registration are compliant with state and local laws. □ For those personnel required to be licensed by the state, the CAH has established and follows procedures

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Certification requirements. ▪ Minimum qualifications. ▪ Training/education requirements.	for that they are properly licensed. ▪ Procedures in place to guarantee licensure of employees working at the CAH under contract or agreement. ▪ Personnel files confirm that information is up to date. □ Verify that all required categories of staff and personnel (direct care, administrative, supervisory – including contract staff) are licensed in accordance with state requirements.
01.01.00 CONDITION OF PARTICIPATION: Status and location A critical access hospital must comply with all of the Medicare Conditions of Participation (CoP), including the status and location requirements at the time of the initial survey and on an ongoing basis. §485.610 Tag C-0822	☐ Compliant ☐ Not Compliant ▪ The CAH must meet the location requirements of §485.610(b) and §485.610(c) at the time of the initial survey. ▪ If the CAH moves to another location, the status and location must be reassessed. ▪ Compliance with location requirements must be reconfirmed at the time of every subsequent recertification (including the recertification of a deemed status CAH whose accreditation has been renewed). ▪ If the CAH moves, its eligibility for continued CAH status must be reassessed in accordance with §485.610(b) and (c). ▪ If a CAH that has been certified on the basis of having been designated by the state as a necessary provider moves, its eligibility for continued CAH status must be reassessed in accordance with §485.610(b) and §485.610(d).	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Assess compliance based on standards 01.01.01 through 01.01.06.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.01.01 Status *The facility is-* 1. *A currently participating hospital that meets all conditions of participation set forth* in subpart F of §485.610*;* 2. *A recently closed facility, provided that the facility–* *i. Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and* *ii. Meets the criteria for designation under subpart* F of §485.610 *as of the effective date of its designation; OR* 3. *A health clinic or a health center (as defined by the State) that--* *i. Is licensed by the State as a health clinic or a health center;* ii. *Was a hospital that was downsized to a health clinic or a health center; AND* *iii. As of the effective date of its designation, meets the criteria fora health clinic or health center designation set forth in* subpart F of §485.610*.* §485.610(a)(1-3)(i-iii) Tag C-0824	☐ Compliant ☐ Not Compliant ACHC will review the basic status requirements prior to scheduling the survey. The appropriate regional office will re-verify the status requirement prior to approving a CAH for Medicare certification.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review the Critical Access Hospital designation document from CMS. ▪ Initial Survey: Verify the facility is a Medicare participating hospital. ▪ Reaccreditation Survey: Verify the facility has current CMS designation as a critical access hospital.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.01.02 Location in a rural area or treatment as rural *The CAH meets the requirements of either* §485.610*(b)(1) or (b)(2) or the requirements of* §485.610*(b)(3),(b)(4), or (b)(5).* 1. *The CAH meets the following requirements:* i. *The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under §412.64(b), excluding* §485.610*(b)(3);* ii. *The CAH has not been classified as an urban hospital for purposesof the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under §412.230(e)and is not among a group of hospitals that have been redesignated to an adjacent urban area under §412.232.* 2. *The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with §412.103.*	☐ Compliant ☐ Not Compliant ☐ N/A Among other requirements, pursuant to §485.610(b), all CAH applicants and existing CAHs, including necessary provider CAHs, must be either: ▪ located in a rural area **or** ▪ treated as rural in accordance with §412.103. in order to be eligible for CAH designation and certification. (The temporary provisions at §485.610(b)(3) and (4) have expired and no longer apply.) **Note:** Only the CMS Location (Regional Office) makes the determination whether a CAH applicant or existing CAH meets the rural location requirement. However, State Survey Agencies (SA) may wish to make informal assessments prior to conducting a survey, following the guidance provided in Section 2256A of the SOM.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Prior to scheduling the survey that the CAH meets the basic location requirement. The appropriate regional office will re-verify the location requirement prior to approving a CAH for Medicare certification. ▪ The CAH designation document from the Centers for Medicare and Medicaid Services (CMS). ▪ The CAH's rural status, following the procedures in Section 2256A of the SOM. If it appears the CAH no longer has rural status, ACHC will confer with the CMS Location prior to scheduling the initial or reaccreditation survey with deemed status.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

3. *Effective for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements §485.610(b)(1) or (b)(2) and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as partof such a Metropolitan Statistical Areaas a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on June 3, 2003.*
4. *Effective for October 1, 2009 through September 30, 2011, the CAH does notmeet the location requirements in either §485.610 (b)(1) or (b)(2) and is located in a county that, in FY 2009, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but, as of FY 2010, was included as part of such a Metropolitan Statistical Area as a result of the most recent census data and implementation of the new Metropolitan Statistical Area definitions announced by the Office of Management and Budget on November 20, 2008.*

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
5. *Effective on or after October 1, 2014, for a period of 2 years beginning with the effective date of the most recent Office of Management and Budget (OMB) standards for delineating statistical areas adopted by CMS, the CAH no longer meets the location requirements in either §485.610(b)(1) or (b)(2) and is located in a county that, prior to the most recent OMB standards for delineating statistical areas adopted by CMS and the most recent Census Bureau data, was located in a rural area as definedby OMB, but under the most recent OMB standards for delineating statistical areas adopted by CMS andthe most recent Census Bureau data, is located in an urban area* §485.610(b)(1-5) Tag C-0826		
01.01.03 Location relative to other facilities or necessary provider certification 1. *The CAH is located more than a 35-mile drive on primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State asbeing a necessary provider of health*	☐ Compliant ☐ Not Compliant ☐ N/A A CAH that has not been designated by a state as a necessary provider prior to December 31, 2005, must be located more than a 35-mile drive on primary roads (as defined by the standard) or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive from any other CAH or hospital. An exception is made for Indian Health Service (IHS) or tribal CAHs and hospitals that are located less than the 35 or 15 miles from another hospital or CAH.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify the facility's CAH designation letter from CMS.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

care services to residents in the area.

A CAH that is designated as a necessary provider on or before December 31, 2005,will maintain its necessary provider designation after January 1, 2006.

2. *Primary roads of travel for determining the driving distance of a CAH and its proximity to other providers is defined as:*
   i. *A numbered Federal highway, including interstates, intrastates, expressways, or any other numbered Federal highway with 2 or more lanes each way; or*
   ii. *A numbered State highway with 2 or more lanes each way.*

§485.610(c)(1-2) Tag C-0830

When an IHS or tribal hospital applies for certification to participate in Medicare as a CAH, CMS will consider only its proximity to other IHS and tribal CAHs and hospitals in determining whether it meets the location requirement under section 485.610(c).

If a CAH is located on an island and the location meets the following characteristics, the CAH is in compliance with the distance requirements relative to other hospitals and CAH under §485.610(c):

- The island is entirely surrounded by water.
- The CAH is the only hospital on the island.
- The island is not accessible by any roads.

CAHs located on islands that meet the criteria above are still required to comply with the rural location requirement under §485.610(b).

"NECESSARY PROVIDER CAH" PRIOR TO JANUARY 1, 2006

A CAH that can document that it was designated by the state as a necessary provider CAH prior to January 1, 2006, does not have to meet the location relative to other facilities standard at §485.610(c).

As of January 1, 2006, states do not have the authority to designate any new necessary provider CAHs.

Necessary provider CAHs that were designated prior to that date are grandfathered by statute, subject to certain conditions if they relocate (see the discussion related to §485.610(d)).

ACHC should have the documentation related to a CAH's original designation as a necessary provider on file. If we do not, the CAH will be asked to supply copies of the original necessary provider designation documents.

NEW CAH PROVIDER AGREEMENT

For applicants seeking a new CAH provider agreement, or for a CAH seeking to relocate that does not have a grandfathered necessary provider designation, the CMS Location will review the application and determine

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	whether it satisfies the CAH location relative to other facilities standard at §485.610(c), using the guidance found in the State Operations Manual, Chapter 2, §2256A. **Note:** At the conclusion of its review, the CMS Location will notify the state agency (SA) of its determination. Existing CAHs that are not grandfathered necessary provider CAHs must be periodically evaluated to determine whether there are any more recently certified Medicare-participating hospitals that are not more than a 35-mile drive, or 15-mile drive, as applicable, from the CAH. If an existing CAH that is not a grandfathered necessary provider no longer meets the minimum distance requirement, it is provided the opportunity to avoid termination of its provider agreement by converting to a certified Medicare hospital after demonstrating compliance with the hospital CoPs.	
01.01.04 <u>Relocation of CAHs with a Necessary Provider designation</u> *A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement §485.610(c) based on the necessary provider designation only ifthe relocated facility meets the requirements as specified in §485.610(d)(1).* 1. *If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of §485.610(c) based on*	☐ Compliant ☐ Not Compliant ☐ N/A Renovation or expansion of a CAH's existing building or addition of building(s) on the existing main campus of the CAH is not considered a relocation. ▪ All newly constructed, Necessary Provider CAH facilities, including entirely new replacement facilities constructed on the same site as the existing CAH main campus, <u>are</u> considered relocated facilities. **Note:** The determination of whether or not a CAH with a necessary provider designation has met the requirements at §485.610(d) will be made by the CMS Location, generally prior to an SA or accreditation survey. The Location will use the evaluation criteria set forth in the SOM, Chapter 2, §2256F to make this determination. At the conclusion of its review, the Location will notify the SA of its results.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Verify whether or not the facility has been relocated since its last survey. If yes, score according to requirements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

the necessary provider designation only if the CAH in its new location—

i. Serves at least 75 percent of the same service area that it served prior to its relocation;

ii. Provides at least 75 percent of the same services that it providedprior to the relocation; and

iii. Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff atthe original location.

2. If a CAH that has been designated asa necessary provider by the State begins providing services at another location after January 1, 2006 and does not meet the requirements §485.610(d)(1), the action will be considered a cessation of business asdescribed in §489.52(b)(3).

§485.610(d)(1-2) Tag C-0832

01.01.05 Off-campus and co-location requirements for CAHs

☐ Compliant ☐ Not Compliant ☐ N/A

This standard is not met as evidenced by:

A CAH may continue to meet the location requirements §485.610(c) only if theCAH meets the following:

- *If a CAH with a necessary provider designation is co-located (that is, it shares a campus, as defined in*

A CAH may not be co-located with another hospital or CAH, because this would violate the minimum distance requirement found at §485.610(c).

- Some CAHs that were designated as necessary providers prior to January 1, 2006, and therefore exempted from this distance requirement, also chose to co-locate with another hospital.

INTERVIEW AND DOCUMENT REVIEW

- Verify through interview and document review whether the facility is grandfathered regarding co-location with another provider (agreement must

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

§413.65(a)(2) with another hospital or CAH), the necessary provider CAH can continue to meet the location requirement §485.610(c) only ifthe co-location arrangement was in effect before January 1, 2008, and thetype and scope of services offered by the facility co-located with the necessary provider CAH do not change. A change of ownership of anyof the facilities with a co-location arrangement that was in effect beforeJanuary 1, 2008, will not be considered a new co-location arrangement.

- *If either a CAH or a CAH that has been designated as a necessary provider by the State does not meet the requirements in §485.610 (e)(1), by co-locating with another hospital or CAH on or after January 1, 2008, or creates or acquires an off-campus provider-based location or off-campusdistinct part unit on or after January 1, 2008, that does not meet the requirements in §485.610 (e)(2),the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3), unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.*

§485.610(e)(1) Tag C-0834

- Co-location occurs when a necessary provider CAH shares the same campus and/or building in which the CAH is currently located with another hospital or necessary provider CAH. For example, a necessary provider CAH shares the same campus with an unrelated psychiatric or rehabilitation hospital.

Effective January 1, 2008, grandfathered necessary provider CAHs may no longer enter into co-location arrangements with another CAH or hospital.

- Necessary provider CAHs that had co-location arrangements in effect prior to January 1, 2008, are permitted to continue these arrangements as long as the type and scope of services offered by the facility co-located with the CAHs do not change.
  - An example of a change in type of services would be when a hospital that provides only rehabilitation services chooses to provide general hospital acute care services.
  - An example of a change in scope of services would be when a grandfathered necessary provider CAH is currently co-located with a 20-bed psychiatric hospital and the psychiatric hospital now decides to increase the number of beds to 30.

The determination of whether or not CAHs with a grandfathered necessary provider designation has met the requirements at §485.610(e)(1) is made by the CMS Location.

- If ACHC becomes aware of a co-location arrangement, ACHC must notify the Location. CMS will use the co-location guidance in §2256G of the SOM to determine if the CAH satisfies the co-location requirements at §485.610(e)(1). The Location will notify the CAH as well as the SA and ACHC, of its determination.

A CAH found out of compliance with the requirements is subject to termination of its Medicare provider agreement under §489.53(a)(3). In such cases the CAH is placed on a 90-day termination track, as outlined in §3012 of the SOM. If the CAH corrects the situation by terminating the co-location

be in place prior to January 1, 2008).

- Verify whether the type or scope of services of the facility co-located at the CAH site has changed since the last survey. If yes, notify the CMS Location for a determination of compliance.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.610(e)(3)	arrangement that led to the non-compliance during this 90-day period, then the provider agreement is not terminated. A facility facing termination of its CAH designation as a result of non-compliance with §485.610(e)(1) could also continue to participate in Medicare by converting to a hospital, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions at §482. Under this scenario, the CAH would apply to convert back to a hospital, with the effective date coinciding with the dateof termination of CAH status. A new CMS Certification Number (CCN) would be assigned accordingly.	
01.01.06 Off-campus and co-location requirements for CAHs (continued) *A CAH may continue to meet the location requirements §485.610(c) only if the CAH meets the following:* ▪ *If a CAH or a necessary provider CAH operates an off-campus provider-based location, excluding an RHC as defined in §405.2401(b) of thischapter, but including a department or remote location, as defined in §413.65(a)(2), or an off-campus distinct part psychiatric or rehabilitation unit, as defined in §485.647, that was created or acquired by the CAH on or after January 1, 2008, the CAH can continue to meet the location requirement §485.610(c) only if the off-campus provider-based location or off-campus distinct part unit is located more than*	☐ Compliant ☐ Not Compliant ☐ N/A §485.610(e)(2) requires that if a CAH operates an off-campus provider-based facility as defined in §413.65(a)(2) (except for a rural health clinic (RHC)) or off-campus rehabilitation or psychiatric distinct part unit as defined at §485.647, that was created or acquired on or after January 1, 2008,then the off-campus facility must meet the requirement at §485.610(c) to be more than a 35 mile drive (or 15 miles in the case of mountainous terrain or an area with only secondary roads) from any other CAH or hospital. ▪ Off-campus CAH facilities that were in existence prior to January 1, 2008, are not subject to this requirement. ▪ If a non-IHS or non-tribal CAH operates an off-campus provider-based facility, its proximity to an IHS or tribal CAH or hospital is not considered when assessing compliance with the requirements of this section. ▪ Similarly, if an IHS or tribal CAH operates an off-campus provider-based facility, its proximity to a non-IHS or non-Tribal CAH or hospital is not considered when assessing compliance. **CALCULATE DISTANCE** The drive to another hospital or CAH is calculated from the provider-based	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Verify the types and locations of off-campus locations. Identify when the sites were acquired. Those acquired after January 1, 2008, must meet the distance requirements specified in the standard unless it is not eligible for provider-based status as indicated in the “Required Elements/Additional Information” for this standard.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

a 35 mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15 mile drive) from a hospital or another CAH.

- *If either a CAH or a CAH that has been designated as a necessary provider by the State [does not meet the requirements in §485.610(e)(1), by co-locating with another hospital or CAH on or after January 1, 2008, or creates or acquires an off-campus provider-based location or off-campusdistinct part unit on or after January 1, 2008, that does not meet the requirements in §485.610(e)(2), the CAH's provider agreement will be subject to termination in accordance with the provisions of §489.53(a)(3), unless the CAH terminates the off-campus arrangement or the co-location arrangement, or both.*

§485.610(e)(2)
§485.610(e)(3)

Tag C-0836

facility's location to the main campus of the other hospital or CAH.

The distance requirement does not apply to the following types of facilities/services, because such facilities or services are not eligible for provider-based status in accordance with §413.65(a)(1)(ii):

- Ambulatory surgical centers (ASC).
- Comprehensive outpatient rehabilitation facilities (CORF).
- Home health agencies (HHA).
- Skilled nursing facilities (SNF).
- Hospices.
- Independent diagnostic testing facilities furnishing only services paid under a fee schedule, such as facilities that furnish only screening mammography services, facilities that furnish only clinical diagnostic laboratory testing, or facilities that furnish only some combination of theseservices.
- ESRD facilities.
- Departments of providers that perform functions necessary for the successful operation of the CAH, but for which separate CAH payment maynot be claimed under Medicare or Medicaid, e.g., laundry, or medical records department.
- Ambulance services.

FEDERALLY QUALIFIED HEALTH CENTERS (FQHC)

FQHCs that were in operation prior to April 7, 2000, are permitted to retain their status as are facilities that participate as FQHC by virtue of being tribally-owned or operated are eligible for provider-based status.

New FQHCs that meet the Health Resources and Services Administration (HRSA) requirements for separate FQHC governance would not meet the provider-based governance requirements for a CAH.

A CAH seeking a provider-based determination for newly created or acquired provider-based departments, remote locations, and/or psychiatric or

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

rehabilitation units located off-campus must submit an attestation to the CMS Location (Regional Office), as specified in §2254H of the SOM, for a determination of whether it satisfies the CAH provider-based criteria at §485.610(e)(2), andthe provider-based rules at §413.65. At the conclusion of its review, CMS will notify the CAH, the SA, and ACHC, of its determination.

If the SA or ACHC becomes aware of a provider-based off-campus facility that appears not to comply with the provider-based location requirements, the SA or ACHC must notify the CMS Location. CMS will determine if the CAH satisfies the provider-based location requirements and will notify the CAH as well as the SA and ACHC of its determination.

TERMINATION

A CAH found out of compliance with the off-campus location requirements is subject to termination of its Medicare provider agreement. In such cases the CAH is placed on a 90-day termination track, as outlined in §3012 of the SOM. If the CAH corrects the situation during this 90-day period, by terminating the off-campus provider-based arrangement, then the provider agreement is not terminated.

A facility facing termination of its CAH status as a result of non-compliance with §485.610(e)(2) could also continue to participate in Medicare by converting to a hospital, assuming that the facility satisfies all requirements for participation as a hospital in the Medicare program under the provisions at §482.

Under this scenario, the CAH would apply to convert back to a hospital, with the effective date coinciding with the date of termination of CAH status. A new CCN number would be assigned.

01.01.07 For future use

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.02.00 CONDITION OF PARTICIPATION: Compliance with CAH requirements at time of application *Except for recently closed facilities as described in §485.610(a)(2), or health clinics or health centers as described in §485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicareprogram as a hospital at the time the hospital applies for designation as a CAH.* §485.612 Tag C-0840	☐ Compliant ☐ Not Compliant ☐ N/A = Not an Initial Survey This COP only applies to Initial Surveys. All facilities that apply to become a CAH are surveyed using the CAH CoP (Condition of Participation) to determine compliance, whether they are: ▪ Currently operational as a CAH. ▪ A re-opened CAH. ▪ A CAH that downsized to become a clinic. **NEW PROVIDER INITIAL SURVEY** If a facility has never been a Medicare-participating hospital and wishes to be a CAH, the facility is a new provider to Medicare and must first meet the requirements for certification as a hospital and submit a change of status request to be a CAH. In these cases, the facility must be surveyed twice. 1. The Initial Survey uses the acute care hospital CoP. 2. When the change request is received, additional survey uses the CAH CoP.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ If this is an Initial Survey, score accordingly. Otherwise, score N/A.
01.03.00 CONDITION OF PARTICIPATION: Agreements §485.616 Tag C-086O §485.610(e)(3)	☐ Compliant ☐ Not Compliant ☐ N/A This CoP is scored based on the scoring in standards 01.03.01 through 01.03.06, if applicable.	This standard is not met as evidenced by: ▪ Review scoring of standards 01.03.01 through 01.03.06 to assess compliance.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.03.01 CONDITION OF PARTICIPATION: Rural Health Network *A rural health network is an organization that meets the following specifications:* *It includes—* *1. At least one hospital that the State has designated or plans to designate as a CAH* *AND* *2. At least one hospital that furnishes acute care services.* §485.603(a)(1-2) Tag C-0802	☐ Compliant ☐ Not Compliant ☐ N/A= Not a member of a rural health network No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review facility documents to determine compliance.
01.03.02 Agreements with network hospitals: Patient referral and transfer *In the case of a CAH that is a member of a rural health network as defined in §485.603, the CAH has in effect an agreement with at least one hospital that is a member of the network for:* ▪ *Patient Referral and Transfer.* §485.616(a) Tag C-0862 §485.610(a)(1) Tag C-0864	☐ Compliant ☐ Not Compliant ☐ N/A See standard 01.03.01 for the definition of a "rural health network."	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the network agreement includes patient referral and transfer. ▪ Review any written agreements with the local EMS.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.03.03 Agreements with network hospitals: Communications systems *In the case of a CAH that is a member of a rural health network as defined in §485.603, the CAH has an agreement in effect with at least one hospital that is a member of the network for:* ▪ *The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system.* *A rural health network is an organization that meets the following specifications:* *The members of the organization have entered into agreements regarding—* ▪ *The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data.* §485.616(a)(2) Tag C-0866 §485.603(b)(2) Tag C-0802	☐ Compliant ☐ Not Compliant ☐ N/A No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify the network agreement includes the development and use of communications systems. ▪ If the CAH is a member of a rural health network with a communications system, ask to see the agreement. □ How does the CAH participate with other hospitals and facilities in the network communications system? □ Is a communications log kept at the facility? □ Ask staff if there have been difficulties incontacting network members. If so, ask how the CAH deals with communication delays. □ How does the network's communications system compare with any available communications equipment in the CAH? □ When the network communications system is not in operation, how does theCAH communicate and share patient data with other network members? ▪ Review any policies and procedures related to the operation of any communication system.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		◻ How is the CAH staff educated on the use of any communication system used in the facility?
01.03.04 Agreements with network hospitals: Inter-facility transfer transportation *In the case of a CAH that is a member of a rural health network as defined in §485.603, the CAH has in effect an agreement with at least one hospital that is a member of the network for:* ▪ *The provision of emergency and non-emergency transportation between the facility and the hospital.* *A rural health network is an organization that meets the following specifications:* *The members of the organization have entered into agreements regarding—* ▪ *The provision of emergency and nonemergency transportation among members.* §485.616(a)(3) Tag C-0868 §485.603(b)(3) Tag C-0802	☐ Compliant ☐ Not Compliant ☐ N/A No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The network agreement includesthe provision of emergency and non-emergency transportation. ▪ Written agreements with the local EMS service.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.03.05 Agreements with network hospitals: Credentialing and Quality Assurance *Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least –* 1. *One hospital that is a member of the network;* 2. *One QIO or equivalent entity; OR* 3. *One other appropriate and qualified entity identified in the State rural health care plan.* §485.616(b)(1-3) Tag C-0870 §485.603(c)(1-3) Tag C-0802	☐ Compliant ☐ Not Compliant ☐ N/A Other qualified entities could include another CAH or any licensed firms, businesses, or agencies that provide credentialing and QA services. The location for these other qualified entities is not limited to local entities. Agreements for QA need to include medical record review as part of the determination of the quality and medical necessity of care at the CAH.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Agreements related to credentialing or quality assurance identify the level of assistance to be provided and the responsibilities of the CAH. ▪ Policies and procedures describe how information is to be obtained, used, and how confidentiality of information will be maintained.
01.03.06 Agreements for credentialing and privileging of telemedicine physicians and practitioners/Hospital based agreement 1. *The governing body of the CAH must ensure that, when telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the agreement is written and specifies that it is the responsibility of the governing body of the distant-site hospital to meet the following requirements with regard to its physicians or practitioners*	☐ Compliant ☐ Not Compliant ☐ N/A = No telemedicine "Telemedicine," as 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 CAH patient either simultaneously, as is often the case with tele-ICU services or non-simultaneously, as with many tele-radiology 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 onsite practitioner when called in	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** If the CAH uses telemedicine services, verify: ▪ Each written agreement(s) with the distant-site hospital(s) include(s) the required elements concerning credentialing and privilegingof the telemedicine physicians and practitioners by the distant-site

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

providing telemedicine services:

i. *Determine, in accordance with State law, which categories of practitioners are eligible candidates for appointment to the medical staff.*
ii. *Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.*
iii. *Assure that the medical staff has bylaws.*
iv. *Approve medical staff bylaws and other medical staff rules and regulations.*
v. *Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.*
vi. *Ensure the criteria for selection are individual character, competence, training, experience, and judgment.*
vii. *Ensure that under no circumstances is the accordanceof staff membership or professional privileges in the hospital dependent solely upon*
viii. *Certification, fellowship or membership in a specialty body or society.*

by a patient's attending physician to see the patient.

"Non-simultaneously" means that the telemedicine physician or practitioner provides clinical services to the patient that may involve after-the-fact interpretation of diagnostic tests in order to provide anassessment 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 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 25552, May 5, 2011)

A CAH may make arrangements with a distant-site Medicare-participating hospital for the provision of telemedicine services to the CAH's patients by physicians or practitioners granted privileges by the distant-site hospital.

If a CAH enters into an agreement for telemedicine services with a distant-site hospital, the agreement must be in writing. The written agreement must specify that it is the responsibility of the distant-site hospital to conduct its credentialing and privileging process for those of its physicians and practitioners providing telemedicine services such that the distant-site hospital:

- Determines, in accordance with state law, which categories of practitioners are eligible candidates for privileges or membership on the distant-site hospital's medical staff.
- Appoints members and grants medical staff privileges after considering therecommendations of the existing members of the distant-site hospital's medical staff.
- Assures that the distant-site hospital's medical staff has bylaws.
- Approves the distant-site hospital's medical staff bylaws and other medicalstaff rules and regulations.
- Ensures that the medical staff is accountable to the distant-site hospital's governing body for the quality of care provided to patients.

hospital?

- Does the CAH have documentation indicating that it granted privileges to each telemedicine physician and practitioner?
- Does the documentation indicate that the CAH's governing body or responsibleindividual made the privileging decision based on the privileging decisions of the distant-site hospital? If yes:
  - □ Does the agreement address the distant-site hospital's Medicare participation, appropriate licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners with privileges, and review by the CAH of the telemedicine physicians' and practitioners' services?
  - □ Review the list provided by the distant-site hospital of the telemedicine physicians and practitioners, their privileges, and licensure information.
  - □ Ask for evidence that the CAH conducts the required review of the telemedicine services provided by the telemedicine physicians and practitioners, including any associated adverse events and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
2. *When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site hospital, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site hospital regarding individual distant-site physicians or practitioners. The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site hospital, that the following provisions are met:* *i. The distant-site hospital providing 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;* *iii. The individual distant-site physician or practitioner holds alicense issued or recognized by the State in which the CAH is located; and*	▪ Ensures the criteria for granting medical staff membership/privileges to an individual are the individual's character, competence, training, experience,and judgment. ▪ Ensures that under no circumstances is the accordance of distant-site hospital medical staff membership or privileges dependent solely upon certification, fellowship or membership in a specialty body or society. Since the distant-site hospital must also participate in Medicare, it has an independent obligation to comply with these same requirements for all of its medical staff under §§482.12(a)(1) through (a) (7). The written telemedicine services agreement between the CAH and the distant-site hospital must explicitly include a provision addressing the distant-site hospital's obligation to comply with these provisions. The CAH's governing body (or the individual responsible for the CAH if it has no governing body) has the option, when considering granting privileges to telemedicine physicians and practitioners, to rely upon the credentialing and privileging decisions of the distant-site hospital for these physicians and practitioners. In order to exercise this alternative credentialing and privileging option, the CAH's governing body must ensure that its written agreement with the distant-site hospital addresses all of the following: ▪ 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 CAH may no longer receive telemedicine services under the agreement. ▪ The distant-site hospital provides a list to the CAH 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.	complaints, and that it provides the required feedback to the distant-site hospital. ▪ Review telemedicine credentialing files for evidence of compliance with credentialing process as outlined in the agreement and governing body bylaws**.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
iv. With respect to a distant-site physician or practitioner, who holds current privileges at the CAH whose patients are receivingthe telemedicine services, the CAH 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 information for use in the periodic appraisal of the individual 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 CAH's patients and all complaintsthe CAH has received about the distant-site physician or practitioner. §485.616(c)(1-2) Tag C-0872	▪ Each physician or practitioner who provides telemedicine services to the CAH's patients under the agreement holds a license issued or recognized by the state where the CAH is located. States may have varying requirements as to whether they will recognize an out-of-state license for purposes of practicing within their state, and they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements governing in the state where the CAH whose patients are receiving the telemedicine services is located must be satisfied. ▪ The CAH 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 CAH 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 and on all complaints the CAH has received about a telemedicine physician or practitioner. If the CAH's governing body or responsible individual does not rely on the privileging decisions of the distant-site hospital, then it must for each physician or practitioner providing telemedicine services under an agreement follow the CAH's standard process for review of credentials and granting of privileges to physicians and practitioners.	

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

01.03.07 Distant site telemedicine entity/Non-hospital-based agreement

- *The governing body of the CAH must ensure that when telemedicine services are furnished to the CAH's patients through an agreement with adistant-site telemedicine entity, the agreement is written and specifies that the distant-site telemedicine entity is a contractor of services to theCAH and as such, in accordance with §485.635(c)(4)(ii), furnishes the contracted services in a manner that enables the CAH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in §485.616 with regard to its physicians and practitioners providing telemedicine services.*
- *When telemedicine services are furnished to the CAH's patients through an agreement with a distant-site telemedicine entity, the CAH's governing body or responsible individual may choose to rely upon the credentialing and privileging decisions made by the governing body of the distant-site telemedicine entity regarding individual distant-site physicians or practitioners.*

☐ Compliant ☐ Not Compliant ☐ N/A= No telemedicine

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

- provides telemedicine services.
- is not a Medicare-participating 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 CAH. (See 76 FR 25553, May 5, 2011)

A CAH may have an agreement with a distant-site telemedicine entity for the provision of telemedicine services to the CAH's patients by physicians or practitioners granted privileges by the distant-site telemedicine entity.

- The distant-site telemedicine entity's credentialing and privileging process must, at a minimum:
  - □ Determine, in accordance with state law, which categories of practitioners are eligible candidates for medical staff privileges or membership at the telemedicine entity.
  - □ Appoint members and grant medical staff privileges after considering the recommendations of the existing members of its medical staff.
  - □ Assure that its medical staff has bylaws.
  - □ Approve its medical staff's bylaws and other medical staff rules and regulations.
  - □ Ensure that the medical staff is accountable to the distant-site telemedicine entity's governing body for the quality of care provided topatients.
  - □ Ensure the criteria for granting distant-site telemedicine medical staff membership/privileges to an individual are the individual's character, competence, training, experience, and judgment.

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

If the CAH uses telemedicine services, review a copy of the written agreement(s) with the distant-site telemedicine entity(ies).

- Does each agreement explicitly state that the distant-site telemedicine entity will provide telemedicine services in a manner that enables the CAH to comply with all applicable CoPs?
- Does the CAH have documentation indicating that it granted privileges to each telemedicine physician and practitioner?
- Does the documentation indicate that the CAH's governing body or responsibleindividual made the privileging decision based on the privileging decisions of the distant-site telemedicine entity? If yes:
  - □ Does the written agreement with the distant-site telemedicine entity address 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,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
The CAH's governing body or responsible individual must ensure, through its written agreement with the distant-site telemedicine entity, that the following provisions are met: *(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at §485.616(c)(1)(i) through (c)(1)(vii).* *(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides a current list to the CAHof 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 CAH 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 CAH whose patients are receiving the telemedicine services, the CAH has evidence of an internal review of*	▫ Ensure that under no circumstances is the accordance of medical staff membership or privileges dependent solely upon certification, fellowship or membership in a specialty body or society. ▪ The distant-site telemedicine entity's list of all its physicians and practitioners covered by the agreement, including their privileges at the distant-site telemedicine entity, must be current, so the agreement must address how the distant-site telemedicine entity will keep the list current. ▪ States may have varying requirements as to whether they will recognize an out-of-state license forpurposes of practicing within their state, and they may also vary as to whether they establish different standards for telemedicine services. The licensure requirements of the state where the patients are receiving the telemedicine services is located must be satisfied, whatever they may be. If the CAH's governing body or responsible individual does not rely on the privileging decisions of the distant-site telemedicine entity, then it must follow its standard process for review of credentials and granting ofprivileges to physicians and practitioners for each practitioner providing telemedicine services under an agreement.	licensure of telemedicine physicians and practitioners, current list of telemedicine physicians and practitioners with privileges at the distant-site telemedicine entity, and written review by the CAH of the telemedicine physicians' and practitioners' services? ▫ Is there a list provided by the distant-site telemedicine entity of the telemedicine physicians and practitioners covered by the agreement, including their privileges and licensure information? ▫ Is there evidence that the CAH 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? ▪ Ask how the CAH verifies that the telemedicine entity fulfills the terms of the agreement with respect to its credentialing and privileging process and otherwise assures that services are provided in a manner that enables the CAH to meet all applicable requirements? (Surveyors do not attempt to independently verify whether or not the distant-site telemedicine entity's credentialing and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such information for use in 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. §485.616(c)(3-4)(i-iv) Tag C-0874		privileging process fulfills the regulatory requirements. Surveyors focus only on what actions the CAH takes to ensure that the distant-site telemedicine entity complies with the terms of the agreement.) ▪ Review telemedicine credentialing files for evidence of compliance with credentialing process as outlined in the agreement and governing body bylaws**.**
01.04.00 CONDITION OF PARTICIPATION: Number of beds and length of stay §485.620 Tag C-0900	☐ Compliant ☐ Not Compliant ☐ N/A This CoP is scored based on the scoring of standards 01.04.01 and 01.04.02.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review scoring of standards 01.04.01 and 01.04.02 to assess compliance. ▪ N/A is possible only for an accreditation survey without deemed status.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.04.01 Number of beds *Except as permitted for CAHs having distinct part units under §485.647,the CAH maintains no more than 25 inpatient beds.* *Inpatient beds may be used for either inpatient or swing-bed services.* §485.620(a) Tag C-0902	☐ Compliant ☐ Not Compliant **DPU BEDS** Section 1820(c)(2)(E) of the Social Security Act permits a CAH to operate: ▪ a 10-bed psychiatric distinct part unit (DPU) and ▪ a 10-bed rehabilitation DPU without counting these beds toward the 25-bed inpatient limit. The limit applies to the number of inpatient beds, not to the number of inpatients on any given day. CAHs that were larger hospitals prior to converting to CAH status may not maintain more than 25 inpatient beds, plus a maximum of 10 psychiatric DPU inpatient beds, and 10 rehabilitation DPU inpatient beds. Any bed used for inpatient services at any time must be counted when assessing compliance with the 25-inpatient bed limit. Beds used for outpatient services, such as observation services, sleep studies, emergency services, etc. do not count towards the CAH's 25-bed limit if they are never used for inpatient services. **BEDS USED FOR OBSERVATION SERVICES** Beds used solely for patients receiving observation services beds are not included in the 25-bed maximum or in the calculation of the average annual acute care patient length of stay. Surveyors must determine that CAHs with observation beds are using them appropriately, and not as a means to circumvent the CAH size and length-of-stay limits. **Note**: Inappropriate use of observation services also subjects Medicare beneficiaries to an increased beneficiary coinsurance liability that could have	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Verify the number of inpatient beds the CAH maintains, excluding any DPU beds. ▪ Ask how frequently observation services are used and review policies and procedures governing use of observation services. □ Confirm that there are specific clinical criteria for placement in and discharge from observation status, and that these criteria are clearly distinguishable from those used for inpatient admission and discharge. ▪ Verify that patients are never pre-registered for observation services; there should be no scheduled observation stays. ▪ If there is a separate unit of observation beds, ask for evidence of how criteria for admission to the observation unit differ from admission criteria for an inpatient bed. □ Count the number of beds in the observation unit and compare them to the number of inpatient beds. The higher the proportion of observation beds, the greater the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

been avoided, had the beneficiary been properly admitted as an inpatient. This is because, as CAHs are not paid under the hospital Outpatient Prospective Payment System (OPPS), the beneficiary in an observation status will be liable for a coinsurance charge equal to 20 percent of the CAH's customary charges for the services. Further, as CAHs also are not subject to the preadmission payment window, a Medicare beneficiary would be liable for the coinsurance charges for the observation status services even when subsequently admitted.
Depending on the terms of their health insurance coverage, other CAH patients may also face similar increased and avoidable costs when inappropriately placed in an observation status.

Observation care is a well-defined set of specific, clinically appropriate services that include ongoing short-term treatment, assessment, and reassessment, that are provided before a decision can be made regarding whether a patient will require further treatment as an inpatient or may be safely discharged.

Observation status is commonly assigned to patients with unexpectedly prolonged recovery after outpatient surgery, and to patients who present to the emergency department and who then require a significant period of treatment or monitoring before a clinical decision is made concerning their next placement. The CAH should ensure that once there is sufficient information to render this clinical decision, the patient is expeditiously admitted, appropriately transferred, or discharged.

A patient may be in an observation status even though the CAH furnishes the patient overnight accommodation, food, and nursing care.

Observation services are not appropriate:

- As a substitute for an inpatient admission.
- For continuous monitoring.
- For medically stable patients who need diagnostic testing or outpatient procedures (e.g., blood transfusion, chemotherapy, dialysis) that are

CAH's burden to prove these are not being used as inpatient beds.

  - Ask for the occupancy rates for the observation unit; the higher the occupancy rate, particularly if there are more than a couple of beds, the greater the burden to prove these are not being used as inpatient beds.

- Review the medical records for patients who are in observation status at the time of survey.
  - Verify that each record includes an order to place the patient in observation status, including the clinical reason for observation, e.g., "Place patient in observation to rule out possible myocardial infarction (MI)."
- Select a sample of closed medical records for patients who were in an observation status.
  - Verify that the medical record includes an order to place the patient in observation status, as well as a later order to admit, discharge, or transfer the patient.
  - Verify that observation services are not a standing order following outpatient surgery or prior to admission from the emergency

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	routinely provided in an outpatient setting. ▪ For patients awaiting nursing home placement. ▪ As a convenience to the patient, his or her family, the CAH, or the CAH's staff. ▪ For routine prep or recovery prior to or following diagnostic or surgical services. ▪ As a routine "stop" between the emergency department and an inpatient admission. Observation services BEGIN and END with an order by a physician or other qualified licensed practitioner of the CAH. The order for observation services must be written prior to initiation of the service, as documented by a dated and timed order in the patient's medical record. The order may not be backdated. Orders should be clear for the level of care intended, such as "admit to inpatient" or "place in observation." **Note**: It is not uncommon for hospitals and practitioners to refer to "admitting" a patient for observation. Technically, only inpatients are "admitted," while patients receiving observation services are in an outpatient status. However, usage of the term "admit" in an order placing a patient in observation status does not violate any CAH CoP and is not cited. Observation services end when the physician or other qualified licensed practitioner orders an inpatient admission, a transfer to another health care facility, or discharge. The inpatient stay begins on the date and time of the new order. Standing orders for observation services are not acceptable, since it is not necessary to employ observation services for every patient in a given category, e.g., every emergency department patient, in order to reach a clinical decision about the appropriate next step in the patient's care. Medicare generally will not pay for observation services lasting more than 48 hours. Some states may have more stringent limits in their licensure or other	department.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

regulatory requirements, e.g., 24 hours. In such cases the state's more stringent limit on the length of an observation stay applies to Medicare beneficiaries as well, but is not enforced through the federal survey process, unless the state has taken a final enforcement action.

The CAHs must provide appropriate documentation upon surveyor request to show that an observation bed is not an inpatient bed.

The CAH must be able to document that it has specific clinical criteria for placing a patient in and discharging from the observation service, and that these criteria are clearly distinguishable from those used for inpatient admission and discharge. CMS expects a CAH to employ the same type of clinical criteria for observation versus inpatient status for all patients, regardless of their payer status.

For example, if a CAH were routinely placing only Medicare beneficiaries in its dedicated observation unit, then this could suggest that non-clinical criteria were being used in the decision to admit versus place in observation status. This would not only call the observation bed status into question but could also violate the CAH's provider agreement requirement that prohibits differential treatment of Medicare beneficiaries. (See §489.53(c)(2).)

CMS expects there to be a reasonable relationship between the size of the CAH's inpatient and observation operations. For example, a 10-bed observation unit in a 25-bed CAH might be disproportionately large, and the surveyor must determine whether the observation unit is actually functioning as an inpatient overflow unit.

A CAH observation unit that routinely operates at a high occupancy rate could also be an indicator of the need to probe further.

OTHER TYPES OF BEDS

Other bed types that do not count toward the 25-inpatient bed limit include, but are NOT limited to:

- Examination or procedure tables.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Stretchers.
- Operating room tables.
- Beds in a surgical recovery room used exclusively for surgical patients during recovery from anesthesia.
- Beds in an obstetric delivery room used exclusively for OB patients in laboror recovery after delivery of newborn infants.
- Newborn bassinets and isolettes used for well-baby boarders. (NOTE: Ifthe baby is being held for treatment at the CAH, his or her bassinet or isolette DOES count towards the CAHs 25-bed limit.)
- Stretchers in emergency departments.
- Inpatient beds in Medicare-certified distinct part rehabilitation or psychiatric units.

BEDS USED FOR HOSPICE SERVICES

A CAH can dedicate beds to a hospice under arrangement, but the beds must count as part of the maximum bed count.

The computation contributing to the 96-hour annual average length of stay does not apply to hospice patients. The hospice patient can be admitted to the CAH for any care involved in their hospice treatment plan or for respite care.

Medicare does not reimburse the CAH for the hospice CAH benefit. Medicare reimburses the hospice. The CAH must negotiate payment for services from the hospice through an agreement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.04.02 Length of stay *The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.* §485.620(b) Tag C-0904	☐ Compliant ☐ Not Compliant **96-HOUR RULE** The Fiscal Intermediary (FI) will determine compliance with this CoP. The FI will calculate the CAH'S length of stay based on patient census data. If a CAH exceeds the length of stay limit, the FI will send a report to the CMS Regional Office as well as a copy of the report to the SA (State Agency). ▪ The CAH will be required to develop and implement a plan of correction (POC) acceptable to the CMS Location (Regional Office) or provide adequate information to demonstrate compliance.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review facility documents regarding average length of stay to determine compliance. ▪ Observation patient days and hospice patient days are not to be included in the count.
01.05.00 CONDITION OF PARTICIPATION: Basis and Scope *This standard is based on section 1820 of the Social Security Act which sets forth the statutory basis for designating certain hospitals as CAHs.* §485.601(a) Tag C-0800	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review facility documents to verify compliance.
01.05.01 Scope *This standard sets forth the conditions that a hospital must meet to be designated as a CAH.* §485.601(b) Tag C-0800	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review facility documents to verify compliance.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
01.06.00 CONDITION OF PARTICIPATION: Designation and certification of CAHs *Criteria for State designation.* 1. *A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Social Security Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in §485 subpart F.* 2. *The State must not deny any hospital that is otherwise eligible for designation as a CAH under §485.606(a) solely because thehospital has entered into an agreement under which the hospital may provide post hospitalSNF care as described in §482.58.* §485.606(a)(1) Tag C-0808 §485.606(a)(2)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the facility has current state designation as a critical access hospital.
01.06.01 Criteria for CMS certification *CMS certifies a facility as a CAH if —* 1. *The facility is designated as a CAHby the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the relevant CMS document to verify the facility has current designation as a Critical Access Hospital.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.606 and all other applicable requirements for participation in §489. 2. *The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997 and is otherwise eligible to be designated as a CAH by the State.* §485.606(b)(1) §485.606(b)(2)	Tag C-0808	

02

EMERGENCY SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
02.00.00 CONDITION OF PARTICIPATION: Emergency services *The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.* §485.618 Tag C-0880	☐ Compliant ☐ Not Compliant All emergency services must be provided as a direct service in the CAH. The ED cannot be a provider-based off-site location. Emergency needs of patients must be met in accordance with acceptable standards of practice. Acceptable standards of practice include maintaining compliance with applicable federal and state laws, regulations, and guidelines governing all services provided in the emergency department, as well as any standards and recommendations promoted by or established by nationally recognized professional organizations such as the American Medical Association, American Association for Respiratory Care, American Society of Emergency Medicine, American College of Surgeons, American Nursing Association, etc. The emergency services must be under the direction of a qualified member of the CAH'S medical staff. The medical staff must establish policies and procedures governing care provided in the emergency services department. Emergency services policies must be current and revised as necessary based on the ongoing monitoring conducted by the medical staff or department quality activities. **QAPI** The emergency services must be integrated into the hospital-wide QAPI Program. **MEDICAL DIRECTOR** The medical staff establishes criteria, in accordance with state law, regulations, and guidelines, delineating the qualifications to be granted privileges for emergency care services. Qualifications include the required education, experience, and any specialized training.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ Emergency services are organized under the direction of a qualified member of the medical staff. ▪ Policies and procedures for emergency medical services (including triage of patients and any respiratory services provided) are established, evaluated, and updated on an ongoing basis. ▪ There is sufficient, qualified medical and nursing personnel for the needs anticipated by the facility and there are specific assigned duties for emergency care. ▪ The CAH follows its own policies and procedures, evidenced through a sample of records for patients treated in the emergency services department. ▪ Emergency services are provided in accordance with acceptable standards of practice. ▪ Staff are knowledgeable, within their own level of participation in emergency care regarding (as evidenced through interview):

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

STAFF

The CAH must staff the emergency department with 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. This would include physicians, specialists, RNs, EMTs, and support staff.

There must be sufficient medical and nursing personnel to respond to the emergency medical needs and care of the patient population served.

The medical staff establishes 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.).

The CAH conducts ongoing assessments of its emergency needs in order to anticipate the policies, procedures, staffing, training, and other resources that may be needed to address likely demands.

Emergency care necessary to meet the needs of its inpatients and outpatients would include the provision of respiratory services as needed by emergency patients. When respiratory services are provided, those services align with acceptable standards of practice. The scope of diagnostic and/or therapeutic respiratory services offered is defined in writing and approved by the medical staff.

In addition to qualified personnel, the CAH must provide the equipment necessary to furnish all services offered in a safe manner in accordance with acceptable standards of practice.

POLICIES AND PROCEDURES

There should be written policies for the delivery of any service provided. The policies and procedures must be developed and approved by the medical staff and include the participation of any mid-level practitioners (nurse practitioner, physician assistant, or clinical nurse specialist) working in the ED.

- □ 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.
- □ Provision of emergency respiratory services.

- The type and amount of respiratory care provided meets the needs of the patients and is delivered in accordance with acceptable standards of practice.
- The scope of the diagnostic and/or therapeutic respiratory care services provided is defined in writing and approved by the medical staff.
- The number and type of staff available is appropriate to the volume and types of treatments furnished evidenced through review of staffing schedules.
- If blood gases or other laboratory tests are performed as part of the delivery of respiratory services, there is a current CLIA certificate.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The written policies should address, as appropriate: ▪ Each type of service provided. ▪ The qualifications, including job title, licensure requirements, education, training, and experience of personnel authorized to perform each type of respiratory care service and whether they may perform it without supervision. ▪ Equipment assembly and operation. ▪ Safety practices, including infection control measures. ▪ Handling, storage, and dispensing of therapeutic gases. ▪ Cardiopulmonary resuscitation. ▪ Procedures to follow in the advent of adverse reactions to treatments or interventions. ▪ Pulmonary function testing. ▪ Therapeutic percussion and vibration. ▪ Bronchopulmonary drainage. ▪ Mechanical ventilator and oxygenation support. ▪ Aerosol, humidification, and therapeutic gas administration. ▪ Administration of medications. ▪ Procedures for obtaining and analyzing blood samples (arterial blood gases).	
02.00.01 Availability of emergency services *Emergency services are available on a 24-hours a day basis.* §485.618(a) Tag C-0882	☐ Compliant ☐ Not Compliant "Available 24-hour emergency services" does not mean that the CAH must remain open 24 hours a day when it does not have inpatients (including swing-bed patients). A CAH that does not have inpatients may close with no staff present, provided that it has an effective system in place to meet the requirement. The system must ensure that a practitioner with training and experience in emergency	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ The CAH ensures that emergency services are available on a 24-hour a day basis.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	care is on call and immediately available by telephone or radio, and available onsite within 30 minutes (or one hour in certain frontier areas), 24 hours a day.	▪ Record review of patients admitted through the emergency department, interviews with staff, patients, and families, and/or observation confirm that ED services were available to patients presenting at any time.
02.00.02 Supplies and medication availability *Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases.* *The items available must include the following:* ▪ *Drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiaarhythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions*. §485.618(b) Tag C-0884 §485.618(b)(1) Tag C-0886	☐ Compliant ☐ Not Compliant The CAH must maintain the types, quality and numbers of supplies, drugs and biologicals, blood and blood products, and equipment required by state and local law and in accordance with accepted standards of practice. See also standards 02.00.03, 02.00.04.	This standard is not met as evidenced by: **INTERVIEW AND OBSERVATION** Verify: ▪ The CAH ensures that the required equipment, supplies and medications are always readily available. □ Interview staff and tour the ER to confirm compliance and ability to provide emergency services. □ How does the CAH ensure that staff knows where drugs and biologicals are kept? □ How is the inventory maintained? □ Who is responsible for monitoring drugs and biologicals? ▪ How are drugs and biologicals replaced?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
02.00.03 Equipment availability	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The items available must include the following: ▪ *Equipment and supplies commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.* §485.618(b)(2) Tag C-0888	In addition, 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. The organization has a policy or process which defines what supplies and equipment are required for medical emergencies. Policies should address: ▪ 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)	**OBSERVATION AND INTERVIEW** Verify: ▪ Policy or process defining emergency equipment required ▪ Adequate supplies are available ▪ Supplies encompass all patient populations. ▪ How does the CAH ensure that required equipment and supplies are readily available to staff? ▪ How does the CAH ensure that staff knows where emergency equipment and supplies are kept? ▪ How is the supply inventory maintained? ▪ Who is responsible for monitoring supplies? ▪ How are supplies replaced? When were emergency supplies last used? ▪ Is there an equipment maintenance schedule (e.g., for the defibrillator)? ▪ Ask staff if equipment has ever failed to work when needed. ▪ Examine sterilized equipment (e.g., tracheotomy sets) for expiration dates when applicable.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ Examine the oxygen supply system to determine functional capabilities. ▪ Check the force of the vacuum (suction) equipment to see that it is in operating condition. ▪ Age-specific resuscitation equipment is readily available. If the facility treats pediatric patients, pediatric sized resuscitation equipment is immediately available.
02.00.04 Blood and blood products *The facility provides, either directly or under arrangements, the following—* *Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on 24-hours a day basis.* §485.618(c)(1) Tag C-0890	☐ Compliant ☐ Not Compliant This requirement can be met by providing blood or blood products on an emergency basis at the CAH, either directly or through arrangement, if that is what the patient's condition requires. There is no requirement that a CAH store blood on-site, although it may choose to do so. In some cases, it may be more practical to transport a patient to the source of the blood supply than to bring blood to the patient at the CAH. A facility that has the capability of providing blood services on-site would be in compliance even if, in virtually all cases, the patients were actually taken to the blood rather than vice versa. **CLIA CERTIFICATE** A CAH that performs CLIA tests on blood on-site must have a CLIA certificate and is subject to survey under CLIA. A CAH that is only storing blood for transfusion and refers all related testing out to another laboratory, is not performing testing as defined by CLIA. However, under this regulation, the CAH must ensure that blood is	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Review policies and procedures regarding blood availability, storage and transfusion, as applicable. ▪ If testing is available on-site, verify the CLIA certificate is current, and supplies are within expiration dates. ▪ If blood is stored on-site, verify storage is appropriate and meets standards.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

appropriately stored to prevent deterioration, including documenting refrigerator temperatures.

The provision of blood services between the CAH and the testing laboratory should be reflected in the written agreement or arrangement between the two. Also, if the CAH is collecting blood, it must register with the Food and Drug Administration.

"Availability" in this context, means that the blood and blood products must be accessible to CAH staff in time to effectively treat emergency patients. In order to comply with this requirement, a CAH must demonstrate that it has the capability (i.e., an effective system is in place regardless of whether, in actual practice, it has been used) of making blood products available to its emergency patients 24 hours a day.

If a CAH performs type and compatibility testing it must have the necessary equipment, (i.e., serofuge and heat block), as well as typing and cross matching reagents, some of which have a 30-day expiration date.

O NEGATIVE PACKED RED BLOOD CELLS

Another way for a CAH to meet this requirement would be to properly store four units of universal donor type O negative packed red blood cells for emergency availability at all times. CAHs that choose to store O negative packed red blood cells for emergency release of uncross-matched blood will require a release form to be signed by a doctor, prior to transfusion, acknowledging that the blood has not been cross matched for the patient.

Facilities that elect to store units of O negative packed red blood cells should be able to demonstrate that they have an arrangement (e.g., with the Red Cross or other similar product provider) for the provision of fresh units of O negative packed red blood cells.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
02.00.05 Pathologist oversight or contracted service approval *The facility provides, either directly or under arrangements, the following —* ▪ *Blood storage facilities that meet the requirements of 42 CFR 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or doctor of osteopathic medicine.* *If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.* §485.618(c)(2) Tag C-0892	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ If blood banking services are provided on-site, confirm that the blood facility is under the control and supervision of a pathologist or other qualified MD/DO. ▪ For blood banking provided under arrangement, verify that the CAH medical staff and the person responsible for CAH operations have approved the arrangement.
02.00.06 Personnel *(1) Except as specified below in 42 CFR 485.618(d)(3), there must be a doctor of medicine or* doctor of osteopathic medicine*, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on-site within the following timeframes:*	☐ Compliant ☐ Not Compliant When state law for emergency services are more stringent (e.g., require more staffing or expanded operational hours), the CAH must act in accordance with state law. For example, if state law requires the CAH emergency department be open and staffed with a MD/DO 24/7, then the CAH must comply.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review on-call schedules to determine how the CAH ensures that a qualified staff member is on call 24 hours a day and available onsite at the CAH within 30 minutes, or 60 minutes in certain frontier areas. ▪ Interview staff to determine how the CAH staff knows who is on call.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(i) *Within 30 minutes, on a 24-hour a day basis, if the CAH is located in an area other than an area described below in 42 CFR 485.618 (d)(1)(ii); or* (ii) *Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:* *A. The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Social Security Act.* *B. The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.* *C. The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it*		▪ What documentation demonstrates that a MD/DO, nurse practitioner, physician assistant, or registered nurse (as allowed under item (2)) with emergency training or experience has been on call and available onsite at the CAH within 30 or 60 minutes, as appropriate?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse with training and experience in emergency care can be utilized to conduct specific medical screening examinations only if —

(i) *The registered nurse is on-site and immediately available at the CAH when a patient requests medical care; and*

(ii) *The nature of the patient's request for medical care is within the scope of practice of a registered nurse and consistent with applicable State laws and the CAH's bylaws or rules and regulations.*

(3) A registered nurse satisfies the personnel requirement specified above in 42 CFR 485.618(d)(1) for a temporary period if —

(i) *The CAH has no greater than 10 beds;*

(ii) *The CAH is located in an area designated as a frontier area or remote location as described in 42 CFR 485.618(d)(1)(ii)(A);*

(iii) *The State in which the CAH is located submits a letter to CMS*

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural healthcare plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified above in 42 CFR 485.618(d)(1). The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified above in 42 CFR 485.618(d)(1);

(iv) *Once a Governor submits a letter, as specified above in 42 CFR 485.618 (d)(3)(iii), a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in 42 CFR 485.618(d).*

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(4) The Governor's request, as specified in 42 CFR 485.618(d)(3)(iii) and the withdrawal of the request, may be submitted to CMS at any time, and are effective upon submission. §485.618(d)(1-4) Tag C-0894		
02.00.07 Coordination with emergency response systems *The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or doctor of osteopathic medicine is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.* §485.618(e) Tag C-0898	☐ Compliant ☐ Not Compliant The CAH, not the local ambulance service, is responsible for ensuring that an effective procedure is in place to meet this requirement.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review policies and procedures to ensure an MD/DO is available by telephone or radio, 24-hours a day to receive emergency calls and provide medical direction in emergencies. □ What evidence demonstrates that the procedures are followed and evaluated for effectiveness? ▪ Interview staff to see how an MD/DO is contacted when emergency instructions are needed.
02.01.00 Additional required policies The Emergency Services policies address: 1. Initial evaluation and triage of patients. (See 489.20 and 489.24 for EMTALA standards.)	☐ Compliant ☐ Not Compliant No patient is denied access to evaluation and care based on inability to pay. Note that # 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.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ Policies are in place for the eight required areas.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
2. Providing sufficient diagnostic and stabilization services for persons whose care will be managed by transfer to another acute care facility. 3. Determining the level of service to be provided under the direction of a physician member of the medical 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. Evaluating the quality and appropriateness of emergency services provided. 7. Provision of care for disasters. 8. Managing medical emergencies in non-emergency department (ED) settings on the hospital main campus, unless present in a non-emergency services hospital policy. **§485.618** **§485.627(a)**	The CAH establishes 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 non-medical professional observer would conclude, based on the person's appearance or behavior, that the person needs emergency examination or treatment.	▪ A policy defines the process to evaluate and conduct a Medical Screening Examination (MSE) in non-ED main campus locations. ▪ Compliance with all required policies.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
02.01.01 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: 1. Cardiac crises. 2. Obstetric/gynecologic crises. 3. Orthopedic - neurological crises. 4. Endocrine crises. 5. Psychiatric crises. 6. Substance abuse. 7. Childhood diseases – conditions. 8. Trauma - highway, industrial, school, domestic. 9. Epidemiologic crises. 10. Pain management. **§485.604**	☐ Compliant ☐ Not Compliant Staff orientation schedules and ongoing education programs are designed to enhance documented competencies appropriate to the level of participation of each provider in the delivery of care that 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. ▪ Cardiopulmonary resuscitation. ▪ Emotional support and intervention to persons in crises situations.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Core competencies and plans for enhancement of these are identified for medical and nursing staff . ▪ A process is established for ongoing evaluation of 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. ▪ Through staff interview, knowledge, within the appropriate level of participation in emergency care, for: □ 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
02.01.02 Records	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
There is a record for each patient presented for emergency services. Records include: 1. Onset and duration of entry complaint. 2. Time and method of arrival. 3. Triage status upon arrival. 4. Treatment attempted prior to arrival. 5. Assessment(s), problem list(s), plan(s). 6. Testing results, and treatment rendered. 7. Patient responses to treatment. 8. Disposition of the case. 9. Further care needs, with plan for same. 10. Time and condition on discharge. **§485.638(a)(4)(iii)** **§485.638(a)(2)**	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, and forwarded 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 required elements are documented in each patient record. ▪ A mechanism exists to provide legible and timely copies of emergency services records to the physician providing follow up care. ▪ Each medical record includes a discharge summary.
02.01.03 Emergency room log	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Permanent logs are maintained of persons seeking emergency care. The register provides data regarding: 1. Date, time and mode of arrival. 2. Age, sex, and name of patient. 3. Nature of complaint.	The data maintained in the permanent register of emergency care patients provides data for long range planning. Logs may be manual or electronic with periodic back up. Additionally, the data may be used in determining statistical sampling for quality and utilization management studies.	**DOCUMENT REVIEW** Verify: ▪ A permanent register of emergency patients exists, and all required elements are included.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
4. Name of physician responsible for care. 5. Brief description of services provided. 6. Disposition (treated/released, admitted to facility, transferred to another acute facility, or death in ER). 7. Condition on discharge. 8. Time of discharge. **§485.638(a)(4)(iii)**		▪ If the register is electronic, a backup process is in place to preserve the integrity of the register from computer failure.
02.01.04 Change in treatment plan log	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
A separate log is maintained as part of the quality management program for the emergency service. The log provides information about patients whose initial treatment plan later resulted in the need for modification based upon significant variation in the final interpretation of radiographic, cardiographic or laboratory findings. **§485.638(a)(4)(iii)**	Maintenance of the 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.	**DOCUMENT REVIEW** ▪ **Review the treatment log to verify:** □ **The three required recall situations (radiographic, cardiographic, and laboratory findings) are actively maintained.** □ **Outcomes of such recalls are noted (contact made/not made).** ▪ **Review medical records to confirm the record reflects the revised treatment plan.**

03

PHYSICAL ENVIRONMENT

INTRODUCTION

ACHC Physical Environment Standards establish a safe, functional, and supportive hospital environment that upholds quality and safety. Critical Access Hospitals (CAH) must coordinate compliance with these Standards with other regulatory agency requirements that the CAH is required to follow.

The chapter emphasizes the significance of effective risk management related to the physical surroundings, which differ from the risks associated with providing care, treatment, and services. Regardless of scale or location, all critical access hospitals encounter environmental risks related to safety, security, hazardous materials and waste, fire hazards, medical equipment, and utility systems. This chapter includes many elements from NFPA 99 Health Care Facilities Code, 2012 edition.

Chapter 14 Life Safety is an extension of Chapter 03 Physical Environment.

HOSPITAL FACILITY MANAGEMENT

The physical environment is the hospital's largest and most critical piece of medical equipment, playing a vital role in patient care. Many ACHC standards in these chapters are based on guidelines adopted from NFPA, OSHA, CDC, and other resources, and reflect the minimum required activity to create a safe environment.

Managing healthcare facilities involves overseeing the development, maintenance, security, and day-to-day operations of buildings that offer healthcare services, like clinics, long-term care facilities, surgical centers, and hospitals.

The facilities management department, often known as HFM, is accountable for ensuring the upkeep, security, and smooth functioning of these spaces. Responsibilities range from supervising major construction projects and meeting federal regulations to handling routine cleaning and maintenance tasks. 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 include documentation that the staff member has the required qualifications, appropriate credentials, adequate training and is competent in their respective duties.

Standards in other chapters are also relevant to the HFM. (See chart, next page, for specific examples.)

Physical Environment		
	06.01 Preparation and Administration of Medications	06.01.05 Compounding (refer to USP 797)
	06.03 Nutritional Services	06.03.09 Lighting, ventilation, and temperature control 06.03.11 Trash disposal
	06.10 Patient Rights	06.10.08 Privacy and safety: Safe setting
	13 Psychiatric Units	13.03.01 Physical facilities 13.03.02 Patient bedrooms: Safety and Security 13.03.04 Handicapped accessibility
	18 Infection Prevention and Control	18.02.01 Risk mitigation measures for infection prevention 18.05.04 Maintenance of ceilings 18.02.06 Reduce the risk of Legionella in water systems 18.04.09 Environmental requirements in decontamination room 18.05.06 Waste disposal

WHAT IS A MANAGEMENT PLAN?

Management plans establish a structure for overseeing the physical environment. These plans should encompass the extent and goals of risk assessment and mitigation, delineate the responsibilities of individuals or teams, and establish specific timeframes for the activities outlined in the plan.

WHAT IS MEANT BY "PROGRAM"?

A program is the overall coordination of policies, procedures, and activities related to a specific function. In this chapter, programs encompass all activities to provide a comprehensive approach to potential or actual environmental risks. Chapter 03 Physical Environment is subdivided into the following sections.

Building Safety Program	addresses the risks in the physical environment and processes to identify, monitor, and mitigate risks.
Building Security Program	addresses security risks, such as access to security sensitive areas and hazardous areas, and workplace violence.
Hazardous Materials and Waste Program	addresses risks associated with radioactive materials, hazardous chemicals, and waste streams.
Fire Safety Program	addresses risks associated with smoke and fire, fire drills, and fire protection systems that are included in **Chapter 14 Life Safety.**
Medical Equipment Program	addresses the selection, inspection, testing and maintenance of patient-care related equipment
Utility Systems Program	addresses inspection, testing and maintenance of Utility equipment, maintaining proper temperatures, humidity and air pressures, and the water management plan. This includes equipment in the building services section of **Chapter 14 Life Safety.**
Design and Construction	addresses building and maintaining a safe, functional, and supportive environment for staff, patients, and visitors. This element also addresses construction related activities while continuing patient care in a safe way.

LIST OF CHAPTER STANDARDS

GENERAL REQUIREMENTS

BUILDING SAFETY PROGRAM

BUILDING SECURITY PROGRAM

HAZARDOUS MATERIALS AND WASTE PROGRAM

FIRE SAFETY PROGRAM

MEDICAL EQUIPMENT PROGRAM

UTILITY SYSTEMS PROGRAM

DESIGN AND CONSTRUCTION PROGRAM

PROGRAM EVALUATION

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

GENERAL REQUIREMENTS

03.00.01 CONDITION OF PARTICIPATION: Physical environment

The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services.

§485.623 Tag C-0910

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

This standard applies to all locations of the CAH (all campuses, all satellites, all provider-based activities, and all inpatient and outpatient locations) regardless of occupancy designation.

The CAH's facility maintenance and departments or services responsible for the buildings and equipment (both facility equipment and patient care equipment) must be incorporated into the CAH's QAPI program and comply with the QAPI requirements.

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

Note: Score this Condition after review of all standards with focus on the list of systems identified in ACHC standard 03.00.02.

One surveyor should conduct the survey of the Physical Environment; however, each surveyor, as he/she conducts his/her survey assignments, should assess the CAH's compliance with this standard.

03.00.02 Required plans and performance standards

The CAH maintains written plans for managing the following areas:

01: Building Safety

02: Building Security

03: Hazardous Materials and Waste

04: Fire Safety

05: Medical Equipment

06: Utility Systems

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Performance improvement goals or indicators are included **in the written plan** for each area**, reported to the Safety Committee on a routine basis, and show follow-up when necessary.**

Safety and security for individuals, equipment, and materials, the handling of hazardous substances and waste, the risk of fire, the utilization of medical equipment, and utility systems are all factors that contribute to environmental risks.

The hospital employs comprehensive written management plans to effectively handle these risks. Although these plans differ from operational plans, they establish a structure for overseeing the physical environment.

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

- Review the CAH's 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 or indicators exist for each area?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
Plans are reviewed and approved at least once every 12 months by the organization's committee that oversees safety in the environment.	**Moreover, these plans should encompass the extent and goals of risk assessment and management, delineate the responsibilities of individuals or teams, and establish specific timeframes for the activities outlined in the plan.** **Note: Management plans for Fire Safety and Utility Systems should include the applicable systems in Chapter 14 Life Safety.** The hospital designates a qualified individual/individuals as responsible for each of the six areas of the physical environment.	▪ Is there an identifiable person or 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 PROGRAM

03.01.01 Building safety

The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of services.

The CAH 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).

§485.608(a)
§485.623(a) Tag C-0912

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Note: This standard was previously numbered 03.01.02.

The CAH must ensure that the condition of the physical plant and overall CAH environment is developed and maintained in a manner to ensure the safety and well-being of patients, visitors and staff.

Note: The existence of observed, unmitigated ligature risks within a psychiatric hospital or unit, as well as any area where patients at risk of suicide are present, may constitute an immediate jeopardy situation.

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.

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.

OBSERVATION

- Verify that the condition of the CAH is maintained in a manner to assure the safety and well-being of patients (e.g., condition or ceilings, walls, and floors, presence of patient hazards, etc.).
- 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**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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.** 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.	**include cleaning agents, disinfectant solutions, mops, brooms, tools, etc.** ▪ **Additional facilities associated with the hospital, either owned or leased, must also be monitored for safety.**
03.01.02 Safety Committee There is a Safety Committee that is developed to identify opportunities to improve issues related to safety existing within the CAH. Multi-disciplinary membership consists of individuals who have knowledge and authority of the operations within their own area/service.	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.01.03.** 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 CAH. **The committee appoints a chairperson whose role is to assure that the concerns identified by the Safety Committee receive timely administrative attention.** The Safety Committee meets periodically to review reports, analyze trends, discuss safety related issues in the physical environment, and to 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.	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's recommendations on physical environment issues. ▪ Evaluate the frequency of Committee meetings. If less frequent than once every two months, then review risk

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	ACHC does not specify the frequency of safety committee meetings, but meetings held less than once every two months require a risk assessment to indicate the effectiveness of less frequent meetings.	assessment indicating the effectiveness of the less-frequent meetings.
03.01.03 Safety officer An individual is appointed by the **governing body** 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.	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.01.05.** The **governing body** annually appoints, **in writing, an individual as its Safety Officer. In designating the safety officer, hospitals should assure that the individual so designated is qualified through education, training, experience, or certification. The safety officer should maintain their qualifications through ongoing education and training, which can be demonstrated by participation in safety related courses, or in local and national meetings organized by recognized professional societies.** Authority to take any action needed relating to situations that pose an immediate threat to life, health, and/or property shall be included in the appointment document. **The safety officer provides oversight and control of the CAH's physical environment programs and policies. Physical Environment programs and policies should address the roles and responsibilities for safety within the CAH; how the various committees and departments interface with the safety program; and how to prevent safety-related injuries; and how to report unsafe conditions to the safety program.** **The successful development, implementation and evaluation of a hospital wide safety 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.**	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the appointment process and content of the appointment document. ▪ Verify the appointment has been reaffirmed annually.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The safety officer's responsibility for measures to identify, investigate, report, and prevent threats to life, health, and/or property include the following activities: **1. Maintenance of a safe hospital environment in the following programs:** **a. Safety Program** **b. Security Program** **c. Hazardous Materials & Waste Program** **d. Fire Safety Program** **e. Medical Equipment Program** **f. Utility Equipment Program** **2. Development and implementation of safety measures related to CAH personnel. CAH personnel, for safety purposes, includes all staff, contract workers (e.g., agency nurses, housekeeping staff, medical staff, etc.), and volunteers.** **3. Active surveillance.** **4. Monitoring compliance with all policies, procedures, protocols, and other physical environment program requirements.** **5. Oversight of program evaluation and revision of the program, when indicated.**	
03.01.04 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.	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.01.08.** People, processes, and characteristics change; therefore, all safety policies and procedures shall be reviewed at least once every 36 months and approved 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: ▪ An appraisal has been documented at least once in the past 36 months within the Safety Committee minutes. ▪ Policies are current.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.01.05 Smoking/tobacco products policy The CAH shall have, disseminate, and enforce a facility-wide policy prohibiting the use and sale of tobacco products within the buildings used for treating or housing patients.	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.01.09.** Smoking and the use of lighting material for smoking is also a fire hazard. Smoke in a CAH 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 The policy shall prohibit smoking by patients unless authorized to smoke by the attending physician. If permitted, smoking must be outdoors 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 outside. Other patients and staff must be protected from exposure.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify policy and observe practice.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.01.06 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. **§485.623(b)(1) Tag C-0914**	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.01.10.** 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. **Eyewash stations and emergency showers are required to be activated weekly and inspected and tested annually. The activation and inspection must be documented.** **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. ▪ Verify the annual **inspection and** testing has been completed and documented. ▪ Examine emergency eyewash and shower equipment to ensure it complies with ANSI Z358.1-2014 standards for installation and operation.

BUILDING SECURITY PROGRAM

03.02.01 Building security The organization shall have policies and other measures in effect to identify and minimize security risks to patients, visitors, and staff. The organization's security features are based on nationally recognized standards	☐ Compliant ☐ Not Compliant 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.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that policies, procedures, and systems are in place. Review documents to determine if the security program is effective or if there are security concerns.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. **§485.623(a)** **Tag C-0912**	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. **A security risk assessment is performed to identify internal and external risks, such as workplace violence, theft, patient health information or at-risk patient populations and may also consider risks in the community. The risk assessment would be used to identify internal and external campus mitigation measures and security sensitive areas.**	▪ 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 to curtail unwanted visitors that pose a safety or security risk to patients and staff.** □ **The CAH'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.**
03.02.02 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. **§485.623(a)** **Tag C-0912**	Smaller facilities may have fulltime 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 to processing supplement security resources in the event of a disaster. This may be accomplished with Memorandums of Understanding **(see standard 17.01.12).**	**INTERVIEW AND DOCUMENT REVIEW** ▪ Interview various CAH employees to determine if they can identify the person or department responsible for security issues. ▪ Does adequate staff and supervision exist?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The CAH 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.	▪ Review security reports for occurrences of security problems. Are security issues handled quickly and thoroughly? Is follow-up appropriate?
03.02.03 Workplace Violence	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH performs an annual risk assessment addressing workplace violence and implements corresponding mitigation measures to address risks. **The risk assessment is documented.** **§485.623(a) Tag C-0912**	**The Occupational Safety and Health Administration (OSHA) defines workplace violence as "any act or threat of physical violence, harassment, intimidation, or other threatening disruptive behavior that occurs at the work site."** **A documented risk assessment must assess both internal and external risks, which may include:** ▪ **At-risk patient populations.** ▪ **Vulnerable staff.** ▪ **High-risk care areas.** ▪ **Visitor management.** ▪ **Risks in the community.** **The CAH takes action to mitigate issues identified in the risk assessment and reports results of activities to the Safety Committee.**	**INTERVIEW AND DOCUMENT REVIEW** ▪ **Review the risk assessment and confirm it has been reviewed within the past year.** ▪ **Determine through interview if the CAH has initiated mitigation strategies to address the risks identified.** ▪ **Review committee minutes to verify that the results of the risk assessment and mitigation measures are discussed.**
03.02.04 Security sensitive areas	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH identifies areas believed to be security sensitive and have control systems in place to protect the areas and contents.	Many different areas can be considered security sensitive: nurseries, pharmacies, cashiers, medical records, etc. The organization must first identify these areas and then have systems in place to control and protect them.	**INTERVIEW AND DOCUMENTATION REVIEW** ▪ Review list of security sensitive areas. Determine if all sensitive areas are included.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
These security sensitive areas are documented. **§485.623(a)** **Tag C-0912**	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 CAH reviews the list of security sensitive areas annually, to determine accuracy and whether additional locations need to be added **based on events or changes in the most recent 12 months**.	▪ Determine through interview if the security control system is sufficient to protect identified areas.
03.02.05 Security incident procedures	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH has written procedures to follow in the event of a security incident. **§485.623(a)** **Tag C-0912**	Security incidents may include an infant abduction, VIP visit, civil disobedience, bomb threat, or unruly patient or guest. The CAH must have written procedures that their security staff must follow in the event of a security incident. **This also includes procedures for incidents of workplace violence, such as:** ▪ **The individual intending to commit a crime has no affiliation or connection with the hospital or its staff.** ▪ **An individual receiving care or services exhibits violent behavior, regardless of whether they are a customer, client, or patient (most reported type of incident for healthcare workers).** ▪ **One employee engages in acts of violence against another employee.** ▪ **The individual responsible has a personal connection with the nurse or employee that extends beyond the workplace, impacting the work environment.**	**INTERVIEW AND DOCUMENTATION** ▪ Review the 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 determine if they have received training on security incident procedures.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

HAZARDOUS MATERIALS AND WASTE PROGRAM

03.03.01 Hazardous Materials and Waste

☐ 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 CAH shall develop and maintain a list of the hazardous materials and wastes housed in the area and/or used by staff.

The CAH ensures that drugs and biologicals are appropriately stored.

§485.623(b)(3) Tag C-0922

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 CAH 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, INTERVIEW AND DOCUMENT REVIEW

- Confirm that the procedures for 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.

03.03.02 Storage and disposal of trash

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

There is proper routine storage and prompt disposal of trash.

§485.623(b)(2) Tag C-0920

"Trash" refers to common garbage as well as biohazardous 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 DOCUMENTATION

Verify that:

- The CAH has developed and implemented policies for the proper storage and disposal of trash.
- Staff adhere to these policies and the CAH has signage, as appropriate.
- Individuals have been trained to sign the EPA manifest.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.03.03 Program minimizes exposure The Hazardous Materials and Waste Program is organized in a manner which minimizes potential exposure to patients, visitors, staff, and the surrounding community. **§485.623(b)(4) Tag C-0924**	☐ Compliant ☐ Not Compliant Policies and procedures should address the prevention and response to spills, slips, falls, and accidents.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review hazardous waste plans for various waste products to determine compliance.
03.03.04 Labels, inventory and SDS The CAH identifies and documents all hazardous materials and waste used, stored, or generated throughout the CAH, and ensures that they are properly labeled. **§485.623(a) Tag C-0912**	☐ 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 **chemical** 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 premises 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 Program. ▪ Check hazardous materials during building tour looking for proper labeling, use, disposal, and storage. ▪ Ask staff to provide you with a Safety Data Sheet for random selected materials. ▪ Confirm paper copies of the Safety Data Sheets are available to the CAH staff, or copies on flash-drives, provided a battery-operated computer is available to display them. ▪ Review **the chemical** inventory and confirm that it is updated annually.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.03.05 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. **§485.623(a)** **Tag C-0912**	☐ 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). Types of protective equipment can range from gloves to a self-contained breathing apparatus. **This standard addresses PPE specific to hazardous materials and wastes, typically used for spill response or exposure control.** The types of protective devices needed for handling chemicals are listed on the warning label accompanying a product or on the SDS (Safety Data Sheet).	This standard is not met as evidenced by: **OBSERVATION** ▪ Review the hazardous materials and waste program for exposure to risk content. ▪ Is PPE available? Look for evidence of its use.
03.03.06 Hazardous materials – routine monitoring Hazardous materials and wastes are monitored to reduce the exposure potential to harmful agents. **§485.623(a)** **Tag C-0912**	☐ Compliant ☐ Not Compliant Routine inspections of the occupied areas of the CAH shall 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**, such as:** ▪ **Ethylene oxide (ETO).** ▪ **Nitrous oxide gases.** ▪ **Vapors generated by glutaraldehyde.** ▪ **Waste anesthesia gas (see NFPA 99-2012: 9.3.8).** ▪ **Medical plume evacuation (see NFPA 99-2012: 9.3.9).** Policies and procedures have been developed to comply with these federal (OSHA) regulations.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review documented routine monitoring of hazardous materials. ▪ Observe 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 Program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

FIRE RESPONSE PLAN

03.04.01 Written fire control plans

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The CAH 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.*

§485.623(c)(1) Tag C-0930

The written fire response 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 must 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 response plan must meet the requirements of chapter 18/19.7.2.1 **and 18/19.7.2** 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.
- Provide instruction in fire-safety procedures and devices to all staff.
- **Provide instruction in the use of fire extinguishers.**

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.

Note: The fire response plan addresses the immediate response to smoke and fire. This is a separate plan from the fire safety control plan requirement at 03.00.02.

Where applicable, an organization should consider a separate fire response plan for specialized areas, including but not limited to: operating room, MRI suites, kitchens, helipad, and battery energy storage system (BESS).

INTERVIEW AND DOCUMENT REVIEW

- Review the CAH's written fire response plans to verify they contain the provisions identified.
- Verify that CAH staff reported all fires as required.
- Interview staff throughout the CAH to verify their knowledge of their responsibilities during a fire.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.04.02 Quarterly fire drills 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. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant The fire plan is practiced without prior warning to the occupants of the building(s). Observers document actual reactions to the enactment. Fire drill 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 CAH'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. ▪ For fire alarm systems – transmitting signal, see standard 14.02.03. **(For full text, refer to NFPA 101-2012: 18/19: 7.1; 7.2)**	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Participation is based upon staff's role in accordance with the fire response 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. ▪ Review logs to ensure off-site business occupancies have had annual fire drills on each shift. ▪ Review CAH fire drill records to determine whether 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 14.02.03.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.04.03 Fire drill critique Each fire drill critique is documented. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant Detailed documentation critiquing the drills is maintained. A proper critique must include: ▪ The staff's response to the alarm. ▪ Response of building elements to the alarm. ▪ The fire alarm response. This information is to be used by the safety team to improve CAH 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. ▪ Review Safety Team/Committee minutes to confirm that they evaluate fire drills to improve the CAH's fire response.
3.04.04 Approval by state and local fire agencies *The CAH maintains written evidence of regular inspection and approval by state or local fire control agencies.* §485.623(c)(4) Tag C-0934	☐ 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 CAH has historical evidence proving longer frequencies between inspections does not present an unsafe environment for the CAH. 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 CAH 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. ▪ Examine documentation from state or local fire control authorities where they refuse to provide inspections.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.04.05 Minimize the risk of danger from fire The CAH shall minimize the risk of danger from fire, smoke, and the harmful products of combustion. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant The CAH 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 CAH 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.
03.04.06 Fire response: Staff training All staff members, including volunteers, students, physicians, and chaplains in the CAH 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. §485.623(c)(1) Tag C-0930	☐ 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: **DOCUMENT REVIEW** ▪ Review training records to ensure staff receives fire response training. ▪ **During the building tour, interview staff about the fire response procedure.**
MEDICAL EQUIPMENT PROGRAM		
03.05.01 Medical equipment and systems The hospital implements a process for medical equipment maintenance. §485.623(b)(1) Tag C-0914	☐ Compliant ☐ Not Compliant **Note: This standard has been rewritten with updates to the required elements to clarify the focus. The previous standard language and AEM requirements are now found at 03.05.03.**	This standard is not met as evidenced by: **DOCUMENT REVIEW AND INTERVIEW** **Note: For maintenance of medical equipment included in an AEM plan, score at 03.05.03.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

'Medical equipment' is defined as a device intended to be used for diagnostic, therapeutic, or monitoring of care to a patient in a CAH.

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 CAHs that elect to perform equipment maintenance in accordance with the manufacturer's requirements, documentation of the manufacturer's recommendations and the CAH'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.

The CAH must have a process that prior to initial utilization and after significant repairs or upgrades, thorough inspection, performance, and safety testing is mandatory for all equipment involved in the Medical Equipment Program.

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 Strategy, is listed in an inventory which includes a record of maintenance activities.

The program must include a process for the initial service inspection, orientation, and demonstration of usage for both rental and physician-owned equipment within the organization.

Relocatable Power Taps (RPTs) must be installed and maintained to comply with NFPA 99-2012: 10.2.3.6.

To ensure the reliability of measurements, the program must ensure the availability and proper upkeep of tools, including hand tools, test equipment, software, and others. This may include routine recertification and/or calibration by a third party. While it is not mandatory to use

- **Review records and/or equipment for evidence of routine inspections and documentation of the CAH's biomedical preventive maintenance.**
  - **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?**
  - **Review records of testing equipment for evidence of routine calibration per hospital policy.**
  - **Observe patient care areas to verify that the process for rental and physician-owned equipment within the organization is being followed.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	manufacturer-recommended tools for maintenance, the tools employed should be capable of yielding results equivalent to the manufacturer's requirements. **Maintenance strategies may include:** ▪ **Preventive Maintenance – involves scheduled activities aimed at minimizing equipment degradation, reducing performance loss, and ensuring reliability, regardless of the need at the time, with most commonly occurring at fixed time intervals but also based on metered equipment usage.** ▪ **Predictive Maintenance – a strategy that includes periodic or continuous monitoring of equipment to detect degradation, predict future maintenance needs, and schedule maintenance just before performance loss occurs.** ▪ **Reactive Maintenance – involves performing maintenance or replacement only after equipment failure or issues occur, which is suitable for disposable or low-cost equipment with minimal or no risk to health and safety upon failure.** ▪ **Reliability-Centered Maintenance – this strategy considers equipment condition, unique factors of individual equipment (including function, consequences of failure, and operational environment), and aims to optimize both reliability and cost effectiveness. See ASHE 2022 *Reliability-Centered Maintenance Guide* for additional guidance.** **(For further guidance, refer to NFPA 99-2012: Chapter 10; Chapter 11)**	
03.05.02 Medical equipment inventory The CAH maintains a written inventory of all medical equipment available for use. **§485.623(b)(1) Tag C-0914**	☐ Compliant ☐ Not Compliant The inventory includes all medical equipment used directly or indirectly for patient treatment and care.	This standard is not met as evidenced by:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	If the CAH is using an AEM strategy, 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 plan 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, CAHs 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.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Review inventory list. Compare with field observed equipment to ensure all medical equipment is included. ▪ If the CAH uses the AEM strategy, does the inventory for the AEM plan contain any equipment which is not eligible for AEM?
03.05.03 Medical Equipment and systems: Alternative Equipment Maintenance There is an established, scheduled preventive maintenance plan for medical equipment relating directly or indirectly to patient care, and shall be maintained and tested periodically in accordance with the manufacturer's recommendations.	☐ Compliant ☐ Not Compliant **Note: The standard, required elements, and scoring procedure were previously part of 11.05.01.** **ALTERNATE EQUIPMENT MANAGEMENT (AEM) STRATEGY** A CAH may, under certain conditions, use equipment maintenance activities and frequencies that differ from those recommended by the manufacturer,	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** **Note: For maintenance of medical equipment not included in an AEM plan, score at 03.05.01.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
CAHs may choose to employ alternative maintenance activities and/or schedules provided they develop, implement, and maintain a documented Alternate Equipment Management (AEM) strategy, to minimize risks to patients and others in the CAH associated with the use of medical equipment. §485.623(b)(1) Tag C-**0914**	provided the activities and frequencies do not reduce the safety of the equipment. CAHs that choose to employ alternate maintenance activities and/or schedules use a documented AEM strategy to minimize risks associated with the use of medical equipment to patients and others in the CAH. The AEM strategy 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*. **(For further guidance, refer to CMS Ref: S&C: 14-07-Hospital)**	**If the CAH is using an AEM strategy for inspection, testing, and maintenance activities, verify:** ▪ **For equipment included in the AEM strategy, the methodology for assessing risk and determining alternative maintenance activities and/or frequencies.** ▪ **Documentation for the AEM strategy addresses the requirements for equipment to have maintenance activities and frequencies less than the manufacturer's recommendations.** ▪ **For the equipment that is included in the AEM strategy, the methodology for applying maintenance strategies and determining alternative maintenance activities and/or frequencies.** ▪ **Verify the hospital is evaluating the safety and effectiveness of the AEM strategy on an annual basis.** ▪ **If the hospital uses the AEM strategy, the annual evaluation addresses:** □ **How the equipment is evaluated.** □ **How incidents of equipment malfunction are investigated.** □ **The use of performance data.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.05.04 Patient call system The CAH maintains a means by which patients can summon help. **§485.623(b)(1) Tag C-0914**	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.05.03.** The CAH maintains a patient call system so patients can summon assistance. A backup system should be available to cover this need during power outages**, partial system failure or total system failure**. Patient call systems are not required in psychiatric nursing units, or psychiatric CAHs 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.
03.05.05 Safe Medical Device Act (SMDA) The CAH has taken actions to comply with the Safe Medical Device Act (SMDA). **§485.623(b)(1) Tag C-0914**	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.05.04.** **The Safe Medical Devices Act (SMDA) was enacted as a federal law in 1990, mandating medical device manufacturers and user facilities like hospitals and ambulatory surgical facilities to notify the U.S. Food and Drug Administration (FDA) about any adverse events related to medical devices.** 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: **DOCUMENT REVIEW** ▪ Review organization policies and procedures, tracking systems, and their ability to demonstrate compliance.
03.05.06 Medical equipment procurement The CAH obtains information and opinions when acquiring new medical equipment from the individuals who operate and service the equipment.	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.05.05.** **It is crucial to involve various stakeholders, including clinicians, department heads, administration, clinical engineering, information technology, end**	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review organization policies and procedures, tracking systems, and their ability to demonstrate compliance.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.623(b)(1) Tag C-0914	**users, and finance, when purchasing medical equipment. This ensures the right team is engaged in the process.** **Additionally, it is important to consider the input of medical professionals who will be using the equipment before finalizing the decision, balancing data-driven discussions with the emotional aspect, ultimately enabling informed and rational decision-making**.	

UTILITY SYSTEMS PROGRAM

03.06.01 Utility equipment and systems: Maintenance

All essential mechanical and electrical equipment is maintained in safe operating condition.

§485.623(b) Tag C-0914
§485.623(b)(1)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Note: This standard includes required elements previously located in 03.06.09. AEM requirements are now separated and found at 03.06.03.

Utility equipment is defined as devices intended to support the physical environment of the CAH. 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 CAHs that elect to perform equipment maintenance in accordance with the manufacturer's requirements, the CAH must maintain documentation of the manufacturer's recommendations as well as the CAH'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.

The CAH must have a process that prior to initial use and after significant repairs or upgrades, thorough inspection, performance, and safety testing is mandatory for all equipment involved in the utility equipment program.

DOCUMENT REVIEW AND INTERVIEW

Note: For maintenance of utility equipment included in an AEM plan, score at 03.06.03.

- **Verify that there is established preventive maintenance of the utility 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 utility equipment preventive maintenance.**
  - **Are inspections conducted in a timely manner? Are past-due inspections common or rare?**

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 strategy, is listed in an inventory that includes a record of maintenance activities. **To ensure the reliability of measurements, the program must ensure the availability and proper upkeep of tools, including hand tools, test equipment, software, and others. This may include routine recertification and/or calibration by a third party. While it is not mandatory to use manufacturer-recommended tools for maintenance, the tools employed should be capable of yielding results equivalent to the manufacturer's requirements.** **Maintenance Strategies may include:** ▪ **Preventive Maintenance – scheduled activities most commonly occurring at fixed time intervals but also based on metered equipment usage and aimed at minimizing equipment degradation, reducing performance loss, and ensuring reliability, regardless of the need at the time.** ▪ **Predictive Maintenance – a strategy that includes periodic or continuous monitoring of equipment to detect degradation, predict future maintenance needs, and schedule maintenance just before performance loss occurs.** ▪ **Reactive Maintenance – involves performing maintenance or replacement only after equipment failure or issues occur, which is suitable for disposable or low-cost equipment with minimal or no risk to health and safety upon failure.** ▪ **Reliability-Centered Maintenance – this strategy considers equipment condition, unique factors of individual equipment (including function, consequences of failure, and operational environment), and aims to optimize both reliability and cost effectiveness. See ASHE 2022 *Reliability-Centered Maintenance Guide* for additional guidance. (For further guidance, refer to NFPA 99-2012: Chapter 9.)**	□ **Review records of testing equipment for evidence of routine calibration per hospital policy.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.06.02 Utility Equipment Inventory The CAH maintains a written inventory of all **utility** equipment available for use. **§485.623(b)** **Tag C-0914** **§485.623(b)(1)**	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.06.10.** The inventory includes all plant equipment used directly or indirectly for the healthcare facility. If the CAH is using an AEM strategy, 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 strategy or not, must also be readily identified as such. To facilitate effective management, a well-designed equipment inventory contains the following information. However, CAHs 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.	This standard is not met as evidenced by: **OBSERVATION AND INTERVIEW** ▪ Review inventory list. Compare with field observed equipment to ensure all plant equipment is included. ▪ If the CAH uses the AEM strategy, does it include any equipment that is not eligible for AEM?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.06.03 Utility equipment and systems: Alternative Equipment Maintenance There is an established, scheduled preventive maintenance program for utility equipment and systems, maintained and tested periodically in accordance with the manufacturers' recommendations. As an alternative approach, CAHs 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 CAH associated with the use of facility equipment. §485.623(b) Tag C-**0914** §485.623(b)(1)	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.06.09.** **ALTERNATE EQUIPMENT MANAGEMENT (AEM) PROGRAM** A CAH 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. CAHs that choose to employ alternate maintenance activities and/or schedules must develop, implement, and maintain a documented AEM Strategy to minimize risks to patients and others in the CAH associated with the use of facility equipment. The AEM Strategy must be based on generally accepted standards of practice for facility equipment maintenance, such as ASHE 2009, *Maintenance Management for Health Care Facilities*. **Note: For further guidance, refer to CMS Ref: S&C: 14-41-CAH.**	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** **Note: For maintenance or utility equipment not included in an AEM plan, score at 03.06.01.** If the hospital is using an AEM strategy for inspection, testing, and maintenance activities, verify, for the AEM equipment: ▪ The methodology for assessing risk and determining alternative maintenance activities and/or frequencies. ▪ Documentation addresses the requirements for equipment to have maintenance activities and frequencies less than the manufacturer's recommendations. ▪ The methodology for applying maintenance strategies and determining alternative maintenance activities and/or frequencies. ▪ The annual evaluation addresses: □ How the equipment is evaluated. □ How incidents of equipment malfunction are investigated. □ The use of performance data.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
03.06.04 Water management plan 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. The hospital takes precautions to monitor the temperature of water. **§485.623(b) Tag C-0914**	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.06.03.** 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 plan compliance activities, refer to Infection Prevention and Control standard 18.02.06. Precautions are taken to assure compliance with state and local standards related to domestic hot water temperature to protect patients against scalding or burning.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Water reports and annual testing are submitted to the water management team and Safety Committee. ▪ Through interview with the maintenance director to verify support for water management plan, 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.
03.06.05 Ventilation, light, and temperature control *There must be proper ventilation, lighting, and temperature controls in pharmaceutical, patient care, and food preparation areas.* §485.623(b)(5) Tag C-**0926**	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.07.03.** 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.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ All food and medication preparation areas are well lit. ▪ The CAH is in compliance with ventilation requirements for patients with contagious airborne diseases, such as tuberculosis, patients receiving treatments with hazardous chemicals, surgical areas, and other areas where hazardous materials are stored.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Note: While manufacturers of supplies and equipment will be expanding the 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. Hospitals are to follow the current IFUs for supplies and equipment used in their ORs.

Acceptable standards such as those from the Association of Operating Room Nurses (AORN) or the Facility Guidelines Institute (FGI) should be incorporated into CAH 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:

- Critical and/or high-risk areas:
  - Operating rooms.
  - Cath labs.
  - Decontamination, sterile processing, and sterile storage.
- Non-high-risk 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.

- Food products are stored under appropriate conditions (e.g., time, temperature, packaging, location) based on nationally accepted sources such as the United States Dept of Agriculture, the FDA, 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 CAH has elected, in writing, to adopt CMS categorical waiver 13-25 LSC **for anesthetizing locations and has a documented risk assessment for all equipment, supplies, and IFUs used in anesthetizing locations.**

Review:

- Monitoring records to ensure that appropriate temperatures are maintained.
- Humidity maintenance records for anesthetizing locations to ensure that, if humidity levels were not within acceptable parameters, corrective actions were performed in a timely manner to achieve acceptable levels.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	□ Soiled utility rooms. □ Clean utility rooms. 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 CAH 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 ask if they feel that their areas have adequate ventilation, light, and temperature control. What guidelines are used in food preparation area? How often is monitoring conducted?
03.06.06 Emergency power and lighting The CAH must provide emergency power and lighting in the emergency room and provide battery lamps and flashlights in other areas. §485.623(c)(2) Tag C-**0942**	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.06.01.** The CAH 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 standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Emergency power and lighting cover at least the minimum required areas. □ Identify how the CAH monitors the readiness of these systems.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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. **Battery operated emergency lighting must be tested monthly for a minimum of 30 seconds and every 12 months for a minimum of 1½ hours. Test results must be documented (see NFPA 101-2012: 7.9.3; 7.10.9).**	▪ Areas of the hospital that are not serviced by the emergency supply source are equipped with battery lamps and flashlights.
03.06.07 Emergency power electrical system CAHs must have a Type I essential electrical system power source powered by a generator set equipped with a 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. §485.623(a) Tag C-**0912**	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.06.02.** 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. 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 for systems needed for life safety, such as egress lighting, fire alarm system and exit signs (6.4.2.2.4).** **2. The critical branch for circuits and equipment that are critical to the function of patient care, such as certain receptacles, and task lighting (6.4.2.2.4).**	This standard is not met as evidenced by: **DOCUMENT REVIEW AND OBSERVATION** Verify: ▪ The CAH has a Type I Essential 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

The third branch is the equipment system branch. This branch supports systems that are vital to building systems, such as HVAC and certain elevators (6.4.2.2.5). The equipment system can use either:

1. **Delayed automatic connection (6.4.2.2.5.3).**
2. **Delayed automatic or manual connection (6.4.2.2.5.4).**

Prior to the development of NFPA 99 standard *Health Care Facilities*, life safety branch and the critical branch were allowed to be one branch and not separated. Therefore, essential electrical systems that were installed, renovated, or modernized after 1983, must comply with NFPA 99 (2012 edition) requirements.

Consideration should be given to generator failure solutions, processes for repair, and how to connect external resources during an emergency.

DESIGN AND CONSTRUCTION PROGRAM

03.07.01 Adequate facilities and supplies

The CAH shall maintain adequate facilities for its services.

Supplies must be maintained to ensure an acceptable level of safety and quality.

The extent and complexity of facilities shall be determined by the services offered.

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

☐ Compliant ☐ Not Compliant

The CAH shall provide facilities adequate to serve the needs of the patients.

Diagnostic and therapeutic facilities must be in rooms or areas specifically designed for the purpose intended.

"Adequate facilities" means the facilities are:

- Designed and maintained in accordance with federal, state, and local laws, regulations, and guidelines.
- 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.

This standard is not met as evidenced by:

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

- Observe the layout and verify that the patient's needs are met. Toilets, sinks, specialized equipment, etc., should be accessible.
- Are facilities appropriate to meet the needs of CAH patients? Discuss with members of the medical executive committee, members of the medical staff; nursing staff, and department heads to determine if the needs of patients are being met.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
walls are considered outside windows for the purposes of this requirement. (i) *The sill height requirement does not apply to newborn nurseries and rooms intended for occupancy for less than 24 hours.* (ii) *Special nursing care areas of new occupancies shall not exceed 60 inches.* §485.623(c)(7) Tag C-0940 §485.623(c)(7)(i-ii)	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 CAH 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 CAH 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 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.	▪ Verify that x-ray, physical therapy, and other specialized services are provided in areas appropriate for the service and provide appropriate safety and security for all persons. ▪ Discuss the adequacy of safety in service placement in the CAH. □ Has the CAH identified supplies that are likely to be needed in emergency situations? □ Has the CAH 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.
03.07.02 Assessing risk prior to construction When the CAH plans for renovation and construction, a written assessment is made to reduce the risk to the organization. **§485.623(b)(1) Tag C-0914**	☐ Compliant ☐ Not Compliant Prior to demolition, construction, and renovation activities a risk assessment is conducted for activities that could affect patients, staff and visitors **(often referred to as a pre-construction risk assessment (PCRA). The risk assessment includes:** **1. Utility requirements** **2. Air quality requirements** **3. Infection control**	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ A risk assessment is conducted prior to construction activities.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	4. Vibrations **5. Noise** **6. Other hazards**.	▪ Actions are taken as a result of risk assessments for current renovation activities.
PROGRAM EVALUATION		
03.08.01 Monitoring the physical environment A process is established by the CAH 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 **including incidents of workplace violence**. ▪ 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 and laboratory equipment.	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 03.07.07.** The appropriate committee for safety may be different depending on the issue, and patient confidentiality. When legal processes are followed, opportunities to make improvements in care, treatment, and services, or to prevent the same or similar incidents from occurring, are not lost. Where confidentiality is required, a summary of the incident must be shared 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Documentation of hazardous surveillance inspections confirm 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Problems, failures, and user errors on utility equipment.
- **Construction related activities and mitigative measures.**

The CAH has housekeeping and preventive maintenance programs to ensure the premises are clean and orderly.

§485.623(b) Tag C-0914
§485.623(b)(4) Tag C-0924

03.08.02 Evaluating the Physical Environment Programs

An evaluation of the Physical Environment Programs is completed annually.

The evaluation is documented.

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

A program is a collection of related policies, assessments, performance measures and activities aimed at achieving strategic objectives.

The documented annual evaluation for each program includes an assessment of:

- **Objectives – assess whether the program objectives require changes, based on changes to standards, regulations, the facility, or operations. Objectives of a program represent the output or what you want to accomplish and provide direction and purpose with the program.**
- **Scope – assess whether the program scope requires changes, based on changes to standards, regulations, the facility, or operations. Identify any new processes needed, or whether any can be deleted. Scope of a program defines the boundaries represented and what is included in the program.**
- **Plan effectiveness – assess whether the program met the objectives. Use ongoing monitoring of performance to demonstrate whether the program was effective or if opportunities for improvement were identified.**

INTERVIEW AND DOCUMENT REVIEW

Verify

- **There is an annual evaluation for each program related to the physical environment standards:**
  - ☐ Safety
  - ☐ Security
  - ☐ Hazardous Materials and Waste
  - ☐ Fire Safety
  - ☐ Medical Equipment
  - ☐ Utility Equipment
- **The annual evaluation(s) has been reviewed by the Safety Committee and documented in the meeting minutes.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- **Ongoing monitoring of performance may include:**
  - **Performance measures and analysis of results**
  - **Results from activities, such as fire drills, fire protection activities, generator testing.**
  - **Results of utility interruptions**
  - **Training and testing**
  - **Effectiveness of policies and procedures.**

- **Plan for improvement – based on the evaluation of the objectives, scope, and effectiveness, identify recommendations for improvement for the next cycle.**

An Executive Summary of the program evaluations may be used to satisfy ACHC Standard 04.01.00 for the annual evaluation summarizing issues relating to the physical environment, construction, equipment and staffing needs.

04

ORGANIZATIONAL STRUCTURE

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
04.00.00 CONDITION OF PARTICIPATION: Organizational structure §485.627 Tag C-0960	☐ Compliant ☐ Not Compliant This CoP is scored based on the scoring of standards 04.00.01 through 04.00.09.	This standard is not met as evidenced by: **Note:** Review scoring of 04.00.01 through 04.00.09 for Condition-level scoring.
04.00.01 Governing body or responsible individual *The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH'S total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.* §485.627(a) Tag C-0962	☐ Compliant ☐ Not Compliant The CAH must have only one governing body (or responsible individual) and this governing body is responsible for the conduct of the CAH as an institution. In the absence of an organized governing body, there must be written documentation that identifies the individual or individuals that are responsible for the conduct of the CAH operations.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The CAH has an organized governing body or documentation that identifies the individual that is responsible for its operations. ▪ The operating policies fully reflect its responsibilities as a CAH (e.g., physician assistant responsibilities, provision of required CAH direct services). ▪ Evidence (e.g., minutes of board meetings) demonstrates that the governing body or the individual who assumes responsibility for CAH operation is involved in the day-to-day operation of the CAH and is fully responsible for its operations.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
04.00.02 Categories of practitioners The governing body, in accordance with state law, determines the categories of practitioners eligible for appointment to the medical staff. §485.627(a) Tag C-0962	☐ Compliant ☐ Not Compliant **No additional information.**	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the governing body (or responsible individual) has identified the categories of practitioners that are eligible candidates for appointment to the medical staff.
04.00.03 Medical staff appointment The governing body appoints members of the medical staff after considering the recommendations of the existing members of the medical staff. §485.627(a) Tag C-0962	☐ Compliant ☐ Not Compliant It is the responsibility of the governing body (or responsible individual) to appoint, with the advice of the medical staff, the individual practitioners to the medical staff. After considering medical staff recommendations, and in accordance with established CAH medical staff criteria and state and federal laws and regulations, the governing body decides whether or not to appoint new medical staff members or to continue appointment of current members of the medical staff.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Records of medical staff appointments substantiate the governing body's involvement. ▪ The governing body (appoints all members to the medical staff in accordance with established policies based on the individual practitioner's scope of clinical expertise and in accordance with federal and state law. ▪ Selection of medical staff for membership, both new and renewing, is based on an individual practitioner's compliance with the medical staff membership criteria.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
04.00.04 Provision of medical staff bylaws The governing body must ensure that the medical staff has bylaws and approve medical staff bylaws and other medical staff rules and regulations. §485.627(a) Tag C-0962	☐ Compliant ☐ Not Compliant The governing body ensures that the medical staff bylaws comply with state and federal law and the requirements of the CAH CoP (Conditions of Participation). 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: ▪ The medical staff operates under current bylaws that are in accordance with federal and state laws and regulations. ▪ Any revisions or modifications in the medical staff bylaws, rules, and policies, have been approved by the medical staff and the governing body. Review the bylaws and check for date of last review and initials by the person(s) responsible.
04.00.05 Medical staff accountability for quality of care The governing body must: ▪ Ensure that the medical staff is accountable to it for the quality of care provided to patients. ▪ Ensure that every patient is under the care of a member of the medical staff, or under the care of a practitioner who is under the supervision of a member of the medical staff. §485.627(a) Tag C-0962	☐ Compliant ☐ Not Compliant The governing body's responsibility for the conduct of the CAH includes the quality of care provided to patients. All patient care is provided by or in accordance with the orders of a practitioner granted privileges to provide or order that care and is in accordance with state law.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The governing body (or responsible individual) is periodically apprised of the medical staff evaluation of patient care services provided at every patient care location of the CAH. ▪ 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 (or

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		responsible individual) for the quality of services provided.
04.00.06 Selection criteria for appointment to the medical staff *The governing body must* ▪ *Ensure the criteria for selection are individual character, competence, training, experience, and judgement.* §485.627(a) Tag C-0962	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ There are written criteria for staff appointments to the medical staff. ▪ At minimum, the criteria for selection to the medical staff include those listed in the standard.
04.00.07 For future use		
04.00.08 Disclosure: Management *The CAH discloses the name and address of the person principally responsible for the operation of the CAH.* §485.627(b)(1) Tag C-0964	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the CAH has a policy and procedure for reporting changes in operating officials to the state agency.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
04.00.09 Disclosure: Medical staff leadership *The CAH discloses the names and addresses of the person responsible for medical direction.* §485.627(b)(2) Tag C-0966	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the CAH implement has a policy and procedure for reporting changes in medical director to the state agency?
04.01.00 Oversight of the physical environment The governing body is responsible for providing a physical environment that is constructed, arranged, maintained, equipped, and staffed to meet the needs and services required for patients. **§485.623** **§485.627(a)**	☐ Compliant ☐ Not Compliant The governing body receives and reviews periodic written reports from appropriate internal and external sources about the adequacy and deficiencies of the physical environment to assure the well-being of patients.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that reports on the physical plant and equipment are periodically submitted to the governing body.
04.01.01 Oversight of the QAPI plan *The CAH's governing body or responsible individual is ultimately responsible for the CAH's QAPI program and is responsible and accountable for ensuring that the QAPI program meets the requirements of* §485.641(b). The QAPI plan and its findings are shared with and approved by the governance. **485.641(c)**	☐ Compliant ☐ Not Compliant The QAPI Program and annual plan reflect 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 include separate findings, as appropriate, for the medical staff and other providers of care and service.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that the governing body has: ▪ Approved the QAPI plan within the last 12 months. ▪ Received and acted upon summary findings at least quarterly for both medical staff and other providers.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Such reports are typically documented at least quarterly and aggregated into an annual evaluation. Report formats may vary to include narration, statistical charts, diagrams, etc.	▪ Received and acted upon an annual QAPI evaluation. 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 open session.
04.01.02 Oversight of Patient Care Supplies The governing body is responsible for ensuring adequate patient care supplies are available to support services offered to patients. Supplies are not outdated, contaminated**, or recalled.** **§485.618(b)(2)** **§485.623(b)(4)**	☐ Compliant ☐ Not Compliant The supplies are of the sizes and quantities needed to accommodate patient care. **Policies and procedures are in place for an effective product recall system that includes:** **1. Receipt and distribution of recall notices.** **2. Identification of product availability within the CAH.** **3. Notification of recalls to appropriate departments/staff.** **4. Verification of recall of all available products.** A recall log is maintained to verify all elements of the process are completed.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ A policy covers each standard requirement. ▪ The policy has been implemented. ▪ Staff are aware of the process for notification and recall of products. ▪ A recall log is maintained. ▪ Non-expired supplies are available throughout the CAH.

05

STAFFING

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
MEDICAL STAFF		
05.00.00 CONDITION OF PARTICIPATION: Staffing and staff responsibilities §485.631 Tag C-0970	☐ Compliant ☐ Not Compliant This CoP is scored based on the scoring of standards 05.00.01 through 05.00.13; 05.02.01 and 05.02.02; 05.03.01 through 05.03.04.	This standard is not met as evidenced by: **Note:** Review scoring of 05.00.01 through 05.00.13; 05.02.01 and 05.02.02; 05.03.01 through 05.03.04 for Condition-level scoring.
05.00.01 Staffing *The CAH has a professional health care staff that includes one or more doctors of medicine or* osteopathic medicine*, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.* §485.631(a)(1) Tag C-0971	☐ Compliant ☐ Not Compliant A CAH may operate with a MD/DO on staff as well as with any combination of mid-level practitioners.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review listings or organizational charts showing the names of all staff MD/DOs, nurse practitioners, clinical nurse specialists and physician assistants on the CAH staff. ▪ Review work schedules showing normal CAH hours of operation and coverage by members of the CAH staff.
05.00.02 Ancillary staff supervision *Any ancillary personnel are supervised by the professional staff.* §485.631(a)(2) Tag C-0972	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Use organizational charts and staff interviews to determine how the CAH ensures that the professional staff supervises all ancillary personnel.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.00.03 Availability of medical/ professional staff *A doctor of medicine or o*steopathic medicine*, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.* §485.631(a)(4) Tag C-0976	☐ Compliant ☐ Not Compliant Section 485.635(b)(1) requires CAHs to provide "those diagnostic and therapeutic services and supplies that are commonly furnished in "a physician's office" such as low intensity outpatient services. In order to demonstrate compliance, a CAH must demonstrate that a practitioner is physically present and prepared to treat patients at the CAH when patients present at the CAH outpatient clinic during announced hours of outpatient clinic operation. This requirement does not mean the CAH must have a practitioner physically present in the facility 24 hours per day, nor does it require their presence 24 hours per day when the CAH has inpatients, including swing-bed patients.	This standard is not met as evidenced by: **INTERVIEW** ▪ If the CAH does not have regular announced hours of operation, ask the individual who is principally responsible for the operation of the CAH, when the CAH is open to the public to provide outpatient services. □ Confirm that arrangements have been made by the CAH to ensure that a practitioner is available onsite at all times the CAH operates to furnish **outpatient clinic** patient care services.
05.00.04 Responsibilities of the MD or DO: Medical direction *The Doctor of Medicine* or Osteopathic Medicine— ▪ *Provides medical direction for the CAH'S health care activities and consultation for, and medical supervision of, the health care staff.* §485.631(b)(1)(i) Tag C-0980 Tag C-0981	☐ Compliant ☐ Not Compliant A CAH must have a physician (MD/DO) on its staff. That individual must perform all medical oversight functions.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ What evidence demonstrates that an MD/DO provides medical direction for the CAH'S health care activities and is available for consultation and supervision of the CAH health care staff?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.00.05 Responsibilities of the MD or DO: Governance *The Doctor of Medicine* or osteopathic medicine— ▪ *In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH'S written policies governing the services it furnishes.* §485.631(b)(1)(ii) Tag C-0982	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW AND INTERVIEW** ▪ What evidence demonstrates that an MD/DO has participated in the development of policies governing CAH services? ▪ How does the CAH ensure that an MD/DO periodically reviews these policies?
05.00.06 Responsibilities of the MD or DO: Clinical responsibilities *The doctor of medicine or* osteopathic medicine— ▪ *In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH'S patient records, provides medical orders, and provides medical care services to the patients of the CAH.* §485.631(b)(1)(iii) Tag C-0984	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW AND INTERVIEW** ▪ How does the CAH ensure that an MD/DO periodically reviews CAH patient records in conjunction with staff mid-level practitioners and provides medical care to CAH patients? ▪ What evidence demonstrates that there is a periodic review of patient records by the CAH MD/DO(s)?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.00.07 Responsibilities of the MD or DO: Reviews and signs medical records *The doctor of medicine or* osteopathic medicine— ▪ *Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.* ▪ *Periodically reviews and signs a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants only to the extent required under State law where State law requires record reviews or co-signatures, or both, by a collaborating physician.* §485.631(b)(1)(iv-v) Tag C-0986	☐ Compliant ☐ Not Compliant All inpatient records for patients whose treatment is/was managed by a nonphysician practitioner in the CAH, i.e., nurse practitioners, clinical nurse specialists, or physician assistants, must be reviewed periodically by a CAH MD/DO who must sign the records after the review has been completed. The MD/DO review is expected to cover all applicable inpatient records open at the time of the review, as well as all applicable inpatient records closed since the last review. In the case of inpatients whose care is/was managed by an MD/DO, as evidenced by an admission order, progress notes, and/or medical orders, etc., but who also received services from a non-physician practitioner, a subsequent MD/DO review of the inpatient record is not required. **CO-SIGNATURES** ▪ In states where state law requires a collaborating physician to review medical records, co-sign medical records, or both for outpatients whose care is managed by a non-physician practitioner, i.e., a nurse practitioner, a clinical nurse specialist, a certified nurse midwife, or a physician assistant, a CAH MD/DO must review and sign a sample of outpatient records. ▪ The outpatient medical record sample reviewed must be representative of all non-physician practitioners providing care to patients of the CAH. ▪ The CAH determines by policy the size of the sample reviewed and signed. If state law requires MD/DO review or signature of a specific percentage of the outpatient records, the CAH must comply with state law. ▪ In states where no physician record review or physician co-signature is required for patients managed by a non-physician practitioner, an MD/DO is not required to review or sign outpatient records of such patients. Neither the regulation nor the preamble to the final rule adopting this regulation (79 Fed. Reg. 27105, May 12, 2014) specify a particular time frame	This standard is not met as evidenced by: **DOCUMENT REVIEW** Select a sample of inpatient and outpatient records, including both open and closed records. For inpatient records, use those of patients whose care is/was managed by a non-physician practitioner. Verify that: ☐ An MD/DO has reviewed and signed all records that were open at the time of the review, and all inpatient records that were closed since the MD/DO's last review. ☐ That reviews take place within the time frame specified by the CAH's policy. ☐ Ask the CAH how many outpatient encounters are managed by non-physician practitioners, what sample size its policy requires for MD/DO review, and what time frame its policy specifies for reviews. ☐ If state law requires a physician to review or co-sign (or both) any outpatient records of patients whose care is/was managed by a non-physician practitioner, confirm that an MD or DO has reviewed and/or co-signed records within the time frame specified in the CAH's

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	to satisfy the requirement for "periodic" review, but the CAH must specify a maximum interval between inpatient record reviews in its policies and procedures. The CAH is expected to consider the volume and types of services it offers in developing its policy. For example, a CAH that has only four certified beds and one MD/DO on staff and which does not always have an inpatient in house would likely establish a different requirement for inpatient record review than a CAH with 25 certified beds, multiple MDs/DOs on staff and a high inpatient occupancy rate. There is no regulatory requirement for the review of records to be performed onsite and in person. This means, if the CAH has electronic medical records that can be accessed and digitally signed remotely by the MD or DO, this method of review is acceptable. CAHs with and without the capability for electronic record review and signature might also develop different policies for the maximum interval between reviews.	policies. □ Ask the CAH to explain how it ensures the sample is representative of the various non-physician practitioners as well as of the various types of outpatient services they provide. □ Ask the CAH to describe the method it uses to make sure that reviews are performed in a timely manner on a sample that complies with the CAH's policy.
05.00.08 <u>Medical staff onsite</u> *A doctor of medicine or o*steopathic medicine *is present for sufficient periods of time to provide the medical direction, consultation, and supervision for the services provided in the CAH, and is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.* §485.631(b)(2) Tag C-0988	☐ Compliant ☐ Not Compliant An MD/DO must be present in the CAH for sufficient periods of time to provide overall medical direction, consultation, and supervision of the healthcare services the CAH furnishes. Being "present" in the CAH means being physically on-site in the CAH. The regulation does not specify a minimum amount of time an MD/DO must spend on-site that applies to all CAHs. Instead, CAHs have the flexibility to develop policies appropriate for their circumstances. With the development of technology such as telemedicine, a CAH may use a variety of ways and time frames for MDs/DOs to provide the necessary medical direction and oversight.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW AND INTERVIEW</u>** ▪ Confirm that policies and procedures address the minimum amount of time and frequency of MD or DO presence on-site at the CAH. Can the CAH demonstrate how its policy reflects sufficient MD/DO presence on-site to support the volume and types of services provided?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	For CAHs that offer a range of more complex services, have more than one MD/DO on staff, and have busy emergency departments and/or extensive outpatient services, an on-site visit by an MD/DO only once every week or every two weeks, for example, would be grossly inadequate. On the other hand, a bi-weekly on-site visit could be unduly burdensome as well as unnecessary for a small CAH in a remote on-site rural area that offers very limited services and has a low patient volume. CAHs are expected to have adequate staffing to provide the services they have chosen to furnish, including staffing or supervision by MDs/DOs as applicable. CMS expects each CAH to evaluate its services and adjust its MD/DO on-site schedule accordingly, as an appropriate MD/DO schedule must reflect the volume and nature of services offered. Note that §485.618(d) also establishes a maximum time frame for an MD, DO, PA, NP, or clinical nurse specialist to be on-call and available to be on-site to provide emergency care, and that §489.20(r)(2) requires the CAH to maintain an on-call list of MDs/DOs who are available to be on-site as part of the CAH's Emergency Medical Treatment and Labor Act obligations. The CAH must consider all pertinent requirements when developing its policies for MD/DO presence on-site. In addition to requiring an MD or DO to be on-site for sufficient periods of time, consistent with the requirement at §485.618(e), the CAH must also ensure an MD/DO is available through direct radio, telephone, or other form of electronic communication, such as video conferencing, for consultation, assistance in handling patient medical emergencies and referral of patients to other healthcare facilities. An MD/DO providing telemedicine services to the CAH may be used to fulfill the requirement for availability via telecommunications.	▪ Is there documentation showing that an MD or DO is on-site for the frequency and duration specified in the CAH's policies? ▪ Can the CAH demonstrate that an MD or DO is always available by telecommunication for consultation, assistance and/or patient referral?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Further, consistent with the requirements for CAH provision of emergency services at §485.618(d), unless a, PA, NP, or clinical nurse specialist with training in emergency care is immediately available via one of these telecommunication methods and available on site within the time frame specified at §485.618(d)(1), an MD or DO must fulfill these requirements.	
05.00.09 Physician assistant, nurse practitioner and clinical nurse specialist responsibilities: Policies and procedures *The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH'S staff—* ▪ *Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes.* §485.631(c)(1)(i) Tag C-0990 Tag C-0991	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview any mid-level professional staff to ascertain their level of involvement in CAH policy development, execution, and periodic review. ▪ Does the CAH ensure that policies are updated to remain consistent with state standards of practice requirements for mid-level practitioners?
05.00.10 Physician assistant, nurse practitioner and clinical nurse specialist responsibilities: Medical record review *The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH'S staff—* ▪ *Participate with a doctor of medicine or osteopathic medicine in a periodic review of the patients' health records.*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ How does the CAH ensure that mid-level practitioners at the CAH participate with an MD/DO in the review of their patients' health records?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.631(c)(1)(ii) Tag C-0993		
05.00.11 Physician assistant, nurse practitioner and clinical nurse specialist responsibilities: Clinical	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathic medicine: ▪ *Provides services in accordance with the CAH'S policies.* §485.631(c)(2)(i) Tag C-0995	No additional information.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Review policies and procedures. ▪ Interview mid-level practitioners to gauge their knowledge and application of CAH policies.
05.00.12 Physician assistant, nurse practitioner and clinical nurse specialist responsibilities: Referrals	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathic medicine*:* ▪ *Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.* §485.631(c)(2)(ii) Tag C-0997	No additional information.	**DOCUMENT REVIEW** ▪ Verify that there are policies and procedures for transferring patients to other facilities.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.00.13 Physician assistant, nurse practitioner and clinical nurse specialist responsibilities: Physician notification and participation *Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or o*steopathic medicine *on the staff of the CAH is notified of the admission.* §485.631(c)(3) Tag C-0998	☐ Compliant ☐ Not Compliant The CAH regulations permit licensed mid-level practitioners, as allowed by the state, to admit patients to a CAH. However, CMS regulations do require that Medicare and Medicaid patients be under the care of an MD/DO if admitted by a mid-level practitioner and the patient has any medical or psychiatric problem present on admission or that develops during hospitalization that is outside the scope of practice of the admitting practitioner. Evidence of being under the care of an MD/DO must be in the patient's medical record. If a CAH allows a mid-level practitioner to admit and care for patients, as allowed by state law, the governing body (or responsible individual) and medical staff would have to establish policies and bylaws to ensure patient safety.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that admitting privileges are limited to those categories of practitioners as allowed by state law. ▪ Verify that patients are admitted only by those practitioners who are currently licensed and have been granted admitting privileges by the governing body (or responsible individual) in accordance with state laws and medical staff bylaws. ▪ Verify that an MD/DO is responsible for and is monitoring the care of each Medicare or Medicaid patient for all medical problems during the hospitalization. ▪ If mid-level practitioners admit patients, verify that every Medicare/Medicaid patient is being monitored by an MD/DO who is responsible for any medical problem outside the scope of practice of the admitting practitioners.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.00.14 Periodic review of clinical privileges and performance	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:

The CAH requires that –

(1) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialist, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a Doctor of Medicine or Osteopathic Medicine or by another Doctor of Medicine or Osteopathy under contract with the CAH.

(2) The quality and appropriateness of the diagnosis and treatment furnished by Doctors of Medicine or Osteopathic Medicine at the CAH are evaluated by—

(i) *One hospital that is a member of the network, when applicable;*

(ii) *One Quality Improvement Organization (QIO) or equivalent entity;*

(iii) *One other appropriate and qualified entity identified in the State rural health care plan;*

(iv) *In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patient under an*

All CAHs must, as a part of their QAPI Program, have an arrangement with an outside entity to review the appropriateness of the diagnosis and treatment provided by each MD/DO providing services to the CAH's patients.

- This includes MDs and DOs providing telemedicine services to the CAH's patients from a distant-site hospital or distant-site telemedicine entity.

Some CAHs may prefer to conduct their own internal review in addition to the outside review; this is neither prohibited nor required under the regulation.

- The regulation does not specify the frequency of the outside review since a quality assurance program is ongoing in nature. The CAH and the outside entity must reach a mutual agreement on the extent and frequency of the outside review.

Entities eligible to provide this outside review for MDs and DOs who provide services on-site at the CAH include a hospital that is a member of the same rural health network as the CAH; a Medicare quality improvement organization, or its equivalent; or another appropriate and qualified entity identified in the state's rural health plan to perform this function.

TELEMEDICINE SERVICES

A. **Distant Site Hospitals**
In the case of MDs or DOs who provide telemedicine services to the CAHs patients under a written agreement between the CAH and a distant-site hospital, the distant-site hospital is the outside entity responsible for reviewing the quality of care provided by these physicians.

B. **Distant-site Telemedicine Entity**
In the case of MDs or DOs who provide telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, the outside entity responsible for reviewing the quality of care provided by these physicians include a

INTERVIEW AND DOCUMENT REVIEW

- What evidence demonstrates that there is an ongoing evaluation of care provided by mid-level practitioners (e.g., reports, periodic written evaluation, QA meeting notes)?
  - How does the CAH ensure that an MD/DO evaluates the quality of care provided by mid-level practitioners in the CAH?
  - How is clinical performance of midlevel practitioners evaluated?
- How does the reviewing MD/DO inform the CAH if he/she determines that there are problems relative to the diagnosis and treatment provided by mid-level practitioners?
  - What follow-up actions are called for in the QA plan?
- Review evidence that the CAH has an agreement for outside review of the quality of *care provided on-site* (i.e., not including telemedicine services) by the CAH's MDs and DOs with at least one of the following:
  - a hospital that is a member of the same rural health network as the CAH.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
agreement between the CAH and a distant-site hospital, the distant-site hospital; or (v) *In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, one of the entities listed in paragraphs (d)(2)(i) through (iii) of this section.* *(3) The CAH staff consider the findings of the evaluation and make the necessary changes as specified in paragraphs (b) through (d) of this section.* §485.631(d)(1-2) Tag C-0999 §485.631(d)(2)(i-v) §485.631(d)(3)	hospital that is a member of the same rural health network as the CAH; a Medicare quality improvement organization, or its equivalent; another appropriate and qualified entity identified in the state's rural health plan to perform this function; or a distant-site hospital with which the CAH has an agreement for provision of telemedicine services.	☐ a Medicare Quality Improvement Organization, or its equivalent. ☐ another appropriate and qualified entity identified in the State's Rural Health Plan. ▪ If the CAH has one or more agreements for the provision of telemedicine services to CAH patients by a distant site hospital(s), does each such agreement include a provision for the distant-site hospital to conduct the required outside review of the quality of telemedicine services provided by the MDs and DOs covered by the agreement? ▪ If the CAH has one or more agreements for the provision of telemedicine services to CAH patients by a distant-site telemedicine entity, does the CAH have an agreement for outside review of the quality of *telemedicine services* provided by the MDs and DOs covered under the agreement? Is the outside review agreement with at least one of the following? ☐ A hospital that is a member of the same rural health network as the CAH; ☐ A Medicare Quality Improvement Organization, or its equivalent;

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		◻ Another appropriate and qualified entity identified in the State's Rural Health Plan; or ◻ A distant-site hospital with which the CAH has an agreement for telemedicine services? ▪ Can the CAH provide examples of any reviews of the quality and appropriateness of diagnosis and treatment of the CAHs MDs and DOs conducted by an eligible outside entity in the prior 12 – 24 months? ▪ Review the QIO reports for the last year. ◻ Have any findings been reported, or any recommendations made? ◻ Has corrective action been taken and documented? Was the action taken effective in resolving the issue? ◻ How are QIO findings used in the reappointment process?
05.00.15 Unified and integrated medical staff for a CAH in a multifacility system. *If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or Rural Emergency Hospitals (REHs), and the system elects to have a unified and integrated medical staff for its*	☐ Compliant ☐ Not Compliant ☐ Not Applicable **MULTI-HOSPITAL SYSTEM** A CAH 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	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Ask the hospital and medical staff leadership if the CAH is part of a multi-hospital system of separately certified hospitals.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
member hospitals, CAHs, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified CAH must demonstrate that– § 485.631(e)	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 regulations, 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, since only one governing body may carry out the governing body's medical staff responsibilities for a unified medical staff. 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. **MULTI–HOSPITAL SYSTEM** The governing body in a multi-hospital system must elect to exercise this option. The existence of a unified medical staff after January 3, 2023, 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.	If no, this standard is scored N/A. If yes: ▪ Did the use of the unified medical staff start after January 3, 2023? ▪ If yes, review documentation of the governing body's 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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 January 3, 2023, effective date of the final rule, then 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 §485.631. ▪ 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 CoP, 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.	
05.00.16 Voting requirements for separately certified critical access hospitals *If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or Rural Emergency Hospitals (REHs), and the system elects to have a unified and integrated medical staff for its member hospitals, CAHs, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified CAH must demonstrate that–* ▪ *The medical staff members of each separately certified CAH in the system (that is, all medical staff members who hold specific privileges to practice at that CAH) have voted by majority, in*	☐ Compliant ☐ Not Compliant ☐ Not Applicable The decision for a particular certified CAH 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 AND ▪ Acceptance by a majority of the medical staff members who hold privileges to practice at that particular CAH, voting in accordance with the medical staff bylaws. The medical staff of each CAH 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	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** **Note:** Compliance is assessed only if the hospital uses a unified medical staff. ▪ Ask CAH leadership when use of the unified medical staff began. □ Is there documentation to support the response? □ If the CAH began using a unified medical staff after January 3, 2023, is there evidence that a majority of the medical staff holding privileges at the CAH voted in favor of using a unified medical staff?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective CAH. § 485.631(e) § 485.631(e)(1)	mean only those practitioners who hold privileges to practice on-site at the hospital. Practitioners who hold only telemedicine privileges at a hospital are not included when identifying which practitioners are not eligible to vote nor what constitutes a majority of the practitioners holding privileges at the CAH, in accordance with the medical staff bylaws. A CAH that is part of a hospital system is expected to have medical staff bylaws, rules and regulations that address the regulatory requirements 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. When a CAH 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 medical staff voting on the questions of acceptance of, or opting out of, a unified medical staff, the medical staff and the governing body, which must approve the revised bylaws have the flexibility to determine the details of the voting process including: ▪ 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 CAH 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:	▪ 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 CAH to produce evidence that a majority of the practitioners holding privileges at the hospital voted against opting out. ▪ Can the CAH 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- CAHs 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 other amendments to the medical staff's bylaws, except as required under the regulation 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.)
- CAHs 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.
- CAHs 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 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 generally required to amend the medical staff's bylaws, rules and regulations.
- 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 regulations 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 fifty percent of the medical staff members practicing at the hospital who have voting privileges.

  On the other hand, in the case where a hospital that is part of a hospital system but has a separate medical staff is holding a vote on whether to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

accept participating in a unified medical staff, a 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.

It is not expected that the medical staff bylaws, rules and regulations that were in effect as of January 3, 2023, would address the issue of a unified medical staff, nor the process of voting by medical staff members at each hospital to accept or opt out of a unified medical staff.

Although it is expected that the medical staff bylaws, rules and regulations of hospitals that are part of a hospital system will be amended in a timely fashion, this does not mean that a vote to accept or opt out of a unified medical staff may not take place prior to enactment of such amendments.

Voting is governed by the hospital's medical staff bylaws in effect at the time of the vote, except that only voting members of the medical staff who hold privileges to practice on-site at that hospital may participate in the vote.

With respect to what constitutes a "majority," the provisions of the bylaws governing voting rights and voting procedures at the time of the vote apply. However, as discussed above, in the case of a vote to opt-out of a unified medical staff, the vote may not be delegated to the executive committee of the unified medical staff.

Since a number of hospital systems interpreted the Medical Staff CoP to permit a unified medical staff prior to publication of the final rule at §485.631 on November 23, 2022 or its effective date of January 3, 2023, in the case of a hospital's use of a unified medical staff which began prior to the latter date, it is not necessary for the hospital to hold a vote among the members of the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	medical staff who hold privileges at that hospital to determine whether the majority accepts the continued use of a unified medical staff. However, the governing body is expected to formally notify the medical staff practicing at each hospital of its preference to continue using a unified medical staff arrangement, as well as of the right of the medical staff holding privileges at each hospital to vote to opt out of the unified medical staff. If the system governing body of a hospital that is part of the multi-hospital system but which has a separate medical staff elects, after January 3, 2023, to create a system unified medical staff structure and/or to include the hospital's medical staff in an already existing unified medical staff structure, the hospital must arrange for a vote by medical staff members, in accordance with the medical staff bylaws, on whether or not to accept use of a unified medical staff for their hospital. The hospital may not use a unified medical staff unless a majority of its medical staff members holding voting rights vote, in accordance with the hospital's medical staff bylaws, to accept a unified medical staff. Even if a majority of a hospital's medical staff has voted to use a unified medical staff in the past, the members of the unified medical staff with voting rights and holding privileges to practice on-site at that hospital still retain the right to hold a vote to opt out of the unified medical staff structure at a future date. If a majority of the staff with voting rights and holding privileges at that hospital vote, in accordance with the unified medical staff's bylaws, to opt out, then the hospital must establish a separate medical staff.	

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.00.17 Medical Staff: Bylaws of the unified medical staff	☐ Compliant ☐ Not Compliant ☐ Not Applicable	This standard is not met as evidenced by:

If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or Rural Emergency Hospitals (REHs), and the system elects to have a unified and integrated medical staff for its member hospitals, CAHs, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified CAH must demonstrate that–

- 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 CAH (that is, all medical staff members who hold specific privileges to practice at that CAH) 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 CAH.*

§ 485.631(e)

ONE SET OF BYLAWS, RULES, AND REQUIREMENTS

A CAH that uses a unified medical staff must ensure that the 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, the documentation of the bylaws, rules, and regulations that apply to the unified medical staff must identify each separately certified hospital that has elected to use a unified medical staff and therefore is covered by the unified medical staff bylaws, rules, and regulations.

- Depending on state law, the unified medical staff bylaws, rules and regulations may be in addition to, or instead of, hospital-specific medical staff bylaws, rules and regulations.

The unified medical staff bylaws, rules and regulations must not conflict with any of the specific requirements for medical staff, 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 CAH 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

INTERVIEW AND DOCUMENT REVIEW

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

- Review evidence that the unified medical staff's bylaws, rules and regulations are readily available, and that it is clear that they apply to that hospital.
- Review evidence that the unified medical staff bylaws, rules and regulations 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 and regulations clearly describe how and when members holding privileges at the hospital will be advised of their rights?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§ 485.631(e)(2)	governing opting out, the unified medical staff, and the system governing body, which must approve the medical staff's bylaws, rules and regulations, 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 each separately certified hospital to vote whether to accept of opt out of the unified medical staff structure. For example: ▪ The bylaws, rules and regulations 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 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 regulations 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 regulations may require a "super-majority" for acceptance or opt-out of a unified medical staff 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 regulations. ▪ In the case where a CAH system has a unified medical staff and members	▪ 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? □ Interview several members of the medical staff to determine if they recall being notified of their right to vote by majority to opt out.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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 regulations 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 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 regulations 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.

05.00.18 Multiple hospital systems: Unique circumstances

If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or Rural Emergency Hospitals (REHs), and the system elects to have a unified and integrated medical staff for its member hospitals, CAHs, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified CAH must demonstrate that–

☐ Compliant ☐ Not Compliant ☐ Not Applicable

This standard is not met as evidenced by:

SEPARATELY CERTIFIED CAH

The separately certified CAHs 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 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,

INTERVIEW AND DOCUMENT REVIEW

Note: Assess compliance with this regulation only if the CAH uses a unified medical staff. (See survey procedures for standards 05.00.15 through 05.00.17.)

Ask the CAH 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ *The unified and integrated medical staff is established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each hospital, CAH, and REH.* § 485.631(e) § 485.631(e)(3)	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. □ 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 from comparatively small hospitals in rural areas or those that provide specialized rehabilitation or long-term care hospital services, to very large, short term acute care hospitals. The differences could have implications for medical staff, 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 with distinct 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. Alternatively, 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.	example, how does the unified medical staff assure that: ▪ The medical staff's specification of procedures and treatments requiring a properly executed informed consent reflects any unique hospital circumstances. (See 07.00.04) ▪ 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 18.01.03) ▪ The medical staff fulfills its joint executive responsibilities, along with the hospital's governing body and administrative officials, for ensuring that the hospital-specific 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	CAH LEADERSHIP In all cases the CAH'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.	◻ Determines annually the number of distinct improvement projects conducted in the hospital. (See 09.01.11) ▪ Medical staff policies governing ordering of outpatient services address any unique hospital circumstances? (See 09.00.05) ▪ 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.)
05.00.19 Policies of the unified medical staff *If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or Rural Emergency Hospitals (REHs), and the system elects to have a unified and integrated medical staff for its member hospitals, CAHs, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified CAH must demonstrate that–* ▪ The unified and integrated *medical*	☐ Compliant ☐ Not Compliant ☐ Not Applicable **MEDICAL STAFF POLICIES** The CAH's unified medical staff must have written policies and procedures that address how it considers and addresses needs and concerns expressed by members who practice at the hospital. 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. These matters are addressed under the other standards. This provision addresses a requirement for the unified medical staff to consider and address concerns that practitioners have concerning their own hospital's needs.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the unified medical staff has policies and procedures addressing how members can raise local concerns and needs. ▪ Do the medical staff bylaws, rules and regulations, or written policies and procedures cover the minimum elements?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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, CAHs, and REHs, 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, CAHs, and REHs are duly considered and addressed. § 485.631(e) § 485.631(e)(4)	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 CAH 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.	▪ Ask the CAH 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.
05.01.00 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 appraise the qualifications of all practitioners appointed to the medical staff/granted medical staff privileges at regular intervals. In the absence of a state law or other regulation that establishes a time frame for periodic reappraisal, a hospital's medical staff must conduct a periodic appraisal of each practitioner at least every 36 months. The purpose of the appraisal is to determine the suitability of continuing the medical staff membership or privileges of each individual practitioner, to determine if that individual practitioner's membership or privileges should be continued, discontinued, revised, or otherwise changed.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Determine whether the medical staff bylaws and practice provide evidence that the Medical Staff organization is adequate to accomplish the required activities listed. ▪ Confirm that the medical staff has a system in place for periodic appraisal of its current members and all other credentialed providers and their qualifications in accordance with approved medical staff bylaws and state law requirements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The medical staff appraisal procedures must evaluate each individual practitioner's qualifications and demonstrated competencies to perform each task or activity within the applicable scope of practice or privileges for that type of practitioner for which he/she has been granted privileges. Components of practitioner qualifications and demonstrated competencies would include at least: current work practice, special training, and quality of specific work, patient outcomes, education and 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 category of practitioner requires an appraisal by the medical staff and approval by the governing body. The appraisal must consider evidence of qualifications and competencies specific to the nature of the request. It must also consider whether the activity/task/procedure are 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.	▪ Confirm that the medical staff bylaws specify the time frames for the periodic appraisal, not to exceed 36 months or sooner if required by state law or other regulation. ▪ Determine whether the medical staff has a system to ensure that practitioners seek approval to expand their privileges for activities/procedures /tasks that go beyond the specified list of privileges for their category of practitioner. ▪ Verify that minutes of Medical Staff meetings are maintained and accurately describe the activities and findings. ▪ Verify that an outcome-oriented appraisal system is conducted for each individual member of the medical staff who has provided patient care at the CAH as well as those who have not provided patient care at the CAH for which he/she is privileged during the appropriate evaluation time frames. □ Is this method in accordance with state law and the hospital's written criteria for medical staff membership and for granting privileges? ▪ Review a select sample of credentialed practitioner files to determine that evaluation of training, experience, and demonstrated competence is a

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Whenever a practitioner's privileges are limited, revoked, or in any way constrained, the hospital must, in accordance with state and/or federal laws or regulations, report those constraints to the appropriate state and federal authorities, registries, and/or data bases, such as the National Practitioner Data Bank.	component of the appointment/ reappointment process.
05.01.01 Responsibilities of credentialed professionals The duties and responsibilities for all credentialed practitioners must include: 1. Participating in medical staff functions, committee activity, educational, and Quality Assessment and Performance Improvement (QAPI) activities. 2. Abiding by medical staff bylaws, rules and regulations. 3. Adhering to ethical practice guidelines. 4. Provision of continuous care/ supervision of his/her patients. 5. Calling for, or responding to, consultations when required by patient condition or hospital requirement. **§482.22(c)** **§482.22(c)(2)**	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review medical staff bylaws, rules and regulations, and policies to determine compliance. ▪ Review a select sampling of files to verify practitioners attest to these responsibilities at appointment/ reappointment.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.01.02 Recommendation of appointment to governance *The medical staff must examine 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 requirements contained in 42 Code of Federal Regulations.* §482.22(a)(2)	☐ Compliant ☐ Not Compliant There must be a mechanism established to examine credentials of individual prospective members (new appointments or reappointments) by the medical staff. The individual's credentials to be examined must include 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 may not make its recommendation solely on the basis of the presence or absence of board certification but must consider all of the elements above This does not mean that the medical staff is prohibited from requiring in its bylaws board certification when considering a physician for medical staff membership or privileges; only that such certification may not be the only factor that the medical staff considers. The medical staff makes recommendations to the governing body for each candidate for medical staff membership/privileges specific to the type of appointment and extent of the individual practitioner's privileges, and then the governing body takes final appropriate action. A separate credentials file must be maintained for each individual medical staff member or applicant. The CAH must ensure that the practitioner and appropriate hospital patient care areas/departments are informed of the privileges granted to the practitioner.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Medical staff bylaws identify the process and criteria to be used for the evaluation of candidates for medical staff membership/privileges. ▪ The criteria used for evaluation 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.01.03 Medical staff responsibilities to the governing body *(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*.* *(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)(1-3) §482.22(b)(3)(i-iii)	☐ Compliant ☐ Not Compliant The medical staff must be accountable to the hospital's governing body for the quality of medical care provided to the patients. The organization of the medical staff must comply with these requirements. This will include: 1. Acting on the reports of services, departments, and committees of the medical staff. 2. Direct reporting to governance regarding medical staff appointments, reappointments, and privilege delineations. 3. Direct reporting to governance regarding medical staff behaviors resulting in suspension, or other corrective action, and any fair hearing results. 4. Direct reporting to governance of organizational proposals including revisions in bylaws, rules and regulations and medical staff officers. 5. Accountability to governance for the findings from ongoing evaluation of the clinical work of the medical staff. 6. Collaborating with administration and governance regarding institutional planning, budgeting and appropriate utilization of available resource.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The medical staff has a formalized organizational structure, that lines of function and responsibility are delineated between the governing body and other parts of the organization, and that the governing body has sanctioned its approval on the organizational structure and relationships. ▪ **The medical staff complies with all six required elements.** ▪ If there is an active executive committee, a majority of the members are doctors of medicine or osteopathic medicine. ▪ An individual MD/DO is responsible for the conduct and organization of the medical staff through review of the organizational structure and interviews with members of the medical staff.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.01.04 Medical staff bylaws *The medical staff must adopt and enforce bylaws to carry out its responsibilities.* §482.22(c)	☐ Compliant ☐ Not Compliant 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The medical staff has bylaws complying with the CoPs and state law. ▪ The bylaws describe a mechanism for enforcement of its provisions along with rules and regulations of the hospital. ▪ The medical staff enforces the bylaws.
05.01.05 Bylaws approval by governance *The bylaws must be approved by the governing body.* §482.22(c)(1)	☐ Compliant ☐ Not Compliant 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the medical staff bylaws have been approved by the medical staff and the governing body.
05.01.06 Bylaws – Categories, duties, and responsibilities of the medical staff *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 state the duties and scope of medical staff privileges available to each category of practitioner may be granted. 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 bylaws address the duties and scope for each category of	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Confirm that the bylaws specify the duties and scope of medical staff privileges for each category of practitioner eligible for medical staff membership or privileges.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	practitioner, each individual practitioner within the category is not automatically granted the full range of privileges. The individual practitioner's ability to perform each task/activity/privilege must be individually assessed.	
05.01.07 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: ▪ Bylaws specify the organization and structure of the medical staff, and a mechanism that delineates accountability to the governing body. ▪ 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.
05.01.08 Bylaws – Process for application, reapplication, and criteria for membership *The bylaws must describe the qualifications and criteria to be met by a candidate in order for the medical staff to recommend that the candidate be appointed and granted privileges by the Governing Body.*	☐ Compliant ☐ Not Compliant The medical staff bylaws must describe the qualifications to be met by a candidate for medical staff membership/privileges for the medical staff to recommend the candidate be approved by the governing body. 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	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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§482.22(c)(4)	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 a physician for medical staff membership; only that such certification is not the only factor that the hospital considers. After analysis of all 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. 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.	health status to be met by an individual candidate for the medical staff to recommend appointment or reappointment. ▪ All practitioner categories are included in the process. ▪ Granting of medical staff membership is based upon an individual practitioner's meeting the medical staff's membership criteria. ▪ Written criteria for appointment to the medical staff are not dependent solely upon certification, fellowship, or membership in a specialty body or society.
05.01.09 <u>Bylaws - History and physical requirement</u> *The bylaws must include:* *(i) A medical history and physical is 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. The medical history and physical*	☐ 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	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Confirm that 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, an oromaxillofacial surgeon,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
examination must be completed and documented by a physician (as defined in section 1861 (r) of the Social Security Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with state law and hospital policy. §482.22(c)(5)(i)	or 24 hours after hospital admission or registration, but prior to surgery or a 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. (71 FR 68676) 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 (as defined in section 1861(r) of the Act), oromaxillofacial 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 CAH is located and providing services within their authorized scope of practice. In addition, the Social Security Act attaches further limitations as to the type of hospital services for which a practitioner is considered to be a "physician." "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	or other qualified licensed individual in accordance with state law and hospital policy. Verify whether the bylaws require completion of the H&P prior to surgery or a procedure requiring anesthesia services. ▪ If CAH policy allows other qualified licensed individuals to conduct H&Ps, confirm 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 and 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: □ An H&P that was completed no more than 30 days before or 24 hours after admission or registration, but, in all cases, prior to surgery or a procedure requiring

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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 split among qualified practitioners, the practitioner who authenticates the H&P will be held responsible for its contents. (71 FR §68675) 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. (71 FR 68675) 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. (71 FR 68675) (See discussion of H&P update requirements at §482.22(c)(5)(ii).) Surveyors should cite noncompliance with the requirements of §482.22(c)(5) for failure by the hospital to comply with any of this standard's components. Portions of the H & P content may be derived from transfer documents, from the documentation of nursing data, or from staff, such as Physician Assistants/Nurse Practitioners, who have been granted delineated privileges. The attending/primary physician authenticates these findings via countersignature and/or augmentation of his/her personal findings.	anesthesia services. □ The H&P was performed by a physician, an oromaxillofacial surgeon, or other qualified licensed individual authorized in accordance with State law and hospital policy. □ Determine that the attending/primary physician is responsible for the content of the H&P as demonstrated by signature.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.01.10 Bylaws – Update to history and physical	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The bylaws must include: ▪ *An updated examination of the patient, including any changes in the patient's 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. 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 Social Security Act), an oromaxillofacial surgeon, or other qualified licensed individual in accordance with state law and hospital policy.* §482.22(c)(5)(ii)	The medical staff bylaws must require an updated medical record entry in the patient's medical record within 24 hours after admission or registration when the medical history and physical examination has been completed within 30 days before admission or registration. The examination must be conducted by a licensed practitioner who is credentialed and privileged 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 on 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. ▪ 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 requiring anesthesia services. ▪ 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. □ "No change" has occurred in the patient's condition since the H&P was completed (71 FR 68676).	**DOCUMENT REVIEW** ▪ Confirm that medical staff bylaws include provisions requiring an updated H&P within 24 hours after admission or registration, when the medical history and physical examination was completed within 30 days before admission or registration documenting an examination for changes in the patient's condition. ▪ Confirm that the bylaws require an update to the H&P for all cases involving surgery or a procedure requiring anesthesia services 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ 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.	anesthesia services, the update was completed and documented prior to the surgery or procedure.
05.01.11 Bylaws – Granting of privileges *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.* §482.22(c)(6)	☐ Compliant ☐ Not Compliant 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. 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 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 §482.12(a)(8) and (a)(9), and §482.22(a)(3) and (a)(4).	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Verify that the medical staff bylaws include criteria for granting, withdrawing, and modifying clinical privileges to individual practitioners of the medical staff and that a procedure exists for applying these criteria. ▪ Verify that 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
	Refer to standards 01.03.05 and 01.03.06, for additional information regarding distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the hospital.	
05.01.12 Nondiscrimination in application of membership criteria Criteria may 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. **482.22(c)(4)**	☐ Compliant ☐ Not Compliant The medical staff bylaws, or the credentials manual, contains a statement of nondiscrimination.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Confirm that the medical staff bylaws or the credentials manual contains a statement of nondiscrimination.
05.01.13 Required application - Initial and reapplication information for review Information covering each of the following areas must be reviewed for each applicant/re-applicant during the review and approval process. A. Licensure History: Current license(s), licensure sanction(s), state(s) of current practice or intended practice, and all previous licenses held.	☐ Compliant ☐ Not Compliant Evaluation of performance for application/reapplication.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Using no fewer than ten files, verify that the credentialing criteria were consistently applied in the recommendations for membership and privilege delineations. **Note:** Documents referenced below should be provided for review to verify compliance with the standard.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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: Actions taken by healthcare facilities, specialty boards, federal or state agencies, malpractice carriers. F. Criminal History: Felony convictions/ criminal history (7-10 years). G. Healthcare Employment History: Healthcare related employment/ appointment history (work history). 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.		Professional credentialing organizations (CVOs) 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. ▪ Primary Source Verification (PSV) from State Licensing Agency (Agencies) and query from the National Practitioner Data Bank (NPDB). □ Information regarding previously successful and/or currently pending challenges to any license, and/or voluntary or involuntary relinquishment of 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 used, review the process for validation of licensure and validate it is being enforced. ▪ 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
J. Information Verified for Comparison: Comparison of applicant-provided information with verified information. K. Meeting Attendance: Required consistent with the medical staff bylaws. **§485.627(a)**		every two years may be requested. ▪ 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. ▪ Documentation regarding specialty board status. □ If certified by a member of ABMS, verify with ABMS. □ If certified by a specialty board of AOA, verify with AOA Official Osteopathic Physician Profile. ▪ The application requests information regarding: □ Disciplinary actions taken or investigations pending by hospitals or other healthcare facilities, specialty boards, CMS. □ 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). □ Criminal history. The hospital conducts a criminal background

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

check based on information provided in the application or as required by federal and state regulations.

- □ 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.

- References from at least one peer, one of whom is an individual with the same professional credential as the applicant /re-applicant. 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-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.

Note: Re-applicants do not need to provide letters of reference. For re-applicants, peer review via routine review (e.g., clinical peer review,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		medical records review, credentials function, Medical Executive Committee) will suffice. However, clinical competence review must be a component of re-credentialing. ▪ Applicants must provide documentation regarding clinical activity (from residency or from facilities where the applicant has been practicing medicine) and competency for consideration of privileges requested. ▪ Re-applicants must provide recommendations from the department 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. ▪ The application/reapplication, including all verified information, is reviewed, evaluated, and summarized by credentialing professionals. The summary provides a clear report of the review of all submitted information (both application information and verified information.)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ Discrepancies, or unusual or problematic areas, are reviewed and discussed by committee members and appropriate members of the medical staff leadership. Appropriate physician leaders, committees, and the governing body review the summary. ▪ Verify that practitioners are working within the scope of the privileges granted by the governing body.
05.01.14 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. **§482.22(c)**	☐ Compliant ☐ Not Compliant The medical staff bylaws contain a provision for their periodic review.	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.
05.01.15 Emergency privileges Medical staff bylaws shall provide for the granting of emergency privileges. **482.22(c)(6)**	☐ Compliant ☐ Not Compliant The medical staff bylaws provide for a medical staff chief and/or the CEO to grant emergency privileges to a practitioner to accomplish lifesaving procedures, within the scope of his/her license, during such times that reasonably suggest that a staff member who is a credentialed practitioner with appropriate privileges is not available. This practice is generally limited to circumstances within an overwhelming disaster; it is not used to "cover" a practitioner who has failed to follow	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine that the medical staff bylaws, or credentialing procedures manual, describe mechanisms to grant emergency privileges per the standard. ▪ Verify that the process is followed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	medical staff guidelines in applying for privileges.	
05.01.16 Temporary privileges 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 is 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 emergency/disaster privileges. **482.22(c)(6)**	☐ 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 for an initial application may only be considered if the application is complete and contains all required elements including: ▪ Verification of current professional licensure, Drug Enforcement Administration (DEA) registration, medical malpractice insurance. ▪ Query of the National Practitioner Data Bank (NPDB). ▪ At least one recent reference from a previous hospital, chief or department chair. Limits to the number of "specific patients" that may be cared for are identified. Locum tenens privileges may be granted for specific periods of time, which are not typically sequential so as to bypass the need for application for provisional appointment. 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 the scope of their license or certification.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Confirm that the medical staff bylaws, or credentials manual, describe mechanisms for the granting of temporary privileges for the four situations described. ▪ Review at least one file where temporary privileges were granted to verify the process was followed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.01.17 Suspension of privileges Provision for corrective action(s) with suspension of privileges shall occur where appropriate. **482.22(c)(6)**	☐ Compliant ☐ Not Compliant **AUTOMATIC SUSPENSION** 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. ▪ Incongruence with medical staff rules regarding delinquent medical records. **SUMMARY SUSPENSION** Summary suspension of privileges is invoked in a situation where 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** ▪ Verify that definitions, with description of 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 that the process is in place and that the defined process is followed.
05.01.18 Fair hearing process The CAH shall have a fair hearing plan for members of the medical staff. Individuals involved in Peer Review activities shall be impartial peers and shall not have an economic interest in and/or a conflict of interest with the subject of the peer review activity. Impartial peer would also exclude	☐ Compliant ☐ Not Compliant The fair hearing and appeal process may differ for members of the medical staff and non-physician practitioners granted privileges. The fair hearing plan outlines the circumstances under which a practitioner may request (or waive) this mechanism, including: ▪ Denial. ▪ Modification or changes in appointment/reappointment category. ▪ Initial or re-granting of privileges with final review/action by the governing body.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the fair hearing mechanism is descriptive of the required elements. (The hospital may choose to include, or exclude, non-physician practitioners from access to the medical staff mechanism.)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. **482.22(c)(6)**		
05.01.19 Bylaws - Definition of a clinical emergency The medical staff, in the rules and regulations, define what constitutes an emergency. **482.22(c)(6)**	☐ Compliant ☐ Not Compliant Clear definitions that distinguish urgent from emergent are noted.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify that the definitions have been determined and disseminated.
05.01.20 Medical Executive Committee The medical staff bylaws require that, even if the medical staff functions as a "committee of the whole," a Medical Executive Committee function or process shall be accomplished. The determination of the meeting frequency and attendance requirements for the Medical Executive Committee shall be responsibility of the hospital. **482.22(c)(3)**	☐ Compliant ☐ Not Compliant 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 to address extremely sensitive issues of self-governance.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine that the medical staff bylaws provide for a Medical Executive Committee (MEC) (function) or process when medical staff operates as a "committee of the whole."

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.01.21 Medical Executive Committee scope The Medical Executive Committee (MEC) is empowered to act on behalf of the medical staff when the medical staff cannot be assembled or between their regular meetings. **482.22(c)(3)**	☐ Compliant ☐ Not Compliant When the medical staff functions as a committee of the whole, there is a mechanism to convene between meetings; this may be accomplished by *ad hoc* meetings of an identified MEC when the entire active medical staff is unable to be assembled, or, for executive session.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine that the medical staff bylaws indicate that the MEC is empowered to act on behalf of the medical staff.
05.01.22 Credentials Committee/ function responsibility The Credentials Committee/function makes recommendations to the Medical Executive Committee on applications received for staff membership and requests for privileging for members and non-members. 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. **482.22(a)(2)**	☐ Compliant ☐ Not Compliant A committee or 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.
05.01.23 Ongoing Professional Practice Evaluation (OPPE) Ongoing professional practice evaluation (OPPE) information is factored into the decision to maintain existing privilege(s),	☐ Compliant ☐ Not Compliant The medical staff has a process to monitor the competency of its members. Through an ongoing review of performance measurements, trends are tracked and trended to allow leadership to identify performance issues and	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ The medical staff bylaws address the ongoing professional practice

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
to revise existing privilege(s), and/or to revoke an existing privilege prior to or at the time of renewal. **482.22(a)(1)**	implement strategies for change. Prospective and real-time evaluation are important to ensure the delivery of safe and competent care. The medical staff develop an ongoing professional practice evaluation plan 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. ▪ Credentials committee.	evaluation (OPPE) process. ▪ The medical staff have identified and approved performance measures. ▪ Credential files reflect the ongoing professional practice evaluation (OPPE) is performed at least three times during the three-year appointment cycle. This quality data is reviewed as part of the reappointment process.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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

Data will be collected on an ongoing basis and summarized **a minimum of** three times **or once annually** during each three-year appointment cycle **or a minimum of two times or once annually during each two-year reappointment 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 mid-level providers, as traditional coding practices may not identify this group of practitioners.

At least every three years, 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 in order to evaluate compliance with medical staff bylaws, rules and regulations, and hospital policies.

  Examples of administrative indicators include:

  - Number of admissions.
  - Number of consultations.
  - Number of weeks on the surgery suspension list.
  - Medical record delinquency rate.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ At least two performance measures are clinical indicators in order to evaluate current competence of privileges granted. Examples of clinical indicators 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 determine data to be collected for the mid-level practitioners (NP, PA, CRNA, CNM) that are relevant to their practice.	
05.01.24 Focused Professional Practice Evaluation (FPPE) The organized medical staff defines the circumstances requiring additional, focused monitoring and evaluation of a practitioner's professional performance. **482.22(a)(1)**	☐ Compliant ☐ Not Compliant 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. Indications for FPPE: 1. When granting initial privileges. 2. When granting new privileges to a practitioner with current privileges. 3. For underperformance/quality of care issues. The medical staff bylaws address: 1. The period of FPPE implemented for all new privileges granted by the	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ The medical staff bylaws address the FPPE process. ▪ The medical staff bylaws clearly defines the triggers requiring a focused review, as well as indications for an external reviewer. ▪ Credential files reflect the period of FPPE.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Board either upon initial appointment or for 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 FPPE 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 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 include:

- Number of adverse events.
- Number of peer review events with adverse determination.
- Infection rates higher than most practitioners.
- Sentinel events.
- Low volume admissions/procedures over an extended period of time.
- Increased length of stay (LOS).

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ 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 resolve performance issues. The measures may include: ▪ Necessary education ▪ Proctoring/assisting for defined privilege ▪ Counseling ▪ Physician/practitioner assistance programs ▪ Suspension of specific privileges ▪ Revocation of specific privilege The improvement plan must be documented and include who is accountable, and how the improvement will be measured and documented. The outcome of FPPE is documented and analyzed. Processes are developed to allow the practitioner to review findings and submit opinions. The medical staff leadership submits recommendations to the governing body regarding: ▪ The need to continue the FPPE. ▪ Continuation or limiting of the privilege.	
05.02.01 Rapid response system	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The medical staff has approved a written policy for the early recognition and response to signs of patient deterioration,	Clinical deterioration is the physiological decompensation that occurs when a patient experiences worsening conditions or an acute onset of a serious physiological disturbance.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Written policies and procedures are approved by the Medical Staff.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
ensuring prompt rescue and treatment. **§485.614(c)(2)**	Early response to clinical deterioration may reduce cardiopulmonary arrests and patient mortality. The organization has a policy and procedure 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.	▪ 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.
05.02.02 <u>Blood transfusion administration</u> Blood transfusions and intravenous medications must be administered in accordance with state law and approved medical staff policies and procedures. **§485.635(d)(3)**	☐ Compliant ☐ Not Compliant Hospital policies and procedures for blood transfusions and IV medications must be based on accepted standards of practice. A. The policy must address: 1. Confirmation of the blood product prior to transfusion to ensure the correct patient and the right blood product. 2. The blood product confirmation is performed by two qualified individuals. 3. Requirements for patient monitoring including frequency of monitoring and documentation. 4. Identification and response to adverse reactions to the transfusion.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Verify the facility has adopted accepted standards of practice for blood administration. ▪ Verify the hospital orientation includes blood administration and the required elements. ▪ Review employee files for evidence of clinical staff competency related to blood transfusions.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	B. Staff Training and Competencies 1. Intravenous (IV) medications and blood transfusions must be administered by qualified personnel, consistent with state law and hospital policy. 2. Staff training during hospital orientation or during other educational programs. C. Blood Transfusion Training to include: 1. Blood components. 2. Blood administration procedures. 3. Patient monitoring and frequency. 4. Verification of the blood product. 5. Identification and response to transfusion reactions.	▪ Review medical records for documentation of blood administration in compliance with hospital policy.
05.02.03 Ventilator bundle The medical staff has approved a written policy or protocol for the care of patients on a mechanical ventilator. **§485.635(a)(1)**	☐ Compliant ☐ Not Compliant The CAH has adopted nationally recognized guidelines for ventilator management that address: ▪ Weaning. ▪ Tasks to prevent Ventilator Associated Pneumonia (VAP). These guidelines should address: 1. Raising the head of the bed. 2. Daily assessment of readiness for extubation. 3. Peptic ulcer prophylaxis. 4. Deep vein thrombosis (DVT) prophylaxis. 5. Daily oral hygiene.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the facility has adopted nationally recognized ventilator care guidelines. ▪ Review medical records to verify implementation of the ventilator bundle.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.02.04 Venous thromboembolism (VTE) The medical staff has approved a written policy or protocol for the assessment, prevention, and treatment of venous thromboembolism (VTE). **§485.635(a)(1)**	☐ Compliant ☐ Not Compliant The CAH has adopted nationally recognized guidelines for the prevention of VTE.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the facility has adopted nationally recognized VTE guidelines. ▪ Review medical records to determine compliance with assessing patients for risk of VTE.
05.02.05 Care of the newborn The medical staff has approved a written policy or protocol for the care of the newborn. **§485.635(a)(1)**	☐ Compliant ☐ Not Compliant The CAH has adopted nationally recognized guidelines for the assessment and care of the newborn. These guidelines should address: 1. Vital signs and measurements. 2. Physical examination. 3. Assessment for problems or complications at birth. 4. Breast feeding. 5. Screening and treatment for group B strep, hyperbilirubinemia, hearing, jaundice, and kernicterus, consistent with state regulations.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the facility has adopted nationally recognized guidelines for assessment and care of the newborn. ▪ Review medical records to verify compliance with screening and treatment protocols for group B strep, hyperbilirubinemia, jaundice, hearing, and kernicterus, consistent with state regulations.
05.02.06 Prevention of pressure ulcers The medical staff has approved a written policy or protocol for the assessment, prevention, and treatment of pressure ulcers.	☐ Compliant ☐ Not Compliant The CAH has adopted nationally recognized guidelines for the assessment, prevention, and treatment of pressure ulcers.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the facility has adopted nationally recognized guidelines relating to the assessment, prevention, and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.635(a)(1)		treatment of pressure ulcers. ▪ Review medical records for compliance with the assessment of patients at risk for pressure ulcers.

HUMAN RESOURCES

05.03.01 Adequate staffing	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The staff is sufficient to provide the services essential to the operation of the CAH. §485.631(a)(3) Tag C-0974	No additional information.	**INTERVIEW AND DOCUMENT REVIEW** ▪ How does the CAH ensure that staff coverage is sufficient to provide essential services at the facility (e.g., emergency services, direct services, and nursing services)? ▪ Review staffing schedules and daily census records.
05.03.02 Nurse on duty	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients. §485.631(a)(5) Tag C-0978	No additional information.	**DOCUMENT REVIEW** ▪ Review nursing staff schedules to ensure that a registered nurse, clinical nurse specialist or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
05.04.01 Personnel qualifications *Staff that furnish services in a CAH must meet the applicable requirements of* 42 CFR 485.604– §485.604 Tag C-0804	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review human resource files to verify that all requirements are met.
05.04.02 Personnel Qualifications – Clinical Nurse Specialist *A clinical nurse specialist must be a person who—* (1) *Is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed in accordance with State nurse licensing laws and regulations; and* (2) *Holds a master's or doctoral level degree in a defined clinical area of nursing from an accredited educational institution.* §485.604(a) Tag C-0804	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review human resource files to verify compliance.
05.04.03 Personnel qualifications – Nurse practitioner *A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review human resource files to verify compliance.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

the qualification of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has successfully completed a one academic year program that —

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of 42 CFR 485.604(a)(2) and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.604(b) §485.604(b)(1-3) Tag C-0804		
05.04.04 Personnel qualifications – Physician assistant *A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:* *(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.* *(2) Has satisfactorily completed a program for preparing physician assistants that —* *(i) Was at least one academic year in length;* *(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and* *(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review human resource files to verify compliance.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(3) *Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of 42 CFR 485.6104(c)(2) and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.* §485.604(c) Tag C-0804 §485.604(c)(1-3)		
05.05.01 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. **§412.25(a)(5)** **§485.608(d)**	☐ Compliant ☐ Not Compliant Mechanisms are established to verify with the appropriate licensing agency, all required 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 confirmation from 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 which demand certification/ licensure/registration for facility employment. ▪ Verify that the hospital has a policy and procedures for determining that all personnel required to be licensed, certified and/or permitted by the state are properly licensed and meet the basic requirements for the positions they hold.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ Review a sample of personnel files including administrative, supervisory, and direct care personnel. Sample contract and agency staff files. Verify that all required information is current.
05.05.02 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. **§485.608(d)** **§485.604**	☐ 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, or 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** ▪ Confirm that 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.
05.05.03 Evaluation of competence 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.	☐ Compliant ☐ Not Compliant 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that there are criteria-based mechanisms for assessing competency: □ At initial phase of affiliation (during orientation).

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. **§485.608(d)**	Written criteria are used for such evaluations. Such criteria include those noted in the facility and service Quality Assessment Performance Improvement plan. Evaluation is repeated at specified intervals; this may be upon the discretion of the facility but occurs at least annually.	☐ At specified periods thereafter, but at least annually.
05.05.04 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. **§485.608(a)**	☐ 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: **INTERVIEW AND OBSERVATION** 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. Interview managers to verify knowledge of nondiscriminatory policies.
05.05.05 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	☐ 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.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Confirm that staffing policies address basic/core staffing with criteria-based modifications for changing/augmenting

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
intensity of services. **§485.631(a)(3)**	▪ 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.	that level. ▪ Interview managers and selected staff to determine if policies are implemented and that there is sufficient numbers of qualified staff to provide the care, treatment, and services required.
05.05.06 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 classification of the professional, support staff, agency or contractual, volunteer, student, etc., including prior experience(s). The documents related to new orientation are readily retrievable. §485.608(d)	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** ▪ Confirm that orientation is available and provided to all categories of personnel. ▪ Determine whether mechanisms exist to readily retrieve the documentation.
05.05.07 Required orientation curriculum	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The orientation curriculum addresses information about the processes expected of the individual (scope of service, the written job description and evaluation tools).	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; this may be via video or booklet material reviewed off-site (such as for agency	**DOCUMENT REVIEW** ▪ Review curriculum content for various providers and affiliates.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. **§485.608(d)**	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.	▪ Confirm that the orientation program is comprehensive and includes: □ Role expectations. □ Evaluation mechanisms. □ The eight required elements.
05.05.08 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 **s**tandard 05.05.07 is documented. **§485.608(d)**	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.	**DOCUMENT REVIEW** ▪ Confirm 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ The implementation of new or revised technology or practices. This standard 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.	▪ Education related to the implementation of new or revised technology or practices.
05.05.09 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 Other information to consider include: ▪ Credentials ▪ Department ▪ Photo	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. 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 human resources policy to determine that the requirement was met. ▪ Observe employees when touring the facility to verify that the requirement is met.
05.05.10 Disruptive behavior	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH has a written policy that establishes: 1. A professional Code of Conduct for employees and members of the medical staff.	The organization establishes a Code of Conduct that clearly identifies unacceptable behaviors and consequences. Staff training is provided regarding the policy.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Has the facility provided staff education regarding unacceptable disruptive behaviors?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
2. Procedures for staff when faced with disruptive behaviors. **§482.22(c)**		□ Ask staff how they would respond to any disruptive behaviors.

06

PROVISION OF SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.00.00 CONDITION OF PARTICIPATION: Provision of services	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
§485.635 Tag C-1004	This condition establishes requirements related to patient care policies, required CAH services, and CAH services provided through agreements or arrangements. Assessment of the manner and degree of noncompliance with any one of the following standards is required in order to determine whether there is noncompliance with this Condition: ▪ Patient Care Policies ▪ Emergency Care ▪ Pharmaceutical Services ▪ Administration of Medications ▪ Drug Reactions and Errors ▪ Infection Control ▪ Nutritional Services ▪ Outpatient Services ▪ Laboratory ▪ Radiology ▪ Contracted Services/Agreements ▪ Nursing Service ▪ Rehabilitation Services ▪ Patient Rights	**Note:** Review scoring of entire chapter (all sections) for Condition-level scoring.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.00.01 Patient care policies	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH'S health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law. §485.635(a)(1) Tag C-1006	The CAH must have written policies governing the health care services the CAH furnishes and these policies must be consistent with applicable state law. The regulation requires the CAH to furnish its health care services in accordance with its written policies. In other words, the CAH must not only have written policies, but must adhere to them in delivering services. **Note**: Neither ACHC nor CMS interprets or enforces local law; that is the responsibility of state or local government. If surveyors identify practices related to delivery of health care services that they believe are not consistent with state law, they will refer the matter to the appropriate state authorities.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Verify that written policies cover the health care services furnished in the CAH. ▪ Observe staff delivering health care services to patients: □ Is the actual provision of services consistent with the written policies?
06.00.02 Policy development	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The policies are developed with the advice of members of the CAH's professional healthcare staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of standard 05.00.01. *These policies are reviewed at least biennially by the professional personnel* indicated above *and updated as necessary by the CAH.* §485.635(a)(2) Tag C-1008 §485.635(a)(4) Tag C-1022	The CAH's written policies governing patient care services must be developed with the advice of members of the CAHs professional healthcare staff. This advisory group must include: ▪ At least one MD or DO. ▪ At least one of non-physician practitioners (physician assistants, nurse practitioners, or clinical nurse specialists), if these professionals are included in the CAH's healthcare staff, as permitted at §485.631(a)(1). A CAH with no non-physician practitioners on staff is not required to obtain the services of an outside non-physician practitioner to serve on the advisory group. The advisory group makes recommendations for new patient care policies, is expected to review the existing patient care policies at least biennially (every two years). and, if it concludes that changes are needed, recommend those changes.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Verify documentation that the advisory group developed written recommendations on the CAH's patient care policies for consideration by the governing body (responsible individual). ▪ Review any meeting minutes for the group of healthcare professionals that advises the CAH's governing body/ responsible individual on patient care policies to determine if the group's composition meets the regulatory requirements. ▪ Interview all staff listed as part of the policy development advisory group to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Policies must be reviewed and, as applicable, revised more frequently when required, for example, in response to a change in federal or state regulations to which the CAH is subject. The CAH must maintain documentation that the advisory group has conducted its reviews and made recommendations concerning patient care policies. **FINAL APPROVAL OF POLICIES** ▪ Although a CAH's patient care policies are developed and periodically reviewed with the advice of members of the CAH's professional healthcare staff, the final decision on the content of the written policies is made by the CAH's governing body or individual responsible for the CAH, consistent with the requirement at §485.627(a). ▪ If recommendations of the advisory group are rejected, the governing body must include in the record of its adoption of the final written policies its rationale for adopting a different policy than that recommended.	verify that they had the opportunity to express opinions and make recommendations for the group's consideration. ▪ Verify that the group reviewed the CAH's existing policies at least biennially and indicated whether or not it recommended any changes.
06.00.03 Policy scope *The policies include a description of the services the CAH furnishes, including those furnished through agreement or arrangement.* §485.635(a)(3)(i) Tag C-1010	☐ Compliant ☐ Not Compliant The CAH's written patient care policies describe the types of health care services that are available. ▪ The services described must include those provided both on-site and off-site, by CAH staff and through an agreement or arrangement. ▪ The descriptions of the services provided may be brief, but informative. For example, statements like "taking complete medical histories, providing complete physical examinations, laboratory tests including" (with a list of tests provided), radiologic tests and their interpretation, surgery (with a list of the types of surgery available)" would satisfy this requirement.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the CAH's health care policies identify and describe all health care services offered, including services provided under arrangement or by agreement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	SERVICES PROVIDED "UNDER AGREEMENT" Health care services provided through agreement or under arrangement include those provided through formal contracts, informal agreements, or lease arrangements. These services may include those provided on-site at the CAH by a contractor and those provided to the CAH's patients outside the CAH. ▪ For example, the CAH may contract with a laboratory to provide some laboratory services on-site, and others at an off-site laboratory; or it may contract with an imaging center for provision of certain advanced radiologic diagnostic services, such as MRI, to CAH inpatients who are temporarily moved to the center for the test and then returned to the CAH.	
06.00.04 Emergency care *The policies include policies and procedures for emergency medical services.* §485.635(a)(3)(ii) Tag C-1012	☐ Compliant ☐ Not Compliant The CAH's written patient care policies must include its policies and procedures for providing emergency services, addressing all of the requirements at §485.618 (see Chapter 02).	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Written policies and procedures detail how the CAH complies with the requirements of §485.618. □ Policies and procedures address: What equipment, supplies, medications, blood, and blood products are maintained on-site, and which are readily available for treating emergency cases by agreement at other facilities. □ What types of personnel are available to provide emergency

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		services and their required on-site response times. □ How the CAH coordinates with local emergency response systems.
06.00.05 For future use		
06.00.06 Emergency procedures *In accordance with the requirements of 42 CFR §485.618, the CAH provides medical services as a first response to common life-threatening injuries and acute illness.* §485.635(b)(4) Tag C-1032	☐ Compliant ☐ Not Compliant Emergency services must be provided by the CAH at its campus either by CAH staff or by individuals providing services under arrangement or agreement. The individuals providing the services must have the ability to recognize a patient's need for emergency care at all times. The CAH must provide medically appropriate initial interventions, treatment, and stabilization to any patient who requires emergency services.	This standard is not met as evidenced by: **DOCUMENT REVIEW** **Note:** Survey procedures for §485.618 apply. (See Chapter 02: Emergency Services.)
06.00.07 Medical management *The policies include guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.* §485.635(a)(3)(iii) Tag C-1014	☐ Compliant ☐ Not Compliant The written policies for the CAH's healthcare services must include guidelines, such as general instructions and protocols, for the medical management of patients' health problems. ▪ The guidelines may include or reference protocols that are documented elsewhere for the treatment of medical conditions that are commonly presented in the CAH. ▪ Because nurse practitioners, clinical nurse specialists, and physician assistants may play a large role in patient care at a CAH, the policies must address the circumstances under which consultation with an MD or DO	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the CAH's written patient care policies address: □ Circumstances under which consultation with other CAH professional healthcare staff, or referral outside the CAH should occur.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	should occur and which situations require them to consult with or refer to an MD/DO for advice on how to treat a patient. ▪ Policies must address circumstances under which patient referral outside the CAH should occur. ▪ The policies must address maintenance of medical records, consistent with the requirements at §485.638. ▪ The policies must address periodic review and evaluation of services, consistent with the requirements of §485.641.	□ Maintenance of medical records, consistent with the requirements at §485.638. □ Periodic evaluation of the CAH's health care services, consistent with the requirements at §485.641.
06.00.08 Evidence-based clinical practice The facility uses current evidence-based practices/clinical practice guidelines regarding patient care, treatments, and services. **§485.635(a)(1)**	☐ Compliant ☐ Not Compliant Clinical practices that are evidence-based are considered when making decisions about patient care and treatment options.	This standard is not met as evidenced by: **DOCUMENT REVIEW AND INTERVIEW** ▪ Verify that the medical staff or patient care departments have adopted current evidence-based practices or clinical practice guidelines in the treatment of patients. □ Are staff members familiar with the use of current evidence-based practices or clinical practice guidelines?

06.01

THE PREPARATION & ADMINISTRATION OF MEDICATIONS

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.01.00 Medication storage and administration *The* policies include *rules for the storage, handling, dispensation, and administration of drugs and biologicals.* *These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.* §485.635(a)(3)(iv) Tag C-1016	☐ Compliant ☐ Not Compliant **RULES FOR MEDICATIONS** The CAH must ensure that drugs and biologicals are managed safely and appropriately, and that its pharmacy system provides all drugs and biologicals prescribed by CAH practitioners for administration to patients in a timely manner. The CAH is expected to identify the sources of accepted professional pharmacy practices that it relies on in developing pharmacy policies and procedures. ▪ Accepted professional principles include compliance with applicable federal and state law and adherence to standards or guidelines for pharmaceutical services and medication administration issued by nationally recognized professional organizations, including, for example: □ U.S. Pharmacopeia (www.usp.org), the American Society of Health-System Pharmacists (http://www.ashp.org/) □ The Institute for Safe Medication Practices (http://www.ismp.org/default.asp) □ The National Coordinating Council for Medication Error Reporting and Prevention (www.nccmerp.org) □ The Institute for Healthcare Improvement (http://www.ihi.org/ihi) □ The Infusion Nurses Society (http://www.ins1.org). **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 and updated regularly. Under the FD&C Act, a drug with a name recognized in the USP/NF must comply with compendial identity standards, or be deemed adulterated, misbranded, or both. To avoid being deemed adulterated, such drugs must	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Pharmacy rules were developed with the advice of the CAH's professional healthcare staff. ▪ Rules address required topics. ▪ Sources of accepted professional principles of pharmacy practice used in developing and implementing pharmacy rules. □ Is the source(s) nationally-recognized?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

also comply with compendial standards for strength, quality, and purity, unless labeled to show all respects in which the drug differs.

CAHs must comply with applicable state law that governs the qualifications, certification, or licensure of staff who administer drugs and biologicals and must adhere to accepted standards of practice for medication administration.

The CAH's written patient care policies must include rules governing pharmacy services within the CAH. The rules may be in the form of pharmacy services policies and procedures.

PHARMACY RULES MUST ADDRESS

Further detail for the items listed below is found in standards 06.01.01 through 06.01.10.

1. Responsibility for pharmacy services.
2. Storage of drugs and biologicals, including the location of storage areas, medication carts, and dispensing machines.
3. Proper environmental conditions.
4. Security.
5. Handling drugs and biologicals.
6. Compounding.
7. Use of outside compounders (outsourcing facilities).
8. Use of compounding pharmacies.
9. Dispensing drugs and biologicals.
10. Administration of drugs and biologicals to patients.
11. Recordkeeping of the receipt and disposition of all scheduled drugs.
12. Ensuring that outdated, mislabeled, or otherwise unusable drugs are not used for patient care.
13. Assessing adverse drug reactions and medication administration errors.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.01.01 Responsibility for pharmacy services The CAH pharmacy policies must identify the qualifications for and designate an individual who has overall responsibility for the CAH's pharmacy services, including development of the rules governing pharmacy services. §485.635(a)(3)(iv) Tag C-1016	☐ Compliant ☐ Not Compliant The CAH and the responsible individual must ensure adherence to state law requirements governing who may perform pharmacy services as well as requirements for supervision of pharmacy staff. The CAH and responsible individual ensure that pharmacy practices adhere to accepted professional principles.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The CAH has identified the qualifications of and designated an individual as responsible for developing and implementing the rules for the CAH's pharmacy services, consistent as applicable with state and federal law. ▪ The responsible individual's qualifications satisfy the CAH's written criteria.
06.01.02 Storage of drugs and biologicals The pharmacy policies, consistent with accepted professional principles, require appropriate storage and preparation of **drugs and biologicals** under proper conditions of sanitation, temperature, light, moisture, ventilation, segregation, and security. §485.635(a)(3)(iv) Tag C-1016	☐ Compliant ☐ Not Compliant **PROPER ENVIRONMENTAL CONDITIONS** ▪ Where the manufacturer's FDA-approved package insert specifies environmental conditions, such as temperature, humidity, exposure to light, etc., for storage of drugs, the CAH is expected to follow the labelled conditions. ▪ Absent the manufacturer's labelled conditions, USP indicates that storage of drugs and biologicals be done according to USP/NF, or the food chemicals codex (FCC) monograph requirements. ▪ CAHs must exercise caution in dispensing or using any drug or biological that is not labelled to indicate proper storage conditions or that may have been stored under inadequate conditions.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the CAH has written policies that addresses the storage and preparation of medications consistent with accepted professional principles.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.01.03 Security The CAH must have policies and procedures that are consistent with state and federal law that address who is authorized to access to the pharmacy or drug storage area. ▪ Drugs and biologicals must be securely stored to prevent unmonitored access by unauthorized individuals. §485.635(a)(3)(iv) Tag C-1016	☐ Compliant ☐ Not Compliant **DEFINING SECURE STORAGE** ▪ If medications are kept in a private office, or other area where patients and visitors are not allowed without the supervision or presence of a health care professional (for example, for ambulatory infusion), they are generally considered secure. ▪ Areas restricted to authorized personnel only would generally be considered secure. ▪ 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, generally would be considered a secure area. ▪ When a patient care area is not staffed, both controlled and non-controlled substances are expected to be locked. □ CAHs are permitted flexibility in the storage of non-controlled drugs and biologicals when delivering care to patients, and in the safeguarding of drugs and biologicals to prevent tampering or diversion. ▪ Medication carts, anesthesia carts, epidural carts and other non-automated medication carts containing drugs or biologicals (hereafter, all referred to as "carts") must be secured when not in use. ▪ A CAH's policies and procedures are expected to address the 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. ▪ If a cart containing drugs or biologicals is in use and unlocked, someone with authorized access to the drugs and biologicals in the cart must be close by and directly monitoring the cart.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that drugs and biologicals are stored securely. □ Are drugs stored in areas with access limited to authorized personnel? □ When drugs or biologicals are kept in a patient care area during hours when patient care is not provided, are they locked? ▪ Spot check drug use and other inventory records to ensure that drugs are properly accounted for.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	◻ That person could be a nurse, a physician, or other individual who in accordance with state and federal law and CAH policy is authorized access to the drugs and biologicals in the cart. ◻ That individual must monitor the cart and be aware of other people's activities near the cart. He/she is responsible for the security of the drugs and biologicals in the cart.	
06.01.04 Handling drugs and biologicals	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Whether performed by CAH staff or a contractor, the CAH is responsible for proper handling of drugs and biologicals. §485.635(a)(3)(iv) Tag C-1016	"Handling" includes reconstituting or mixing medications in accordance with directions contained in approved labeling provided by the drug's manufacturer. "Handling" includes compounding or admixing of sterile intravenous preparations or of other drugs, either on- or off-site, using either CAH staff or a contracted pharmacy service. Except in emergencies or when not feasible (for example, when the product's stability is short), only the pharmacy performs reconstituting, mixing, admixing, or compounding.	**DOCUMENT REVIEW** ▪ Confirm that the CAH has a written policy or procedure that addresses the handling of drugs and biologicals in accordance with manufacturer's instructions.
06.01.05 Compounding	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Pharmacy policies require that all compounding of medications used or dispensed by the CAH is performed consistent with accepted professional principles applicable to both sterile and non-sterile compounding. §485.635(a)(3)(iv) Tag C-1016	**Performed "consistent with accepted professional principles" means in a manner that is equivalent to or more stringent than what is decribed in the compounding-related chapters in USP/NF, which are recognized as authoritative standards for safe practice.** **DEFINITION OF COMPOUNDING** The definition of compounding as that term is used in the USP is found in USP Chapter <795>:	**INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that only a pharmacist or other personnel authorized by state and federal law compounds, labels and dispenses drugs or biologicals, regardless of whether the services are provided by CAH staff or under arrangement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

"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:

1. Preparation of drug dosage forms for both human and animal 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.

Compounding does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling or supplemental materials provided by the product's manufacturer.

USING USP AS THE AUTHORITY

A CAH pharmacy must demonstrate how it assures that all sterile and non-sterile compounded preparations dispensed and/or administered to patients are being compounded consistent with accepted professional standards to ensure safety.

- The applicable standards for safe compounding are, at a minimum, the most current standards published in USP Chapters <795> ("Pharmaceutical Compounding – Nonsterile Preparations"), <797> ("Pharmaceutical

- Can the CAH 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>, <797>, **<800>, and <825>**?
- Does the individual responsible for the pharmacy service, including compounding policies, practices and quality assurance within the CAH, and selecting and overseeing any external sources of compounded medications, have the expertise to conduct effective quality oversight consistent with USP <795>, <797> , <800>, and <825>(or equivalent/more stringent) standards?
- Can the individual responsible for the pharmacy services explain the categories of the CSPs being produced in-house and/or obtained from external sources? Can he or she demonstrate that the assigned categories are consistent with USP <797> or equivalent/more stringent standards?

If any CSPs are produced in the CAH:

- 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Compounding – Sterile Preparations") and other relevant USP-NF Chapters.

- The CAH must be able to provide evidence that its standard operating procedures for compounding, if performed in-house, and for quality oversight of compounding, regardless of source, are consistent with accepted professional principles.

USP <797> outlines minimum standards of practice to be followed by all health care personnel**, including but not limited to pharmacists, technicians, nurses and physicians, in any setting, including but not limited to healthcare institutions, medical and surgical patient treatment sites, infusion facilities, pharmacies and physician practice sites,** when preparing, storing, and transporting "compounded sterile preparations" (CSPs).

Pharmacy policies, and standard operating procedures (SOPs) align with current USP <795>, <797>, <800>, and <825> requirements based on the pharmacy's scope of services. Policies and SOPs are reviewed at the frequency defined by USP requirements, state and federal requirements and hospital policy.

- **The labeling on each CSP should indicate that the preparation was compounded.**

COMPOUNDING IN THE ON-SITE CAH PHARMACY

Compounding may take place in the CAH's pharmacy on-site and/or the CAH may obtain some or all of its compounded medications from external sources.

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 serious adverse consequences for the patients who receive them.

Interview pharmacy personnel assigned to carry out this function within the CAH 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 CAH's rules, policies and procedures?

- Interview staff who engage in sterile and non-sterile compounding. Are they knowledgeable about applicable levels of aseptic practices?
- Ask the individual responsible for pharmacy services 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 categories of CSPs being produced for/dispensed to CAH patients:
  - ☐ Verification of compounding accuracy and sterility.
  - ☐ Environmental quality and controls, including environmental sampling; testing and monitoring; and cleaning and disinfection;
  - ☐ 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

USE OF 503B PHARMACIES (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 FD&C Act 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 FD&C Act.

Facilities that elect to register as outsourcing facilities:

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: https://www.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 and providing FDA with certain information about the products they compound.

The 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:

disinfection; appropriate work practices within and adjacent to the direct compounding area; verification/calibration of equipment; sterilization; and post-production quality checks.

- Review the CAH'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 CAH ensure that such information is effectively conveyed to non-pharmacy health care personnel and/or to patients/caregivers, if applicable?
- Review the pharmacy rules, policies and procedures for determining BUDs (for medications compounded in-house as well as from external sources).
  - □ Can the CAH demonstrate that the policies and procedures are consistent with or more stringent than the applicable USP standards?
  - □ Can it demonstrate that the pharmacy personnel assigned to determining BUDs when a manufacturer's instructions are not available have the expertise and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	http://www.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 PHARMACIES** If a CAH obtains compounded medications from a compounding pharmacy rather than a manufacturer or a 503B registered outsourcing facility, then the CAH must demonstrate how it ensures 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 state or federal laws or regulations. For example, the contract with the vendor would include provisions: ▪ Ensuring that the CAH has access to quality assurance data verifying that the vendor is adhering to current USP <795> and <797> requirements. ▪ Requiring the vendor to meet the requirements of Section 503A of the FDCA concerning pharmacy compounding of human drug products. Note that these types of compounding pharmacies are also popularly referred to as "503A pharmacies" and generally are subject to oversight only by their state pharmacy board.	technical support needed to properly conduct the assessments needed to make such determinations in a manner consistent with standards and hospital policies? ▪ If the CAH obtains compounded products from **a 503A pharmacy** (an external source that is not an FDA registered **503B** outsourcing facility), can it demonstrate that it systematically evaluates and monitors whether the source adheres to accepted professional principles for safe compounding?
06.01.06 Dispensing and administration of drugs and biologicals: Staff qualifications Pharmacy policies address compliance with applicable state law governing: ▪ The qualifications, certification, or licensure of staff who dispense drugs and biologicals.	☐ Compliant ☐ Not Compliant There must be sufficient numbers and types of personnel to provide accurate and timely medication delivery.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Interview pharmacy and CAH staff to determine how drugs and biologicals are dispensed. ▪ Observe on-site dispensing operations.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ The qualifications, certification, or licensure of staff who administer drugs and biologicals and must adhere to accepted standards of practice for medication administration. §485.635(a)(3)(iv) Tag C-1016		▪ Review records to see if drugs and biologicals are removed from the pharmacy by unauthorized personnel. ▪ Do the CAH's pharmacy rules address automatic dispensing cabinets (ADC), if used within the CAH? Are the ADC used in the manner prescribed by the CAH's rules?
06.01.07 Dispensing drugs and biologicals in a timely manner Pharmacy policies address a system that ensures medication orders get to the pharmacy promptly and medications are available for administration to patients when needed, including when the pharmacy is not open. §485.635(a)(3)(iv) Tag C-1016	☐ Compliant ☐ Not Compliant Medications must be dispensed in a timely manner. 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. Concerns, issues, or questions pharmacy staff have about any medication order must be clarified with the prescribing practitioner or another practitioner responsible for the care of the patient before dispensing. A CAH may use a unit dose system, individual prescription, floor stock system or a combination of these systems. ▪ 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 only by accessed by authorized personnel.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview CAH practitioners, nursing, and pharmacy staff regarding whether the CAH's pharmacy service dispenses prescribed drugs and biologicals in a timely manner. ▪ If there is evidence in medical records reviewed of late administration of prescribed medications, probe to determine whether delays are due to pharmacy dispensing delays.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Policies and procedures must address who can access medications after-hours.

Note: For Information Only – Not Required/Not to be Cited
In addition to the required pharmacy policies and procedures above, a well-designed pharmacy service would have policies and procedures addressing medication safety practices such as:

1. Implementation of a do-not-use abbreviation list. CAHs may wish to refer to lists offered by the Institute for Safe Medication Practices (ismp.org/recommendations/error-prone-abbreviations-list).
2. A high alert drug list. CAHs may wish to refer to a high alert drug list offered by the Institute for Safe Medication Practices (ismp.org/recommendations/high-alert-medications-acute-list).
3. For specific high alert medications designated by the CAH, having two health professionals independently check doses. CAHs may wish to refer to guidance from the Institute for Safe Medication Practices concerning appropriate use of double-checks (ismp.org/resources/independent-double-checks-undervalued-and-misused-selective-use-strategy-can-play?id=51).
4. Quantities of medications are dispensed which minimize diversion and potential adverse events while meeting the needs of the patient.
5. Whenever possible, medications are dispensed in the most ready-to-administer form available from the manufacturer or, if feasible, in unit doses that have been repackaged by the pharmacy.
6. The CAH consistently uses the same dose packaging system, or, if a different system is used, provides education about the use of the dose packaging system.
7. The American Society of Health-System Pharmacists (ASHP) recommends that floor stocks of medications should be limited to medications for emergency use and routinely used safe items (e.g., mouthwash, antiseptic solutions).

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	When using automated dispensing cabinets (ADC), security processes are established to ensure adequate control of medications outside of the pharmacy and to reduce the potential for medication diversion from ADCs. 1. Use biometric user identification or, at a minimum, change user passwords quarterly. 2. 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 health care professional. 3. Limiting the availability of overrides to the ADC system. 4. Limiting access to drugs based on the patient's profile so to decrease medication selection errors. 5. Store each medication and strength in an individual lidded ADC compartment that opens only when the specific medication is selected. 6. Document the destruction of medication waste at the time of removal of the 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. 7. Return all medications to a common secure one-way return bin that is maintained by pharmacy, not to an individual pocket or bin within the ADC.	
06.01.08 Record keeping for the receipt and disposition of all scheduled drugs Pharmacy policies address accurately tracking the receipt and disposition of all scheduled drugs used in the CAH. §485.635(a)(3)(iv) Tag C-1016	☐ Compliant ☐ Not Compliant The U.S. Department of Justice Drug Enforcement Administration (DEA) classifies drugs that are controlled in accordance with the Controlled Substances Act into five "schedules," ranging from Schedule I substances, which have a high potential for abuse and no currently accepted medical use in treatment, to Schedule V substances, which have a low potential for abuse	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the CAH has a system that tracks movement of all scheduled drugs from the point of entry into the CAH to the point of departure either through administration to the patient,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	relative to substances listed in Schedule IV and consist primarily of preparations containing limited quantities of certain narcotics. Components of a record system for scheduled drugs would include: 1. Locked storage of scheduled drugs when not in use. 2. Accountability procedures to ensure control of the distribution, use, and disposition of all scheduled drugs. 3. The record system 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. 4. Any discrepancies in count are reconciled promptly. The CAH 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 determination of the extent of loss or diversion.	destruction of the drug, or return to the manufacturer. □ Does this system provide documentation on scheduled drugs in a readily retrievable manner to facilitate reconciliation of the receipt and disposition of all scheduled drugs? ▪ Review records of scheduled drugs over a recent time period. Is there evidence of discrepancies, and if so, of efforts by the CAH to reconcile and address the discrepancies? ▪ Interview the person responsible for pharmacy services as well as other CAH staff to determine their understanding of the CAH's controlled drug policies.
06.01.09 <u>Ensuring that outdated, mislabeled, or otherwise unusable drugs are not used for patient care</u> Pharmacy policies address a pharmacy labeling, inspection, and inventory management system that ensures that outdated, mislabeled, or otherwise unusable drugs and biologicals are not available for patient use. This would include drugs that are the subject of a manufacturer's recall. §485.635(a)(3)(iv) Tag C-1016	☐ Compliant ☐ Not Compliant 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. **Note:** 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. A drug or biological is also outdated after its "beyond-use date" (BUD), which may be reached before the expiration date, but never later.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Spot-check the labels of individual drug containers to verify that they conform to state laws, and/or include, at a minimum: □ The patient's full name, the prescriber's name, the strength, and quantity of the drug dispensed. Appropriate accessory and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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 CAH 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.

- USP <797> section "Determining Beyond-Use Dates," addresses sterile compounding, noting 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 error.

cautionary statements are included as well as the expiration date, and, when applicable, a BUD.

- □ Each floor stock container bears the name and strength of the drug, lot and control number of equivalent, and expiration date, and, when applicable, a BUD.

- If the unit dose system is used, verify that each single unit dose package bears name and strength of the drug, lot and control number equivalent, and expiration date, and, when applicable, a BUD.
- Spot check patient-specific and floor stock medications to identify expired, mislabeled, or unusable medications, including medications that are past their BUD.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	INDIVIDUAL DRUG CONTAINERS Each floor stock drug container is expected to be labelled 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. For multi-dose medication vials with antimicrobial preservatives which have been opened or entered (e.g., needle-punctured), the USP standard for BUD is 28 days, unless otherwise specified by the manufacturer. In addition, where applicable, each patient's individual drug container is expected to be labelled 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 labelled 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 FD&C Act address the labeling of prescription drugs generally (e.g., section 503(b)(2)). Section 503B of the FD&C Act includes labeling requirements for drugs compounded by registered outsourcing facilities (see section 503B(a)(10)). Although CAHs are expected to comply with these requirements, surveyors conducting a Medicare survey do not assess compliance with other federal law.	
06.01.10 Assessing adverse drug reactions and medication administration errors Pharmacy policies address a system for the pharmacy to assesses adverse drug reactions and medication administration errors.	☐ Compliant ☐ Not Compliant The pharmacy is expected to assess all reports to determine if problems or errors in pharmacy services caused or contributed to the adverse reaction or medication administration error. Where such problems or errors are identified, the CAH is expected to take effective action to address the identified issues.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Does the CAH have a process for following up on adverse drug reactions and errors in medication administration

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.635(a)(3)(v) Tag C-1016		reported by CAH staff in accordance with §485.635(a)(3)(v)? □ If any have been reported, did the CAH thoroughly assess and analyze them? □ Has the CAH taken effective preventive action to address identified issues?
06.01.11 Reporting drug reactions and errors in administration of drugs *The policies include procedures for reporting adverse drug reactions and errors in the administration of drugs.* §485.635(a)(3)(v) Tag C-1018	☐ Compliant ☐ Not Compliant CAH staff must report all drug (medication) administration errors and all adverse drug reactions. This required reporting includes two distinct steps: 1. The first and highest priority reporting relates to the care of the patient, at time of occurrence. 2. The second reporting step is related to the CAH-wide Quality Assurance review as addressed in §485.641(b). **MEDICATION 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."	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** **MEDICATION ADMINISTRATION ERROR** ▪ Assess whether the CAH ensures that medication administration errors and ADRs are reported to practitioners in a timely manner. □ Are nursing staff familiar with the concepts of medication errors that do and do not reach the patient, as well as ADRs? □ Ask nursing staff what they would do in the case of a medication administration error that reaches the patient or an adverse drug event. □ Ask nursing staff if they can provide examples of cases where they needed to report an ADR. Is the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

A medication administration error is one that occurs in the phase of the administration process where the drug actually enters the patient by one of various possible routes, e.g., orally, intravenously, etc.

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:

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."

PATIENT CARE

In the case of ADRs or medication administration errors, a "report" must be made to a practitioner responsible for the care of the patient.

- For example, if a medication is administered to a patient when it should not be, or the wrong dose is administered, or the wrong route of administration is used, etc., or a medication that should have been administered to the patient has not been administered in a timely manner, report to the practitioner documented in the medical record?
- Review records of medication errors and ADRs to verify that they are reported immediately in accordance with written procedures, and that medications administered and/or drug reactions are promptly recorded in the patient's medical record.

ADVERSE DRUG REACTIONS

- Can the CAH demonstrate that it has a system for reporting/identifying ADRs and medication administration errors for quality assurance/improvement purposes?
- Interview CAH staff (nursing, pharmacy, and medicine) to verify awareness of the CAH's policy on reporting ADRs for quality improvement purposes.

PATIENT CARE

- Interview CAH staff to identify the procedure for reporting ADRs and any medication administration error that harmed or reached the patient and could potentially cause harm.
  - □ Do staff report to a practitioner immediately after the identification of the adverse reaction?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

then the medication administration error has reached the patient and must be reported to the responsible practitioner.

- If the wrong dose of a drug is prepared for a patient, but a nurse catches this and does not give that dose to the patient, then a medication administration error has occurred, but the error has not reached the patient, and thus does not need to be reported to the responsible practitioner.

Not every medication administration error that reaches the patient causes harm or has the potential to cause harm; it depends both on the drug and on the patient's condition.

REPORT ERRORS TO THE PRACTITIONER

1. In the case of all ADRs and any medication administration error that has harmed or has reached the patient and could potentially cause harm, the report to a practitioner must be made immediately after the staff identify the adverse reaction or (potentially) harmful error, to enable a timely assessment and intervention.
2. The report must be made directly in a manner that confirms a practitioner received the report, for example, via a phone call.
3. If the impact of the medication error that reached a patient is unknown, the error must be reported to a practitioner immediately.
4. Documentation of the error or reaction, including notification to the practitioner, must be in the patient's medical record.
5. Medication administration errors that have reached the patient but result in no harm and do not have the potential to cause harm can be reported to a practitioner during usual working hours.
   - For example, if an over-the counter analgesic dose is missed during the night shift, it can be reported first thing in the morning as no further intervention would be required by the practitioner.
   - CAHs should provide clinical staff with expected guidance on how to respond to these situations.

QAPI

- Does the CAH have evidence of staff training on reporting expectations?
- Does the CAH rely only upon internal staff incident reporting or does it use other methods to identify potential/actual medication errors and ADRs?
- Ask the individual responsible for the QA program to demonstrate how the CAH determines if the number of medication administration errors and ADRs reported is consistent with the size and scope of services provided by the CAH.
- Review QA activities for medication administration errors and ADRs to determine if, upon analyses of the reports, potential corrective actions are identified and implemented, if appropriate.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

QUALITY ASSURANCE/IMPROVEMENT REPORTING

Reduction of medication administration errors and ADRs may be facilitated by effective internal CAH reporting that can be used to assess vulnerabilities in the medication process and implement corrective actions to reduce or prevent reoccurrences.

To facilitate reporting, the CAH must educate staff on medication administration errors and ADRs including the criteria for those errors and ADRs that are to be reported for quality assurance/improvement purposes, and how, to whom, and when they should be reported.

Reporting for quality assurance/improvement purposes covers all identified medication errors, regardless of whether or not they reach the patient, and those ADRs meeting the criteria specified in the CAH's policies.

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

To improve staff willingness to report medication errors and ADR incidents, CAHs 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 CAH disciplinary action.

In addition to internal staff reporting, the CAH is expected to take other steps to identify medication administration errors and ADRs. Reliance solely on staff-generated incident reporting fails to identify most adverse drug events.

Proactive identification includes observation of medication passes, concurrent and retrospective review of patient's clinical records, 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 CAH must assess the effectiveness of its internal reporting system to determine whether it is identifying the number of medication errors and ADRs that would be expected for the size and scope of services provided by the CAH. In making such assessments the CAH could refer to established

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	benchmarks or studies on error or ADR rates published in peer-reviewed journals. **Note:** For Information Only – Not Required/Not to be Cited CAHs are encouraged to participate in state-wide and national patient safety organizations for reporting of drug administration errors, ADRs, and drug incompatibilities. National organizations include, but are not limited to, the FDA MedWatch Reporting Program and the Institute for Safe Medication Practices (ISMP) Medication Errors Reporting Program. These organizations, along with other patient safety organizations, collect and analyze data, identify trends, and provide feedback and recommendations to health care organizations to reduce the risk of medication related errors and events.	
06.01.12 Drugs and medication administration *All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or a doctor of osteopathic medicine, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.* §485.635(d)(3) Tag C-1049	☐ Compliant ☐ Not Compliant The CAH must have written policies and procedures for the administration of all drugs and biologicals that adhere to accepted standards of practice and federal and state laws. Examples of nationally recognized organizations with expertise in medication administration include, but are not limited to: ▪ National Coordinating Council for Medication Error Reporting and Prevention. ▪ Institute for Healthcare Improvement (ihi.org/ihi). ▪ U.S Pharmacopeia (usp.org). ▪ Institute for Safe Medication Practices (ismp.org) ▪ Infusion Nurses Society (ins1.org).	This standard is not met as evidenced by: **INTERVIEW, OBSERVATION, AND DOCUMENT REVIEW** ▪ Ask the person responsible for nursing services what personnel categories administer drugs and biologicals, including IVs. □ Are they practicing within their permitted scope? □ If anyone other than an MD/DO, RN or PA administers drugs or biologicals, are they supervised by an RN or if permitted under state law and CAH policy, a PA?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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.

WHO MAY ADMINISTER MEDICATIONS?

- Drugs and biologicals, including intravenous (IV) medications, must be administered by, or under the supervision of, an MD or DO, an RN, or where permitted by state law, a PA.
- Other personnel, such as LPNs, may administer medications when permitted by state law and CAH policy, so long as they are supervised by an MD, DO, RN or where permitted by state law, a PA.
  - □ The CAH's written policies must delineate the categories of clinical staff authorized to administer medication at the CAH.

06.01.13 Medication orders

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Drugs and biologicals, including intravenous (IV) medications, may only be administered in accordance with orders written and signed by a practitioner who is authorized by CAH policy, and in accordance with State law, to write orders and who is responsible for the care of the patient as specified under §485.631(b)(1)(iii).

§485.635(d)(3) Tag C-1049

ACCEPTED STANDARDS OF PRACTICE

Based on accepted standards of practice for medication administration, the CAH must assure compliance with the following requirements concerning:

1. Minimum content of medication orders.
2. Policies and procedures for verbal and standing orders.
3. Self-administration of medications if the CAH permits this.
4. Training.
5. Basic safe practices.
6. Timing of medication administration.
7. Assessment/monitoring of patients receiving medications.
8. Intravenous (IV) medications.
9. Documentation.

OBSERVATION AND DOCUMENT REVIEW

- Review a sample of medication orders and confirm that they include the required elements.
  - □ Are orders legible, timed, dated, and authenticated with a signature by the practitioner or practitioners responsible for the care of the patient?
  - □ Was administration of the medication consistent with the order, i.e., the correct medication was administered to the right patient

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

CONTENT OF THE MEDICATION ORDER

In accordance with accepted standards of practice, the minimum elements that must be present in orders for all drugs and biologicals to ensure safe preparation and administration include:

1. Name of the patient.
2. Age and weight of the patient, 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 CAH's policies.

   Note: Dose calculations are based on metric weight (kg, or g for newborns). If a CAH 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, CAHs must specify a uniform approach to be used by prescribing practitioners. For example, a CAH could require all prescribers to use pounds or ounces and have the electronic ordering system or the pharmacy convert to metric.
3. Date and time of the order.
4. Drug name.
5. Exact strength or concentration, when applicable.
6. Dose, frequency, and route.
7. Dose calculation requirements, when applicable.
8. Quantity and/or duration, when applicable.
9. Specific instructions for use, when applicable.
10. Name of the prescriber.

VERBAL AND STANDING ORDERS

- Although the regulation requires medication administration be based on a written, signed order, this does not preclude the CAH from using:
  - □ Verbal orders.

at the right dose via the correct route?

- □ Did timing of administration comply with the hospital's policies and procedures?
- □ Confirm that the practitioner's order was still in force at the time the drug was administered.

VERBAL ORDERS

- Ask nursing staff if the CAH permits verbal orders and, if so, what the policy is for a verbal order.
  - □ If staff are unaware of any policy, or if their description of a policy suggests it is incomplete or inconsistent with accepted standards of practice, ask to see the written policy.

STANDING ORDERS

- Ask the hospital if they use standing orders/protocols. **If yes, ask them to provide a list of the approved standing orders/protocols. Ask the hospital to describe how a standing order/protocol is developed, monitored, reviewed, and approved.**
- **Review the hospital policy to verify all required elements are written in the policy.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	◻ Standing orders. ▪ In the case of both verbal and standing orders, a practitioner responsible for the care of the patient must authenticate the order in writing as soon as possible after the fact. ▪ The CAH must adopt policies and procedures regarding verbal and standing orders. **NOTE:** CAHs that have a distinct part psychiatric and/or rehabilitation unit must follow the hospital CoPs for all services provided in those units, including the hospital requirements for verbal and standing orders. **Verbal Orders** For verbal orders, CAH policies must, at a minimum: 1. Describe situations in which verbal orders may be used, as well as limitations or prohibitions on their use. 2. Provide a mechanism to establish the identity and authority of the practitioner issuing a verbal order. 3. List the elements required for inclusion in the verbal order process. 4. Establish protocols for clear and effective communication and verification. 5. Identify the categories of clinical staff who are authorized to receive and act upon a verbal order. 6. Provide for prompt documentation in the medical record of the receipt of a verbal order. **Standing Orders** There is no single definition of a "standing order," 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 or protocol" to refer interchangeably to an order or group of orders for which hospital policy permits initiation of treatment without receiving a prior order from the treating physician/practitioner by a healthcare worker who is functioning**	◻ Ask the nursing staff if they are familiar with the hospital's policies and procedures for using standing orders/protocols. ◻ Are they following the policies and procedures? ▪ **Review medical records where standing orders/protocols were used to verify authentication was completed according to hospital policy.** ◻ Determine whether all standing orders which were initiated by a nurse were authenticated by an authorized practitioner.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

within their licensure, scope of practice, and who has been granted authority by the hospital's medical staff.

The lack of a standard definition for these terms and their interchangeable and indistinct use by hospital and healthcare professional may result in confusion regarding what is or is not subject to the requirements of §485.635(d)(3). It is recommended that hospitals include definitions of standing orders/protocols, pre-printed paper, electronic, and evidence-based order sets in their policies to avoid confusion.

For standing orders, CAH policies must, at a minimum, address:

1. The process by which a standing order/protocol is developed, approved, monitored and evaluated.
2. **Standing orders/protocols must be reviewed and approved annually.**
3. Staff members who may initiate standing orders/protocols and under what circumstances.

Note: Under no circumstances may a CAH use standing orders in a manner that requires any staff not authorized to write patient orders to make clinical decisions outside of their scope of practice in order to initiate such orders.

4. The requirements for subsequent authentication by a practitioner responsible for the care of the patient.

CAHs must maintain an up-to-date list of all approved standing orders/protocols.

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

Verbal Orders

CAHs are encouraged to minimize the use of verbal orders as much as possible and not permit their use merely as a convenience to practitioners. Verbal orders carry a higher risk of miscommunication and error and thus should only be used when necessary. With increasing prevalence of Electronic Health Records and Computerized Physician Order Entry systems, the need for verbal orders is declining.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Standing Orders

CAHs are encouraged to focus on those situations where their use of "standing orders" permits treatment outside the scope of practice of a non-practitioner, such as a nurse, to be initiated by the non-practitioner without a prior specific order from the practitioner responsible for care of the patient. 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 practitioner prior to the provision of care.

Appropriate use of standing orders can contribute to patient safety and quality of care by promoting consistency of care, based on objective evidence. Much evidence of the effectiveness of standing orders 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 CAH of its obligations under the Emergency Medical Treatment and Labor Act (EMTALA) to have qualified medical personnel complete required screening and, when applicable, provide 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.

CAHs are encouraged to address at least the following in their standing orders policies and procedures:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Review and approval of each standing order by a multi-disciplinary team that includes the following individuals or their designees: the MD/DO providing medical direction and the individuals designated responsible for nursing and pharmacy services.
- Documentation 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, but that the content of each standing order used is consistent with recognized guidelines for providing care.
- Clear, specific criteria in the protocol for the order for authorized non-practitioners to initiate the execution of the order, i.e., the specific clinical situations, patient conditions, or diagnoses by which initiation of the order would be justified.
- Instructions that the clinical 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.
- At least annual review of each standing order as well as 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. Among other things, reviews should consider:
- 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. 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; and
- 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.01.14 Self-administration of medications If the CAH permits patients to self-administer medication, it must develop policies and procedures for self-administration of drugs by patients or their informal caregivers. §485.635(d)(3) Tag C-1049	☐ Compliant ☐ Not Compliant The CAH may choose to allow practitioners to write orders allowing patients to self-administer CAH-issued drugs and biologicals or drugs the patient has brought from home into the CAH for use during their stay, e.g., an insulin pen for a diabetic patient.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Ask nursing staff if the CAH permits patient self-administration of medications. □ If yes, does the CAH have policies and procedures addressing this? □ Is there an order from a practitioner responsible for the care of the patient permitting self-administration of medications, either issued by the CAH or brought from home?
06.01.15 Medication administration: Staff training The CAH ensures staff receive medication administration training. ▪ Medication administration education and training is typically included in the CAH's orientation or other continuing education programs for nursing staff and other authorized healthcare personnel. §485.635(d)(3) Tag C-1049	☐ Compliant ☐ Not Compliant Training or continuing education topics regarding medication administration may include but are not limited to: ▪ Safe handling and preparation of drugs, biologicals, and IV medications. ▪ Knowledge of the indications, side effects, drug interactions, compatibility, and dose limits of administered medications. ▪ Equipment, devices, special procedures, and/or techniques required for medication administration. Policies and procedures must address the required components of the training and evaluation of whether the training provided during CAH orientation imparts sufficient education or whether ongoing in-services or continuing education will be required to demonstrate competence.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify that nursing staff administering drugs have completed training consistent with CAH training policy.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.01.16 Basic safe practices for medication administration The CAH's policies and procedures must reflect accepted standards of practice prior to each administration of medication. §485.635(d)(3) Tag C-1049	☐ Compliant ☐ Not Compliant CAHs are encouraged to promote a culture in which it is not only acceptable, but 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. Policies and procedures must reflect accepted standards of practice that confirm the "five rights" of medication administration practice: 1. Right Patient: the patient's identity— acceptable patient identifiers include but are not limited to: the patient's full name; an identification number assigned by the CAH; or date of birth. Identifiers must be confirmed by patient wrist band, patient identification card, patient statement (when possible), or other means outlined in policy. The patient's identification must be confirmed to be in agreement with the medication administration record and medication labeling prior to medication administration. 2. Right Medication: The medication being given to the patient matches that prescribed for the patient and the patient does not have a documented allergy to it. 3. Right Dose: The dosage of the medication matches the prescribed dose, and the prescription itself does not reflect an unsafe dosage level (i.e., a dose that is too high or too low). 4. Right Route: The method of administration – oral, intramuscular, intravenous, etc., is the appropriate one for that particular medication and patient. 5. Right Time: Administration time adheres to the prescribed frequency and time of administration.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Observe the preparation of drugs and their administration to patients (medication pass) in order to verify: ▪ The patient's identity is confirmed prior to medication administration. ▪ Procedures ensure the correct medication, dose, and route are followed. ▪ Drugs are administered in accordance with the hospital's established policies and procedures for timely medication administration. ▪ The nurse remains with the patient until medication is taken unless they are permitted to self-administer.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The medication process is generally recognized as consisting of five stages: ordering/prescribing; transcribing and verifying; dispensing and delivering; administering; and monitoring/reporting. Errors may occur in other components of the process, even when there is strict adherence to the "five rights" of medication administration, for example when there has been a prescribing or a dispensing error. CAHs are also expected to comply with requirements for pharmacy services at §485.635(a)(3)(iv), using a systems approach to all components of the medication process.	
06.01.17 Timing of medication Administration CAH policies and procedures address the timing of medication administration, based on the nature of the medication and its clinical application. §485.635(d)(3) Tag C-1049	☐ Compliant ☐ Not Compliant Appropriate timing of medication administration accounts for: ▪ the complex nature and variability among medications. ▪ indications for which they are prescribed. ▪ clinical situations in which they are administered. ▪ 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 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 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 workarounds that jeopardize patient safety due to the imposition of unrealistic or unnecessary time constraints for medication administration.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ 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 for time critical and non-time critical medications in accordance with the hospital's policies?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

POLICIES AND PROCEDURES

CAH policies and procedures must specifically cover the timing of medication administration, based on the nature of the medication and its clinical application, to ensure safety and timeliness, by addressing, at least:

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.

MEDICATIONS NOT ELIGIBLE FOR SCHEDULED DOSING TIMES

1. 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.
2. 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 CAHs 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).

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

3. Policies and procedures must specify whether they apply to administration of these medications throughout the CAH or only for specific units or specific clinical situations or types of diagnoses.

MEDICATIONS ELIGIBLE FOR SCHEDULED DOSING TIMES

1. 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.
2. Medication administration policies and procedures typically establish standardized dosing times for the administration of all 'scheduled' medications.

   For example, medications prescribed for BID administration might, under specific policies and procedures, be scheduled to be administered at 8 AM and 8 PM. Use of these standardized times facilitates the medication administration process, e.g., by alerting the pharmacy 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.
3. Policies and procedures for medications eligible for scheduled dosing times must also address:
   - □ First dose medications, including parameters within which nursing staff can 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

TIME-CRITICAL SCHEDULED MEDICATIONS

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 CAH'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 one 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, CAH policies and procedures must address the process for 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

NON-TIME-CRITICAL SCHEDULED MEDICATIONS

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.

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 one hour before or after the scheduled dosing time, for a total window that does not exceed two hours.

MISSED OR LATE ADMINISTRATION OF MEDICATIONS

1. 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.
   - other reasons that result in missed or late dose administration.

2. Likewise, 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 practitioner responsible for the care of the patient is required prior doing so. In

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	either case, errors in the administration of medication must be reported internally as required at §485.635(a)(1)(v). **EVALUATION OF MEDICATION ADMINISTRATION TIMING POLICIES** CAHs must periodically evaluate their medication administration timing policies, including staff adherence to the policies, to determine whether they assure safe and effective medication administration. Medication errors related to the timing of medication 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 CAH must consider whether there is a need to revise the policies and procedures governing medication administration timing.	
06.01.18 Assessment/monitoring of patients receiving medications CAH 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 requirements for the method(s) of communication. §485.635(d)(3) Tag C-1049	☐ Compliant ☐ Not Compliant 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 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.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ Patients are assessed by nursing and/or other staff, per hospital policy, for their risk regarding their prescribed medications. ▪ Patients who are at higher risk and/or receiving high-alert medications are monitored for adverse effects. ▪ Staff are knowledgeable about intervention protocols when patients experience adverse medication-related events.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- 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—"high alert 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.

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

The Institute for Safe Medication Practices (ISMP) makes available a list of high alert medications, which it defines as those medications that bear a heightened risk of causing significant patient harm when they are used in error. See ismp.org/recommendations/high-alert-medications-acute-list.

Some 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 first-time medication use place certain patients at greater risk for adverse effects of medication.

Patient risk factors and the risks inherent in a medication must be taken into account when determining the type and frequency of monitoring.

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 moved for tests, at change of shift, etc. This would apply to hand-offs to any 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 CAH protocols.

  An example of vigilant post-medication administration monitoring in the case of a high-alert medication where patient factors may increase risk

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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. Patients can become overly sedated and suffer respiratory depression or arrest, which can be fatal. Timely assessment and appropriate monitoring are essential in all parts of the CAH in which opioids are administered, to permit intervention to counteract respiratory depression should it occur. (See also the discussion below for intravenous medications.) ▪ 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 monitoring requires awakening 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. CAHs are encouraged to educate the patient and his/her representative and/or family members to notify nursing staff promptly when there is difficulty breathing or other changes that might be a reaction to medication.	
06.01.19 IV medications and blood transfusion The CAH policies address the following: ▪ Safe practices specific to all IV medication administration ▪ Policies and procedures must address blood administration procedures that are consistent with accepted standards of transfusion practice.	☐ Compliant ☐ Not Compliant Many of the medications included in the high-alert categories are administered intravenously. CAH policies and procedures for IV medications must address at least: **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. IV medications, such as fluids, antibiotics, and chemotherapy, may require specific types of access, such as peripheral or central catheters versus	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Interview nursing staff who administer IV medications and blood transfusions to verify knowledge with respect to: □ Venipuncture techniques. □ Safe medication administration practices, including general practices applying to all types of medications

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ There must be a procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs. §485.635(d)(3) Tag C-1049	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, additional safe practices specific to IV medication administration include but are not limited to: ▪ Tracing invasive lines and tubes prior to administration to ensure the 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). **IV BLOOD ADMINISTRATION PROCEDURES** Policies and procedures must address blood administration procedures that are consistent with accepted standards of transfusion practice, including but not limited to: 1. Prior to each blood transfusion, confirming: □ patient identity. □ verification of the right blood product for the patient. (The standard of practice calls for two qualified individuals, one of whom will be administering the transfusion, to perform the confirmation.) 2. Requirements for patient monitoring, including frequency and documentation of monitoring. 3. How to identify, treat, and report any adverse reactions the patient may experience during or related to transfusion.	and practices concerning IV tubing and infusion pumps. □ Maintaining fluid and electrolyte balance. □ Patient assessment for risk related to IV medications and appropriate monitoring. □ 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. ▪ 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 for IV medications?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		◻ 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.
06.01.20 Monitoring patients receiving IV medications Policies and procedures for IV medication administration must address appropriate IV medication monitoring requirements. §485.635(d)(3) Tag C-1049	☐ Compliant ☐ Not Compliant To the extent that IV medications have a more rapid effect on the body, it is important that staff administering medications via IV understand each medication and its monitoring requirements. Policies and procedures for IV medication administration must include 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 CAH 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	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ CAH policy addresses IV medication monitoring and patient assessments. ▪ Policy addresses monitoring of patients for over-sedation after receiving high-alert medications such as IV opioids.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

practitioner responsible for the care of the patient would be expected to determine on a timely basis whether 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 any concerns they might have about whether an adjustment in the medication is needed with a practitioner responsible for the care of the patient.

CAH policies and procedures related to monitoring patients receiving IV medications address, but are not limited to:

1. Monitoring for fluid and electrolyte balance.
   - □ Whenever IV medications and blood transfusions are administered, the patient may become at risk for fluid and electrolyte imbalance.
   - □ Policies and procedures must address monitoring and treatment for fluid and electrolyte imbalances that may occur with blood transfusions and IV medications
2. Monitoring patients receiving high-alert medications.
   - □ Policies and procedures related to IV medication administration must address those medications the CAH has identified as high-alert medications and the monitoring requirements for patients receiving such drugs intravenously.

POST-OPERATIVE IV 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. The effects of IV opioids in post-operative patients must be monitored vigilantly via serial assessments of pain, respiratory status, and sedation levels.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

In addition to patient characteristics that may increase general risk of adverse effects from medication mentioned above, other factors placing patients receiving IV opioids at higher risk for over-sedation and respiratory depression include, but are not limited to[1]:

- Snoring or a 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.
- Preexisting pulmonary or cardiac disease
- Thoracic or other surgical incisions that may impair breathing

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, the monitoring frequency and duration, what is to be monitored, and how.
- Whether and under what circumstances practitioners prescribing IV opioids are allowed to establish protocols for IV opioid administration and monitoring that differ from the CAH's policies and procedures.
- The frequency of the serial assessments and duration of the monitoring time frame for post-operative patients receiving IV opioids 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.
- Minimum monitoring must include:
  - Vital signs (blood pressure, temperature, pulse, respiratory rate).
  - Pain level.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- ☐ Respiratory status.
- ☐ Sedation level. Sedation is a useful assessment parameter to observe the effects of opioids since sedation typically precedes respiratory depression.[2] See the box below for information on sedation assessment methods**.**

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

In addition to assessing risk for respiratory depression, the Institute for Safe Medication Practices recommends hospitals use a standard sedation scale when assessing patients receiving PCA. Scales such as the Richmond Agitation Sedation Scale, Pasero, Ramsey, or Glasgow Coma Scale are useful in assessing sedation.

In addition to vigilant nursing assessment at appropriate intervals, CAHs may choose to use technology to support effective monitoring of patients' respiratory rate and oxygen levels.

For additional information regarding recommendations of expert organizations on post-operative opioid monitoring, including technology-supported monitoring, see notes below. The practices described are not required under the regulations.

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 to assess effects of the medications. In addition, CAHs 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 to IV medications require timely and appropriate intervention, per established protocols.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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

Anesthesia Patient Safety Foundation (APSF) calls for every patient receiving postoperative opioid analgesics to be managed based on the following clinical considerations*:

- Individualize the dose and infusion rate of opioid while considering the unique aspects of each patient's history and physical status.
- Make continuous monitoring of oxygenation (pulse oximetry) the routine rather than the exception.
- Assess the need for supplemental oxygen, especially if pulse oximetry or intermittent nurse assessment are the only methods of identifying progressive hypoventilation.
- When supplemental oxygen is indicated, monitoring of ventilation may warrant the use of technology designed to assess breathing or estimate arterial carbon dioxide concentrations. Continuous monitoring is most important for the highest risk patients, but depending on clinical judgment, should be applied to other patients.

APSF also has issued a video on opioid induced ventilatory impairment: www.apsf.org/videos/monitoring-for-opioid-induced-ventilatory-impairment-oivi-video/

*Stoelting, RK.,Weinger MB. Dangers of postoperative opioids: Is there a Cure? APSF Newsletter 2009;24:2.

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

The Patient Safety Movement Foundation (PSMF) recommends all patients receiving IV opioids have continuous measure-through motion and low perfusion pulse oximetry, and that patients on supplemental oxygen also have continuous respiration rate monitoring. It also calls for the monitoring system to be linked with a notification system to clinical staff who can respond immediately. It calls for an escalation protocol so that if a staff person does not acknowledge the alert in 60 seconds a second person will be notified.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

[1] Jarzyna D., Junquist C., Pasero C., et al. American Society for Pain Management Nursing - Guidelines on Monitoring for Opioid-Induced Sedation and Respiratory Depression. Pain Management Nursing, Vol 12, No. 3 (September), 2011: pp 118-145

[2] Institute for Safe Medication Practices (ISMP), Medication Safety Alert – Fatal PCA Adverse Events Continue to Happen…Better Patient Monitoring is Essential to Prevent Harm. May 30, 2013

06.01.21 Documentation of medication administration

The CAH policies address documentation after actual administration of the drugs or biologicals to the patient.

§485.635(d)(3) Tag C-1049

☐ Compliant ☐ Not Compliant

This regulation requires that the record contain:

> "All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment…."

DOCUMENTATION EXPECTATIONS

- Documentation is expected to occur after actual administration of the drugs or biologicals to the patient; advance documentation is inappropriate and may result in medication errors.
- Proper documentation of medication administration actions and their outcomes is essential for planning and delivering future care of the patient. See the guidance for the various parts of §485.638 concerning documentation in the medical record.

This standard is not met as evidenced by:

OBSERVATION AND DOCUMENT REVIEW

- Verify the CAH has a written policy that addresses the required elements.
- Review medical records to verify documentation of medications occur after the administration of the drug or biological.

Note: Score a deficiency at 07.00.06.

- Verify through observation that documentation occurs only after the administration of medications.

06.01.22 Pharmacy access "after hours"

When a pharmacist is a not available, drugs and biologicals may be removed from the pharmacy or storage area only by personnel designated in the policies of

☐ Compliant ☐ Not Compliant

Routine after-hours access to the pharmacy by non-pharmacists for access to medication should be eliminated as much as possible.

This standard is not met as evidenced by:

OBSERVATION AND DOCUMENT REVIEW

- Verify that policy limits pharmacy access to an RN or physician, consistent with state and federal law.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
the medical staff and pharmaceutical service, in accordance with federal and state law.	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. 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. 2. Only trained, designated prescribers and nurses are permitted access. 3. A quality control process is in place to prevent medication retrieval errors. 4. A qualified pharmacist is available on-call or at another location to answer questions or provide medications beyond those accessible to non-pharmacy staff. 5. The process is evaluated regarding access issues. 6. Change is implemented to reduce access frequency. **MEDICATION REMOVALS FROM PHARMACY OR DRUG CABINET** Medication removals from the pharmacy or drug cabinet are recorded and in quantities sufficient only to dose until a pharmacist can review the order and the removal record. (This activity is in preparation for immediate dosing only; dispensing by non-pharmacists is not permitted.) Some states prohibit entry into the pharmacy proper unless a pharmacist is present thus requiring use of "night" closets or drug cupboards for after-hours supply. All after-hour withdrawals are logged.	▪ Review the withdrawal log for at least three different nights to verify that each withdrawal is for a named patient and not "to stock supply."
06.01.23 Automatic stop medication orders The professional medical staff, via policy and/or rules and regulations, establishes	☐ Compliant ☐ Not Compliant Drugs and biologicals ordered as single dose, or as a specific number, are dispensed and administered as ordered.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify that pharmacy policies and procedures and medical staff

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
time frames for time limiting of medication orders. There are mechanisms for automatically discontinuing medications which are written without a specific number of doses. *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)	A maximum time frame (such as 21 – 30 days) for all other drugs, not written in a time/dose limited fashion, is determined by the medical staff. Suggested "maximal" time frames for specific groups of drugs are identified which require review prior to renewal or automatic stop. The practitioner is to be notified prior to such automatic stop. Drugs usually included with the automatic stop procedure include: ▪ Antibiotics ▪ DEA Schedules II, IIN, III, IIIN, and IV ▪ Oxytocics ▪ Anticoagulants ▪ Corticosteroids ▪ Antineoplastics	rules/regulations address order timeframes and automatic stops. ▪ Observe the mechanism employed by the pharmacy and nursing service to alert practitioners of impending automatic stop orders. ▪ Medication orders are automatically reviewed and renewal is requested or an automatic stop is instituted in accordance with the time frame approved by the professional medical staff.
06.01.24 Sample drugs The use of "sample" drugs, if permitted, is controlled by the pharmacy director, and conforms to federal and state laws. **§485.635(a)(3)(iv)**	☐ 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 their use, storage, and distribution. 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 DOCUMENT REVIEW** ▪ Review the policy regarding samples. Verify the practice; observe for samples located in employee lounges, obstetrics, and the ER. If these are the physician's personal property, sample medications should be secured. ▪ The pharmacist has control of sample drugs. ▪ Verify that there is an effective, accurate recall process, consistent with the pharmacy recall process.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.01.25 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, which includes data designed to assure safe and accurate administration of drugs and biologicals. The profile is reviewed with every order change by an RPh. The review occurs 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, 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. **§485.635(a)(3)(iv)** **§485.614(c)(2)**	The profile may be manual or electronic and may be used as a charge document. The patient and drug data entered into medication profiles includes, at least: 1. Height, weight, diagnoses, and age. 2. Food and drug sensitivities. 3. Allergies. 4. Diet order(s). 5. History of prescribed/non-prescribed 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. Methods are established to assure the profile review by a pharmacist. A log is maintained of pharmacist interventions resulting from the profile review. The pharmacist/prescriber interact, as appropriate, for notification of food service for potential food-drug interactions.	**DOCUMENT REVIEW** Verify: ▪ Policy defines what would be considered a medically acceptable delay in pharmacist review of new orders. ▪ The medication profiles for five sample active inpatient records and one active serial outpatient record (such as chemo) consistently document each of the seven required elements. ▪ The pharmacist and nursing staff are knowledgeable regarding the profile review process. ▪ Profiles are reviewed with order changes. ▪ A log is maintained for pharmacist interventions stemming from review for potential interactions, interferences or incompatibilities

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.01.26 Antithrombotic therapy	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The facility has a written protocol, approved by the medical staff, for antithrombotic therapy. The organization uses dedicated antithrombotic services that facilitate coordinated care management. Explicit organizational policies and procedures are in place regarding anti-thrombotic services. **§485.635(a)(3)(iv)** **§485.635(d)(3)**	The facility has adopted nationally recognized guidelines to ensure the safe and effective use of antithrombotic therapy. A process is in place to identify staff to coordinate the management of patients receiving anti-thrombotic therapy. The process addresses: ▪ Staff training requirements. ▪ Dose scheduling. ▪ Patient tracking. ▪ Accessible, accurate, and frequent Prothrombin Time (PT)/International Normalized Ratio (INR) testing. ▪ Patient-specific decision support and interaction. ▪ Ongoing patient education.	**DOCUMENT REVIEW** Verify: ▪ The CAH has adopted antithrombotic guidelines approved by the medical staff. ▪ The policy is explicit regarding staff training requirements, dose scheduling and tracking mechanisms, and patient education materials and mechanisms for training. ▪ Medical records of patients receiving antithrombotic therapy reflect compliance with the protocol guidelines.
06.01.27 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 transition point, specifically: 1. Upon admission, a complete list of pre-admission medications the patient takes at home is prepared.	Preventable adverse drug events are associated with as many as one out of five patient injuries or deaths. 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.	**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. ▪ Medication reconciliation occurs at admission, at transfer to the next level of care, and at discharge.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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 given to the patient upon discharge. **§485.638(a)(4)(iii), §485.638(a)(2) §485.614(c)(2)**	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 including the dose and frequency for each drug. 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 is 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 are <u>not</u> acceptable notes: ▪ "Resume previous orders" ▪ "Resume preoperative orders" ▪ "Resume all home medications" **DISCHARGE** As part of 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.	▪ The patient/family participates in the reconciliation process, when possible. ▪ The patient receives a copy of the complete medication list upon discharge. ▪ A process measures the effectiveness of this initiative in reducing adverse drug events.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	At time of discharge, a copy of the final medication list is provided to: 1. The patient/family. 2. The next level of care such as home health agency, skilled nursing facility, or transfer to a higher level of care. **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** ▪ 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 and etc. ▪ 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.	
06.01.28 <u>Standardization of labeling</u>	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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. **§485.635(d)(3)** **§485.635(a)(3)(iv)**	Improper labeling and packaging of medications are well-known as causes of serious medication errors. 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.	**<u>OBSERVATION AND DOCUMENT REVIEW</u>** ▪ Verify the medication labeling policy addresses: □ Labeling of all medications until they are administered to the patient. □ Validation of compliance for all areas.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		◻ An institution-wide approach. ◻ Storage of look alike, sound alike and varied strengths of medications in physically separate locations. ▪ 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.

06.02

FOR FUTURE USE

06.03

NUTRITIONAL SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.03.00 Nutritional support	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The policies include the following: ▪ *Procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices.* §485.635(a)(3)(vi) Tag C-1020	A CAH may provide dietary services under arrangement with a food vendor, but the CAH retains responsibility for ensuring that all dietary services meet the regulatory requirements. **SWING-BEDS** If the CAH provides swing-bed services, then it must also comply with the following requirement for resident nutrition: §483.25(i): Nutrition. Based on a resident's comprehensive assessment, the facility must ensure that a resident— (1) Maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible; and (2) Receives a therapeutic diet when there is a nutritional problem. **RECOGNIZED DIETARY PRACTICES** The CAH ensures it meets the nutritional needs of those patients in observation status whose stay is sufficiently long that they must be fed. Each CAH inpatient (including residents) must have their nutritional needs met in a manner that is consistent with recognized dietary practices. 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 healthy persons.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Among patients who were assessed as having special nutritional needs, were dietary orders reflective of the assessment written and implemented? ▪ If the CAH has swing bed patients, verify that it has documentation of maintaining acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	2. Adequate Intake (AI) for a nutrient is similar to the Estimated Safe and Adequate Daily Dietary Intake (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. USDA provides access to an interactive DRI tool and DRI tables at http://fnic.nal.usda.gov/dietary-guidance/dietary-reference-intakes	
06.03.01 For future use		
06.03.02 For future use		
06.03.03 Diet orders *All patient diets, including therapeutic diets, must be ordered by the practitioner responsible for the care of the patients or by a qualified dietitian or qualified nutrition professional as authorized by the medical staff in accordance with State law governing dietitians and nutrition professionals and that the requirement of §483.25(i) of this chapter is met with*	☐ Compliant ☐ Not Compliant 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. **PRACTITIONERS WITH DIET-ORDERING PRIVILEGES** When permitted under state law, the CAH may choose to designate qualified dietitians or qualified nutrition professionals as practitioners with diet-ordering privileges.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that all inpatient diets are prescribed by a practitioner(s) responsible for the care of the patient. ▪ If the state and the CAH permit dieticians or other nutrition professionals to order diets, has the CAH verified that they meet any requirements for licensure or certification under state law?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
respect to inpatients receiving post CAH SNF care. §485.635(a)(3)(vi) Tag C-1020	In many cases state law determines what criteria an individual must satisfy in order to be a "qualified dietician." ▪ State law may define the term to mean a "registered dietician" registered with a private organization or the Commission on Dietetic Registration, or state law may impose different or additional requirements. Terms such as "nutritionist," "nutrition professional," "certified clinical nutritionist," and "certified nutrition specialist" are also used to refer to individuals who are not dieticians, but who may be qualified under state law to order patient diets. ▪ It is the responsibility of the hospital to ensure that individuals are qualified under state law before appointing them to the medical staff or granting them privileges to order diets.	
06.03.04 For future use		
06.03.05 For future use		
06.03.06 For future use		
06.03.07 <u>Policy requirements: Tube feedings</u> Food service policies address the role of the department regarding the storage, distribution, and administration of enteral/tube feedings. **§485.635(a)(3)(vi)** **§483.25(g)(1-5)** **§485.645(d)(8)**	☐ 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. ▪ Distribution. ▪ Administration .	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Verify that the required policies are in place. □ Policies reflect collaboration between food service, dietetic services, patient care services, and pharmacy, as applicable.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.03.08 Policy requirements: Food preparation and storage	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Policies and processes are in place relative to food storage centers located in the patient care areas. Minimally, policies 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: a. Patient food b. Employee food c. Breast milk, as applicable d. Medications that must be stored at a cool temperature 8. Guidelines for ordering infant formulas.	Food products must be maintained to ensure an acceptable level of safety and quality. The food service department collaborates with patient care services in development of policies related to 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 describes 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** 1. Check and record food refrigerator temperatures at least daily. 2. Desired temperature ranges: □ Refrigerators: Between 32° and 40° Fahrenheit (0° to 5° Celsius) □ Freezers: Between minus 10° and minus 0.4° F (minus 23° to minus 18° C)	**OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ 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. (Requirement for temperatures does not apply 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
9. Guidelines that govern acceptable ingredients that may be added to infant formulas. 10. Guidelines for aseptic infant formula preparation techniques. 11. Storage, preparation, and temperature control of breast milk and infant formula products. 12. Patient safety with heating breast milk and infant formula. **§485.635(a)(3)(vi)**	3. 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. 4. A process is in place to repair the refrigerator in a timely manner if the temperature should fall out of range. Thirty (30) minutes following the repair, recheck the temperature to ensure the proper temperature has been achieved.	
06.03.09 Lighting, ventilation, and temperature control 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.	☐ Compliant ☐ Not Compliant **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 grilles.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Request dishwasher temperature guidelines. ▪ 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
4. Hot foods are maintained at appropriate temperatures. 5. If dish machines are used, dish machine temperatures are recorded for each cycle. 6. Food preparation areas have adequate lighting. 7. Ceiling light bulbs are shielded. **§485.623(b)(5)**	**FOOD TEMPERATURE DANGER ZONE** The food temperature danger zone is between 41° Fahrenheit and 135° F. To avoid bacterial growth: ▪ Store cold foods at 40° F (5° Celsius) or less. ▪ Hot foods should be held and stored at 135 ° F (60° C) 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° F, discard it. If frozen food has thawed, do not refreeze. **REFRIGERATOR TEMPERATURES** Refrigerator temperatures should be maintained: ▪ Between 32° and 40° F (0° to 5° C) for all refrigerated goods. ▪ For fresh meat, poultry, and seafood: 30° – 34° F (minus 1° to 1° C). **FREEZER TEMPERATURES** Freezer temperatures should be maintained: ▪ Between minus 10° and minus 0.4° F (minus 23° to minus 18° C) for dairy, ice cream, frozen vegetables, meat, poultry and seafood.	▪ 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 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- For ice cream in scooping cabinets: Between minus 0.4° and 10° F (minus 18° to minus 12° C).

DISHWASHING MACHINES

Records are kept of the dishwasher temperatures.

Setting the right temperature for your commercial dishwasher is critical to ensure cookware, dishes and utensils are properly sanitized to prevent foodborne illnesses.

Temperatures:

- 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
- Hospitals are in compliance with any federal, state, and local regulations.

LIGHTING

There is sufficient lighting in the food handling area to ensure safety.

LIGHT BULBS

- 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.
- 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.

06.03.10 For future use

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.03.11 Trash disposal	☐ 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. 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 trash cans.	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. □ Practice is consistent with policies. ▪ Verify through observation that staff adhere to the policies relative to trash disposal and removal. Ensure that garbage does not present a health hazard
06.03.12 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. **§482.28** **§485.608(d)**	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: 1. Employee health policies: a. Mandatory self-reporting procedures related to hazardous health issues.	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Review orientation and ongoing training curricula, schedules, attendance, and competency assessments to verify: ▪ Orientation/training material is appropriate. ▪ Training is provided on an ongoing basis consistent with state and local regulations.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	b. Personnel with hazardous health issues, e.g., open skin lesions, respiratory infections, or gastroenteritis, are prohibited from handling food. 2. Personal hygiene and hand-washing. 3. Sanitation, food safety (food preparation and storage), physical environment, prevention of cross contamination, and infection control practices.	▪ Staff have received proper training, e.g., sanitation techniques, employee health policies.
06.03.13 Staff hygiene and health There are policies and procedures regarding the personal hygiene and health of food service employees. **§482.42(a)(2)** **§485.640(a)(2)**	☐ Compliant ☐ Not Compliant Food service policies are in place and provide guidelines. These include but are not limited to: 1. Hairnets/bonnets, hand washing facilities, gloves, and aprons are used on an ongoing basis. 2. Employees with open skin lesions and respiratory infections are not assigned to food preparation.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review policies for specific food service requirements. ▪ Personal hygiene practices are consistent with policies.
06.03.14 China and utensils China, glassware, and utensils must be of an acceptable level of safety and quality. **§485.640(a)(2)**	☐ 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 that there are no chipped or damaged china, glassware, utensils, or pitted cookware in use. ▪ Unglazed china is not used. ▪ Dishes and utensils are clean and without water spots.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.03.15 Traffic control Traffic through the food preparation area is limited to authorized personnel wearing appropriate sanitation garb. **§485.640(a)(2)**	☐ 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: 1. Identification of authorized and non-authorized personnel. 2. Use of hairnets/bonnets and other protective clothing to be worn by all individuals entering the area.	This standard is not met as evidenced by: **OBSERVATION** ▪ Verify that practice conforms to policy. □ 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.) ▪ Traffic through the food preparation area is limited.
06.03.16 Food storage and preparation in remote areas All areas in the facility that stores, prepares, or distributes food to patients, visitors, or staff shall meet the same requirements as the central kitchen. **§485.635(a)(3)(vi)**	☐ Compliant ☐ Not Compliant Food preparation requirements relating to sanitation and safety are not limited to the hospital kitchen. When food is prepared in areas outside of the central kitchen, to ensure food and patient safety, all requirements, including education and training, are applicable. In healthcare facilities, typically there are two situations in which food may be stored, prepared, and/or served outside of the central kitchen. Snack Shops: This first group includes snack shops, gift shops, and coffee shops that are managed by the hospital, volunteers, auxiliary groups, or outside vendors. Coffee, baked goods, fountain drinks, ice cream, soup, sandwiches, or full meals may be served. Patient Activities: The second group of food preparation outside the central kitchen occurs in patient care areas. Food preparation is an important activity of daily living. To assist the patient with achieving these therapeutic goals,	This standard is not met as evidenced by: **OBSERVATION** Verify that these standards are consistently applied throughout the facility: ▪ The food preparation and serving area is a safe and clean environment. Hand-washing facilities are in the immediate food preparation area. ▪ Refrigeration and dishwashing capabilities are in good working order. Dishes, glassware, and utensils are clean and in good condition. Pots and pans are not pitted or with water spots.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	hospitals may have food, cooking utensils, and kitchen appliances located in the Occupational Therapy/Recreational Therapy/Physical Rehabilitation department, skilled nursing unit, or psychiatric units. **EXCLUSIONS** This requirement does not apply to: 1. Gift shops that only store and sell packaged food items, such as candy, chips, and canned beverages. 2. Areas of the hospital that makes coffee available to staff and visitors, e.g., surgical waiting rooms.	▪ Requirements for monitoring refrigerator and dishwasher temperatures per policy are met. ▪ Food is covered. Food products are labeled with expiration dates and patient identifier, when applicable. Food is not outdated. ▪ Employees, contract workers, and volunteers receive orientation and ongoing training regarding personal hygiene, sanitation, and food safety. These personnel adhere to food preparation, infection control, and employee health policies (e.g., refrigerator temperatures, hairnets, hand washing, gloves, food is covered, etc.).
06.03.17 Local health standards The food service is in compliance with state and local health standards. **§485.608(b)** **§485.640(a)(2)**	☐ 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 Food Service 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. Confirm that deficiencies have been corrected and improvements sustained.

06.04

ACUTE INPATIENT AND OUTPATIENT SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.04.00 Patient services: General *The CAH provides those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department.* *These CAH services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.* §485.635(b)(1)(i) Tag C-1024	☐ Compliant ☐ Not Compliant **OUTPATIENT SERVICES** This regulation addresses the minimum level of outpatient services (except for emergency services – see §485.635(b)(4)) the CAH must provide. Such services must be provided at the hospital but may be provided either by CAH staff or under an arrangement or contract. The CAH must provide at least those diagnostic and therapeutic services and supplies which are typically found in an ambulatory healthcare setting where patients first come into contact with the healthcare delivery system. Such services include, but are not limited to: ▪ taking a patient's medical history. ▪ conducting a physical examination of the patient. ▪ specimen collection. ▪ assessment of health status. ▪ treatment for a variety of medical conditions. The extent of the CAH's outpatient services is expected to be sufficient to meet the needs of the patients it serves for basic ambulatory care services. The CAH's outpatient services must be integrated with its inpatient services. For outpatient services that fall only within the scope of practice of a physician or non-physician practitioner, a CAH physician or non-physician practitioner must be available to treat patients at the CAH when such outpatient services are provided. This requirement does not mean the CAH must have a practitioner physically present 24 hours per day, seven days per week. See the discussion of required emergency services at §485.618(d) concerning required response times for a physician or non-physician practitioner.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ The types of outpatient services provided. □ Does the CAH provide on-site outpatient services typical of those provided in a physician office or low intensity hospital outpatient or emergency department (medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions)? ▪ Outpatient services are integrated with the appropriate inpatient services in accordance with the needs of the patient care provided. ▪ The types and number of qualified personnel are appropriate for the scope and complexity of the outpatient services offered. □ Review personnel files or contracts to verify current licensure, certifications, and training of staff consistent with applicable state laws.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ Equipment, staff, and facilities are adequate to provide the outpatient services and are in accordance with acceptable standards of practice.
06.04.01 Acute inpatient care *The CAH furnishes acute care inpatient services.* §485.635(b)(1)(ii) Tag C-1026	☐ Compliant ☐ Not Compliant Acute inpatient services must be furnished to patients who present to the CAH for treatment as long as the CAH has an available inpatient bed and the treatment required to appropriately care for the patient is within the scope of services offered by the CAH. **AVERAGE LENGTH OF STAY DOES NOT EXCEED 96 HOURS** CAHs are expected to provide less complex inpatient services in order to comply with the length of stay requirement that does not exceed 96 hours (§485.620(b). **CERTIFY EXPECTED INPATIENT LENGTH OF STAY** In accordance with Medicare payment regulations, the CAH is required, for each admitted patient who is a Medicare beneficiary, to have the admitting practitioner certify that the beneficiary may reasonably be expected to be discharged or transferred within 96 hours following admission to the CAH. CAHs generally are not expected to handle patients requiring complex, specialized inpatient services, such as those services provided by trauma centers or cardiac surgery centers but should be able to handle a range of patient needs requiring inpatient admission. **Note:** CMS does not believe it is in the best interest of patients to routinely transfer to a more distant hospital if care can be provided locally without compromising quality or the length of stay requirements (78 FR 50749).	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the CAH is furnishing acute care inpatient services by reviewing data on the number of patients admitted over the prior year. ▪ Determine the percentage of ED visits that result in an admission to the CAH. □ If fewer than 8% of ED visits lead to an inpatient admission, review data on transfers of ED patients, overall staffing, the volume, and type of outpatient services offered, including observation services, and swing bed services to determine whether there is a reasonably proportionate relationship among the various services the CAH provides. ▪ Review a sample of records of the patients the CAH transferred and determine if the transfers were appropriate based on the services available at the CAH.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

SEASONAL VARIATIONS WITH TREATING PATIENTS

Given the resources of the CAH, the needs of the community it serves, and the variable nature of a CAH's inpatient census, a CAH may not be actively treating inpatients at all times. CAHs may experience significant seasonal variations in the inpatient occupancy rates as well as variations that are a function of the size of the community in which the CAH is located.

AVERAGE DAILY CENSUS

A CAH is not required to maintain a minimum average daily census of patients receiving inpatient acute care services or maintain a minimum number of beds that are to be used for inpatient services.

However, determining compliance with this requirement includes consideration of:

1. The average volume of emergency services the CAH provides measured quarterly and annually.
2. The number of certified inpatient beds.
3. The presence of dedicated observation beds in the CAH (if any) compared to the number of inpatient beds.
4. The average acute care occupancy rate for the CAH's inpatient beds measured quarterly and annually.
5. Acute inpatient admissions measured quarterly and annually.
6. The volume of patients placed in observation status in the CAH measured quarterly and annually.
7. The percentage of emergency department patients admitted to the CAH versus those transferred to another facility measured quarterly and annually
8. The range, volume, and complexity of outpatient services the CAH provides.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

BENCHMARK: 8% OF ED PATIENTS ARE ADMITTED

Given that a CAH may offer fewer services than even the average rural hospital and is expected to achieve a 96-hour average length of stay or less, CMS has no expectation that every CAH will admit 8% of its ED patients. This benchmark can, however, provide a useful starting point for assessing compliance.

- Generally, if a CAH admits at least 8% of its ED patients annually, it would be considered compliant with the requirement to provide inpatient services and surveyors do not have to investigate further.
- If a CAH admits less than 8% of its ED patients annually, this is not in and of itself evidence of noncompliance.
- Compliance may be assessed by determining whether the volume of activity and number of staff the CAH has for its ED, other outpatient, and inpatient services are reasonably related to each other.

ADDITIONAL ASSESSMENT FOR DISPROPORTIONATE ADMISSIONS

Surveyors are alert to disproportionate relationships among the CAH's various services. Examples are presented below to indicate variation of circumstance and the types of factors to be considered when determining whether the CAH satisfies the requirement to provide inpatient services:

- **Example 1:** A CAH has only four certified beds and an average of three acute care inpatients per month but has 18 observation beds that have an annual occupancy rate of 85%, an ED staffed by physicians 24/7 that sees 9,000 ED patients/year, offers extensive and complex outpatient services, including chemotherapy, advanced diagnostic imaging, sleep lab services, and same day surgery, but transfers to another hospital from the ED almost all patients who need inpatient admission. These inpatient services would not be reasonably proportional to the overall mix and volume of services offered by the CAH.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- **Example 2:** A CAH has a very low volume of ED visits; two or fewer patients per day on average, discharges over 90% of its annual ED patients, has a total professional health care staff that consists of one physician who spends a limited amount of time onsite, and one nurse practitioner who works days, five days per week. In this case it would not be unreasonable for the CAH to admit a patient for acute inpatient services only occasionally and transfer most of those ED patients who require inpatient services to a hospital.
- **Example 3:** A CAH has 50 ED visits per day on average, four certified inpatient beds, two inpatient admissions per month on average (all elective surgery patients who started as outpatient cases), ten dedicated observation beds and places about two ED patients per day in observation; transfers out to a neighboring hospital an average of 15 ED patients per week who require admission, has 20 physicians on staff, is performing an average of 3,000 outpatient surgeries per year, provides outpatient chemotherapy, cardiology and advanced diagnostic imaging, and has a total of about 40,000 outpatient visits per year, not counting ED visits.

  This CAH's services are very skewed toward outpatient services, and the needs of its patient population for inpatient services do not appear to be met by the CAH. The CAH might arguably have the staff to provide a larger volume of inpatient services to many of the ED patients who require admission.

  The CAH would be expected to demonstrate to the Surveyor why it could be reasonable for its inpatient capacity and admissions to be so disproportionately small compared to its outpatient services volume and capabilities, in view of the needs of its ED patients for inpatient services. The Surveyor would also review the medical records of a sample of ED patients transferred out to see if they required services the CAH's professional healthcare staff is not able to provide. (This case might also raise EMTALA issues related to on-call lists and appropriate transfers.)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- **Example 4:** A CAH has 25 ED visits per day, 25 certified beds, 23 of which, on average, are used for swing-bed services and are occupied by nursing home or skilled nursing facility residents. The CAH transfers out to a neighboring hospital an average of eight ED patients per week who require admission and admits an average of one patient per month for acute inpatient services.

  The CAH has 15 physicians on staff, is performing an average of 800 outpatient surgeries per year, provides outpatient chemotherapy, cardiology, and advanced diagnostic imaging, and has a total of about 20,000 outpatient visits per year, not counting ED visits. In this situation the CAH's services are skewed towards outpatient and long-term care services and the needs of its patient population for inpatient services do not appear to be met by the CAH.

  The CAH would be expected to demonstrate to the Surveyor why it could be reasonable for its inpatient acute care capacity and admissions to be so disproportionately small compared to its outpatient and long-term care services and to the needs of its ED patients for inpatient services.

  As in example 3, the surveyor would also review the medical records of a sample of ED patients transferred out to see if they required services the CAH's professional healthcare staff is not able to provide. (This case might also raise EMTALA issues related to on-call lists and appropriate transfers.)

06.05

LABORATORY SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.05.00 Laboratory services *The CAH provides basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in 42 CFR 493.)* *The services provided include the following:* *(i) Chemical examination of urine by stick or tablet method or both (including urine ketones);* *(ii) Hemoglobin or hematocrit;* *(iii) Blood glucose;* *(iv) Examination of stool specimens for occult blood;* *(v) Pregnancy tests; and* *(vi) Primary culturing for transmittal to a certified laboratory.* §485.635(b)(2) Tag C-1028	☐ Compliant ☐ Not Compliant Laboratory services that must be provided on-site at the CAH's main campus are the tests specified in the regulation, which would be considered the minimum necessary for diagnosis and treatment of a patient. Surveyors are expected to refer potential issues they may identify to the program responsible for CLIA certification.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Laboratory services provided meet minimum requirements. ▪ Required lab services are provided at the CAH's main campus.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.05.01 Meet the needs of the patient *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 §493.* *The hospital must have laboratory services available, either directly or through a contractual agreement with a certified laboratory that meets requirements of 42 CFR §493 (CLIA).* §485.635(b)(2) Tag C-1028	☐ Compliant ☐ Not Compliant These services may be provided by the CAH staff or under arrangement or agreement with a laboratory, or through a combination of CAH staff and a laboratory under arrangement. Laboratory services, whether provided directly by the CAH or under an arrangement with a laboratory contractor, must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed and meet the laboratory requirements specified in Part 493 of this chapter.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The CAH has a CLIA certificate or waiver, as applicable, for all laboratory tests performed. ▪ If the CAH refers specimens to another laboratory for testing, the CAH has documentation that the referral laboratory is CLIA-certified for the relevant tests.
06.05.02 Emergency laboratory services *Emergency laboratory services must be available 24 hours a day.* *A written description of services provided must be available to the medical staff* and other staff as appropriate. §485.635(b)(2) Tag C-1028	☐ Compliant ☐ Not Compliant The CAH must determine which laboratory services are to be immediately available to meet the emergency needs of patients and how the services are to be provided. **SCOPE OF SERVICES PROVIDED** The emergency laboratory services available should reflect the scope and complexity of the CAH'S emergency services operations. The provision of laboratory services that exceed the minimum tests specified is optional. The scope and complexity of the CAH's laboratory service must be adequate to support the clinical services the CAH offers to patients. Additional laboratory services may be offered directly or through arrangement.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The CAH has identified laboratory services available to support the emergency services it provides. ▪ With staff who furnish emergency services, that these laboratory services are available whenever they provide emergency services.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The CAH should have a written description of all the laboratory services that it provides, including those delivered on routine and stat basis.	▪ The written description of the laboratory services provided, including those furnished on routine and stat basis (either directly or under an arrangement with an outside facility). ▪ There is a procedure for obtaining tests that are needed but unavailable at the CAH laboratory.
06.05.03 Receipt and reporting of tissue specimens *The laboratory must make provision for proper receipt and reporting of tissue specimens.* §485.635(b)(2) Tag C-1028	☐ Compliant ☐ Not Compliant The laboratory must have written policies and procedures for the collection, preservation, transportation, receipt, and reporting of tissue specimen results. **MEDICAL RECORD REQUIREMENTS** Patient laboratory results and all other laboratory clinical patient records are considered patient medical records, and the CAH must comply with the requirements of the clinical records CoP at §485.638(a)(4)(ii).	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The laboratory has the required policies. ▪ The CAH has written policies and procedures to ensure that all laboratory results are recorded in the medical record. ▪ Medical records confirm compliance with reporting laboratory results.
06.05.04 Point of care testing When the facility performs blood gas testing or other laboratory tests in the respiratory care unit or any other unit in the facility, the testing meets the applicable requirements for the general laboratory services.	☐ Compliant ☐ Not Compliant Other typical laboratory tests include point of care (POC) testing, such as bedside glucose monitoring, performed in any nursing or ancillary department.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The respiratory unit or other units in the facility are included by the policies and under the review of the general laboratory manager or an individual

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.635(b)(2)		designated by the medical director listed on the applicable CLIA certificate. ▪ All laboratory testing done outside the lab is overseen by the laboratory manager (or designee) and meets all requirements for competency testing, quality control, and monitoring.
06.05.05 Critical test results The laboratory has written policies to establish safe and reliable processes for reporting critical test results. **§485.635(b)(2)**	☐ Compliant ☐ Not Compliant Facility policies define: 1. The processes for prompt notification of critical test results to the ordering provider. 2. The range of critical laboratory test results to be promptly reported, for example electrolytes, INR, etc.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The facility has the required policy. ▪ Through chart review, that the facility is compliant with reporting critical results.

06.06

RADIOLOGY SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.06.00 Radiology services *Radiology services furnished by the CAH are provided by personnel qualified under State law, and do not expose CAH patients or personnel to radiation hazards.* The CAH must maintain or have available radiology services to meet the needs of the patients. §485.635(b)(3) Tag C-1030	☐ Compliant ☐ Not Compliant Radiologic services encompass various modalities of medical imaging to provide information related to diagnosis, monitoring, and treating possible disease, injury, or the effectiveness of medical treatment for an individual patient. All modalities use some form of radiation (ultrasound, magnetic resonance imaging) and some use enough energy to potentially cause damage to DNA, e.g., forms of ionizing radiation like radiography, computed tomography, fluoroscopy. ▪ Radiological services furnished by the CAH may be provided by CAH staff or under arrangement. ▪ The CAH must maintain and have available diagnostic radiological services to support the services it provides to meet the needs of its patients. These services must be available at all times the CAH provides services, including emergency services. ▪ The CAH has the flexibility to choose the types and complexity of radiologic services offered. This may acceptably range from a minimal set of services to complex services (including nuclear medicine). ▪ All radiological services provided by the CAH, including diagnostic, therapeutic, and nuclear medicine, must be provided in accordance with acceptable standards of practice and must meet professionally approved standards for safety. The scope and complexity of radiological services offered is specified in writing and approved by the governing body (or responsible individual). ▪ Acceptable standards of practice include maintaining compliance with appropriate federal and state laws, regulations, and guidelines governing radiological services, including facility licensure and/or certification requirements, as well as any standards and recommendations promoted by nationally recognized organizations such as the American Medical Association, Radiological Society of North America, Alliance for Radiation	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Identify radiologic services the CAH offers at its main campus. ▪ At off-site locations ask how the CAH ensures patient needs for radiologic services are met, if applicable. ▪ Verify how the CAH ensures that radiologic services provided are consistent with acceptable standards of practice.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Safety in Pediatric Imaging, American Society of Radiologic Technologists, American College of Cardiology, American College of Neurology, American College of Physicians, American College of Radiology, etc. **Note:** For Information Only – Not Required/Not to be Cited Well-designed radiologic services include a medical physicist, who, in conjunction with the person responsible for radiologic services, performs or supervises the procedures necessary to assure the safe and effective delivery of radiation to achieve a diagnostic or therapeutic result. The responsibilities of the medical physicist include: protection of the patient and others from potentially harmful or excessive radiation; establishment of adequate protocols to ensure accurate patient dosimetry; the measurement and characterization of radiation; the determination of delivered dose; advancement of procedures necessary to ensure image quality; development and direction of quality assurance programs; and assistance to other health care professionals in optimizing the balance between the beneficial and deleterious effects of radiation (www.aapm.org). CAHs are encouraged to involve a medical physicist in the calibration of the imaging equipment and monitoring of radiation dosage exposures.	
06.06.01 Qualified radiologic personnel Written policies consistent with state law are developed and approved by the governing body or responsible individual that designate which personnel are qualified to use the radiological equipment, administer procedures, and which studies require interpretation by a radiologist.	☐ Compliant ☐ Not Compliant ▪ When telemedicine is used to provide tele-radiology services, radiologists who interpret radiological tests must satisfy the telemedicine privileging requirements §485.616(c)(3). ▪ In addition to radiologists, there are other types of healthcare personnel who, depending on state law and the scope and complexity of the CAH's radiologic services, may be involved in the delivery of radiologic services including radiologic technologists and medical physicists. Radiologic technologists perform diagnostic imaging examinations and administer radiation therapy treatments. They are educated in anatomy, patient	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Studies are interpreted only by qualified staff approved to do so by the CAH's governing body or responsible individual. ▪ Staff using various pieces of radiological equipment and/or administering patient procedures meet the qualifications for

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
Only personnel designated as qualified by the medical staff may use the radiological equipment and administer procedures. §485.635(b)(3) Tag C-1030	positioning, examination techniques, equipment protocols, radiation safety, radiation protection and basic patient care.	tasks they perform, as established in the CAH's policies and consistent with state law as evidenced in personnel files. □ The CAH has written protocols and staff is adhering to them.
06.06.02 Safety from radiation hazards *Patients and staff are not exposed to radiation hazards. Proper safety precautions must be maintained against radiation hazards. This includes shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.* §485.635(b)(3) Tag C-1030	☐ Compliant ☐ Not Compliant The CAH must adopt and implement policies and procedures that ensure safety from radiation hazards for patients and personnel. The CAH must ensure compliance with its established safety standards. The policies address safety practices, including at least: 1. Shielding built into the CAH's physical plant, as appropriate. 2. Conditions and types of personal protective shielding to be used for patients (including high risk patients as identified in radiologic services policies and procedures) and CAH personnel. 3. Containers to be used for various radioactive materials when stored, in transport, in use, and when disposed. 4. Clear signage identifying hazardous radiation areas. 5. Labeling of all radioactive materials, including waste, with clear identification of all material(s). 6. Transportation of radioactive materials between locations within the CAH. 7. Security of radioactive materials, including who may have access to radioactive materials and controlling access to radioactive materials. 8. Periodic testing of equipment for radiation hazards. 9. Periodic checking of relevant staff for their level of radiation exposure, via exposure meters or badge tests. 10. Storage of radio nuclides and radio pharmaceuticals as well as radioactive waste.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Radiologic services staff is familiar with the policies and procedures related to safety. ▪ Patient shielding (aprons, etc.) are properly maintained and routinely inspected by the CAH. ▪ Areas where radiologic testing is done are clear of safety problems. ▪ Hazardous materials are clearly labeled. ▪ Records reflect that hazardous materials are tracked, handled, and stored in a safe manner using the requisite containers.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	11. Disposal of radio nuclides, unused radio pharmaceuticals, and radioactive waste.	
06.06.03 Radiologic equipment maintenance *Periodic inspections of equipment must be made and hazards identified must be promptly corrected.* §485.635(b)(3) Tag C-1030	☐ Compliant ☐ Not Compliant Policies and procedures ensure that periodic inspections of radiology equipment are conducted and that problems identified are corrected in a timely manner. ▪ The CAH must ensure that equipment is inspected and maintained in accordance with federal and state laws and regulations, as applicable, and the manufacturer's recommendations. ▪ The CAH must have a system in place to correct identified problems. ▪ The CAH must have evidence of its inspections and corrective actions.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Inspection records confirm that periodic inspections and maintenance are conducted in accordance with the manufacturer's recommendations. ▪ Problems identified are properly corrected in a timely manner and the correction is maintained over time.
06.06.04 Radiology records *Records of radiologic services must be maintained.* *The hospital must maintain the following, consistent with policy and State law.* *1. Copies of reports and printouts.* *2. Films, scans, and other image records, as appropriate.* §485.635(b)(3) Tag C-1030	☐ Compliant ☐ Not Compliant The CAH radiology records are to be treated in the same manner as any other part of a medical record. The medical records CoP at §485.638(a)(4)(ii) requires that the CAH maintain reports of physical examinations, diagnostic and laboratory test results, and consultative findings. Policies and procedures address the protection, confidentiality, and integrity of radiology records.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The CAH has the required, written policies. ▪ Radiology records are maintained consistent with policy and state law.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.06.05 Exposure meters *Personnel who are at risk for exposure to radiation must be checked periodically, by the use of exposure meters or badge test, for the amount of radiation exposure.* §485.635(b)(3) Tag C-1030	☐ Compliant ☐ Not Compliant The facility has policies describing: ▪ Categories of "at-risk" personnel required to wear exposure badges. ▪ Frequency, e.g., monthly or quarterly, of sending exposure badges for reading, consistent with state requirements. ▪ Review, recordkeeping, and communication of exposure reports to the respective individuals. The CAH identifies those personnel considered to be "at-risk" for radiation exposure. Certain personnel who work outside the radiology department may also be considered in this group. Exposure records for each person are maintained and readily accessible. A physicist or qualified radiologist reviews 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** Verify: ▪ Verify the facility has identified the staff to be "at risk" for radiation exposure ▪ The CAH requires periodic tests of all radiology personnel and records reflect that periodic tests of radiology personnel by exposure meters or test badges are performed. ▪ Personnel are knowledgeable about radiation exposure and their respective test results. ▪ Verify that a physicist or radiologist has signed the forms indicating review of the radiation exposure test results.
06.06.06 Ionizing radiation safety *Facilities providing computerized tomography/diagnostic imaging services adopt and implement current national guidelines regarding the safe delivery of ionizing radiation.* §482.26(b)	☐ Compliant ☐ Not Compliant The facility has policies addressing: 1. Documentation in the patient's medical record of the dose of radiation for every diagnostic CT study of each body part imaged. 2. Notification of the referring physician by the radiation oncologist of any of the following: □ Any incident in which the total dose of therapeutic ionizing radiation delivered differs from the prescribed dose by 20% or more. □ Any delivery of therapeutic ionizing radiation to the wrong individual or wrong treatment site.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the facility has adopted current national guidelines regarding the safe delivery of ionizing radiation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.06.07 Physicist inspections *A radiation physicist or equivalent conducts inspections to identify hazards.* §482.26(b)(2)	☐ Compliant ☐ Not Compliant Radiology equipment is inspected at least annually by a qualified regulatory agency. The radiology department has procedures for compliance with regulatory agencies; the physicist or regulatory agency authority approves these policies at least annually, or consistent with manufacturer's recommendations. Equipment is placed on a regular preventive maintenance schedule. Hazards identified during inspections are corrected promptly. The physicist monitors radiation doses administered to patients; validity and quantitative results; and absorbed doses of radiation in individual patients (as requested by the director).	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Inspection records (logs) reflect that periodic inspections are conducted in accordance with manufacturer's instructions, federal and state laws, regulations, and guidelines, and CAH policy. ▪ Problems identified are properly corrected in a timely manner. ▪ Reports are in place indicating that a physicist or regulatory agency authority has inspected the radiology equipment **annually, at a minimum every 12 months apart, not to exceed 14 months and in accordance with state law and manufacturer instructions for use.** ▪ Radiology equipment is placed on a preventive maintenance schedule.
06.06.08 Equipment output monitoring All radiation producing equipment emits radiation within acceptable limits. The output of the equipment is measured at least annually.	☐ Compliant ☐ Not Compliant Each piece of radiation producing equipment is monitored at least annually to measure the level of radiation it emits at various settings. Emission output is within acceptable limits.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ There are emission testing documents for each piece of radiation producing equipment.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
Records of the radiation output are maintained. **§485.635(b)(3)**		▪ Emission/output testing is conducted at least annually for each piece of radiation producing equipment.
06.06.09 Medical supervision *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 a doctor of osteopathic medicine *who is qualified by education and experience in radiology.* §482.26(c)(1)	☐ Compliant ☐ Not Compliant 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 medical staff who maintains regular contact with administration and participates in medical staff activities.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ Records reflect that a radiologist interprets those tests that have been designated by the medical staff to require interpretation by a qualified radiologist. ▪ Supervision of radiology services is restricted to an individual who is credentialed by the medical staff. ▪ The radiology director is qualified as evidenced by education and experience.
06.06.10 Order requirements *Each request for imaging services shall contain the reason(s) for the examination.* §482.26(b)(4)	☐ Compliant ☐ Not Compliant 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Orders for radiology services include the reason for the procedure.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.06.11 Critical test results The radiology department has written policies that establish safe and reliable processes for reporting critical diagnostic results. **§485.635(b)(3)**	☐ Compliant ☐ Not Compliant The facility has written policies that: 1. Require diagnostic findings to be promptly reported, such as critical radiology results. 2. Identify critical diagnostic results, e.g., pneumothorax. 3. Define the processes for prompt notification of critical diagnostic results to the ordering healthcare provider.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The facility has the required policy. ▪ Chart review reflects that the facility is compliant with reporting critical results.
06.06.12 Contrast media The organization uses validated protocols to evaluate patients who are at risk for contrast media-induced renal failure and a clinically appropriate method for reducing risk of renal injury based on the patient's kidney function evaluation. Requirements to meet standard compliance include, but are not limited to: 1. The CAH has organizational policies and procedures regarding the prevention of contrast media-induced nephropathy. 2. CAH protocols ensure that a patient undergoing IV contrast procedures is hydrated sufficiently according to standard protocol.	☐ Compliant ☐ Not Compliant Many radiologic procedures use 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Organizational policies on the prevention of contrast media-induced nephropathy define the risk-assessment process and the method used for risk-reduction. ▪ Patient records reflect: □ Documentation of the risk assessment. □ Implementation of risk reduction interventions.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
3. The serum creatinine level is checked prior to scheduling a contrast study in a patient who has uncertain kidney function. 4. CAH protocol addresses use of low osmolar contrast media to prevent contrast media-induced renal failure in a patient with impaired renal function. **§485.635(b)(3)**		
06.06.13 Labeling of radiographs The organization has implemented a standardized **policy** to prevent the mislabeling of radiographs. Minimally, the **policy** includes: 1. Flash/marking of x-ray images with the correct patient information in the darkroom (if applicable). 2. Mark "left" or "right" on each radiographic image to prevent misinterpretation on a light box. **§485.638(a)(2)** **§485.635(b)(3)**	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review the protocol for compliance. ▪ Observe the process to validate implementation.

06.07

CONTRACTED SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.07.00 Contracted services ▪ *The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including* ▪ *In the case of distant-site physicians and practitioners providing telemedicine services to the CAH's patients under a written agreement between the CAH and a distant-site telemedicine entity, the distant-site telemedicine entity is not required to be a Medicare-participating provider or supplier.* §485.635(c)(1),(5) Tag C-1034	☐ Compliant ☐ Not Compliant All agreements for providing health care services to the CAH's patients must be with a provider or supplier that participates in the Medicare program, except in the case of an agreement with a distant-site telemedicine entity for the provision of telemedicine services. The governing body (or responsible individual) has responsibility for ensuring that CAH services are provided according to acceptable standards of practice, irrespective of whether the services are provided directly by CAH employees or indirectly by agreement or arrangement. The agreements must: ▪ Describe routine procedures (e.g., for obtaining outside laboratory tests). ▪ Confirm that the CAH's governing body (or responsible individual) is responsible for these services provided under agreement or arrangement. Individual agreements or arrangements should be revised when the nature and scope of services provided has changed. The governing body must take actions through the CAH'S QAPI Program to: 1. Assess services furnished directly by CAH staff and those services provided under agreement or arrangement. 2. Identify quality and performance problems. 3. Implement appropriate corrective or improvement activities. 4. Ensure monitoring and the sustainability of those corrective or improvement activities.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The CAH confirms that every entity providing health care services to the CAH's patients under an agreement participates in Medicare, with the exception of a distant-site telemedicine entity providing telemedicine services under an agreement or arrangement. ▪ The governing body, through the QAPI Program, assesses the services furnished directly by CAH staff and those services provided under agreement or arrangement. ▪ The governing body takes actions, identifies quality and performance problems, implements appropriate corrective or improvement activities, and ensures the monitoring and sustainability of those corrective or improvement activities.
06.07.01 For future use		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.07.02 Agreements: Services of MDs or DOs	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:

(1) *The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including:*

(i) *Services of doctors of medicine or* doctors of osteopathic medicine*.*

(2) *If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.*

- When a CAH has a primary hospital to which it refers patients requiring a higher level of care, a written transfer agreement is in place.
- When a CAH has a preferred service provider for transporting patients, a written agreement is in place for emergency and non-emergency transportation of patients.

§485.635(c)(1)(i) Tag C-1036
§485.635(c)(2)

The CAH is required to have at least one doctor of medicine or osteopathy (MD or DO) on its staff who is responsible for the functions described in §485.631(b).

- CAHs may have additional MDs or DOs on staff, part- or full-time.
- MDs and DOs who have been credentialed and privileged to provide services on-site at the CAH are part of the CAH's professional healthcare staff, even if they are not at the CAH full-time. They would not be considered to be providing services under an arrangement and would not be covered by these regulatory provisions.
- Similarly, these regulations do not apply to MDs and DOs who provide telemedicine services to the CAH's patients, even when they are provided under arrangement. (See §485.616(c) and §485.635(c)(5) concerning telemedicine requirements.)

POLICIES AND PROCEDURES: PATIENT REFERRALS

Under §485.635(c)(1)(i) and §485.635(c)(2), the CAH must have policies and procedures for referring patients it discharges who need additional specialized MD or DO services not available at the CAH.

- The policies and procedures must, at a minimum, identify the services for which the CAH has referral arrangements or agreements, as well as the information to be provided to referred patients.
- MDs and DOs to whom the CAH refers its patients must participate in Medicare.
- The CAH is not required to have referral arrangements in writing, but if it does not, then it must be able to document that patients it has referred to an outside MD or DO have been offered appointments and treatment.

Exceptions: Patients presenting to a CAH may require a higher level of care than the services available. When a CAH has a primary hospital to which it

INTERVIEW AND DOCUMENT REVIEW

Verify:

- The CAH has arrangements with one or more MDs or DOs for referral of discharged CAH patients who need medical services not available at the CAH.
  - ☐ Are the referral arrangements in writing?

    If not, can the CAH document that patients referred to an outside MD or DO have been offered appointments and treatment?
- Policies and procedures address referral of discharged patients.
  - ☐ Are the CAH's practitioners and staff who handle the discharge of patients familiar with these policies and procedures?
- The CAH has:
  - ☐ a written hospital transfer agreement.
  - ☐ Written agreements for emergency and non-emergency transportation of patients.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

refers patients, a written hospital transfer agreement is required to formalize the expectations of both parties to ensure a safe and efficient transfer of the patient. The CAH has a policy that defines the responsibility to notify the hospital and receive acceptance prior to transfer, as well as to provide patient care information and related documents, consistent with state regulations. Similarly, a written agreement is required when a CAH has a preferred service provider for transporting patients, such as EMS or a helicopter transferring service.

06.07.03 Agreements: Diagnostic services

(1) *The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including:*

(ii) *Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH; and*

(2) *If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.*

§485.635(c)(1)(ii) Tag C-1038
§485.635(c)(2)

☐ Compliant ☐ Not Compliant

AGREEMENTS/ARRANGEMENTS FOR LABORATORY SERVICES

The CAH is required to furnish, either directly by the CAH staff, under arrangement or agreement, or through a combination of CAH staff and a laboratory under arrangement, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under §353 of the Public Health Service Act (42 USC §236a).

These services must be provided on-site at the CAH and may be provided either by CAH staff or under an arrangement with a laboratory.

The CAH is also free to provide additional laboratory services on-site, beyond the minimum required services.

Note: The provision at §485.635(c)(1)(ii) does not apply to laboratory services provided on-site.

- This provision addresses the requirement for the CAH to have an arrangement or agreement with a laboratory that can provide additional or specialized clinical laboratory services that are not available at the CAH.
- The arrangement or agreement may provide for the CAH to draw the specimens to be examined and send them to the outside laboratory. The CAH is not required to have a written agreement or arrangement, but if it

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

AGREEMENTS FOR LABORATORY SERVICES:

- Verify that the CAH has an agreement or arrangement with an outside laboratory for services not provided in the CAH.
  - ☐ Do policies and procedures address which lab services are provided under arrangement, as well as, for lab services, collection, preservation, transportation, receipt, and reporting of tissue specimen results?
- Ask the CAH how it ensures that the laboratory with which it has an agreement or arrangement holds the necessary CLIA certification.
- If the agreement or arrangement is not in writing, can the CAH document that it is sending specimens to an outside

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

does not, it is expected to be able to document that an outside laboratory to which it sends specimens provides the CAH with test results.

CLIA REQUIREMENTS

1. Laboratories that provide additional diagnostic and clinical laboratory services to a CAH under agreement or arrangement must have a current Clinical Laboratory Improvement Act (CLIA) certificate or waiver for all tests performed and meet the laboratory requirements specified in §493.
2. The CAH is expected to have evidence of the outside laboratory's current CLIA certificate or waiver.
3. The CAH policies and procedures for additional or specialized laboratory services provided under arrangement or agreement address, at least:
   - The specific services provided under arrangement.
   - The collection, preservation, transportation, receipt, and reporting of tissue specimen results.

AGREEMENTS/ARRANGEMENTS FOR RADIOLOGY SERVICES

Although the CAH is expected to provide radiology services (in accordance with §485.635(b)(3)), it is also expected to have an arrangement or agreement, as appropriate, with other providers or suppliers of diagnostic imaging services, including advanced diagnostic imaging services, such as magnetic resonance imaging, computed tomography, etc.

The CAH is not required to have a written agreement or arrangement, but if it does not, it is expected to be able to document that an outside diagnostic imaging facility to which it sends patients provides the CAH with the resulting studies and reports.

Patient diagnostic imaging studies and reports, laboratory results and all other laboratory clinical patient records must be included in the patient's medical record and meet all requirements at §485.638(a)(4)(ii).

laboratory when needed, and that it is receiving test results?

AGREEMENTS FOR RADIOLOGY SERVICES:

- Verify that the CAH has an agreement or arrangement with an outside diagnostic imaging facility for services not provided in the CAH.
  - Do policies and procedures address which imaging services are provided under arrangement?
- If the agreement or arrangement is not in writing, can the CAH document that it is sending patients to an outside diagnostic imaging facility when needed, and that it is receiving test results?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.07.04 Agreements: Food services *The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including:* ▪ *Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.* §485.635(c)(1)(iii) Tag C-1040	☐ Compliant ☐ Not Compliant If the CAH does not provide all food and other services required to meet the nutritional needs of its inpatients using CAH staff, then the CAH must provide these services under an agreement or arrangement. The CAH must ensure that dietary services provided under an agreement or arrangement are provided in accordance with the CAH's policies adopted as required by §485.635(a)(3)(vii). **GRANDFATHERED AND CO-LOCATED** 1. Unless the CAH is a grandfathered co-located CAH (see §485.610(e)(1)) that has an arrangement with the co-located facility to provide food services to the CAH's inpatients, it is expected that the CAH's vendor provides dietary services on-site at the CAH in order to meet the needs of the CAH's inpatients. 2. Surveyors assess compliance with the requirements of §485.635(a)(3)(vii) in the same manner, regardless of whether the services are provided by CAH staff or a vendor. 3. In the case of a grandfathered co-located CAH that obtains food services from the co-located facility, surveyors must assess the food service operations in the co-located facility as part of the CAH survey.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the CAH has an agreement or arrangement with a vendor to provide dietary services to inpatients if the CAH does not use its own staff to provide these services.
06.07.05 For future use		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.07.06 List of contracted services *The CAH maintains a list of all services furnished under arrangements or agreements.* *The list describes the nature and scope of the services provided.* §485.635(c)(3) Tag C-1042	☐ Compliant ☐ Not Compliant The list must be updated each time a contracted service is added or removed. For each service the list must include, at a minimum: ▪ The service(s) being offered. ▪ The individual(s) or entity providing the service(s). ▪ Whether the services are offered on- or off-site. ▪ Whether there is any limit on the volume or frequency of the services provided. ▪ When the service(s) are available.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The list of contracted services contains all required information. ▪ Evidence that the list is updated whenever there are changes. ▪ Through interview with various staff during the course of the survey whether they work directly for the CAH or some other entity; confirm that services provided by staff employed by outside entities are on the list of contracted services.
06.07.07 Responsibility for contract services *The person principally responsible for the operation of the CAH, such as the Chief Executive Officer (CEO), under 42 CFR §485.627(b)(2) is also responsible for the following:* (i) *Services furnished in the CAH whether or not they are furnished under arrangements or agreements.* (ii) *Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all*	☐ Compliant ☐ Not Compliant **RESPONSIBILITIES OF THE CEO** The person principally responsible for the operation of the CAH (in accordance with §485.627(b)(2)) is responsible for the operation of all patient care services furnished at the CAH. ▪ This includes services provided directly by CAH staff and services provided by the CAH under arrangement or agreement. ▪ It includes not only care provided directly to patients, but also services related to patient care, such as environmental cleaning, instrument cleaning and sterilization, laundry, pharmacy services, laboratory services, etc.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Ask the CAH's CEO to demonstrate how he or she provides oversight of all contracted services related to patient care. ▪ Ask for specific examples (e.g., policies and procedures, by-laws, etc.) of how the CEO assures that services furnished in the CAH comply with the CoPs that the individual responsible for its operations

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
applicable conditions of participation and standards for the contracted services. §485.635(c)(4)(i-ii) Tag C-1044	**RESPONSIBILITIES OF THE GOVERNING BODY** ▪ This requirement does not relieve the CAH's governing body of its ultimate responsibility for the CAH's total operation in those CAHs where there are both a governing body and a CEO. ▪ The CEO must take actions to assure that all services furnished by the CAH through a contractor comply with the applicable requirements of the CoPs. ▪ When assessing compliance of a service provided by a contractor with the CoPs, deficiencies cited under other CoPs warrant a citation of this requirement, because the CEO has failed to assure that the contractor provides services in a manner that allows the CAH to comply with the CoPs.	is responsible for all services provided through arrangements or agreements.

06.08

NURSING SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.08.00 Nursing services *Nursing services must meet the needs of patients.* *A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH.* *The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.* §485.635(d) Tag C-1046 §485.635(d)(1)	☐ Compliant ☐ Not Compliant In order to meet the needs of patients, nursing must be a well-organized service of the CAH. **CHIEF NURSING OFFICER/DIRECTOR OF NURSING** ▪ The CAH designates an individual who is responsible for nursing services, including development of policies and procedures for nursing services. ▪ The designated individual is a registered nurse, licensed in the state where the hospital is located and provides patient care. ▪ Various titles may be used for the responsible nurse leader may have (e.g., director of nursing services, nurse executive, chief nursing officer, or nurse manager). ▪ The leadership, in collaboration with the medical staff, establish the education, training, and experience requirements for this nursing position. The nurse leader is responsible for the overall management and evaluation of nursing care in the CAH, including, but not limited to: 1. Development and maintenance of nursing policies and procedures. 2. Supervision of nursing staff, either directly, or, depending on the size of the CAH, indirectly through other nursing managers. 3. Ongoing review and analysis of the quality of nursing care.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify that an RN has been designated responsible for nursing services at the CAH. ▪ Observe the nursing care in progress to determine the adequacy of staffing and to assess the delivery of care. Sources of information to use in the evaluation of the nursing services include: □ Staffing schedules. □ Nursing care plans for inpatients. □ Credentialing and training files (including contracted staff). □ QA activities and reports. ▪ Interview the RN responsible for nursing services to determine: □ How nursing needs of patients are identified. Who makes this determination? □ How staff is assigned to provide nursing care to patients. □ How the CAH ensures that care provided meets the needs of each patient.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- ☐ How staff are trained and oriented. If temporary outside agency nurses are used, how are they oriented and supervised?

06.08.01 Staffing and delivery of care

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The CAH must have a registered nurse, clinical nurse specialist, or licensed practical nurse on duty whenever the CAH has one or more inpatients (including patients in a swing bed receiving long term care services.)

§485.635(d)(1) Tag C-1046

NURSES ON DUTY

The CAH must ensure that, for outpatient nursing services, appropriate nursing staff are available in accordance with state law and CAH policy.

For both inpatient and outpatient services there must be sufficient numbers of supervisory and non-supervisory nursing personnel with the appropriate education, experience, licensure (as applicable), competence and specialized qualifications to respond to the nursing needs of the patient population of each CAH department or nursing unit. Staffing schedules must be reviewed and revised as necessary to meet patient care needs and to make adjustments for nursing staff absenteeism.

ASSIGNING AND COORDINATING NURSING CARE

- The CAH must have a procedure for assigning and coordinating the nursing care for every patient.
- A registered nurse must either provide directly, or assign to other staff, the required nursing care for each CAH patient, including patients receiving swing bed services.
- The RN making the assignment must consider the specialized qualifications and competence of the CAH's available nursing staff in order to meet patients' nursing care needs.
- Nursing care duties may be assigned to appropriate personnel, such as a licensed practical nurse, nursing assistant or nurse's aide, so long as such

INTERVIEW AND DOCUMENT REVIEW

- Review nursing assignments in one or more inpatient units, the emergency department, and one other outpatient department.
  - ☐ Did an RN make the assignments?
  - ☐ Were the complexity of patient care needs and the competence and specialized qualifications of the nursing staff taken into consideration?
- Review written staffing schedules.
  - ☐ Do they adhere to the policies and procedures for staffing levels and types of nursing personnel?
- Verify that there is supervision of personnel performance and nursing care for each nursing unit.
- If there are temporary agency nurses providing services, interview one or more to determine if they are familiar with the nursing policies and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	assignment is consistent with state law and the individual has the qualifications and competence to perform the assigned tasks. **STAFF ARE TRAINED AND ORIENTED** The CAH must ensure that all CAH nursing staff are adequately trained and oriented, aware of CAH nursing policies and procedures, supervised, and that their clinical activities are evaluated. **NOTE**: Regular nursing services may be provided under arrangement instead of using CAH employees, but in this case the CAH is responsible for the ongoing training and supervision of these regular nursing staff.	procedures of the unit or department where they are working. ▪ Review personnel files to confirm that nursing staff have required licenses and competencies**.**
06.08.02 <u>Supervision of care</u> *A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.* §485.635(d)(2) Tag C-1048	☐ Compliant ☐ Not Compliant The nursing care of each patient of the CAH must be supervised by a registered nurse or a physician assistant where permitted by state law. **NOTE:** Even where permitted under state law, a CAH is not required to have nursing care supervised by a physician assistant. This is simply an option for the CAH. **EVALUATION OF NURSING CARE** ▪ For inpatients, including patients receiving long term care services in swing beds, evaluation of their nursing care includes evaluating the care for each patient upon admission and, when appropriate, on an ongoing basis in accordance with accepted standards of nursing practice and CAH policy. ▪ Evaluation would include assessing the patient's care needs, patient's health status/conditioning, as well as the patient's response to interventions.	This standard is not met as evidenced by: **<u>OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW</u>** ▪ Verify that a registered nurse (or physician assistant where permitted by state law and CAH policy) supervises and evaluates the nursing care for each patient. ▪ Interview one or more registered nurses (or physician assistants, if applicable) who supervise and evaluate the nursing care for CAH patients.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Nursing care plans are not developed for outpatients, so the focus of the evaluation would be on adherence to generally acceptable standards of nursing care practice, including requirements for medication administration (at §485.635(d)(3)).	
06.08.03 Nursing plan of care *A nursing care plan must be developed and kept current for each inpatient.* §485.635(d)(4) Tag C-1050	☐ Compliant ☐ Not Compliant **INPATIENT CARE PLANS** Nursing care planning starts upon admission. It includes planning the patient's care while in the CAH as well as planning for transfer to a hospital, to a post-acute care facility, or for discharge. 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, with updated or revision to the patient's nursing care plan in response to assessments. The nursing care plan is part of the patient's clinical record and must comply with the clinical records requirements at §485.638. CAHs have the flexibility of developing the nursing care plan as part of a larger, coordinated interdisciplinary plan of care. The interdisciplinary plan of care does not minimize or eliminate the need for a nursing care plan. It does, however, serve to promote collaboration and communication among disciplines and reinforce an integrated, multi-faceted approach to a patient's care, resulting in better patient outcomes.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a representative sample of nursing care plans based on the number of inpatient records reviewed. □ Are the care plans created as soon as possible after admission for each patient? □ Are the care plans based on the nurse's assessment of the individual patient? □ Is there evidence that the care plans are reviewed on an ongoing basis? □ Is there evidence that the nursing care is revised as needed? □ Is there documentation of nursing reassessment? ▪ Verify that there is evidence that the nursing care plans have been implemented.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.08.04 For future use		
06.08.05 For future use		
06.08.06 For future use		
06.08.07 Staffing system	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The nursing staffing system is based on factors for needs relating to: 1. Physical care. 2. Equipment/technology. 3. Emotional support. 4. Education for self-care 5. Social needs/discharge planning. 6. Patient safety. The organization has developed and implemented explicit organizational policies and procedures on nurse staffing including staff mix and patient-staff ratios for all work areas with regular monitoring and documentation of the level of compliance. The six factors related to staffing needs are taken into consideration in development of the ratios for each area. **§485.631(a)(3)** **§485.631(a)(5)**	Studies have demonstrated that the level of nurse staffing in a healthcare institution is strongly associated with the risk of adverse events encountered by patients. Specifically, lower staffing rates are associated with increased risk of adverse events. The level of education and training of the nursing staff is also a factor, with more adverse events typically being found in hospitals that have a lower proportion of registered nurses. The staffing system shall be based on more than physical care needs and activities of daily living. Descriptors should exist in at least the six identified groups.	**DOCUMENT REVIEW** ▪ Review the staffing plan and the compliance monitoring by department.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.635(d)(1) **§485.635(d)(2)**		
06.08.08 Identify patients correctly The facility has a written patient safety policy that requires at least two methods for patient identification prior to medication administration, testing, treatment, and procedures. **§485.614(c)(2)**	☐ Compliant ☐ Not Compliant 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.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify the facility has the required policy. ▪ Validate through the observation of patient care.
06.08.09 For future use		
06.08.10 Patients at risk The facility has a written policy for identifying patients on admission that are at-risk for developing the following complications: 1. Pressure ulcers 2. Deep vein thrombosis (DVT/venous thromboembolism (VTE) 3. Aspiration 4. Malnutrition	☐ Compliant ☐ Not Compliant 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. ▪ 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the admission assessment policy to verify that it includes the five required risk assessments and defines when reassessments are required. The policy must also include a plan, process, or intervention to prevent complications in at-risk patients.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
5. Fall Risk/Prevention **§485.635(d)(4)**		▪ Examine ten medical records to confirm that they contain documentation that risk assessments for each of the five elements was completed on admission and periodically as indicated by patient status change.
06.08.11 Falls prevention	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The facility has a written policy or protocol for the identification and prevention of patients at risk for falls. **§485.635(d)(4)**	The facility has adopted nationally recognized guidelines for the prevention of patient falls. 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** ▪ Verify the facility has the required written policy or protocol. ▪ Review medical records to determine compliance with assessing patients for risk of falling.
06.08.12 Pain Management	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The facility has a written policy or protocol that addresses pain management. **§485.635(d)(4)**	The facility policy addresses: ▪ Frequency of initial patient assessment and re-assessments. ▪ The assessment of pain prior to and following administration of pain medication. ▪ Use of a standardized pain assessment tool, such as: □ A scale of 1 to 10. □ Visual tool such as "FACES."	**DOCUMENT REVIEW** ▪ Verify the facility has a written policy, as required. ▪ Review medical records to verify compliance with the pain assessment policy.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.08.13 Hand-offs in care	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The facility has a written policy or protocol that establishes expectations for the handoff of care. **§485.635(d)(4)**	The information communicated to staff at change of shift or transition of care is to be standardized to ensure continuity of patient care. Hospital policy standardizes the communication of patient information to ensure care is seamless and without interruption.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Verify the facility has the written policy, as required. ▪ Through observation, validate handoff communication that includes all essential elements of the change of shift report: □ Diagnosis. □ Patient condition. □ Care. □ Treatment and medications. □ Pending test or procedure results. □ Planned tests or procedures. □ Discharge plans. □ Changes in the plan of care.

06.09

REHABILITATION SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

☐ **N/A. This chapter is not applicable to this CAH. No rehabilitation services are provided.**

06.09.00 Rehabilitation therapy services

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Physical therapy, occupational therapy, and speech-language pathology services furnished at the CAH, if provided, are provided by staff qualified under State law, and consistent with the requirements for therapy services in 42 CFR §409.17.

§485.635(e) Tag C-1052

Rehabilitation services are optional CAH services.

If a CAH provides any rehabilitative services to its patients, either directly or under arrangement or agreement, either inpatient or outpatient, the services must be provided by qualified staff.

POLICIES AND PROCEDURES

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 §484.4.

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 and is consistent with state law.

INTERVIEW AND DOCUMENT REVIEW

If the CAH provides rehabilitation services, verify:

- The medical staff has defined the qualifications and competencies for all therapy staff.
- 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 these staff qualifications to ensure they remain compliant with changes in state law.
- Review personnel files to confirm that the 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 consistent with the medical staff-approved specifications and state law.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.09.01 Orders for rehabilitation services *Rehabilitation services can be initiated only upon the order of a practitioner responsible for the care of the patient.* §485.635(e) Tag C-1052	☐ Compliant ☐ Not Compliant Rehabilitation services orders must be documented in the patient's medical record.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the rehabilitation service orders are legible, complete, dated, timed, authenticated, and meet all other medical record requirements specified at §485.638(a)(2).
06.09.02 Rehabilitation plans of care requirements The provision of care and the personnel qualifications must be in accordance with nationally-acceptable standards of practice. §485.635(e) Tag C-1052	☐ Compliant ☐ Not Compliant Rehabilitation services must be provided according to 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. Physical therapy, occupational therapy, or speech-language pathology must be furnished in accordance with the regulation at §409.17, which specifies the following rehabilitation services plan of care requirements: **A. 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."	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review clinical records of patients who received rehabilitation services to verify whether the required care plan was developed and implemented. ▪ Ask what national standards of rehabilitation practice provide the basis for its rehabilitation services. Is there supporting documentation?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

B. 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."

C. Changes in the plan:

"Any changes in the plan are implemented in accordance with the provider's policies and procedures."

06.10

PATIENT RIGHTS

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.10.00 CONDITION OF PARTICIPATION: Patient's rights *A CAH must protect and promote each patient's rights.* §485.614	☐ 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, as well as the other Conditions of Participation in §485.614 apply to all parts and locations of the Medicare participating CAH.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ The CAH protects and promotes each patient's rights throughout the facility. Note: This full Condition of Participation (CoP) applies to all §485.614 standards listed within this chapter. Survey of the CoP is coordinated by one surveyor. However, each member of the survey team, as they conduct their survey assignments, should assess the hospital's compliance with the Patients' Rights CoP.
06.10.01 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.* § 485.614(a) § 485.614(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. ▪ Whenever possible, this notice must be provided before providing or stopping care.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ The CAH has a policy for notifying all patients (inpatient and outpatient) of their rights. ▪ The CAH policy provides for determining when a patient has a representative and who that representative is, consistent with this guidance and state law.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- 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.
- 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 Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons (August 8, 2003, 68 FR 47311). 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 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

- 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 interviews, that 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 know what steps to take to inform a patient about their rights, including those with special communication needs.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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.	
06.10.02 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.* §485.614(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,*	☐ 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 conspicuous place(s) likely to be noticed by all individuals seeking care.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ Posted and promulgated statements of patient's rights are congruent with these and any other known requirements. ▪ The emergency department patient rights are posted in a conspicuous place. Note: Facility compliance with the rights listed will be scored individually in the standards following.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. §485.614(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, in accordance with §§489.100, 489.102, and 489.104 of this chapter.* §485.614(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.* §485.614(b)(4) ▪ *The right to personal privacy.* §485.614€(1) ▪ *The right to receive care in a safe setting.* §485.614€(2) ▪ *The right to be free from all forms of abuse or harassment.* §485.614€(3)	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.	Noncompliance is scored at the relevant standard.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ *The right to the confidentiality of his or her clinical records.* §485.614(d)(1) ▪ *The right to access their medical records, including current medical records, upon an oral or written request, in the 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 and format as agreed by the facility and the individual and within a reasonable time frame. The hospital must not frustrate the legitimate efforts of the individual to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.* §485.614(d)(2) ▪ *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*		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

and must be discontinued at the earliest possible time.

§485.614€

- *The right to safe implementation of restraint or seclusion by trained staff.*

§485.614(f)

A CAH 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.*

§485.614(h)(1)

- *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.*

§485.614(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.*

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.614(h)(3) ▪ *Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.* §485.614(h)(4)		
06.10.03 Exercise of rights *The patient has the right to participate in the development and implementation of their plan of care.* §485.614(b)(1)	☐ Compliant ☐ Not Compliant The CAH 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: ▪ participate in the development and implementation of his/her inpatient treatment/care plan or 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.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Does the CAH have policies and procedures to involve the patient or the patient's representative (as appropriate) in the development and implementation 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 CAH 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ 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)?
06.10.04 Participation in decision making *The patient or their representative (as allowed under state law) has the right to make informed decisions regarding their care. The patient's rights include being informed of their 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.* §485.614(b)(2)	☐ Compliant ☐ Not Compliant 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). CAH's 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 06.10.01. 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 CAH. The patient or the patient's representative should receive adequate information,	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ CAH 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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: For further detail, see chapter 8 Surgical Services regarding informed consent, chapter 7 Medical Records, and chapter 19 Discharge Planning. CAH's must also establish policies and procedures that assure a patient's right to request or refuse treatment. Such policies should indicate how the patient's request will be addressed. However, CAH's 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.	▪ 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 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.10.05 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 §§489.100, 489.102, and 489.104.* §485.614(b)(3)	☐ Compliant ☐ Not Compliant An advance directive is defined at §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 §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 §485.614(f), for purposes of exercising the patient's visitation rights.) When a patient who is incapacitated has executed an 11dvancee 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 decisions about the patient's care. (See also the requirements at §485.614 (b)(1).) The CAH 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.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ The CAH'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 CAH staff comply with the advance directive (in accordance with state law). □ The notice includes a clear, precise, and valid statement of limitation if the CAH 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 CAH promotes and protects each patient's right to formulate an advance directive. ▪ The CAH educates its staff regarding advance directives. ▪ Interview staff to determine their knowledge of the advance directives of the patients in their care.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

§489.102 also requires the CAH 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 CAH 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€) Notice to the patient or the patient's representative of the patient's rights applies to provision of notice concerning the CAH's advance directive policies.
- Although both inpatients and outpatients have the same rights under §485.614(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 §485.614(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.
- 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.
- The CAH 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 CAH compliance with advance directive notice requirements.
  - Does every inpatient or applicable outpatient record contain documentation that notice of the CAH'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 advance directives that delegate decisions about the patient's care to a designated individual.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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 CAH 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 CAH'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 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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. CAH's 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.	
06.10.06 <u>Admission notification</u> *The patient has the right to have a family member or representative of their choice and their own physician notified promptly of their admission to the hospital.* §485.614(b)(4)	☐ Compliant ☐ Not Compliant **IDENTIFYING WHO IS TO BE NOTIFIED** For every inpatient admission, the CAH 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 CAH 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.	This standard is not met as evidenced by: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** ▪ Determine if the CAH 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

The hospital must also ask the patient whether the CAH should notify his/her own physician. If the patient requests notice to and identifies the physician, the CAH 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 CAH 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 CAH, or who comes to or contacts the CAH 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 CAH 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 06.10.04 for additional information regarding the identification of a patient's representative.

The CAH facilitates efficient 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 CAH 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 CAH must promptly notify the patient's physician of the admission.

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:
  - □ Records provide evidence that the patient was asked about notifying a family member/representative and his/her physician,
  - □ There is a record of when and how notice was provided. Was notice provided promptly?
  - □ Is there a record of the patient declining to have notice provided to a family member/representative and his/her physician?
  - □ There is 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
	PROMPT NOTICE The CAH 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 CAH 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.	
06.10.07 Privacy and safety *The patient has the right to personal privacy.* §485.614(c) §485.614(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 CAH. **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	This standard is not met as evidenced by: **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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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.

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.

- Review CAH 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 CAH 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 CAH, observe whether monitor screens and/or speakers are readily visible or audible to visitors or the public.
- Is the CAH promoting and protecting each patient's right to privacy?
  - □ Are patient names posted in public view?
  - □ Is patient information posted in public view?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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.
  4. business planning, development, management, and administration and certain hospital-specific fundraising activities.

CAHs 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 CAH 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 CAH 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 CAH 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 CAH may use patient information to notify, 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 CAH 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 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 CAH 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	For example, CAH 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. CAHs 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: ▪ 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.	
06.10.08 <u>Patient and safety: Safe setting</u> *The patient has the right to receive care in a safe setting.* §485.614(c) §485.614(c)(2)	☐ Compliant ☐ Not Compliant **The intent of this requirement is to specify that each** patient receives care in an environment that a reasonable person**, in the patient's position**, would consider safe. CAH staff follow current standards of practice for patient environmental safety, infection control, and security.	This standard is not met as evidenced by: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** Verify: ▪ Patient and staff incident and accident reports to identify incidents or patterns

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

The CAH protects vulnerable patients, including newborns and children.

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, CAHs 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.

ENVIRONMENTAL RISK ASSESSMENT

To provide care in a safe setting, hospitals identify patients at risk of intentional harm to self or others, identify environmental safety risks for such patients, and provide education and training for staff and volunteers.

Although all risks cannot be eliminated, hospitals **must be able to demonstrate** the steps taken to minimize those risks in **the environment in** accordance with nationally recognized standards and guidelines.

Environmental risk assessments are conducted in accordance with hospital policy, but at a minimum, annually in patient care areas or units or sooner if required by state law or other regulation. Examples of environmental risk assessment tool content may include:

1. **Ligature risks such as 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 potentially 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.**

of incidents concerning safety of the environment. **Expand the review if you suspect a problem with safe environment in the hospital.**

- QAPI, Safety, and Infection Control Committee or Committee function 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 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 CAH'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 CAH providing appropriate security to protect patients?
  - Are appropriate security mechanisms in place and being followed to protect patients?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

5. **Unprotected lighting fixtures.**
6. **Staffing levels inadequate to provide appropriate patient observation and monitoring.**
7. **Hospital staff should be trained to identify environmental safety risks.**

Environmental risk assessment strategies may not be the same in all hospitals or in all units. The hospital implements risk mitigation appropriate to its specific care environment and patient population. This does not mean that a unit which does not typically care for patients with psychiatric conditions should not be conducting environmental risk assessments. It means that 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.

IDENTIFYING PATIENTS AT RISK

There are many tools available to identify patients at risk for harm to self or others. The tool used should be appropriate to the patient population, care setting, and staff competency. This may mean using more than one risk assessment strategy. For example, a patient risk assessment strategy in a post-partum unit may not be the same strategy used in the emergency department.

Note: Hospitals may find the recommendations and resources in the 2018 report, *Recommended standard care for people with suicide risk: Making health care suicide safe*, issued by the National Action Alliance for Suicide Prevention (Action Alliance), to be useful in developing practices for effective patient screening and assessment for those patients at risk for harm to themselves, as well as for improving the care of patients at risk of suicide.

Patients at risk of suicide or other forms of self-harm, or who exhibit violent behaviors toward others, receive healthcare services in both inpatient and outpatient locations of hospitals.

- Security mechanisms are based on nationally recognized standards of practice.

- **Observe patient care environments for potential ligature points.**
- **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.**
- **Review the annual hospital environmental risk assessments and observe the documented mitigation strategies (including but not limited to implementation of a 1:1 sitter for patients identified at risk upon screening).**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- **Non-psychiatric settings of the hospital where patients with psychiatric conditions may be cared for shall identify patients at risk for intentional harm to self or others.**
- **Hospital policies and procedures shall specify which outpatient departments will screen and identify patients at risk for intentional harm to self or others based upon the patient population served.**
- **All inpatients and Emergency Department patients are screened to identify risk for harm to self or others.**
- **The hospital uses screening, identification, and assessment processes or tools that are developed in accordance with nationally recognized guidelines.**

RISK MITIGATION

- Psychiatric patients requiring medical care in a non-psychiatric setting (medical inpatient units, ED, ICU, etc.) must be **evaluated, monitored, and cared for appropriately, when** demonstrating suicidal ideation or harm to others.
- The care should include a designated, ligature resistant space. If ligature-resistant space is not available, examples of mitigation strategies could include, but are not limited to:
  - 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: LIGATURE RESISTANT ENVIRONMENT

- The focus for a "ligature-resistant" environment **may apply to** psychiatric units, **emergency department psychiatric space/rooms,** and psychiatric hospitals.
- **If an environment is not ligature-resistant and free from safety risks within an inpatient psychiatric unit or designated psychiatric area, patients who are assessed to be at risk for suicide must have appropriate mitigation strategies in place and in accordance with hospital policy.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

06.10.09 Privacy and safety: Free from abuse or harassment

The patient has the right to be free from all forms of abuse or harassment.

§485.614(c)(3)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

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 from abuse during investigation.

INTERVIEW AND DOCUMENT REVIEW

Verify:

- Staffing levels across all shifts are sufficient to care for individual patient's needs.
- The CAH implemented an abuse protection plan.
- The CAH 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.
  - ☐ Is there evidence the hospital employs people with a history of abuse, neglect, or harassment?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ 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.	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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

06.10.10 Confidentiality of patient records
 	
The patient has a right to the confidentiality of their clinical records.
§485.614(d)(1)
	☐ Compliant ☐ Not Compliant
	
	The right to confidentiality means the CAH 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 CAH may disclose patient information, without a patient's 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.
	▪ CAH operations include administrative, financial, legal, and quality improvement activities of a CAH 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 CAH 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 CAH 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
		This standard is not met as evidenced by:
		
		OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW
		
		Verify:
		The CAH has policies and procedures addressing the protection of information in patients' medical record from unauthorized disclosures.
		
		▪ 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 CAH 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	system is designed and operated with safeguards that ensure that only authorized disclosures are made. The CAH 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.	where people not involved in the patient's care could likely read the information?
06.10.11 Access to medical records *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.* §485.614(d)(2)	☐ Compliant ☐ Not Compliant The regulation at §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 ▪ Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding. ▪ 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The CAH promotes and protects the patient's right to access information contained in his/her clinical record. ▪ The CAH has a procedure for providing records to patients within a reasonable time frame. ▪ The CAH'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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- 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 USC §263a, to the extent that 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 §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 permitted 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).

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

06.10.12 Patient visitation rights

A CAH 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 CAH may need to place on such rights and the reasons for the clinical restriction or limitation.

§485.614(h)~~35(f)~~ Tag C-1054

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

CAHs that unnecessarily restrict patient visitation may 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, medications, and allergies, particularly if the patient has difficulties with recall or articulation or is totally unable to recall or articulate this vital personal information. Often, visitors who may know the patient best act as an intermediary for the patient, helping to communicate the patient's needs to CAH 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.

- A same-day surgery patient may wish to have a support person present during the pre-operative patient preparation or post-operative recovery.
- An outpatient clinic patient may wish to have a support person present during their examination by a physician.

Accordingly, CAH visitation policies must address both the inpatient and outpatient settings.

CAHs are required to develop and implement written policies and procedures that address the patient's right to have visitors.

- If the CAH's policy establishes restrictions or limitations on visitation, such restrictions/limitations must be clinically necessary.
- The CAH's policy must include the 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 CAHs some flexibility so that health care professionals may exercise their best clinical judgment when determining when visitation

INTERVIEW AND DOCUMENT REVIEW

- Verify that the CAH has written policies and procedures that address the right of patients to have visitors.
- Review the policy to determine if there are limitations or restrictions on visitation.
  - ☐ If there are, does the policy explain the clinical rationale for the restrictions or limitations?
  - ☐ Is the rationale clear and reasonably related to clinical concerns?
- Is there documentation of how the CAH identifies and trains staff that play a role in facilitating or limiting/restricting access of visitors to patients?
- Are CAH staff aware of the visitation policies and procedures? Can staff on a given unit correctly describe the CAH's visitation policies for that unit?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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 CAH.

Broad examples of clinically reasonable bases for restrictions or limitations on visitors might include, but are not limited to situations in which:

- There may be infection control issues.
- Visitation may interfere with the care of other patients.
- The CAH 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 needs rest or privacy.
- The patient is undergoing care interventions. While there may be valid reasons for limiting visitation during a care intervention, we encourage CAHs to 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.
- In the case of an inpatient substance abuse treatment program, there are protocols limiting visitation.

It may also be reasonable to limit the number of visitors for any one patient during a specific period of time, as well as to establish minimum age requirements for child visitors. However, when a CAH adopts policies that limit or restrict patients' visitation rights, the burden of proof is upon the CAH to demonstrate that the visitation restriction is reasonably necessary to provide safe care.

CAHs are expected to provide a clear explanation in their written policy of the clinical rationale for any visitation restrictions or limitations reflected in that policy.

- CAHs are not required to delineate each specific clinical reason for policies limiting or restricting visitation, given that it is not possible to anticipate

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

every instance that may give rise to a clinically appropriate rationale for a restriction or limitation.

- If visitation policies differ by type of unit, e.g., separate policies for intensive care units, or for newborn nurseries, the CAH policy must address the clinical rationale for this differentiation explicitly.

The CAH's policies and procedures are expected to address how CAH staff who play a role in facilitating or controlling visitor access to patients will be trained so as to assure appropriate implementation of the visitation policies and procedures and avoidance of unnecessary restrictions or limitations on patients' visitation rights.

06.10.13 Notification of rights

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

A CAH 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 CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, in advance of furnishing patient care whenever possible.

(2) Inform each patient (or support person, where appropriate) of the right, subject

CAHs are required to inform each patient (or the patient's support person, where appropriate) of his/her visitation rights.

A patient's "support person" does not necessarily have to be the same person as the patient's representative designated under an advance directive who is legally responsible for making medical decisions on the patient's behalf.

A patient's support person could be a family member, friend, or other individual who supports the patient during the CAH stay. Not only may the support person visit the patient, but he or she 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. CAHs must accept a patient's designation, orally or in writing, of an individual as the patient's support person.

INCAPACITATED PATIENTS

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 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 CAH must accept this designation, provide the required

INTERVIEW, OBSERVATION, AND DOCUMENT REVIEW

- Determine whether the CAH'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 the patient's representative.
- Review the CAH'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, or unit-specific restrictions, etc., and the clinical rationale for such limitations or restrictions?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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.

§485.614(h)(1-2) Tag C-1056

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 and no one has presented an advance directive designating them as the patient's support person, 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 CAH 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. If more than one individual claims to be the patient's support person, it would not be inappropriate for the CAH to ask each individual for documentation supporting his/her claim to be the patient's support person.

- CAHs 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 CAH 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 must, along with the specific basis for the refusal.

The required notice of the patient's visitation rights must be provided, whenever possible, before the CAH provides patient care.

The notice to patients must be in writing in a language or manner that the patient (or the patient's support person) can understand. Surveyors may refer concerns about possible noncompliance to the Office of Civil Rights in the applicable Department of Health and Human Services Regional Office.

The required visitation rights notice must address any clinically necessary or reasonable limitations or restrictions imposed by CAH policy on visitation

- ☐ 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 for documentation that the required notice was provided and to verify it was provided in advance of care, unless circumstances made this unfeasible.
- Identify 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 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 CAH's visitation policies and notice, or was inappropriate.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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. ▪ Withdraw or deny his/her consent to receive specific visitors, either orally or in writing. The medical record must contain documentation that the required notice was provided to the patient or, if appropriate, the patient's support person.	▪ Ask whether the CAH failed to limit some or all visitors, contrary to the patient's wishes.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

06.10.14 Reasonable restrictions to patient rights

A CAH 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 CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements:

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

§485.614(h)(3-4) Tag C-1058

☐ Compliant ☐ Not Compliant

The CAH's visitation policies and procedures may not use the race, color, national origin, religion, sex, gender identity, sexual orientation, or disability of either the patient (or the patient's support person, where appropriate) or the patient's visitors (including individuals seeking to visit the patient) as a basis for limiting, restricting, or otherwise denying visitation privileges.

The CAH's policies and procedures must ensure that all visitors (including individuals seeking to visit the patient) 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 for others but it is not permissible for the CAH, 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 §485.635(f)(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.

The CAH is responsible for ensuring that its staff treat all individuals seeking to visit patients equally, consistent with the preferences of the patient (or, where appropriate, the patient's support person) and do not use the race, color, national origin, religion, sex, gender identity, sexual orientation, or disability of either the patient (or the patient's support person, where appropriate) or the patient's visitors (including individuals seeking to visit the patient) as a basis for limiting, restricting, or otherwise denying visitation privileges.

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

- Review the CAH's visitation policies and procedures to determine whether they restrict, limit, or otherwise deny visitation to individuals on a prohibited basis.
- Verify how the CAH educates staff to assure that visitation policies are implemented in a non-discriminatory manner.
- Ask 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 related to the CAH's clinically-based policies?
- Ask CAH patients (or patients' support persons, where appropriate) whether the CAH has limited visitors against their wishes.
  - □ If yes, verify whether the restriction/limitation on visitors was addressed in the CAH's visitation policies and in the patient notice, and whether it was appropriately based

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	CAHs are expected to educate all staff who play a role in facilitating or controlling visitors on its visitation policies and procedures and are responsible for ensuring that staff implement the policies correctly. CAHs are urged to develop culturally competent training programs designed to address the range of patients served by the CAH.	on a clinical rationale rather than impermissible discrimination.
06.10.15 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.* § 485.614(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 §485.614(2)(ii) addresses 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 that has licensure 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	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 CAH follows its grievance policies and procedures. ▪ The CAH’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 representative knows that he/she has the right to file a complaint with the

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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 §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 §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 CoP. For the purposes of this requirement, an email or fax is considered "written."

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 state agency as well as or instead of using the hospital's grievance process.

- The CAH 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
	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 CoP, 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 CAH), must be incorporated in the CAH's Quality Assessment and Performance Improvement (QAPI) Program.	
06.10.16 <u>Governing body responsibility for the grievance process</u> *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*	☐ Compliant ☐ Not Compliant The CAH'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 CAH's compliance with all the CMS grievance process requirements.	This standard is not met as evidenced by: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** Verify: ▪ The CAH's governing body approved the grievance process. □ Is the governing body responsible for the operation of the grievance

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
responsibility in writing to a grievance committee. § 485.614(a)(2)	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.	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 CAH 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 CAH's QAPI Program.
06.10.17 Timely grievance referrals *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.* § 485.614(a)(2)	☐ Compliant ☐ Not Compliant 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	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Through review of patient discharge materials that the CAH is in compliance with §489.27. ▪ The CAH grievance process includes a mechanism for timely referral of Medicare patient concerns to the QIO? □ What time frames are established?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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 §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.	▪ Through interview of Medicare patients, that they are aware of their right to appeal premature discharge.
06.10.18 <u>Grievance process</u> *The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.* § 485.614(a)(2)(i)	☐ Compliant ☐ Not Compliant The patient or patient's representative should be able to clearly understand the hospital's procedure for submission of written or verbal grievances.	This standard is not met as evidenced by: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** Verify: ▪ The information provided to patients clearly explains the hospital's grievance procedures. ▪ The procedure identifies how the patient is to submit a verbal or written grievance. ▪ Through patient/patient representative interview, that the grievance process is understood.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.10.19 Grievance process response time frames *The grievance process must specify time frames for review of the grievance and the provision of a response.* § 485.614(a)(2)(ii)	☐ Compliant ☐ Not Compliant The CAH 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. Regardless of the nature of the grievance, the CAH 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 06.10.20 specifies information the CAH 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 CAH's grievance policy. The CAH must attempt to resolve all grievances as soon as possible.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ CAH policy and procedure specifies time frames for responding to grievances. ▪ The CAH responds to grievances within those time frames.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
06.10.20 Patient notification of the grievance *In its resolution of the grievance, the hospital must provide the patient with 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.* § 485.614(a)(2)(iii)	☐ Compliant ☐ Not Compliant The CAH 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 CAH 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. However, in all cases the CAH must provide a written notice (response) to each patient's grievance(s)that includes: 1. The CAH's decision. 2. The name of the CAH 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 CAH via email the hospital may provide its response via email pursuant to CAH policy. When the email response contains the information stated in this requirement, the email meets the requirement for a written response. ▪ The CAH 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 CAH 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 CAH's actions. In these situations, the CAH may consider the grievance closed for the purposes of these requirements. The CAH must maintain	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The policy and procedure for resolution patient grievances meets the requirement. ▪ Grievance response letters include all required components. ▪ The CAH retains copies of written notices (responses) to patients.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	documentation of its efforts and demonstrate compliance with CMS requirements. In its written response, the CAH is not required to include statements that could be used in a legal action against the hospital, but the CAH must provide adequate information to address each item stated in this requirement. The CAH is not required to provide an exhaustive explanation of every action the CAH has taken to investigate the grievance, resolve the grievance, or other actions taken by the CAH.	

07

MEDICAL RECORDS

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.00.00 CONDITION OF PARTICIPATION: Clinical records §485.638 Tag C-1100	☐ Compliant ☐ Not Compliant Compliance with this CoP is assessed based on the scoring of standards 07.00.01 through 07.01.03.	This standard is not met as evidenced by: **Note**: Review scoring of 07.00.01 through 07.01.03 for Condition-level scoring.
07.00.01 Clinical Records System *The CAH maintains a clinical records system in accordance with written policies and procedures.* The texting of patient information **and orders** among members of the health care team is permissible if accomplished through a secure platform **and in compliance with Conditions of Participation.** In order 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 CoP. It is expected that providers will implement procedures/processes that routinely assess the security and integrity of the texting systems/platforms that are used, in order to avoid negative outcomes that could compromise the care of patients.	☐ Compliant ☐ Not Compliant The CAH must have a system of patient records, pertinent medical information, 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. The medical record system must protect the security of all entries. The medical record system must ensure that medical record entries are not lost, stolen, destroyed, altered, or reproduced in an unauthorized manner. All locations where medical records are stored or maintained must ensure the integrity, security and protection of the records. The CAH must have a system that ensures that the identity of the author of each entry is correct. The author of every entry must take a specified action to identify himself/herself as the author (or responsible person) of the entry, to time and date the entry, to confirm that the entry is accurate, and that he/she takes responsibility for accuracy of the entry. If the CAH uses computer entries there must be security in place to ensure the integrity of the record system, to ensure that the author of each entry is correctly identified, to ensure that record entries are not altered or lost, that access to medical records is limited to only authorized persons, and to ensure that records are not released to unauthorized individuals.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ A medical record is maintained for each person receiving care. ▪ Written procedures ensure the integrity of authentication and protect the security of patient records. ▪ Medical records are stored and maintained in locations where they are secure, with protection from damage, flood, fire, theft, etc., and that limit access to authorized individuals. ▪ Records are accurate, completed promptly, easily retrieved and readily accessible. ▪ An established system addresses at least the following activities of the medical records services: □ Timely processing and retrieval of records. □ Protecting the confidentiality of medical information.

STANDARD		REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.638(a)(1)	Tag C-1102	**Note:** For the purposes of this regulation, electronic signatures comply with those medical record entries that include a requirement for a signature. There should be a current list of authenticated signatures, as well as a list of computer codes and signature stamps (when used for authorship purposes) that have been authorized by the governing body and are protected by adequate safeguards. CAH policies and procedures provide for appropriate sanctions for unauthorized or improper use of computer codes or signature stamps. The CAH maintains a medical record for each inpatient and outpatient evaluated or treated in any part or location of the CAH. A unit record for both inpatients and outpatients may be used; however, when two different systems are used, they must be appropriately cross referenced. When a patient reimbursement status changes from acute care services to swing bed services, a single medical record may be used for both. If a single medical record is used, the sections for acute care services and swing bed services must be separated and each section must independently include admission and discharge orders, progress notes, nursing notes, graphics, laboratory support documents, any other pertinent documents, and discharge summaries. The medical record must be properly filed, retained, and accessible. The CAH must have a medical recording system that ensures the prompt retrieval of any medical record of any patient evaluated or treated at any location of the CAH within the past 6 years by appropriate staff, 24 hours a day, 7 days a week, whenever that medical record may be needed. **TEXTING** **Texting patient information among members of the health care team and texting of orders by physicians or other qualified health care providers, is permissible in accordance with the hospital medical staff policies, provided the information or order is texted using systems/platforms that are secure**	▫ Compiling and retrieval of data for QAPI activities. ▪ Policies and procedures are reviewed and revised as needed. ▪ Medical records are promptly completed in accordance with state law and CAH policy. ▪ **If the facility permits health care team members to text patient information and/or orders into their EHR, the hospital uses a system/platform that is compliant with the HIPAA Security Rule, the HITECH Act Amendment 2021, and the CoP.** ▪ **The hospital routinely assesses the security and integrity of the texting systems/platforms used to avoid negative outcomes that could compromise the care of patients.** ▪ Select and request a sample of past patients of the CAH (inpatient and/or outpatient). ▫ Can the CAH promptly retrieve those records?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

and encrypted to ensure the integrity of author identification as well as to minimize risks to patient privacy and confidentiality, as per the Health Insurance Portability and Accountability Act of 1996 (HIPAA) regulations.

SECURE SYSTEMS/PLATFORMS

To be compliant with the CoP, all providers must use and maintain systems/platforms that are secure, encrypted, and minimize the risks to patient privacy and confidentiality.

Hospitals that permit texting of patient orders into their EHR and texting of patient information between health care team members are expected to implement a system/platform that meets the requirement of the HIPAA Security Rule, the HITECH Act Amendment 2021 and the CMS CoPs.

Providers must implement procedures for routine assessment of the security and integrity of the texting systems/platforms that are being used, to avoid negative outcomes that could compromise the care of patients.

CPOE

Computerized Provider Order Entry (CPOE) is the preferred method of order entry by a provider. CMS has held to the long-standing practice that a physician or Licensed Independent Practitioner (LIP) should enter orders into the medical record via a handwritten order or via CPOE.

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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.00.02 Record requirements	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The records are legible, complete, accurately documented, readily accessible, and systematically organized. *The CAH must have a system of patient records, pertinent medical information, author identification, and record maintenance that ensures the integrity of the authentication and protects the security of all record entries.* §485.638(a)(2) Tag C-1104	The CAH must ensure that all medical records accurately and completely document all orders, test results, evaluations, treatments, interventions, care provided, and the patient's response to those treatments, interventions, and care.	**DOCUMENT REVIEW** ▪ For CAH surveys that are conducted after the initial certification survey, examine a sample of records using an adequate sample size to evaluate the scope of services provided. ▪ In a very small CAH, look at all inpatient and outpatient records, if appropriate.
07.00.03 Record oversight	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized. §485.638(a)(3) Tag C-1106	The CAH must have one unified medical record service with a department head who has been appointed by the governing body (or responsible individual). The director of medical records has responsibility for all medical records including both inpatient and outpatient records.	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Review the organizational structure and policy statements and interview the person responsible for the service to ascertain that the medical records service is structured appropriately to meet the needs of the CAH and the patients.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.00.04 Record content requirements *For each patient receiving health care services, the CAH maintains a record that includes, as applicable--* ▪ *Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;* §485.638(a)(4)(i) Tag C-1110	☐ Compliant ☐ Not Compliant The medical record must contain information such as progress and nursing notes, documentation, records, reports, recordings, test results, assessments etc. sufficient to: ▪ Justify admission. ▪ Support the diagnosis. ▪ Describe the patient's progress. ▪ Describe the patient's response to medications. ▪ Describe the patient's response to interventions, care, treatments, etc. The medical record must include evidence of properly executed informed consent forms for any procedures specified by the medical staff or by federal or state law that require written patient consent. Informed consent means the patient or patient representative is given the information, explanations, consequences, and options needed in order to agree to a procedure or treatment. Medical staff policies address which procedures and treatments require written informed consent. **INFORMED CONSENT 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 than the patient, may give informed consent for surgery.**	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ A sample of open and closed medical records are complete and accurate in accordance with federal and state laws and regulations and CAH policy. Note: The sample should be at least 10 percent of the average daily census. ▪ The medical staff policies specify procedures or treatments that require a written informed consent. ▪ Medical records contain consent forms for all procedures or treatment per policy. ▪ Consent forms are properly executed. ▪ A sample of patient records and/or facility records of requests for information contained in patient records include signed and dated consent forms (when required), medical history, health status and care needs assessment, and discharge summary. □ The sample should be at least 10 percent of the average daily census.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

5. **The content of the informed consent form and instructions for 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, using plain language that is easily understood, and in the patient's primary language.

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.

INFORMED CONSENT FORMS
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 regulation.

A properly executed informed consent form contains at least:

1. The patient's name, and when appropriate, the name of the patient's legal representative.
2. The name of the hospital.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

3. The name of the specific procedure, or other type of medical treatment for which consent is being given.
4. The name of the practitioner(s) performing the procedure **or administering the medical treatment and anesthesia. (See standard 08.00.06 for additional detail specific to surgical consent forms.)**
5. A 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.)**
6. The name and signature of the practitioner who conducted the informed consent discussion with the patient or the patient's legal representative, with the date and time.
7. Signature of the patient or the patient's legal representative, with date and time.
8. Signature of the person witnessing the signature of the patient or the patient's legal representative with date and time.

If there is applicable state law governing the content of the informed consent form, then the hospital's form must comply with those requirements.

DISCHARGE SUMMARY

A discharge summary addresses:

- The outcome of the CAH stay.
- Disposition of the patient.
- Provisions for follow-up care, including:
  - Post-CAH appointment.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	☐ How post-CAH patient care needs are to be met. ☐ Plans for post-CAH care by providers such as swing-bed services, home health, hospice, nursing homes, or assisted living. A discharge summary is required following any CAH acute care stay prior to and following a swing-bed admission and discharge. The MD/DO or other qualified practitioner who admitted the patient is responsible for the patient during their stay in the CAH. This responsibility would include developing and entering the discharge summary. The MD/DO may delegate writing the discharge summary to other qualified health care personnel such as nurse practitioners and physician assistants to the extent recognized under state law or regulation. The MD/DO may also delegate writing the discharge summary to another MD/DO who is familiar with the patient.	
07.00.05 Assessment requirements *For each patient receiving health care services, the CAH maintains a record that includes, as applicable—* ▪ *Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;* §485.638(a)(4)(ii) Tag C-1114	☐ Compliant ☐ Not Compliant All or part of the history and physical exam (H&P) may be delegated to other practitioners in accordance with state law and CAH policy, but the MD/DO must sign the H&P and assume full responsibility for the H&P. This means that a nurse practitioner or a physician assistant meeting these criteria may perform the H&P.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Bylaws require a physical examination and medical history be completed for each patient. ▪ From sampled records that the appropriate practitioner signs reports of physical examinations, diagnostic and laboratory test results, and consultative findings.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.00.06 Monitoring requirements *For each patient receiving health care services, the CAH maintains a record that includes, as applicable—* ▪ *All orders of doctors of medicine or doctors of osteopathic medicine or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment.* §485.638(a)(4)(iii) Tag C-1116	☐ Compliant ☐ Not Compliant All information necessary to monitor the patient's condition must be in the patient's medical record. In order for the information to be used, it must be promptly filed so that healthcare staff involved in the patient's care can access/retrieve it when monitoring the patient's condition and providing care. The medical record must contain all: ▪ practitioners' orders (properly authenticated). ▪ nursing notes. ▪ reports of treatment (including complications and CAH-acquired infections). ▪ medication records (including unfavorable reactions to drugs). ▪ radiology reports. ▪ laboratory reports. ▪ vital signs. ▪ other information necessary to monitor the patient's condition. All medical records must be promptly completed and include: ▪ documentation of orders. ▪ diagnosis. ▪ evaluations. ▪ treatments. ▪ test results. ▪ consents. ▪ interventions. ▪ discharge summary. ▪ care provided along with the patient's response to those treatments, interventions, and care.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Patient records contain appropriate documentation of practitioners' orders, interventions, findings, assessments, records, notes, reports, and other information necessary to monitor the patient's condition. ▪ Information is entered promptly so that healthcare staff have access to needed information.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.00.07 Authentication requirements *For each patient receiving health care services, the CAH maintains a record that includes, as applicable—* ▪ *Dated signatures of the doctor of medicine or doctor of osteopathic medicine or other health care professional.* §485.638(a)(4)(iv) Tag C-1118	☐ Compliant ☐ Not Compliant Entries in the medical record may be made only by individuals as specified in CAH and medical staff policies. All entries in the medical record must be timed, dated, and authenticated, and a method established to identify the author. The identification may include written signatures, initials, computer key, or other code. **Rubber stamps for signature are permitted in accordance with state and federal law, as well as the Rehabilitation Act of 1973 in the case of an author with a physical disability that can provide proof of his/her inability to sign their signature due to their disability. By affixing the rubber stamp, the provider is certifying that they have reviewed the document.** When rubber stamps are authorized, the individual whose signature the stamp represents shall place in the administrative offices of the CAH a signed statement to the effect that he/she is the only one who has the stamp and uses it. There shall be no delegation to another individual. A list of computer or other codes and written signatures must be readily available and maintained under adequate safeguards. There shall be sanctions for improper or unauthorized use of stamp, computer key, or other code signatures. The CAH must have policies and procedures in place and operational before an electronic medical record system would be deemed acceptable. The parts of the medical record that are the responsibility of the MD/DO must be authenticated by this individual. ▪ When non-MD/DOs have been approved for such duties as taking medical histories or documenting aspects of physical examination, such information is appropriately authenticated by the responsible MD/DO. ▪ Any entries in the medical record by house staff or non-MD/DOs that require counter signing by supervisory or attending medical staff	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ For sampled records, there are dated and authenticated signatures by appropriate MD/DOs and/or mid-level practitioners, as needed. ▪ The department maintains a current list of authenticated signatures, written initials, codes, and stamps when such are used for authorship identification. ▪ Computer or other code signatures are authorized by the CAH'S governing body and that a list of these codes is maintained under adequate safeguards by the CAH administration. ▪ Policies and procedures provide for appropriate sanctions for unauthorized or improper use of the computer codes. ▪ Policies and procedures for using the system to confirm that documents are authenticated after transcription.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	members are defined in the medical staff rules and regulations. Authentication would include, at a minimum: ▪ a specific action by the author to verify that the entry is theirs or that they are responsible for the entry, and that the entry is accurate. ▪ The CAH has 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. **Note:** Failure to disapprove an entry within a specific time period is not acceptable as authentication. ▪ The timing of the entry is noted and correct. 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 entries establishes a baseline for future actions or assessments and a timeline of events. Many patient interventions or assessments are based on time intervals or timelines of various signs, symptoms, or events. A system of auto-authentication in which a MD/DO or other practitioner authenticates a report before transcription is not consistent with these requirements. There must be a method of determining that the practitioner did, in fact, authenticate the document after it was transcribed.	
07.01.00 Record protection *The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.* §485.638(b)(1) Tag C-1120	☐ Compliant ☐ Not Compliant The CAH has sufficient safeguards to ensure that access to all information regarding patients is limited to those individuals designated by law, regulation, and policy, or duly authorized as having a need to know. No unauthorized access or dissemination of clinical records is permitted. Medical records are kept secure and are only viewed when necessary by those persons having a part in the patient's care.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ Only authorized persons are permitted access to records maintained by the medical records department.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The right to confidentiality means safeguarding the content of information, including records in any form, including but not limited to paper, video, audio, and electronic from unauthorized disclosure without the specific informed consent of the individual, parent of a minor child, or legal guardian. CAH staff and consultants, hired to provide services to the individual, should have access to only that portion of information that is necessary to provide effective responsive services to that individual. Confidentiality applies to both central records and medical record information that may be kept at dispersed locations.	▪ The CAH has a policy to grant patients direct access to their medical record if the responsible official (e.g., practitioner responsible for patient's care) determines that direct access is not likely to have an adverse effect on the patient. ▪ Medical records are released only for patient care evaluation, utilization review, treatment, quality assurance programs, in-house educational purposes, or in accordance with federal or state law, court orders, or subpoenas. ▪ Copies of medical records are released outside the CAH only upon written authorization of the patient, legal guardian, or person with an appropriate power of attorney to act on the patient's behalf, or in the case of a properly executed subpoena or court order, or as mandated by statutes. ▪ Precautions are taken to prevent physical or electronic alteration, damage or deletion/destruction of patient records or information in patient records.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.01.01 Policies regarding records *Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.* §485.638(b)(2) Tag C-1122	☐ Compliant ☐ Not Compliant The CAH'S medical record system must ensure the security of patient records. Patient records must be secure at all times and in all locations. This includes open patient records for patients who are currently inpatients of the CAH and outpatients in outpatient clinics.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Observe the CAH'S security practices for patient records. □ Are patient records left unsecured or unattended in hallways, patient rooms, nurses' stations, or on counters where an unauthorized person could gain access to patient records? ▪ If the CAH uses electronic medical records, are appropriate security safeguards in place? □ Is access to patient records controlled? ▪ Verify that the CAH has policies and procedures for the use and release of records and that these policies and procedures are enforced.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.01.02 Consent for record release *The patient's written consent is required for release of information not required by law.* §485.638(b)(3) Tag C-1124	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review facility policies to verify they support the standard. ▪ Review records of patients to determine the requirement was met in practice.
07.01.03 Retention of records *The records are retained for at least six years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.* *For CAH DPUs, the hospital medical record CoPs applies in those units.* §485.638(c) Tag C-1126	☐ Compliant ☐ Not Compliant Medical records are retained in their original or a legally reproduced format in hard copy, microfilm, or electronic storage. The CAH must be able to promptly retrieve the complete medical record of every individual evaluated or treated in any part or location of the CAH within the last six years. Some medical records may have retention requirements that exceed six years, for example: FDA, OSHA, and EPA.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that records are retained for at least six years, or longer if required by state or local laws.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

07.01.04 Electronic patient event notifications

If the CAH 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 CAH must demonstrate that—

1. *The system's notification capacity is fully operational and the CAH uses it in accordance with all State and Federal statutes and regulations applicable to the CAH'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 of health information, at the time of:*
   - *(i) The patient's registration in the CAH's emergency department (if applicable).*
   - *(ii) The patient's admission to the CAH's inpatient services (if*

☐ Compliant ☐ Not Compliant ☐ N/A (hospital does not have EMR or EMR does not have notification capability)

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 CAHs 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. CAHs are to send notifications to those practitioners or providers that have an established care relationship with the patient.

NOTIFICATION POLICY

The CAH 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: CAHs are not prohibited from sending more detailed information, if consistent with all State and Federal statutes and regulations.
- 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.

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

- Interview 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.
- Medical records confirm patient event notifications containing the minimum required information have been sent, in accordance with federal and state laws and regulations and CAH policy.
- The organization has made reasonable efforts to send electronic notifications to post-acute care practitioners/providers.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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 CAH's emergency department (if applicable).*
   - *(ii) The patient's discharge or transfer from the CAH's inpatient services (if applicable).*
5. *The CAH 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, 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*

- 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 07.00.01.)

A CAH 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 CAH 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 CAH 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(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. §485.638(d) §485.638(d)(1-3) §485.638(d)(3)(i-ii) §485.638(d)(4) §485.638(d)(4)(i-ii) §485.638(d)(5) §485.638(d)(5)(i-iii)		
07.02.00 Staffing The hospital must employ adequate personnel to ensure prompt completion, filing, and retrieval of records. 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. **§485.631(a)(3)**	☐ Compliant ☐ Not Compliant Additional medical record staff are available to assure that medical records are processed in a timely manner.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review written job descriptions and staffing schedules to determine if staff is carrying out all designated responsibilities. ▪ Verify that there are sufficient employees with required education, skills and qualifications to maintain workload of the department by reviewing the volume of backlog, if any, and causes. □ These reports may include information related to medical record delinquency, coding or billing issues, etc.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.02.01 Consultations The attending physician is responsible for requesting a consultation. There should be documentation of the indication for the consultation as well as the expectations of the consultant. **485.635(a)(3)(iii)**	☐ Compliant ☐ Not Compliant Each request for consultation must include the indication for the consultation. Requests for diagnostic testing which require professional interpretation include sufficient detail to facilitate the interpreter's review.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review 10-20 medical records with consultations. Check to see if the attending physician states the expectations of the consultant.
07.02.02 Completion of the discharge summary A concise discharge summary must be completed on each patient within seven days of patient discharge. **§485.638(a)(4)(i)**	☐ Compliant ☐ Not Compliant In order 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, INTERVIEW 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
07.02.03 Medical record delinquency	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The medical records must contain the final diagnosis with completion of medical records within 30 days following discharge. §482.24(c)(4)(viii)	Mechanisms exist to review records for completeness and delinquency. Facilities shall monitor incomplete and delinquent medical records on a continuing basis. Medical staff bylaws and/or rules and regulations include sections addressing delinquent medical records.	**DOCUMENT REVIEW** ▪ Verify the facility time frame for delinquent records does not exceed 30 days and that potential sanctions are identified within staff documents.
07.02.04 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, 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 medical staff.	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. Likewise, 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 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 AND DOCUMENT REVIEW** ▪ Review the organizational policies and procedures regarding the use of standardized abbreviations and dose designations. ▪ Request copies of facility-approved list of abbreviations, symbols, and dose designations and the list of abbreviations and dose designations that should never be used. Using a sample of the last 30 discharges, confirm that these are used appropriately. ▪ Interview staff to confirm awareness of the approved and do not use lists.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
All staff entering data into the medical record are educated on use of abbreviations. Policy compliance is monitored. **§485.638(a)(2)**		

08

SURGICAL SERVICES

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

☐ **N/A. This chapter is not applicable to this CAH. No surgical services are provided.**

08.00.00 CONDITION OF PARTICIPATION: Surgical Services

If a CAH provides surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the CAH in accordance with the designation requirements under §485.639(a).

§485.639 Tag C-1140

☐ Compliant ☐ Not Compliant

The provision of surgical services is an optional CAH service.

However, if a CAH provides any degree of surgical services to its patients, the CAH must comply with all the requirements of this Condition of Participation (CoP).

If surgical services are provided, they must be organized and staffed to ensure the health and safety of patients. The CAH must provide the appropriate equipment and types and numbers of qualified personnel necessary to furnish these services.

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 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 periOperative Registered Nurses, Association for Professionals in Infection Control and Epidemiology, etc.).

If outpatient surgical services are offered, the services must be **consistent in quality** with the CAH'S inpatient surgical services.

This standard is not met as evidenced by:

OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW

View all inpatient and outpatient operative rooms and suites. Request the use of proper attire.

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 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; that persons working in the operating suite wear only clean surgical attire; and that surgical attire is designed for maximum skin and hair coverage.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ Equipment is available for rapid and routine sterilization of operating room materials. ▪ Equipment is monitored, inspected, tested, and maintained by the CAH'S biomedical equipment program **in accordance with federal and state law, regulations, and guidelines and per 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.
08.00.01 Scope of services The surgery department has a written scope of services. §485.639 Tag C-1140	☐ Compliant ☐ Not Compliant The scope of surgical services provided by the CAH is defined in writing and approved by the governing body or responsible individual.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Surgical privileges granted are consistent with the scope of services. ▪ Surgical instruments and equipment are available to meet the needs of the patient population.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
08.00.02 Supervision in the OR	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The operating room (inpatient and outpatient) must be supervised by an experienced staff member authorized by state law. §485.639 Tag C-1140	The supervisor's experience could include education, background working in surgical services, and specialized training in the provision of surgical services/management of surgical service operations. The CAH should address its required qualifications for the supervisor of the CAH'S operating rooms in its policies.	**DOCUMENT REVIEW** ▪ Review the CAH'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.
08.00.03 Supervision of staff	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH ensures the operating room has the appropriate numbers and types of staff. §485.639 Tag C-1140	If the CAH uses LPN or operating room technicians as "scrub nurses," those personnel must be under the supervision of an RN who is immediately available to physically intervene and provide care, as required by state law.	**DOCUMENT REVIEW** ▪ If LPNs and surgical technologists (ST) are performing circulating duties, verify that they do so in accordance with applicable state law and approved medical staff policies and procedures. ▪ Where LPNs and STs are permitted to circulate, verify that a qualified RN supervisor is immediately available to respond to emergencies.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
08.00.04 **Policies and procedures** The CAH ensures written policies are in place governing the surgical services. §485.639 Tag C-1140	☐ Compliant ☐ Not Compliant 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 governing surgical care contain: ▪ Aseptic surveillance and practice, including scrub techniques. ▪ Identification of infected and non-infected cases. ▪ Housekeeping requirements/procedures. ▪ Patient care requirements, including: □ Preoperative work-up. □ Patient consents and releases. □ Clinical procedures. □ Safety practices. □ Patient identification procedures. ▪ Duties of scrub and circulating nurse. ▪ Safety practices. ▪ The requirement to conduct surgical counts in accordance with accepted standards of practice. ▪ Scheduling of patients for surgery. ▪ Personnel policies unique to the OR. ▪ Resuscitative techniques. ▪ DNR status. ▪ Care of surgical specimens. ▪ Malignant hyperthermia. ▪ 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	This standard is not met as evidenced by: **DOCUMENT REVIEW** • Review policies and procedures to verify that they contain the minimum policies specified in the required elements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	assignments. ▪ Sterilization and disinfection procedures. ▪ Acceptable operating room attire. ▪ Handling infections and biomedical/medical waste.	
08.00.05 Pre-operative history and physical A complete history and physical must be conducted in accordance with acceptable standards of practice, and the written document placed on the medical record, prior to surgery. §485.639 Tag C-1140	☐ Compliant ☐ Not Compliant All or part of the **history and physical** (H&P) may be delegated to other practitioners in accordance with state law and CAH policy, but the surgeon must sign the H&P and assume full responsibility for the H&P. ▪ This means that a nurse practitioner or a physician assistant, meeting these criteria, may perform the H&P. In all circumstances, when an H&P has been conducted, but is not present in the chart prior to surgery, or in emergency situations where a complete H&P cannot be conducted prior to surgery, a brief admission note on the chart is necessary. ▪ The note should include, at minimum, critical information about the patient's condition including pulmonary status, cardiovascular status, BP, vital signs, etc.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of medical records of surgical patients to verify that a complete history and physical examination is completed and authenticated by a surgeon prior to surgery, except in an emergency, and in accordance with the methodology described.
08.00.06 Informed consent The responsible practitioner must disclose to the patient any information necessary to enable the patient to evaluate a proposed medical or surgical procedure before submitting to it.	☐ Compliant ☐ Not Compliant **SURGICAL CONSENT FORM** A properly executed **surgical/procedural** informed consent form contains at least: 1. The patient's name, and when appropriate, the name of the patient's legal representative. 2. Name of the CAH.	This standard is not met as evidenced by: **MEDICAL RECORD REVIEW** ▪ Review a sample of medical records of surgical patients to verify that they contain consent forms.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
Informed consent requires that a patient have a full understanding of that to which he or she has consented. §485.639 **§482.51(b)(2)** Tag C-1140	3. Name of the procedure(s). 4. Name(s) of the practitioner(s) performing the procedure(s) or important aspects of the procedure(s), as well as the name(s) and specific significant surgical tasks that will be conducted by practitioners other than the primary surgeon/practitioner **including but not limited to advanced practice provider (such as nurse practitioners and physician assistants), and other applicable students**. Note: Significant surgical tasks include: opening and closing, harvesting grafts, dissecting tissue, removing tissue, implanting devices, altering tissues, **and examination or invasive procedures performed for education and training purposes which include but are not limited to breast, pelvic, prostate, and rectal examinations, as well as others specified under state law.** 5. Statement that the procedure, **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.)**. 6. Name/signature of person who explained the procedure to the patient or the patient's legal representative, with date and time. 7. Signature of the patient or the patient's legal representative, with date and time. 8. Signature of professional person witnessing the consent with date and time.	☐ Do the completed forms contain at least the information specified in this standard?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	CONSENT PROCESS Patients must be given sufficient information (in a language or means of communication he/she understands) to allow them to make intelligent choices from among the alternative courses of available treatment for their specific ailments. Informed consent must be given despite a patient's anxiety or indecisiveness. An informed consent process would include, at least, explanation of: ▪ the nature and purpose of the proposed procedures. ▪ risks and consequences of the procedures. ▪ risks and prognosis if no treatment is rendered. ▪ the probability that the proposed procedure will be successful. ▪ alternative methods of treatment (if any) and their associated risks and benefits. The responsible practitioner must provide as much information about treatment options as is necessary based on a patient's personal understanding of the practitioner's explanation of the risks of treatment and the probable consequences of the treatment. An authorization from a patient who does not understand what he/she is consenting to is not informed consent.	
08.00.07 Post-operative care/recovery There must be adequate provisions for immediate post-operative care. §485.639 Tag C-1140	☐ Compliant ☐ Not Compliant Adequate provisions for immediate post-operative care means: ▪ Post-operative care must be in accordance with acceptable standards of practice. ▪ The post-operative care area or recovery room is a separate area of the CAH. Access is limited to authorized personnel.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The CAH provides for post-operative care. ▪ Policies and procedures govern the recovery room area.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Policies and procedures specify transfer requirements to and from the recovery room. Depending on the type of anesthesia and length of surgery, the post-operative check before transferring the patient from the recovery room may include: □ Level of activity. □ Respirations. □ Blood pressure. □ Level of consciousness. □ Patient color. If the patients are not transferred to the recovery room, provisions must be made for close observation until they have regained consciousness, e.g., direct observation by an RN in the patient's room.	
08.00.08 **Operating room register** The operating room register(s) must be complete and up to date. §485.639 Tag C-1140	☐ Compliant ☐ Not Compliant The register should include, at least: ▪ Patient's name. ▪ Patient's date of birth. ▪ Patient's CAH identification number. ▪ Date of the operation. ▪ Inclusive or total time of the operation. ▪ Name of the surgeon and any assistant(s). ▪ Name of nursing personnel (scrub and circulating). ▪ Type of anesthesia used and name of person administering it. ▪ Operation performed. ▪ Pre- and post-op diagnosis.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the OR register or equivalent record lists all surgery performed and includes items specified.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
08.00.09 Operative report The operative/procedure report is made immediately available so that care of the patient can be transferred if the surgeon is unable to attend to their immediate needs. §485.639 Tag C-1140 §485.638(a)(2) Tag C-1104 §485.638(a)(4)(iii) Tag C-1116	☐ Compliant ☐ Not Compliant The operative report would include at least: ▪ Name and CAH identification number of the patient. ▪ Date and times of the surgery. ▪ Name(s) of the surgeon(s) and assistants or other practitioners who performed surgical tasks (even when performing those tasks under supervision). ▪ Pre-operative and post-operative diagnosis. ▪ Name of the specific surgical procedure(s) performed. ▪ Type of anesthesia administered. ▪ Complications, if any. ▪ A description of techniques, findings, and tissues removed or altered. ▪ Surgeons or practitioners name(s) and a description of the 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). ▪ Prosthetic devices, grafts, tissues, transplants, or devices implanted, if any.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that medical records of surgical patients contain a surgical report that is dated and signed by the responsible surgeon and includes the information specified.
08.00.10 Required equipment in the operating room suite The surgical service maintains an adequate inventory of instrumentation, supplies and equipment. The following equipment must be available to the operating room suites:	☐ Compliant ☐ Not Compliant 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 are considered standard.	This standard is not met as evidenced by: **OBSERVATION** Verify: ▪ All required systems in surgical and invasive procedure rooms are working.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ Call-in system (intercom or equivalent) ▪ Cardiac monitor ▪ Resuscitator (ventilator) ▪ Defibrillator ▪ Aspirator (suction equipment/vacuum) ▪ Tracheotomy set. §485.639 Tag C-1140	**Note:** A cricothyroidotomy set is not a substitute for a tracheotomy set. "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 be able to summon 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, neonatal/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 cart 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.	▪ All required equipment is readily available with adequate inventory for patient care. ▪ All equipment is working and, as applicable, in compliance with the CAH'S biomedical equipment inspection, testing, and maintenance program. ▪ Age-specific resuscitation equipment is readily available. If the facility treats neonatal/pediatric patients, ensure neonatal/pediatric-sized endotracheal tubes/tracheostomy set are immediately available.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
08.00.11 **Qualified practitioners** *The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws.* *Surgery is performed only by--* 1. *A doctor of medicine or* osteopathic medicine*, including an osteopathic practitioner recognized under section 1101(a)(7) of the Social Security Act;* 2. *A doctor of dental surgery or dental medicine; or* 3. *A doctor of podiatric medicine.* §485.639(a) Tag C-1142 §485.639(a)(1-3)	☐ Compliant ☐ Not Compliant The medical staff is accountable to the governing body for the quality of care provided to patients. The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Surgical privileges are granted in accordance with the competencies of each practitioner. The CAH must delineate the surgical privileges of all practitioners performing surgery and surgical procedures. This would include practitioners such as: ▪ MD/DOs. ▪ Dentists. ▪ Oral surgeons. ▪ Podiatrists. ▪ RN first assistants. ▪ Nurse practitioners. ▪ Surgical physician assistants. ▪ Surgical technicians, etc. The medical staff appraisal procedures evaluate each individual practitioner's training, education, experience, and demonstrated competence as established by the CAH'S QAPI program, credentialing process, the practitioner's adherence to CAH policies and procedures, and in accordance with scope of practice and other state laws and regulations. Surgical privileges must be reviewed and updated at **regular intervals. In the absence of a state law that establishes a time frame for periodic reappraisal, an appraisal is conducted at least every 36 months for each practitioner**.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The method for reviewing the surgical privileges of practitioners includes a written assessment of the practitioner's training, experience, health status, and performance **and is conducted at least every 36 months, or at a shorter interval if required by state law, other regulation, or hospital policy**. ▪ A current roster listing each practitioner's specific surgical privileges is available in the surgical suite and the area where the scheduling of surgical procedures is done. ▪ 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
	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. A current list of surgeons suspended from surgical privileges or whose surgical privileges have been restricted must be retained in these area/locations. **SUPERVISION** When a practitioner may perform certain surgical procedures under supervision, the specific tasks/procedures and the degree of supervision (to include whether or not the supervising practitioner is in the same OR in line of sight) is delineated in that practitioner's surgical privileges and included on the surgical roster. **Note:** When practitioners whose scope of practice for conducting surgical procedures requires the 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. 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 surgical privileges in accordance with those criteria established by the governing body (or responsible individual), and who is working within the scope of those granted and documented privileges.	
08.01.00 Anesthesia risk and evaluation 1. *A qualified practitioner, as specified in §485.639(a), must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.*	☐ Compliant ☐ Not Compliant **PRE-ANESTHESIA EVALUATION** A pre-anesthesia evaluation must be performed prior to inpatient or outpatient surgery by an individual qualified to administer anesthesia. The pre-operative anesthetic evaluation notes: ▪ Assessment of anesthesia risk.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Each patient has a pre-anesthesia evaluation by an individual qualified to administer anesthesia.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
2. *A qualified practitioner, as specified in §485.639(c), must examine each patient before surgery to evaluate the risk of anesthesia.* 3. *Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in §485.639(c).* §485.639(b) Tag C-1144 §485.639(b)(1-3)	▪ Anesthesia, drug, and allergy history. ▪ Any potential anesthesia problems identified. ▪ Patient's condition prior to induction of anesthesia. **POST-ANESTHESIA EVALUATION** A post-anesthesia recovery report must be written on all inpatients and outpatients prior to discharge from surgery and anesthesia services by an individual qualified to administer anesthesia. ▪ An MD/DO may delegate the post-anesthesia assessment and the writing of the post-anesthesia report to practitioners qualified to administer anesthesia in accordance with state law and CAH policy. ▪ When delegation of the post-anesthesia report is permitted, the medical staff must address delegation requirements and methods in its bylaws. The post-anesthesia follow-up report must be documented in the patient's medical record whether the patient is an inpatient or outpatient of the CAH, and must include, at minimum: ▪ Cardiopulmonary status. ▪ Level of consciousness. ▪ Any follow-up care and/or observations. ▪ Any complications occurring during post-anesthesia recovery.	▫ The evaluation is performed prior to surgery. ▪ A post-anesthesia report is written for each patient who received anesthesia services prior to discharge from anesthesia services by the individual who administered the anesthesia or their designee in accordance with law and CAH policy. ▫ Documentation includes those items specified in the standard.
08.01.01 <u>Administration of anesthesia</u> *The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.* 1. *Anesthesia must be administered by only–*	☐ Compliant ☐ Not Compliant **ANESTHESIA PRIVILEGES** The medical staff bylaws must include criteria for determining the privileges to be granted to an individual practitioner and a procedure for applying the criteria to individuals requesting privileges. Anesthesia privileges are granted in accordance with state law and CAH policy. The CAH must specify the anesthesia privileges for each practitioner who administers anesthesia, or who supervises the administration of anesthesia by	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review the qualifications of individuals authorized to deliver anesthesia. ▪ Verify that there is documentation of current licensure or current certification status for all persons administering anesthesia.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
i. A qualified anesthesiologist; *ii. A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Social Security Act;* *iii. A doctor of dental surgery or dental medicine;* *iv. A doctor of podiatric medicine;* *v. A certified registered nurse anesthetist (CRNA), as defined in §410.69(b);* *vi. An anesthesiologist's assistant, as defined in §410.69(b); or* *vii. A supervised trainee in an approved educational program, as described in §413.85 or §413.86.* §485.639(c) Tag C-1145 §485.639(c)(1)(i-vii)	another practitioner. The type and complexity of procedures for which the practitioner may administer anesthesia, or supervise another practitioner supervising anesthesia, must be specified in the privileges granted to the individual practitioner. **PRIVILEGES INCLUDE THE SUPERVISION OF CRNA** When a CAH permits operating practitioners to supervise CRNAs administering anesthesia, the medical staff must specify in the statement of privileges for each category of operating practitioner, the type and complexity of procedures they may supervise. A CRNA may administer anesthesia when under the supervision of the operating practitioner or of an anesthesiologist who is immediately available if needed (unless supervision is exempted in accordance with §485.639(e)). An anesthesiologist's assistant may administer anesthesia when under the supervision of an anesthesiologist who is immediately available if needed. **IMMEDIATELY AVAILABLE** Immediate availability means, at minimum, that the supervising anesthesiologist or operating practitioner, as applicable, is: ▪ Physically located within the operative suite or in the labor and delivery unit. ▪ Is prepared to immediately conduct hands-on intervention if needed. ▪ Is not engaged in activities that could prevent the immediate, hands-on intervention if needed.	
08.01.02 CRNA supervision *In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as*	☐ Compliant ☐ Not Compliant See standard 08.01.04 for state exemption requirements.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Non-physician anesthesia providers are supervised.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
provided by state exemption *in* §485.639(e). *An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.* §485.639(c)(2) Tag C-1147		▪ Policies define practice for supervision.
08.01.03 Discharge requirement *All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure*. §485.639(d) Tag C-1149	☐ Compliant ☐ Not Compliant Any exceptions to this requirement must be made by the attending practitioner and noted on the clinical record.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Policies and procedures govern discharge procedures and instructions. ▪ Patient records confirm the process is followed and documented. ▪ Medical records reflect that an adult assumed responsibility for the patient.
08.01.04 State exemption for supervision of CRNAs 1. *A CAH may be exempted from the requirement for physician supervision of CRNAs as described in §485.639(c)(2), if the State in which the CAH 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 physician supervision*	☐ Compliant ☐ Not Compliant See 08.01.02.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Interview anesthesia leadership to determine if a state exemption is in place for anesthesia supervision. If yes, verify: ▪ The exemption is documented with a signed opt-out letter.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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 physician 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.*

§485.639(e)(1-2) Tag C-1150

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
08.02.00 Circulating nurse *Qualified registered nurses may perform circulation duties in the operating room.* *In accordance with applicable state laws and approved medical staff policies and 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)	☐ Compliant ☐ Not Compliant The circulating nurse must be an RN. The CAH must establish the qualifications required for RNs who perform circulating duties and for LPNs and surgical technologists who assist with circulating duties. **SUPERVISION OF LPN AND SURGICAL TECHNOLOGISTS** The supervising RN would not be considered immediately available if the RN was outside the operating suite or engaged in other activities/duties that would prevent the RN from immediately intervening and assuming whatever circulating activities/duties that were being provided by the LPN or surgical technologist. If a case is circulated by other than an RN, the operative record must be co-authored by the RN who was immediately available.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** If LPNs and surgical technologists (STs) are performing circulating duties, verify: ▪ They do so in accordance with applicable state laws and approved medical staff policies and procedures. ▪ A qualified RN supervisor is immediately available to respond to emergencies.
08.03.00 Moderate sedation (conscious sedation) The use of moderate sedation (conscious sedation) is limited to qualified individuals. **§485.635(d)(3)**	☐ Compliant ☐ Not Compliant Moderate sedation (conscious sedation) is the responsibility of the ordering practitioner; there must 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 receiving moderate sedation (conscious sedation).	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review three anesthesia provider files to verify: ▪ Qualifications, including current certifications, are present in the files of the reviewed practitioners. ▪ Non-anesthesia practitioners who are administering moderate sedation (conscious sedation) have requested and been granted privileges.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
08.03.01 First assistants The medical staff rules and regulations and/or policies identify the hazardous cases, which require a physician first assistant to be scrubbed, the types of cases wherein a qualified non-physician first assistant may be scrubbed, and the types of cases where no assistant other than the scrub and circulator are required. **§485.639** **§485.639(a)** **§482.22(c)**	☐ Compliant ☐ Not Compliant Policy defines: 1. Hazardous procedures performed at the facility. The definition may vary from one facility to another. Typically, open cranial and thoracic procedures are noted as those requiring a physician first assistant. 2. The qualification process for non-physician first assistants. 3. The types of cases that require: a. A scrubbed physician first assistant. b. A scrubbed non-physician first assistant. c. No assistant other than the scrub and circulating RN.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify a policy regarding hazardous procedures and use of first assistants is readily available. ▪ Practice is consistent with policy.
08.03.02 Physician availability The medical staff rules and regulations and/or policies require that when the entire surgical team is non-physicians, a physician is immediately available to the procedure. **§485.639** **§485.639(a)** **§482.22(c)**	☐ Compliant ☐ Not Compliant When the surgeon is a dental or podiatric (non-MD/DO) practitioner, and the anesthesia provider is a non-physician, a physician responsible for management of medical crises must be notified of the case start and immediately available to provide intervention (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. ▪ This documentation includes whether or not the supervising practitioner is required to be physically present in the same operating room or in the line of sight of the practitioner being supervised.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Medical staff rules and regulations require that a physician is notified, accepts accountability, and is immediately available if a surgical team is entirely non-physician. ▪ Medical staff rules and regulations define requirements for supervision. ▪ This practice is consistently implemented.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
08.03.03 Supply and instrumentation availability and immediate use steam sterilization	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Instrumentation, supplies, and equipment are sufficient in quantity to minimize movement in and out of the area during cases. Processed instruments are protected from surface/airborne contamination. "IUSS" (Immediate Use Steam Sterilization) is limited to rare circumstances. The facility follows IUSS criteria and guidelines for sterilization. Shipping cartons are not permitted in the "clean" environment. **§485.639** **§485.640(a)(2)**	The design of the operating and invasive procedure rooms is such that personnel and supply movement in the "clean" areas are protected. 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 is not 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.	**OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ General and "clean" areas are clearly identified. ▪ Staff adhere to traffic flow rules to minimize movement in and out of the area. ▪ Shipping cartons from the outside environment are not stored in the clean storage area or on the floor. ▪ Sterile packages are intact and protected from dust, moisture, and other sources of contamination. ▪ The sterilization log demonstrates that IUSS is only used for emergency purposes. ▪ The facility uses IUSS guidelines. ▪ Staff use safety measures with the chemicals disinfectants/cold sterilant products. These products are labeled and reflect current dates.
08.03.04 Intra-operative anesthesia record	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
There is an intraoperative anesthesia record. This record accurately reflects critical techniques, management and patient responses including condition at	If a non-physician performs the anesthesia service and completes the intraoperative anesthesia record, supervision is required, unless a state exemption is documented.	**DOCUMENT REVIEW** Review collaborative agreements, intraoperative records, medical staff bylaws,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
the end of the anesthetic. §482.52(b)(2)	The intraoperative anesthesia record must include the following time-based record of events: 1. Immediate review prior to initiation of anesthetic procedures including patient re-evaluation and a check of equipment, drugs, and gas supply. 2. Monitoring of the patient (e.g., recording of vital signs). 3. Amounts of drugs and agents used, and times of administration. 4. The types and amounts of intravenous fluids used, including blood and blood products, and times of administration. 5. The techniques used. 6. Unusual events during the administration of anesthesia. 7. The status of the patient at the conclusion of anesthesia. Individuals noted under Anesthesia Services are qualified to provide anesthesia services. Physician supervision of non-physician providers of anesthesia services may be demonstrated through collaborative statements or agreements, documentation in the intraoperative record, or as defined in medical staff bylaws, rules and regulations.	rules and regulations and clinical records to verify: ▪ The intraoperative anesthesia records reflect the techniques, management and responses required as identified in the required elements. ▪ The process for supervision of non-physician providers of anesthesia is described in policy. ▪ If a state exemption does not apply, physician supervision was provided for anesthesia, as required.
08.03.05 <u>Anesthesia policies</u> *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 Policies governing anesthesia are consistent with federal, state, and other regulations and include, at least: 1. The qualifications, responsibilities, and supervision required of all personnel who administer anesthesia. 2. Patient consent. 3. Infection control measures. 4. Safety practices in all anesthetizing areas.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** Verify: ▪ All required policies for anesthesia service are in place. ▪ Policies have received approval in the past two years.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

5. Protocol for supportive life functions, e.g., cardiac and respiratory emergencies.
6. Reporting requirements.
7. Documentation requirements.
8. Equipment requirements, as well as the monitoring, inspection, testing and maintenance of anesthesia equipment in the hospital's biomedical equipment program.

Patient care policies are reviewed every two years.

PATIENT CONSENT

The medical record must contain documentation of the patient consent for **the type of planned** anesthesia **and the provider administering the anesthesia on an anesthesia consent form. The anesthesia consent** may be accomplished through a separate written informed consent **document specific to** the administration of anesthesia or integrated into the surgical informed consent **in a separate section of the document if the practitioner responsible for the administration of anesthesia has participated in the informed consent process and discussion of the planned anesthesia care.**

Hospital policy defines the categories of practitioners that are able to obtain informed consent for the delivery of anesthesia. Informed consent requires a discussion of the risks, benefits, and alternatives to anesthesia. Therefore, it is critical that an individual acting within their scope of practice participate in the discussion with the patient and/or representative regarding the anesthesia plan of care, risks, benefits, and alternatives.

See standard 07.00.04 for required elements of an informed consent.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
08.03.06 Equipment safety All anesthetizing equipment is maintained to conform to Safe Medical Devices/Food and Drug Administration requirements. **§482.52(b)** **§485.623(a)**	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW AND FILE REVIEW** Verify: ▪ The anesthesia machine "number" and "machine safety check" are documented on the record prior to use. ▪ Preventive maintenance is performed consistent with manufacturer's recommendations for semiannual gas waste, gas testing, and electrical safety testing.
08.03.07 Security of medications **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.** All anesthesia carts must be locked when not in use. Unused drugs shall be disposed of after each case. **§485.635(a)(3)(iv)**	☐ Compliant ☐ Not Compliant **Hospital policy addresses the preparation, distribution, administration, and proper disposal of hazardous medications. 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.** **MEDICATION CARTS** Due to their mobility, mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts containing **Schedule II, III, IV, and V drugs** or biologicals (hereafter, all referred to as "carts") must be locked **within a secure area** when not in use. Hospital policies and procedures are expected to address the security and monitoring of carts containing these drugs and biologicals, locked or unlocked, in all patient care areas to ensure their safe storage and patient safety.	This standard is not met as evidenced by: **OBSERVATION** Verify: ▪ **Written policies and procedures address security and monitoring of all medication carts**. ▪ Mobile nursing medication carts, anesthesia carts, epidural carts and other medication carts are locked **within a secure area** when not in use. ▪ Schedule II, III, IV and V drugs are discarded properly **using secure disposal containers that prevent access to unused medication**.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	A secure area means the drugs and biologicals are stored and disposed of in a manner to prevent unmonitored access by unauthorized individuals.	
08.03.08 Post-anesthesia documentation requirements A post anesthesia care record is prepared for each patient and documents: 1. Nature of surgical/invasive/ manipulative procedure. 2. Date/time of arrival and **name of individual who transported the patient**. 3. Level of consciousness and vital signs at time of arrival. 4. Name of anesthesia provider and anesthesia technique employed. 5. Condition of patient upon 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. These include vital signs, reactivity, sensorium, fluid intake/output/balance and pain management; and medications given with appropriate observations and according to patient need, EKG, SaO2 and other monitoring results.	☐ Compliant ☐ Not Compliant Post-anesthesia care reports are consistent wherever 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 monitored to allow a determination that a patient can be safely transferred to another level of care. Transfer/discharge from the PACU is only by physician order or per medical staff-approved criteria.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that each record includes a post-anesthesia care report.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
7. Name of the licensed independent practitioner discharging the patient from PACU care. 8. Name of the nurse receiving the patient from the PACU. **§485.639(b)(1-3)**		
08.03.09 Discharge criteria Medical staff rules and regulations/policy define the discharge criteria from PACU. These, if used in lieu of a practitioner assessment/order, are used consistently for post anesthesia recovery. **§485.639(b)(3)** **§482.22(c)**	☐ Compliant ☐ Not Compliant The criteria provide quantifiable data consistent to support discharge-related decisions.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Medical records reflect the consistent and appropriate use of approved discharge criteria in determining discharge readiness from the PACU.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
08.03.10 Discharge instructions Outpatient surgical/invasive procedure patients, and their families/companions as appropriate, are provided with instructions regarding post procedure management in language that the patient or accompanying responsible person can understand. **§485.639(d)** **§485.638(a)(4)(i)**	☐ Compliant ☐ Not Compliant 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. 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The medical record for patients discharged following outpatient procedural care reflects that post procedure care instructions were provided to the patient/responsible adult.
08.03.11 Post-procedure follow-up Outpatient surgical/invasive procedure patients are contacted, when possible, by the facility within 24- to 72-hours post-procedure to determine their status.	☐ Compliant ☐ Not Compliant Policy identifies patients "at risk" who should receive a follow-up call to assess clinical well-being post-surgery. A process is in place to document these follow-up calls. 1. The clinical evaluation information 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.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Staff can describe the process that is implemented for follow-up calls. ▪ Medical records contain documentation of these follow-up calls. ▪ There is a mechanism to review and trend outcome or process issues as a result of the follow-up calls. ▪ Findings are reported to the QAPI program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	3. Patient satisfaction with the facilities and the service can also be assessed; however, this information is not ordinarily recorded in the medical record.	
08.03.12 Operative site verification The facility has a policy and procedure to document verification of the operative site before surgery occurs. The operative site verification policy and procedure 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. □ Availability of implants/special equipment/requirements.	☐ Compliant ☐ Not Compliant 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 CAH operative site verification policy must clearly describe the process for site marking; it must not be ambiguous. The operative site must be identified prior to surgery. The non-surgical site must never be marked.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Policy and procedure meet the requirements. ▪ Closed medical records confirm consistent implementation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- ☐ Required documentation for each element.

§485.639
§485.614(c)(2)

08.03.13 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 organization has policies and procedures for the proper use and maintenance of pneumatic tourniquets, including a risk assessment protocol and the plan to prevent complications.

The risk assessment and the complication prevention plan are documented in the patient record.

§485.639

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 are as follows:

1. Provide training in the proper use of the pneumatic tourniquet device for all perioperative staff. Follow inflation and deflation procedures as recommended by the manufacturer.
2. Perform regular inspection and maintenance of the device according to the manufacturer's written instructions.
3. Ensure 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. Perform continuous monitoring of the tourniquet inflation time and pressure display.

DOCUMENT REVIEW

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

08.03.14 Label medications and solutions on the sterile field
 	
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.
 	
Policies and processes include, but are 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.
 	
§485.639
§485.635(d)(3)
§485.614(c)(2)
	☐ Compliant ☐ Not Compliant
	
	All surgery settings and procedure rooms are expected to handle chemicals, reagents, specimen preservation agents, and diluents with the same caution as medications.
	
	All solutions used in the surgical area are labeled 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 is not acceptable to write on 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 must 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 identified and implemented when preparing labels to differentiate these.
		This standard is not met as evidenced by:
		
		DOCUMENT REVIEW
		
		Verify:
		
		▪ Policies and procedures meet the requirements including:
		  □ Required labeling of solutions and medications on and off the sterile field.
		  □ Differentiating look-alike and sound-alike medications/solutions.
		  □ Individually verifying and labeling medications/solutions and respective labels.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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 verbally and visually confirm each medication/solution and respective label; 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.	

09

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.00.00 CONDITION OF PARTICIPATION: Quality Assurance and Performance Improvement	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH must develop, implement, and maintain an effective, ongoing, CAH-wide, data-driven quality assessment and performance improvement (QAPI) program. The CAH must maintain and demonstrate evidence of the effectiveness of its QAPI program. *Definitions. For the purposes of this section–* ▪ *"Adverse event" means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof.* ▪ *"Error" means the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim. Errors can include problems in practice, products, procedures, and systems; and* ▪ *"Medical error" means an error that occurs in the delivery of healthcare services.* §485.641 Tag C-1300 §485.641(a)	The facility demonstrates the ongoing review and analysis of 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.	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The hospital has an ongoing QAPI Program. ▪ The scope of the QAPI Program is to identify and reduce medical errors and improve health outcomes. ▪ The focus of the program is to identify high-risk opportunities and take action to reduce errors. ▪ The required processes are monitored, including: □ Quality of care provided. □ Effectiveness and safety of services provided. □ Adverse patient events.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.00.01 <u>QAPI Program design and scope</u> *The CAH's QAPI program must:* ▪ *Be appropriate for the complexity of the CAH's organization and services provided.* ▪ *Be ongoing and comprehensive.* §485.641(b)(1) Tag C-1302 §485.641(b)(2) Tag C-1306	☐ Compliant ☐ Not Compliant The **QAPI Program is comprehensive and designed with the goal of reducing medical errors and improving health outcomes. Every department and function contributes to the Program.** The Program identifies: 1. Quality indicators, including adverse patient events, that will be measured, analyzed, and tracked on an ongoing basis. 2. Performance indicators and data collection activities for: ▪ Every department. ▪ Every service (including **patient care associated** contracted services). 3. The frequency and detail of data collection activities. 4. The methods to monitor the effectiveness and safety of services and quality of care. 5. The plan to use data collected to monitor the effectiveness and safety of services. 6. The strategies used to identify opportunities for improvement and change. The facility provides evidence of: ▪ Ongoing review and analysis of the quality indicators. ▪ Identification of patterns and trends in the services and care provided. ▪ 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: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** Review the QAPI Program and related documents, (e.g., plans, meeting minutes, reports, and follow-up communication relative to corrective actions) to verify that: ▪ Data collection activities are appropriate to the scope of the hospital. ▪ The governing body has specified the frequency and detail of data collection.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.00.02 QAPI scope	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH's QAPI program must: ▪ *Involve all departments of the CAH and services (including those services furnished under contract or arrangement).* §485.641(b)(3) Tag C-1306	The QAPI Program identifies performance indicators and data collection activities for: ▪ Every department and service. ▪ Every **patient care-associated** contracted service.	**INTERVIEW AND DOCUMENT REVIEW** Verify that: ▪ Data collection activities include: □ Every hospital department and service. □ Each **patient care-associated** contracted service. ▪ Data is analyzed to identify patterns and trends. Data is used to monitor the effectiveness of services provided.
09.00.03 Objective measures	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH's QAPI program must: ▪ *Use objective measures to evaluate its organizational processes, functions and services.* §485.641(b)(4) Tag C-1309	No additional information.	**INTERVIEW AND DOCUMENT REVIEW** ▪ The QAPI Program has identified improvement indicators that will improve health outcomes and identify and reduce medical errors.
09.00.04 Outcome indicators and adverse events	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH's QAPI program must: *Address outcome indicators related to:* 1. *improved health outcomes and the prevention and reduction of medical errors,*	Data must be used to achieve the objectives of the QAPI Program, addressing outcome indicators. The CAH's quality improvement efforts are evidenced based and focused on the needs of the population served by the CAH in a manner that best suits the unique characteristics of the CAH.	**DOCUMENT REVIEW** ▪ The hospital has selected meaningful outcome indicators as the basis of the QAPI Program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
2. *adverse events,* 3. *CAH-acquired conditions, and* 4. *transitions of care, including readmissions.* §485.641(b)(5) Tag C-1311		▪ The data collection activities are appropriate to the scope of the hospital.
09.00.05 Governance and leadership *The CAH's governing body or responsible individual is ultimately responsible for the CAH's QAPI program and is responsible and accountable for ensuring that the QAPI program meets the requirements of paragraph (b) of this section.* §485.641(c) Tag C-1313	☐ Compliant ☐ Not Compliant The governing body 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 setting expectations for safety and for allocating adequate resources for measuring, assessing, improving, and sustaining the hospital's performance 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.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ 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? ▪ Does the QAPI program include patient safety initiatives, such as reduction of medical errors? ▪ What is the evidence that the governing body prioritized the performance improvement projects and data collection activities? ▪ 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.00.06 Program activities For all departments and services, including contracted services *the CAH must:* ▪ *Focus on measures related to improved health outcomes that are shown to be predictive of desired patient outcomes.* ▪ *Use the measures to analyze and track its performance.* ▪ *Set priorities for performance improvement, considering either high-volume, high-risk services, or problem-prone areas.* §485.641(d) §485.641(d)(1) Tag C-1315 §485.641(d)(2) Tag C-1319 §485.641(d)(3) Tag C-1321	☐ Compliant ☐ Not Compliant The facility has a process to identify opportunities, prioritize, and select annual performance improvement activities based on 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: **DOCUMENT REVIEW** ▪ The facility has a process to establish priorities for performance improvement activities that focus on high-risk, high volume, or problem prone areas.
09.00.07 Program data collection and analysis *The program must incorporate quality indicator data including patient care data, and other relevant data, in order to achieve the goals of the QAPI program.* §485.641(e) Tag C-1325	☐ Compliant ☐ Not Compliant 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.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Identify: ▪ Who is responsible to evaluate CAH patient care services. ▪ How patient care services are evaluated. ▪ What other services are evaluated.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The facility provides measurable evidence of improvement in the following areas: ▪ health outcomes. ▪ reduction of identified medical errors.	▪ How the CAH ensures quality assurance data is provided to the medical staff and governing body. Verify that: ▪ 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.
09.00.08 Evaluation of infection control and medication administration *The program requires that–* ▪ Nosocomial infections and medication therapy are evaluated. §485.641(b)(2) Tag C-1306	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ What methodology does the CAH use to evaluate nosocomial infections and medication therapy? ▪ Review committee meeting minutes for current issues or projects, etc.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.00.09 Unified and integrated QAPI program for a CAH in a multifacility system	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have a unified and integrated QAPI program for all of its member facilities 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 CAHs meets all of the requirements of this section. Each separately certified CAH subject to the system governing body must demonstrate that: ▪ *The unified and integrated QAPI program is established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH; and* ▪ *The unified and integrated QAPI program establishes and implements policies and procedures to ensure that*	If a decision is made to use a unified and integrated QAPI Program for a multi-hospital system, the hospital must maintain documentation of this determination by its governing body. The requirement that the QAPI Program be well organized and accountable to the system's governing body remains. Each separately certified hospital is responsible for independently meeting all requirements in this Condition of Participation.	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Whether 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, 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
the needs and concerns of each of its separately certified CAHs, 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 CAHs are duly considered and addressed. §485.641(f)(1-2)		
09.00.10 For future use		
09.00.11 For future use		
09.00.12 Quality assurance deficiencies The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program. §485.641(b)(5) Tag C-1311	☐ Compliant ☐ Not Compliant **The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.**	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The CAH ensures that remedial actions are taken to correct deficiencies identified in the QAPI Program. ▪ Who is responsible for implementing actions to correct deficiencies identified by the program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.00.13 Documentation of remedial action The CAH documents the outcome of all remedial action. §485.641(b)(5) Tag C-1311	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify how the CAH documents the outcome of any remedial action.
09.01.00 Quality management position There is an individual, trained in quality principles and appointed by the hospital leadership, in charge of the QAPI Program. §482.21(e)(4)	☐ Compliant ☐ Not Compliant 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. The quality manager has received formal training in principles of quality improvement to prepare the individual for the required duties.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review documentation of training to confirm that the individual has attended formal quality training programs and has a plan for future training. ▪ Interview the quality manager regarding the amount of time devoted to the quality program and the nature of past quality improvement training. □ Verify that sufficient time is devoted to the program.
09.01.01 Leadership accountability The hospital chief executive officer, leadership from the medical staff, the nurse executive, and the individual assigned overall responsibility for quality management ensure that hospital QAPI efforts and training programs address	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the QAPI Program to identify accountability for the program in regard to resource allocation consistent with the standard.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
identified priorities. Hospital leadership, medical staff and the staff assigned responsibility for quality management, are actively involved in the oversight and assessment of the quality program. Their support is evident in resource allocation for problem resolution and/or mitigation, as well as allocation of human resources to provide education on the quality program and program outcomes throughout the organization. This includes allocation of staff hours to attend education sessions and participate in quality teams and projects as needed. §482.21(e)		▪ Review education rosters or employee files to verify that education hours are made available to staff on the quality process and outcomes. ▪ Verify: □ There is a defined process for dissemination of information about improvements/changes made as a result of a quality initiative. □ The senior and middle management group receive regular education or training on quality management techniques. □ QAPI related education is provided to the administrative team, governing board, medical staff, and hospital line staff.
09.01.02 Annual quality plan	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The facility prepares an annual quality plan which is approved by the Quality Committee/function and the governing body. As part of its QAPI Program, the hospital must conduct performance improvement projects. The annual plan identifies the performance improvement projects for the year.	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.	**DOCUMENT REVIEW** Review the hospital's program to verify that: ▪ The governing body has specified the frequency and detail of the data to be collected. ▪ The governing body has approved the annual quality plan.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
The annual plan also includes the detail of data to be measured and the frequency of data collection, as specified by the hospital's governing body. §482.21(a)		
09.01.03 Quality committee/function There is a multidisciplinary, hospital wide quality assessment and performance improvement committee/function. The committee/function is responsible for the development and implementation of a program for measuring, assessing, and improving outcomes. Participants in the committee/function are representatives of leadership, the medical staff, and other hospital staff as necessary to fulfill its responsibilities. Committee/function activity must be conducted at formal meetings. **§485.641(b)(1)** **§485.641(b)(2)**	☐ Compliant ☐ Not Compliant The participants in the committee/function include individuals within the organization with the expertise necessary to review and improve the processes that affect outcomes. Minutes must be kept in sufficient detail to track the progress of the QAPI Program. The minutes reflect opportunities for improvement and corrective actions implemented.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the QAPI plan and list of committee/function participants. ▪ Verify that: □ There is a structured coordinated process for development and implementation of the quality program. □ The committee/function is multidisciplinary and includes medical staff representation. ▪ 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.01.04 Data to be collected	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The scope of data collection must measure, analyze, and track the processes of care, hospital services and operations. At a minimum, the following processes are monitored: 1. Medication therapy. 2. Infection control. 3. Surgical/invasive and manipulative procedures. 4. Blood product usage. 5. Data management. 6. Discharge planning. 7. Utilization management. 8. Complaints. 9. Restraint/seclusion use. 10. Mortality review. **§485.641(b)(1)** **§485.641(b)(2)**	The following criteria are relevant in establishing priorities among those clinical topics that meet items 1-4 in the standard: ▪ previous projects or pilot studies. ▪ adequacy of program resources. ▪ availability of partnerships. ▪ ability to enable or facilitate ongoing quality improvement. ▪ likelihood of success.	**DOCUMENT REVIEW** ▪ Review the process for measuring, analyzing, and tracking quality indicators to determine the requirement was met. ▪ Verify: □ The scope of data collection is appropriate to the scope of the hospital. □ All required processes are monitored. □ Data collection includes **patient care associated** contract services.
09.01.05 Medical errors	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The hospital must have a process for monitoring medical errors. The process includes all areas of the hospital where patient care is provided.	The hospital should review information from its own risk management data and external sources such as the National Patient Safety Foundation, and the quality indicators from the Healthcare Cost and Utilization Project (HCUP QIs).	**INTERVIEW AND DOCUMENT REVIEW** ▪ Review documents and interview the quality manager.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
Errors identified shall be reviewed to determine their cause, and whether the error represents a systemic problem, a periodic occurrence, or an isolated incident. The facility prepares a database for tracking errors by category in order to determine if there is a pattern(s), and to monitor the impact of corrective action taken. §482.21(a)(2)	Examples of medical errors to be monitored include, but are not limited to: ▪ medication error. ▪ surgical errors. ▪ diagnostic errors. ▪ equipment failures. ▪ infections. ▪ blood transfusion-related injuries. ▪ deaths due to seclusion or restraint.	▪ Verify that: □ A system is in place to monitor medical errors in all patient care areas of the facility. □ Review summary reports by category to determine whether patterns are identified.
09.01.06 <u>Performance improvement in medication use</u> 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 improve these processes. If technological advances are not an option, the organization will implement alternatives that will resolve identified issues and reduce medication events. §482.21(a)(2)	☐ 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. **Note:** Studies have demonstrated that a significant decrease in medication errors and adverse drug events can be achieved by using computerized prescriber order entry technology(CPOE). **(See standard 07.00.01.)** 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: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** ▪ Review medication event data. Review minutes where improvement of the medication system and processes are discussed. ▪ Verify that: □ 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.01.07 Analysis of medical errors 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 Review of errors shall involve the individual(s) directly involved as well as representatives of any involved hospital services. Tracking and analysis of underlying causes of adverse events should lead facilities to assess processes and systems that affect patient care and quality. It is important that each error incident be used as an opportunity for education and learning for the individuals and areas involved. **Note: See standard 09.01.21.**	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview the person responsible for monitoring medical errors to determine that the requirement is met. Review medical error reports. ▪ Review documents to determine that there is evidence of involvement by staff from each area related to the error. ▪ Review specific error files to determine whether causes were identified. Verify that: ▪ The hospital has a method for tracking, analyzing, implementing corrective strategies/preventive actions, providing feedback, and training. ▪ Corrective strategies have been implemented for identified medical errors. ▪ Implemented strategies have been effective with correcting the identified medical error(s).

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.01.08 Corrective action Corrective action is taken to eliminate the cause of the error. §482.21(c)(3)	☐ Compliant ☐ Not Compliant The hospital must implement improvement actions and mechanisms for identified areas that need improvement and then measure its success and track its ongoing performance to ensure that the improvements are sustained. Identified areas include adverse patient events, medical errors; safety concerns regulatory noncompliance and improvement opportunities.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview leadership to inquire of specific medical errors identified and corrective actions implemented. ▪ Review quality minutes to determine whether corrective action has been taken.
09.01.09 Sustained improvements The hospital must take actions aimed at performance improvement, and after implementing those actions the hospital must measure its success and track performance to ensure that improvements are sustained. §482.21(c)(3)	☐ Compliant ☐ Not Compliant The hospital should take actions such as education of the staff relative to the changes initiated to improve patient care. The implemented strategies should be re-evaluated periodically thereafter to determine the effectiveness of the change as evidence by improved outcomes.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review tracking methodology to confirm that the requirement was met.
09.01.10 Statistical analysis Cumulative data and statistical reports shall be developed reflecting the hospital's progress in identifying and correcting medical errors. §482.21(a)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the database and statistical reports with the individual assigned the responsibility of managing the monitoring system.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.01.11 Performance improvement projects The hospital must set priorities for its performance improvement activities that: ▪ Focus on high-risk, high-volume, or problem-prone areas. ▪ Consider the incidence, prevalence, and severity of problems in those areas. ▪ Affect health outcomes, and quality of care. ▪ Affect patient safety. §482.21(d)	☐ Compliant ☐ Not Compliant Each quality assessment performance improvement project should begin with valid and representative baseline data. The baseline data may be from QAPI organization data or from another source.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Determine by interviewing the individual assigned to the overall responsibility for the QAPI activity and reviewing the top DRG's and aggregated risk management reports that the hospital is meeting the requirement. ▪ Review the performance improvement projects to determine that they are representative of the scope and complexity of the hospital.
09.01.12 Documentation of QAPI projects The hospital must document QAPI projects being conducted, the reasons for conducting these projects, and the measurable progress achieved on these projects. §482.21(d)	☐ Compliant ☐ Not Compliant Each QAPI project initiated shall have documentation that addresses: 1. The reason for conducting the project, e.g., high volume, low volume, problem prone activity. 2. Baseline data. 3. Data to be collected and frequency. 4. Monthly/quarterly audit summaries reflecting performance and trending over time, e.g., tables, charts. 5. Measurable progress. 6. Strategies selected and implemented to improve outcomes. 7. Evaluation of the success of the implemented changes.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview the person responsible for the QAPI Program and review documentation to verify that the requirement was met.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.01.13 Educational program	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
There is a planned, hospital-wide, QAPI education plan. Training shall include general quality approaches and where appropriate team and individual approaches. §482.21(e)(4)	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 does not have to reach all individuals by the time of the survey; however, there shall be an education plan which details how the hospital will accomplish the education within one year from the date of the QAPI plan. The education plan shall include the executive staff, the governing body, the medical staff, and all non-temporary staff.	**DOCUMENT REVIEW AND INTERVIEW** ▪ 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 to verify: □ Hospital staff, medical staff and members of the governing body are able to articulate quality improvement priorities in the organization. ▪ The hospital leadership attended an education session relative to QAPI within the past year.
09.01.14 Information technology system	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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 development, does not need to demonstrate measurable improvement in indicators related to health outcomes.	Hospitals may, as an alternative to a performance improvement project, invest in information technology. In recognition of the time required to develop and implement the type of system, CMS and ACHC do not require that such activities have a demonstrable benefit in their initial stages. It is expected that quality assessment and performance improvement goals and their achievement would be incorporated in the plan for the program. Initial stages of development include activities such as installation of hardware and software, testing of an installed system training of staff,	**INTERVIEW AND DOCUMENT REVIEW** ▪ Review the information systems project that the hospital has initiated and interview the person responsible for the project to determine why it was started and how they monitor the project for the desired outcome to determine that the requirement was met.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.641(d) **§485.641(d)(1-3)**	piloting the system, and hospital-wide implementation of the system. Upon implementation of the system, monitoring will begin, and data will be collected over time as part of the process to evaluate the impact of the new system on patient safety and quality.	
09.01.15 Errors related to information technology systems	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Information Technology system incidents resulting in patient care or treatment errors are investigated and reported to the QAPI Committee. **§485.641(b)** **§485.641(e)**	Information Technology (IT) system-related incidents have the potential for hospital-wide patient harm. Incidents are thoroughly investigated and reported to the QAPI Committee. Corrective actions are implemented and measured to ensure effectiveness of the strategy.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Interview individuals in the IT department, the quality director, the chief nursing officer, and/or the medical staff, to learn of IT related incidents. How were these corrected? ▪ Review reports and minutes of the QAPI committee to verify inclusion.
09.01.16 Reporting of QAPI data	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Periodic reports shall be prepared and presented to the QAPI Committee, and the Pharmacy and Therapeutics Committee/function for their review, and action as necessary. **§485.641(b)(1)** **§485.641(b)(2)**	The annual quality plan addresses the plan and frequency for reporting QAPI data to the respective committees.	**DOCUMENT REVIEW.** ▪ Review reports and minutes of the QAPI committee to verify reporting.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.01.17 Reporting to the board Periodic reports indicating medical errors, patterns identified, and any corrective actions taken are prepared and presented to the governing body of the hospital for review. **485.641(b)(1)**	☐ Compliant ☐ Not Compliant The annual quality plan addresses the plan and frequency for reporting QAPI data to the governing body.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review reports and minutes of the governing body. ▪ Verify that medical error reports and corrective actions are presented to the governing body for review.
09.01.18 Annual quality report There is an annual report based on the annual plan, which details all quality activities and their progress or resolution during the year. The report shall be submitted to the governing body for review and approval. **§485.641** **§485.641(a)**	☐ Compliant ☐ Not Compliant The annual report should include the CEO's review including a summary of senior leadership activities in support of the QAPI Program. This review 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. ▪ Verify that: □ An annual quality report is prepared and includes a CEO summary of senior leadership activities supporting the QAPI Program. □ The governing body has approved the annual quality report. □ The annual QAPI report serves as the basis for the subsequent year's annual QAPI plan.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.01.19 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. **485.641(b)**	☐ Compliant ☐ Not Compliant 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. 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review patient records documentation that patient and/or family were notified of adverse events.
09.01.20 Support of caregivers The healthcare organization must have a program designed to provide support to their staff that are experiencing 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 adverse events so that they can better care for their patients, healing can occur, and 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. □ Confirm that debriefing occurred by and with appropriate staff.
09.01.21 Adverse event review process Adverse events are injuries resulting from medical care, as opposed to adverse outcomes arising from underlying disease.	☐ Compliant ☐ Not Compliant **Note: Due to the confidential nature of information in the RCA, it is NOT to be submitted to ACHC.** Adverse events like hospital-acquired conditions and serious reportable events (SRE) requiring RCA include:	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the hospital's QAPI Program to verify that it meets the requirement for adverse event reporting.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
Upon discovery of an adverse event, the healthcare organization conducts a root cause analysis (RCA) and prepare an action plan in a manner that ensures compliance with all applicable federal, state, and local requirements. **485.641(b)**	1. Artificial insemination with the wrong donor sperm or donor egg. 2. Unintended retention of a foreign object in a patient after surgery or other procedure. 3. Patient death or serious disability associated with patient elopement (disappearance). 4. Patient death or serious disability associated with a medication error (e.g., errors involving the wrong drug, wrong dose, wrong patient, wrong time, wrong rate, wrong preparation or wrong route of administration). 5. Patient death or serious disability associated with a hemolytic reaction due to the administration of ABO/HLA-incompatible blood or blood products. 6. Patient death or serious disability associated with an electric shock or elective cardioversion while being cared for in a healthcare facility. 7. Patient death or serious disability associated with a fall while being cared for in a healthcare facility. 8. Surgery performed on the wrong body part. 9. Surgery performed on the wrong patient. 10. Wrong surgical procedure performed on a patient. 11. Intraoperative or immediately postoperative death in an American Society Anesthesia (ASA) Class I patient. 12. Patient death or serious disability associated with the use of contaminated drugs, devices, or biologics provided by the healthcare facility. 13. Patient death or serious disability associated with the use of function of a device in patient care, in which the device is used or functions other that as intended. 14. Patient death or serious disability associated with intravascular air embolism that occurs while being cared for in a healthcare facility. 15. Infant discharged to the wrong person. 16. Patient suicide or attempted suicide, resulting in serious disability, while being cared for in a healthcare facility.	▪ The CAH must record, investigate (through root cause analysis) and use information to improve process (action plan). □ Confirm staff participation in root cause analysis ▪ Record and retain actions for review during survey. ▪ Verify that the organization is using information to improve processes.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

17. Maternal death or serious disability associated with labor or delivery in a low-risk pregnancy while being cared for in a healthcare facility.
18. Patient death or serious disability associated with hypoglycemia, the onset of which occurs while the patient is being cared for in a healthcare facility.
19. Death or serious disability (kernicterus) associated with failure to identify and treat hyperbilirubinemia in neonates.
20. Stage 3 or 4 pressure ulcers acquired after admission to a healthcare facility.
21. Patient death or serious disability due to spinal manipulative therapy.
22. Any incident in which a line designated for oxygen or other gases to be delivered to a patient contains the wrong gas or is contaminated by toxic substances.
23. Patient death or serious disability associated with a burn incurred from any source while being cared for in a healthcare facility.
24. Patient death or serious disability associated with the use of restraints or bedrails which being cared for in a healthcare facility.
25. Abduction of a patient of any age.
26. Sexual assault on a patient within or on the grounds of the healthcare facility.
27. Death or significant injury of a patient or staff member resulting from a physical assault (i.e., battery) that occurs within or on the grounds of the healthcare facility.
28. Information Technology system-related occurrences.
29. Computerized tomography (CT) ionizing radiation dosing related errors.

Note: The list may not be all inclusive as the "Reporting Events" may change. An annual review of hospital-acquired conditions and SRE is highly recommended in order to keep current with this standard. Please check www.qualityforum.org for an updated list.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
09.01.22 Culture of safety	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The organization will create a healthcare culture of safety. Standardized policies and procedures are in place to: 1. Prioritize patient safety events that should be reported. 2. Implement a non-punitive "close call" reporting system. 3. Define a process for analysis of patient safety events. 4. Implement remedial action and measure effectiveness of such action. 5. Ensure that organizational leadership is kept knowledgeable about patient safety issues present within the organization and continuously involved in processes to assure 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. Train all staff in techniques of teamwork-based problem solving and management.	In most settings today, the high-risk, error-prone nature of modern healthcare and the shared responsibility for risk reduction are not widely recognized. Free and open communication and non-punitive reporting of adverse events and patient safety concerns are not the norm, and organizational objectives and rewards are not clearly aligned with the goal of improving patient safety. To address these issues, there is a need to promote a culture of safety that overtly encourages and supports the reporting of any situation or circumstance that threatens or potentially threatens the safety of patients or caregivers and that views the occurrence of errors and adverse events as opportunities to make the healthcare system better.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Review policies and procedures on safety to validate all required elements have been addressed. ▪ Review safety reports and event analysis reports to validate process as defined in policy is actual practice. ▪ Review minutes of meetings where safety is discussed. ▪ Review staff files to validate education on teamwork techniques have been conducted. ▪ Interview staff members regarding the organization's focus on safety.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
485.641(b)		

10

ORGAN DONATION

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
10.00.00 CONDITION OF PARTICIPATION: Organ, Tissue, and Eye Procedures *The CAH must have and implement written protocols.* §485.643 Tag C-1500	☐ Compliant ☐ Not Compliant The CAH must have written policies and procedures to address its organ procurement responsibilities.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review scoring of the standards in this chapter to determine Condition-level compliance.
10.00.01 Organ procurement protocols *The CAH must have and implement written protocols that—* ▪ *Incorporate an agreement with an OPO designated under 42 CFR 486, 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 CAH.* *The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, 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 CAH for this purpose.* §485.643(a) Tag C-1503	☐ Compliant ☐ Not Compliant The CAH must have a written agreement with an Organ Procurement Organization (OPO) designated under §486. At a minimum, the written agreement must address: ▪ The criteria for referral, including the referral of all individuals whose death is imminent or who have died in the CAH. ▪ 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 CAH-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. ▪ Ensuring that the designated requestor training program offered by the OPO has been developed in cooperation with the tissue bank and eye bank designated by the CAH. ▪ Permitting the OPO, tissue bank, and eye bank access to the CAH'S death record information according to a designated schedule, e.g., monthly or quarterly.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The written agreement with the OPO addresses all required information. ▪ The CAH'S governing body has approved the organ procurement policies. ▪ A sample of death records demonstrate that the CAH has implemented its organ procurement policies. ▪ Staff are aware of the CAH'S policies and procedures for organ, tissue, and eye procurement. ▪ Organ, tissue, and eye donation is integrated into the CAH'S QAPI Program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- That the CAH 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.
- The interventions the CAH will use to maintain potential organ donor patients so that the patient organs remain viable.

WHEN DEATH IS IMMINENT

- CAHs must notify the OPO of every death or imminent death in the CAH.
- When death is imminent, the CAH must notify the OPO both before a potential donor is removed from a ventilator and while the potential donor's organs are still viable.

DEFINITION

The definition for "imminent death" should strike a balance between the needs of the OPO and the needs of the CAH'S caregivers 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 CAHs will create a partnership that furthers donation, while respecting the perspective of CAH 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

- has clinical findings consistent with a Glascow Coma Score that is less than or equal to a mutually-agreed-upon threshold.

Note: In determining the appropriate threshold for the Glasgow 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 CAH'S OPO or organizations such as the Association of Organ Procurement

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Organizations.

OR

- for whom MD/DOs are evaluating a diagnosis of brain death.

OR

- for whom an MD/DO has ordered that life sustaining therapies be withdrawn, pursuant to the family's decision.

The CAH and its OPO should develop a definition of "imminent death" that includes specific triggers for notifying the OPO about an imminent death.

The definition agreed to by the CAH 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 particular circumstances in each CAH.

Note: 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.

BATCH REPORTING

CAHs 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 CAH to another, it is the receiving CAH'S responsibility to notify the OPO.

TIMELY NOTIFICATION

- "Timely notification" means a CAH 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 CAH 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 CAH does not consider an individual who is not on a ventilator to be a potential donor, the CAH must call the OPO as soon as possible after the death of that individual has occurred.

Referral by a CAH to an OPO is timely if it is made:

- as soon as it is anticipated a patient will meet the criteria for imminent death agreed to by the OPO and CAH or as soon as possible after a patient meets the criteria for imminent death agreed to by the OPO and the CAH (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), ensures that the family is approached only if the patient is medically suitable for organ donation, and ensures that an OPO representative is available to collaborate with the CAH 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 CAH, 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 CAH for this purpose.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
10.00.02 Tissue and eye bank agreements *The CAH 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 an agreement does not interfere with organ procurement;* §485.643(b) Tag C-1505	☐ Compliant ☐ Not Compliant The CAH must have an agreement with at least one tissue bank and at least one eye bank. The OPO may serve as a "gatekeeper" receiving notification about every CAH death and should notify the tissue bank chosen by the CAH about potential tissue and eye donors. It is not necessary for a CAH 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 CAH to have a separate agreement with an eye bank if its OPO provides eye procurement services. The CAH 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 OPO, chosen by the CAH. The CAH may continue current successful direct arrangements with tissue and eye banks as long as the direct arrangement does not interfere with organ procurement.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the CAH has an agreement with at least one tissue bank and one eye bank that specifies criteria for referral of all individuals who have died in the CAH. □ The agreement must also acknowledge that it is the OPO's responsibility to determine medical suitability for tissue and eye donation unless the CAH has an alternative agreement with a different tissue and/or eye bank.
10.00.03 Designated requestors *The CAH must have and implement written protocols that—* ▪ *Ensure, in collaboration with the designated OPO, that the family of*	☐ Compliant ☐ Not Compliant It is the responsibility of the OPO to screen for medical suitability to select potential donors.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The family of each potential donor is

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. ▪ *The individual designated by the CAH to initiate the request to the family must be 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 community in the methodology for approaching potential donor families and requesting organ or tissue donation.* §485.643(c) Tag C-1507	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 CAH will decide together how and by whom the family will be approached. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A "designated requestor" is defined as a CAH-designated individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community. If possible, the OPO representative and a designated requestor should approach the family together.	informed of its options to donate organs, tissues, or eyes, including the option to decline to donate. ▪ All designated requestors have completed the required training. □ How does the CAH ensure that only designated requestors are approaching families to ask them to donate?
10.00.04 <u>Training of designated requestors regarding discretion and sensitivity</u> *The CAH must have and implement written protocols that—* ▪ *Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the family of potential donors*. §485.643(d) Tag C-1509	☐ Compliant ☐ Not Compliant All potential donor families must be approached and informed of their donation rights. CAHs should approach each family with the belief that a donation is possible and should take steps to ensure the family is treated with respect and care. The 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.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Interview a CAH-designated requestor regarding approaches to donation requests. ▪ Review the designated requestor training program to verify that it addresses the use of discretion. ▪ Review the facility complaint file for any relevant complaints.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
10.00.05 Staff education and death record review *The CAH must have and implement written protocols that—* ▪ *Ensure that the CAH 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, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes takes place.* ▪ *For purpose of these standards, the term "organ" means a human kidney, liver, heart, lung, pancreas, or intestines (or multi visceral organs).* §485.643(e-f) Tag C-1511	☐ Compliant ☐ Not Compliant Appropriate staff, including all patient care 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 and how to work with the OPO, tissue bank and eye bank. 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 CAH's QA program. **REVIEW OF DEATH RECORDS** CAHs must cooperate with OPOs, tissue banks and eye banks in regularly/ periodically reviewing death records. ▪ This means that a CAH must develop policies and procedures which permit the OPO, tissue bank, and eye bank access to death record information that will allow assessment of donor potential, ensure that all deaths or imminent deaths are being referred to the OPO in a timely manner, and identify areas where the CAH, OPO, tissue bank, and eye bank staff performance might be improved. ▪ The policies must address how patient confidentiality will be maintained during the review process.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ All appropriate staff have attended an educational program regarding donation issues and how to work with the OPO, tissue bank, and eye bank. □ Review in-service training schedules and attendance sheets. ▪ The CAH works with the OPO, tissue bank, and eye bank in reviewing death records. ▪ The effectiveness of any protocols and policies is monitored as part of the CAH'S quality improvement program. ▪ Protocols that are in place to guide record reviews and analysis. □ Validate how often the reviews are to occur. ▪ Confidentiality is ensured. ▪ Policies and procedures ensure coordination between the facility staff and the OPO staff in maintaining the potential donor. ▪ Policies and procedures ensure that potential donors are identified and declared dead by an appropriate practitioner within an acceptable timeframe.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	POLICIES AND PROCEDURES The CAH must have policies and procedures, developed in cooperation with the OPO, that ensure that potential donors are maintained in a manner that support viability of their organs. The CAH must have policies in place to ensure that potential donors are identified and declared dead within an acceptable time frame by an appropriate practitioner.	

11

SWING BEDS

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

☐ N/A. This chapter is not applicable. The facility has no swing-beds.

11.00.00 CONDITION OF PARTICIPATION: Special requirements for hospital providers of long-term care services ("Swing-Beds")

A CAH must meet the following requirements in order to be granted an approval from CMS to provided post-CAH SNF care, as specified in 42 CFR §409.30, and to be paid for SNF-level services, in accordance with 42 CFR §485.645(c).

§485.645 Tag C-1600

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The swing-bed concept allows a CAH 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 services and reimbursement to receiving skilled nursing (SNF) services and reimbursement.

SWING-BED APPROVAL FROM MEDICARE

Medicare allows a CAH to operate swing-beds through the issuance of a "swing-bed approval."

- If the facility fails to meet the swing-bed requirements, and the facility does not develop and implement an accepted plan of correction, the facility loses the approval to operate swing-beds and receive swing-bed reimbursement. The facility does not go on a termination track. If the CAH continues to meet the CoP for the provider type, it continues to operate but loses swing-bed approval.

LOCATION OF SWING BEDS

- Swing beds need not be located in a special section of the CAH.
- The patient need not change location in the facility merely because his/her status changes unless the facility requires it.
- The change in status from acute care to swing-bed status can occur within one facility, or the patient can be transferred from another facility for swing-bed admission.

OBSERVATION, INTERVIEW AND DOCUMENT REVIEW

- Based on document review, observations, and interviews, verify that the CAH meets the swing-bed requirements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

DISCHARGE ORDERS

- There must be discharge orders from acute inpatient care 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.

MEDICAL RECORD

The same clinical record may be used for a swing-bed patient:

- It must include discharge orders from acute care and admission orders to swing-bed services.
- The swing-bed services which may be skilled nursing facility (SNF)- or nursing facility (NF)-level services, must be clearly delineated within the clinical record.

LENGTH OF STAY

- There is no length of stay restriction for any CAH 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 the CAH 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 CAH should document in the patient's medical record efforts made for nursing facility placement.

3-DAY QUALIFYING STAY

- Medicare coverage rules require that, in order to be eligible for coverage of post-hospital swing-bed care, a beneficiary must have a qualifying 3-day inpatient stay in a participating or qualified CAH prior to admission to a swing-bed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ There is no requirement for a CAH to use the Minimum Data Set (MDS) tool for recording the patient assessment or for nursing care planning. **REIMBURSEMENT** ▪ Swing-bed patients receive a SNF level of care, and the CAH is reimbursed for providing a SNF level of care, however swing-bed patients are not SNF patients. ▪ Swing-bed patients in a critical access hospital are considered patients of the CAH. **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 CAH but is a separately certified provider with its own Medicare provider agreement**.**	
11.00.01 Eligibility *A CAH must meet the following eligibility requirements:* *(1) The facility has been certified as a CAH by CMS under 42 CFR §485.606(b); and* *(2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under 42 CFR 485.645(a).* §485.645(a)(1) Tag C-1602 §485.645(a)(2)	☐ Compliant ☐ Not Compliant CAHs seeking swing-bed approval are screened prior to survey for their eligibility for swing-beds. The CMS Location (Regional Office) determines whether the CAH has satisfied the eligibility criteria, not ACHC. An initial CAH applicant may seek swing-bed approval. If the CAH applicant meets all federal requirements for participation, including those for swing-bed approval, the CAH applicant's approval for swing-bed services will be effective with the CAH's effective date of Medicare participation.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The CAH has a Medicare provider agreement. ▪ The facility has been certified as a CAH by CMS. ▪ The CAH satisfies CMS Location eligibility criteria for swing beds. □ The facility has received a CMS swing-bed approval letter OR

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		◻ for an initial CAH application to CMS, the facility's swing bed approval is pending. ▪ The number of beds available for patient occupancy in an inpatient, observation or swing bed status does not exceed 25 beds.
11.00.02 Facilities participating as rural primary care hospitals *These facilities must meet the following requirements:* *(1) Notwithstanding 42 CFR 485.645(a), a CAH that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions, and limitations that were applicable at the time these approvals were granted.* *(2) A CAH that was granted swing-bed approval under 42 CFR 485.645(b)(1) (above) may request that its application to be a CAH and swing-bed provider be reevaluated under 42 CFR 485.645(a) (above).* *If this request is approved, the approval is effective not earlier than October 1,*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine if the CAH has participated in Medicare as a rural primary care hospital on or before September 30, 1997, and has been approved by CMS to provide post-hospital SNF care or swing-bed services.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
1997. As of the date of approval, the CAH no longer has any status under 42 CFR 485.645(b)(1) and may not request reinstatement under 42 CFR 485.645(b)(1). §485.645(b)(1) §485.645(b)(2) Tag C-1604		
11.00.03 Payment		**Note**: This standard regarding payment is not scored by surveyors.
Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in 42 CFR 485.645(a) (see above) is made in accordance with 42 CFR §413.70. *Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in 42 CFR §413.114.* §485.645(c) Tag C-1606	No additional information.	
11.00.04 Skilled Nursing Facility services		**Note:** These requirements are scored individually throughout the chapter.
The CAH is substantially in compliance with the following SNF 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), (g)(8), (g)(17), (g)(18) introductory text, and (h)*	No additional information.	

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(2) Admission, transfer, and discharge rights (§483.5 definition of transfer & discharge, §483.15(c)(1), (c)(2), (c)(3), (c)(4), (c)(5), (c)(7), (c)(8), and (c)(9)

(3) Freedom from abuse, neglect, and exploitation (§483.12(a)(1), (a)(2), (a)(3)(i), (a)(3)(ii), (a)(4), (b)(1), (b)(2), (c)(1), (c)(2), (c)(3), and (c)(4) (c)),

(4) Social services (§483.40(d)),

(5) Comprehensive assessment, comprehensive care plan, and discharge planning (§483.20(b), §483.21(b) and (c)(2)),

(6) Specialized rehabilitative services (§483.65),

(7) Dental services (§483.55),

(8) Nutrition (§483.25(g)(1) (g)(2)).

§485.645(d)(1) Tag C-1608
§485.645(d)(2) Tag C-1610
§485.645(d)(3) Tag C-1612
§485.645(d)(4) Tag C-1616
§485.645(d)(5) Tag C-1620
§485.645(d)(6) Tag C-1622
§485.645(d)(7) Tag C-1624
§485.645(d)(8) Tag C-1626

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.01.01 Resident rights	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH must be in substantial compliance with the following skilled nursing facility requirements: ▪ *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 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) ▪ *To be informed of, and participate in, his or her treatment.* §483.10(c) ▪ *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)(1) ▪ *To be informed, in advance, of changes to the plan of treatment.* §483.10(c)(2)(iii)	Long-term residents have rights guaranteed to them under federal and state law. The CAH provides a written list of resident rights to the swing-bed resident upon admission to the program.	**OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The facility has a process to provide a written list of resident rights to the swing-bed resident. ▪ The list of resident rights includes all required elements. ▪ Medical records confirm the resident rights have been provided to the resident/resident's representative.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ *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) ▪ *To choose his or her attending physician.* §483.10(d) ▪ *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) ▪ *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) ▪ *To have immediate access to the resident's immediate family and other relatives of the resident, subject to the resident's right to deny or withdraw consent at any time.* §483.10(f)(4)(ii) ▪ *To have immediate access to others who are visiting with the consent of the resident, subject to reasonable clinical and safety restrictions and the*		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

resident's right to deny or withdraw consent at any time.
§483.10(f)(4)(iii)

- *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 the postal services.*
  §483.10(g)(8)
- *To be informed at time of admission, when the resident becomes eligible for Medicaid, and periodically during the resident's stay of items and services included under the State plan for which the resident may not be charged; and those other items and services the facility offers for which the resident may be charged and the amount of charges for those services.*
  §483.10(g)(17); §483.10(g)(18)
- *To have personal privacy and confidentiality of personal and medical records.*
  §483.10(h)

§485.645(d)(1) Tag C-1608

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.01.02 Resident adjudged incompetent	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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 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) §485.645(d)(1) Tag C-1608	The CAH has written policies that describe the process for ensuring the representative of the incompetent resident acts on behalf of the resident.	**DOCUMENT REVIEW** ▪ Review facility policies to verify all required elements are met. ▪ Review the medical record of at least one patient adjudged incompetent by a court to determine these requirements are met.
11.01.03 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.	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ On-going efforts on the part of facility staff to keep residents informed and involved with care planning. ▪ 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

STANDARD		REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.645(d)(1)	Tag C-1608	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: ▪ 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.	when they are expressing concerns, raising questions, and on an on-going basis? ▪ Evidence that the resident was afforded the right to participate in care planning or was consulted about care and treatment changes. □ 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. ▪ If there appears to be a conflict between a resident's right and the resident's health or safety, determine whether 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, were they kept informed and consulted on personal preferences to the level of their ability to understand?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.01.04 Informed of changes to the plan of care *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.* §483.10(c)(2)(iii) §485.645(d)(1) Tag C-1608	☐ 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 decision.	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 changes in care.
11.01.05 Right to request, refuse, and/or discontinue treatment *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) §485.645(d)(1) Tag C-1608	☐ Compliant ☐ Not Compliant "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	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Facility policies meet all required elements. ▪ Advance directives were requested for all patients and copies are available in medical records. ▪ Facility compliance with advance directive notice requirements. □ 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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 healthcare 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 §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 (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. ▪ 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 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	▪ The hospital educates its staff regarding advance directives. ▪ The hospital provides education for the community regarding individual rights under state law to formulate advance directives.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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.	
11.01.06 Choice of attending physician *The resident has the right to choose his or her attending physician.* *(1) The physician must be licensed to practice, and* *(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.* *(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*	☐ Compliant ☐ Not Compliant A resident in a swing-bed 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.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Facility policies meet all required elements. ▪ Patients confirm they were given the opportunity to select their own personal physician.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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 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) §485.645(d)(1) Tag C-1608	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.	
11.01.07 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) §485.645(d)(1) Tag C-1608	☐ 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** Verify: ▪ Facility policies meet all required elements. ▪ Personal possessions are apparent in patient rooms. If few personal possessions are evident, ask residents and families if: □ They are encouraged to have and use personal items.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		☐ Their personal property is safe in the facility.
11.01.08 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) §485.645(d)(1) Tag C-1608	☐ 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** Verify: ▪ Policies meet required elements. ▪ Married residents have a shared room, if requested.
11.01.09 Access to family and visitation rights *The resident has a right to receive visitors of his or her choosing at the time of his or her choosing, subject to the resident's right to deny visitation when applicable, and in a manner that does not impose on the rights of another resident.* *(i) 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.* *(ii) 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*	☐ 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 confirm that the process is in force.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
restrictions and the resident's right to deny or withdraw consent at any time. §483.10(f)(4)(ii-iii) §485.645(d)(1) Tag C-1608		
11.01.10 For future use		
11.01.11 Mail *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) Access to stationery, postage, and writing implements at the resident's own expense.* §483.10(g)(8) §483.10(g)(8)(i-ii) §485.645(d)(1) Tag C-1608	☐ Compliant ☐ Not Compliant Prompt delivery of mail is expected. "Prompt" 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.	This standard is not met as evidenced by: **INTERVIEW** ▪ Interview the person responsible for the swing bed unit to determine how the requirement is met. ▪ Interview a resident to verify that the requirement is met.
11.01.12 Medicare and Medicaid notification *The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of*	☐ Compliant ☐ Not Compliant 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.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review facility policies, documents, and patient medical records to verify

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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;*

(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 §483.10(g)(17)(i)(A) and (B).

§483.10(g)(17)
§483.10(g)(17)(i)(A)
§483.10(g)(17)(i)(B)(i-ii)
§483.10(g)(18)
§485.645(d)(1) Tag C-1608

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
- 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

that notification of covered services and charges is enforced.

- Ask a 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
11.01.13 Personal privacy and confidentiality *The resident has the right to personal privacy and confidentiality of 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.* (i) *The resident has the right to refuse the release of personal and medical records except as provided at §483.70(i)(2) or other applicable Federal or State laws.*	☐ 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, 20xx. Identify the responsible party, if possible.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(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) §483.10(h)(1-2) §483.10(h)(3)(i-ii) §485.645(d)(1) Tag C-1608		
11.02.01 Admission, transfer, and discharge rights *The facility must be in substantial compliance with the following skilled nursing facility requirements which are scored individually*. *(1) Definition of Transfer (§483.5).* *(2) Transfer and Discharge §483.15(c)(1), (c)(3), (c)(4), (c)(5), (c)(7), (c)(8), and (c)(9)* §485.645(d)(2) Tag C-1610	See additional information at standards below.	**Note:** Deficiencies regarding transfers and discharge will be scored at the relevant standards that follow.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.02.02 Definition of transfer and discharge *Transfer and discharge includes 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 does not refer to movement of a resident to a bed within the same certified facility.* §483.5 §485.645(d)(2) Tag C-1610	☐ Compliant ☐ Not Compliant The intent of the regulation on transfer and discharge provisions 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** Verify: ▪ Facility policies meet all required elements. ▪ The records of at least five swing-bed patients transferred/ discharged from the facility since the last survey reflect that the reasons for transfer/discharge were documented by the physician.
11.02.03 Transfer and discharge: Facility requirements (1) *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 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 the record if the resident was transferred/discharged for the sake of the resident's welfare and

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 42 CFR §431.230, when a resident exercises his or her right to appeal a transfer or discharge notice from the facility pursuant to 42 CFR §431.220(a)(3), unless the failure to discharge or transfer would endanger the*		the resident's needs could not be met in the facility (e.g., a resident develops an acute condition requiring hospitalization) or 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
health 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) §483.15(c)(1)(A-F) §483.15(c)(1)(F)(ii) §485.645(d)(2) Tag C-1610		
11.02.04 Transfer and discharge: Documentation requirements *When the facility transfers or discharges a resident under any of the circumstances specified above in 42 CFR* §483.15(c)(1)(i)(A) through (F), *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) *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*	☐ Compliant ☐ Not Compliant Transfer and discharge documentation may be completed by a physician extender unless prohibited by state law or facility policy.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review medical records of patients who were transferred to confirm that the reason for transfer was documented by a physician or physician extender.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

needs, and the service available at the receiving facility 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) *A physician when transfer or discharge is necessary as described above in 42 CFR 483.15(c)(1)(i)(C) or (D)*

(iii) *Information provided to the receiving provider must include a minimum of the following:*

(A) *Contact information of the practitioner responsible for the care of the resident.*

(B) *Resident representative information including contact information.*

(C) *Advance Directive information.*

(D) *All special instructions or precautions for ongoing care, as appropriate.*

(E) *Comprehensive care plan goals,*

(F) *All other necessary information, including a copy of the resident's discharge summary, consistent with 42 CFR §483.21(c)(2), as applicable, and any other documentation, as*

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
applicable, to ensure a safe and effective transition of care. §483.15(c)(2) §483.15(c)(2)(i-iii) §483.15(c)(2)(iii)(F) §485.645(d)(2) Tag C-1610		
11.02.05 Notice before transfer *Before a facility transfers or discharges a resident, the facility must—* (i) *Notify the resident and the resident's representative(s) of the transfer or 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 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 in accordance with 42 CFR 483.15(c)(2) (see above); and* (iii) *Include in the notice the items described in 42 CFR 483.15(c)(5).* §483.15(c)(3)(i-iii) §485.645(d)(2) Tag C-1610	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **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 criteria. □ The resident/representative was provided written notification of the transfer/discharge in a language they understood. □ A copy of the transfer/discharge notification was sent to the Office of the State Long-Term Care Ombudsman.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.02.06 Timing of the notice	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
(i) 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. *(ii) 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.* (D) *An immediate transfer or discharge is required by the resident's urgent medical needs;* *or* (E) *A resident has not resided in the facility for 30 days.* §483.15(c)(4)(i) §483.15(c)(4)(ii)(A-E) §485.645(d)(2) Tag C-1610	No additional information.	**DOCUMENT REVIEW** ▪ Review the policy and a minimum of three transfer discharge records to verify that notice was given 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.02.07 Content 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;* (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*	No additional information.	**DOCUMENT REVIEW** ▪ Review a minimum of three transfer/discharge records to verify compliance.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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)(i-vii) §485.645(d)(2) Tag C-1610		
11.02.08 <u>Orientation for transfer or discharge</u> *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) §485.645(d)(2) Tag C-1610	☐ Compliant ☐ Not Compliant "Sufficient preparation" means the facility informs the resident about where he or she is going and takes steps within its control to assure safe transportation. Orientation may include: ▪ Trial visits, if possible, by the resident to a new location. ▪ Working with family by requesting their assistance in assuring the resident that valued possessions are not left behind or lost. ▪ Orienting staff in the receiving facility to resident's daily patterns. ▪ Sharing with the resident the routine for handling transfers and discharges to minimize avoidable anxiety or depression and recognizing/addressing characteristic resident reactions identified by the care plan. The medical record documents the preparation and orientation.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review social service notes to see if appropriate referrals have been made and, if necessary, resident counseling has occurred.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.02.09 Notice in advance of facility closure *In the case of facility closure, the individual who is the administrator of the facility must provide written notification prior to the impending closure to the State Survey Agency, the Office of the State Long-Term Care Ombudsman, residents of the facility, and the resident representatives, as well as the plan for the transfer and adequate relocation of the residents, as required at 42 CFR §483.70(l).* §483.15(c)(8) §485.645(d)(2) Tag C-1610	☐ Compliant ☐ Not Compliant The facility has a written policy that describes the processes to be implemented in the event the facility closes. In the event a facility closes, the administrator is responsible to provide written communication regarding the plan to transfer or relocate the residents to each of the following: 1. The state Survey Agency. 2. The Office of the State Long-Term Care Ombudsman. 3. The residents' representatives.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview the facility administrator to identify the process in place. ▪ Verify that the facility has a written policy that includes all required elements.
11.02.10 Room changes in composite distinct part unit (DPU) *Room changes in a facility that is a composite distinct part (as defined in 42 CFR §483.5) are subject to the requirements of 42 CFR §483.10(e)(7) and must be limited to moves within the particular building in which the resident resides, unless the resident voluntarily agrees to move to another of the composite distinct part's locations.* §483.15(c)(9) §485.645(d)(2) Tag C-1610	☐ Compliant ☐ Not Compliant In accordance with §483.10(e)(7), the resident has the right to refuse to transfer to another room in the facility, if the purpose of the transfer is: ▪ to relocate a resident of a SNF from the distinct part of the institution that is a SNF to a part of the institution that is not a SNF. ▪ to relocate a resident of a NF from the distinct part of the institution that is a NF to a distinct part of the institution that is a SNF. ▪ solely for the convenience of staff.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify the facility has a written policy that contains all required elements. ▪ Interview the staff to confirm that a process is in place.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.03.01 Freedom from abuse, neglect, and exploitation		**Note:** Deficiencies related to these requirements will be scored at the relevant standards that follow.
The facility must be in substantial compliance with the following skilled nursing facility requirements which are scored individually. *Freedom from abuse, neglect, and exploitation* §483.12(a)(1-2) §483.12(a)(3)(ii) §483.12(a)(4) §483.12(b)(1-2) §483.12(c)(1-4) §485.645(d)(3) Tag C-1612	No additional information.	
11.03.02 Resident rights: 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.* *The facility must -* *(1) Not use verbal, mental, sexual, or*	☐ 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	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW AND DOCUMENT REVIEW** ▪ Review the policy on abuse to confirm that it addresses the six types of abuse identified in the standard in item (1). ▪ 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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 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)(1-2) §485.645(d)(3) Tag C-1612	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, 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 or saying things to frighten a resident, such as telling a resident that they will never be able to see their 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 of time 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	▪ Offsite, pre-survey review of complaints can focus the survey team's on-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? ▪ Manipulate the resident's

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

consent.

The facility has written policies establishing the staff treatment of residents including unacceptable behaviors and consequences.

The intent of this regulation is to assure that the facility has in place an effective system that prevents mistreatment, neglect and abuse of residents, and misappropriation of resident's property.

"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 not required to treat medical symptoms.

"Discipline" is defined as any action taken by the facility for the purpose of 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).

environment?

- ☐ Can the cause(s) be removed?
- ☐ If the cause(s) cannot be removed, has the facility attempted to use alternatives short of separation?
- ☐ Does the facility use the separation for the least amount of time?
- ☐ To what extent has the resident, surrogate or representative participated in care planning and made an informed choice about separation?
- ☐ Does the facility monitor and adjust care to reduce negative outcomes, while continually trying to find and use less restrictive alternatives?
- ☐ If residents are temporarily separated in secured units, staff should carry keys to these units at all times.

Note: 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 resident rights, as long as the resident's individual care plan indicates the need for the stated purpose and services provided in the unit

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		and the resident, surrogate, or representative has participated in the placement decision. ▪ Interview the person responsible for the swing bed unit to determine how the requirement was met.
11.03.03 Employment restrictions and screening of staff *The facility must –* ▪ *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; 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;* ▪ *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)(i-ii) §483.12(a)(4) §485.645(d)(3) Tag C-1612	☐ Compliant ☐ Not Compliant The facility has written policies establishing both: 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. 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. 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...by a court of law" 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. 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	This standard is not met as evidenced by: **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. ▪ Spot check employment applications for questions about convictions or mistreatment, neglect or abuse of residents, or misappropriation of their property. □ Determine if applicants have answered these questions and if affirmative answers or findings had resulted in rejections of employment candidates. ▪ Contact the State Nurse Aide Registry or Board of Nursing, as appropriate.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	entered into the nurse aide registry, or reported to the licensing authority, as appropriate. "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.	
11.03.04 Facility prohibits and prevents abuse *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)(1-2) §485.645(d)(3) Tag C-1612	☐ Compliant ☐ Not Compliant The facility has written policies that address: ▪ Abuse, neglect, and exploitation of residents and their property are prohibited. ▪ Processes to investigate allegations of abuse, neglect, and exploitation of residents and their property.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the facility's policies to verify that 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.
11.03.05 Reporting allegations of patient mistreatment, neglect, or abuse *In response to allegations of abuse, neglect, exploitation, or mistreatment, the facility must:* *(1) Ensure that all alleged violations involving abuse, neglect, exploitation or mistreatment, including injuries of unknown source and misappropriation of resident property are reported*	☐ Compliant ☐ Not Compliant The facility has written policies establishing the procedure to be implemented in response to allegations of abuse, neglect, exploitation, or mistreatment of a resident. Investigations should occur as close to the time of the incident as possible. The chain of evidence should be secured in a safe place.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the policy and procedure to verify that it meets the requirement. ▪ Verify that reported cases of abuse have been investigated by review of the documentation. ▪ Interview the administrator to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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 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. *(2) Have evidence that all alleged violations are thoroughly investigated.* *(3) Prevent further potential abuse, neglect, exploitation, or mistreatment while the investigation is in progress.* *(4) 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)(1-4) §485.645(d)(3) Tag C-1612		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. □ Was the administrator notified of the incident and when? □ 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 the alleged victim from further abuse (particularly where no suspect has been identified)? □ What actions were taken as a result

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		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)?
11.04.01 For future use		
11.05.01 Social Services *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) §483.645(d)(4) Tag C-1616	☐ Compliant ☐ Not Compliant "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 obtaining needed 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	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review medical records for 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 social work staff monitor the resident's progress in improving physical, mental and psychosocial functioning? Has goal attainment been evaluated, and the care plan

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	preplanning 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 or not 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. ▪ 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.	changed accordingly? □ How does the care plan link goals to psychosocial functioning/well-being? □ Has the social work staff established and maintained relationships with the resident's family or legal representative? □ What does the facility do 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.
11.05.02 For future use		
11.06.01 <u>Comprehensive assessment</u> *A facility must make a comprehensive assessment of a resident's needs, strengths, goals, life history and preferences. The assessment must include at least the following:* *(i) Identification and demographic information.*	☐ Compliant ☐ Not Compliant The CAH has identified the components of a comprehensive assessment, including at a minimum, all elements listed in the standard. **Note:** The CAH is not required to use the resident assessment instrument (RAI) specified by the state that is required under §483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in §413.343(b) of this chapter.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review a sample of medical records to verify that a complete assessment has been completed for each resident, consistent with the standard.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(ii) Customary routine.

(iii) Cognitive patterns.

(iv) Communication.

(v) Vision.

(vi) Mood and behavior patterns.

(vii) Psychosocial well-being.

(viii) Physical functioning and structural problems.

(ix) Continence.

(x) Disease diagnoses and health conditions.

(xi) Dental and nutritional status.

(xii) Skin condition.

(xiii) Activity pursuit.

(xiv) Medications.

(xv) Special treatments and procedures.

(xvi) Discharge planning.

(xvii) Documentation of summary information regarding the additional assessment performed on the care areas triggered by the completion of the Minimum Data Set (MDS).

(xviii) Documentation of participation in assessment. The assessment process must include direct observation and communication with the resident, as well as communication with licensed and non-licensed direct care staff members on all shifts.

§483.20(b)(1)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§483.20(b)(1)(i-xviii) §483.645(d)(5) Tag C-1620		
11.06.02 Assessment timeframes Assessments must be conducted: *(i) Within 14 calendar days after admission, excluding readmissions in which there is no significant change in the resident's physical or mental condition.* §483.20(b)(2) §483.20(b)(2)(i) §483.645(d)(5) Tag C-1620	☐ Compliant ☐ Not Compliant For purposes of this standard, "readmission" means a return to the facility following a temporary absence for hospitalization or for therapeutic leave.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review medical records for assessments and timing.
11.06.03 Reassessments Reassessments must be conducted: ▪ *Within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition.* ▪ *Not less often than once every 12 months.* §483.20(b)(2)(ii) §483.20(b)(2)(iii) §483.645(d)(5) Tag C-1620	☐ Compliant ☐ Not Compliant For purposes of this standard, a "significant change" means a major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status and requires inter-disciplinary review or revision of the care plan, or both.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review medical records for reassessments, timing, and frequency.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
11.06.04 Comprehensive care plans	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The facility must develop and implement a comprehensive person-centered care plan for each resident, consistent with the resident rights set forth at 42 CFR §483.10(c)(2) and 42 CFR §483.10(c)(3), that includes measurable objectives and timetables to meet a resident's medical, nursing, mental and psychosocial needs that are identified in the comprehensive assessment. *The comprehensive care plan must describe the following—* *(i) The services that are to be furnished to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being as required under, 42 CFR §483.25, 42 CFR §483.40; and* *(ii) Any services that would otherwise be required under, 42 CFR §483.25, or 42 CFR §483.40 but are not provided due to the resident's exercise of rights under 42 CFR §483.10, including the right to refuse treatment under 42 CFR §483.10(c)(6).* *(iii) Any specialized services or specialized rehabilitative services the nursing facility will provide as a result of PASARR recommendations. If a facility*	An interdisciplinary team, in conjunction with the resident, resident's family, surrogate, or representative, as appropriate, should develop quantifiable objectives for the highest level of functioning the resident may be expected to attain, based on the comprehensive assessment. The care plan must reflect intermediate steps for each outcome objective if identification of those steps will enhance the resident's ability to meet his/her objectives. Facility staff will use these objectives to follow resident progress. Facilities may, for some residents, need to prioritize needed care. This should be noted in the clinical record or on the plan of care. The requirements reflect the facility's responsibility to provide necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. If the needs of the patient include interest-based group and/or individual activities that support the patient's well-being, the CAH will provide these activities. However, in some cases, a resident may wish to refuse certain services or treatments that professional staffs believe may be indicated to assist the resident in reaching his or her highest practicable level of well-being. Desires of the resident should be documented in the clinical record. **Note:** CAHs are not required to complete the PASARR. However, if a patient had a PASARR completed by a facility that was required to do so prior to admission into a CAH swing bed, the recommendations from the PASARR should be included in the CAHs comprehensive treatment plan for the patient.	**INTERVIEW AND DOCUMENT REVIEW** Review a sample of medical records to assess: ▪ Does the care plan address the needs, strengths and preferences identified in the comprehensive assessment? ▪ Is the care plan oriented toward preventing avoidable declines in functioning or functional levels? ▪ How does the care plan attempt to manage risk factors? ▪ Does the care plan build on resident strengths? ▪ Do treatment objectives have measurable outcomes? ▪ Does the care plan reflect standards of current professional practice? ▪ Corroborate information regarding the resident's goals and wishes for treatment in the plan of care by interviewing residents; especially those identified as refusing treatment. ▪ Determine whether the facility has provided adequate information to the resident so that the resident was able to make an informed choice

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
disagrees with the findings of the PASARR, it must indicate its rationale in the resident's medical record. *(iv) In consultation with the resident and the resident's representative(s)—* (A) *The resident's goals for admission and desired outcomes.* (B) *The resident's preference and potential for future discharge. Facilities must document whether the resident's desire to return to the community was assessed and any referrals to local contact agencies and/or other appropriate entities, for this purpose.* (C) *Discharge plans in the comprehensive care plan, as appropriate, in accordance with the requirements set forth in 42 CFR 483.12(c).* §483.21(b) §483.21(b)(1)(i-iii) §483.21(b)(1)(iv)(A-C) §483.645(d)(5) Tag C-1620		regarding treatment. ▪ If the resident has refused treatment, does the care plan reflect the facility's efforts to find alternative means to address the problem?
11.06.05 <u>Care plan requirements</u> *A comprehensive care plan must be—* (i) *Developed within 7 days after the*	☐ Compliant ☐ Not Compliant "Interdisciplinary" means that professional disciplines, as appropriate, will work together to provide the greatest benefit to the resident.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Was interdisciplinary expertise used

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

completion of the comprehensive assessment;

(ii) *Prepared by an interdisciplinary team, that includes but is not limited to:*

(A) *The attending physician* (MD/DO).

(B) *A registered nurse with responsibility for the resident.*

(C) *A nurse aide with responsibility for the resident.*

(D) *A member of the food and nutrition services staff.*

(E) *To the extent practicable, the participation of the resident and the resident's representative(s). An explanation must be included in a resident's medical record if the participation of the resident and their resident representative is determined not practicable for the development of the resident's care plan.*

(F) *Other appropriate staff or professionals in disciplines as determined by the resident's needs or as requested by the resident.*

(iii) *Reviewed and revised by the interdisciplinary team after each assessment, including both the comprehensive and quarterly review assessments.*

- It does not mean that every goal must have an interdisciplinary approach. The mechanics of how the interdisciplinary team meets its responsibilities in developing an interdisciplinary care plan (e.g., a face-to-face meeting, teleconference, written communication) are at the discretion of the facility.
- The MD/DO must participate as part of the interdisciplinary team, and may arrange with the facility for alternative methods, other than attendance at care planning conferences, of providing his/her input, such as one-to-one discussions and conference calls.

The resident has the right to refuse specific treatments and to select among treatment options before the care plan is instituted. The facility should encourage residents, surrogates, and representatives to participate in care planning, including encouraging attendance at care planning conferences if they so desire.

to develop a plan to improve the resident's functional abilities?

- For example, did an occupational therapist design need-adaptive equipment or a speech therapist provide techniques to improve swallowing ability?

Did the dietitian and the speech therapist determine optimum textures and consistency for the resident's food that provide both a nutritionally adequate diet and their oropharyngeal capabilities?

Is there evidence of MD/DO involvement in development of the care plan (e.g., presence at care planning meetings, conversations with team members concerning the care plan, conference calls)?

- In what ways does staff involve residents and families, surrogate, and/or representatives in care planning?
  - For example, are care plan meetings scheduled at the best time of the day for residents and their families?

Does facility staff attempt to make the process understandable to the resident/family?

Is the care plan evaluated and revised as the resident's status

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
The services provided or arranged by the facility, as outlined by the comprehensive care plan, must— (i) *Meet professional standards of quality.* (ii) *Be provided by qualified persons in accordance with each resident's written plan of care.* (iii) *Be culturally-competent and trauma-informed.* §483.21(b)(2-3)(iii) §485.645(d)(5) Tag C-1620		changes? ▪ Ask in your resident interviews, "Have you had concerns or questions about your care and brought them to the attention of facility staff?" If yes, ask "What happened as a result?"
11.06.06 Discharge summary	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
When the facility anticipates discharge, a resident must have a discharge summary that includes, but is not limited to the following: *(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 483.20(b)(1), 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, and*	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. "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:	**DOCUMENT REVIEW** Review a select group of medical records to verify: ▪ The discharge summary includes information pertinent to continuing care for the resident ▪ There is evidence of discharge planning in the records of discharged residents who had an anticipated discharge or those residents to be discharged shortly (e.g., in the next 7-14 days). ▪ Discharge plans address necessary post discharge care. ▪ The facility aided the resident and their family in locating and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(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 participations of the resident and, with the residents' 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)(i-iv) §485.645(d)(5) Tag C-1620	▪ personal care. ▪ sterile dressing. ▪ physical therapy. ▪ resident/caregiver education needs to prepare the resident for discharge.	coordinating post discharge services. ▪ Pre-discharge preparation and education has been provided to the resident and their family?
11.07.01 Specialized rehabilitative services*:* Provision of services *If specialized rehabilitative services such as but not limited to physical therapy, 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*	☐ Compliant ☐ Not Compliant The intent of this regulation is to assure that residents receive necessary specialized rehabilitative services as determined by the comprehensive 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	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review the medical record for physical therapy. Determine the extent of follow through with the comprehensive care plan. Verify from the chart that the resident is receiving the type of therapy at the frequency outlined in the care plan. **Physical Therapy**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(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(a)(1-2) §483.645(d)(6) Tag C-1622	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 MI or ID 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 that 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. Rehabilitative services for MI and ID may include, but are not limited to: 1. Consistent implementation during the resident's daily routine and across settings, of systematic plans which are designed to change inappropriate behavior. 2. 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. 3. Provision of a structured environment for those individuals who are	▪ 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 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	determined to need such structure (e.g., structured socialization activities to diminish tendencies toward isolation and withdrawal). 4. Development, maintenance and consistent implementation across settings of those programs designed to provide each individual 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. 5. Crisis intervention services. 6. Individual, group, and family psychotherapy. 7. Development of appropriate personal support networks. 8. Formal behavior modification programs.	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? **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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		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?
11.07.02 Rehabilitative service orders: Qualifications *Specialized rehabilitative services must be provided under the written order of a physician by qualified personnel.* §483.65(b) §485.645(d)(6) Tag C-1622	☐ Compliant ☐ Not Compliant Specialized rehabilitative services are provided for individuals under a physician's order by a qualified professional. 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review medical records for physician orders and the record for the services performed. ▪ Determine if there are any problems in quality of care related to maintaining or improving functional abilities. □ Are these problems attributable in part to the qualifications of

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	"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.	specialized rehabilitative services staff? ▪ Verify 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 experienced in 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 services to be provided?
11.08.01 Dental services *The facility must assist residents in obtaining routine and 24-hour emergency dental care.* §483.55 §485.645(d)(7) Tag C-1624	☐ 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. The CAH 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	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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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.	
11.08.02 SKILLED NURSING FACILITY: Dental services *A facility –* ▪ *May charge a Medicare resident an additional amount for routine and emergency dental services.* ▪ *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;* §483.55(a)(2-3) §485.645(d)(7) Tag C-1624	☐ Compliant ☐ Not Compliant ☐ NA (if a Nursing Facility) 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 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the facility's policies to determine all elements of the requirement are met.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	"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 facility is aggressively working at replacing the dentures.	
11.08.03 SKILLED NURSING FACILITY: Dental appointments ▪ The facility *must, if necessary or requested, assist the resident–* (i) *In making appointments; and* (ii) *By arranging for transportation to and from the dental services location; and* ▪ *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.* §483.55(a)(4-5) §485.645(d)(7) Tag C-1624	☐ Compliant ☐ Not Compliant ☐ NA (if a Nursing Facility) "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: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the facility's policies to determine all elements of the requirement are met. ▪ Interview staff/patients to determine if the policy defines actual practice. □ Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them? □ Are resident's dentures intact? Properly fitted? □ Are residents missing teeth and may be in need of dentures? □ Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene?
11.08.04 NURSING FACILITY: Provision of Dental services *The facility-*	☐ Compliant ☐ Not Compliant ☐ NA (if a SNF) If the facility does not employ a qualified professional person to furnish a	This standard is not met as evidenced by: **DOCUMENT REVIEW**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(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)(1)(i-ii) §485.645(d)(7) Tag C-1624	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.	▪ Review the facility's policies to determine all elements of requirement are met. ▪ Observe and interview patients to determine if the policy is being followed.
11.08.05 <u>NURSING FACILITY: Dental appointments</u>	☐ Compliant ☐ Not Compliant ☐ NA (if a SNF)	This standard is not met as evidenced by:
▪ The facility *must, if necessary or if requested, assist the resident—* (i) *In making appointments.* (ii) *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*	"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.	**<u>OBSERVATION, INTERVIEW AND DOCUMENT REVIEW</u>** ▪ Review the facility's policies to determine all elements of the requirement are met. ▪ Interview staff/patients to determine if the policy defines actual practice. □ Do residents selected for comprehensive or focused reviews, as appropriate, with dentures, use them? □ Are resident's dentures intact? Properly fitted? □ Are residents missing teeth/in need of dentures?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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)(2-5) §485.645(d)(7) Tag C-1624		□ Do sampled residents have problems eating and maintaining nutritional status because of poor oral health or oral hygiene?
11.09.01 Assisted nutrition and hydration *Assisted nutrition and hydration includes:* ▪ *Naso-gastric and gastrostomy tubes, both percutaneous endoscopic gastrostomy and percutaneous endoscopic jejunostomy, and enteral fluids.* *Based on a resident's comprehensive assessment, the facility must ensure that a resident:* *(1) Maintains acceptable parameters of nutritional status, such as usual body*	☐ Compliant ☐ Not Compliant Parameters of nutritional status that are unacceptable include unplanned weight loss as well as other indices such as peripheral edema, cachexia and laboratory tests indicating malnourishment (e.g., serum albumin levels). Weight: Since ideal body weight charts have not yet been validated for the institutionalized elderly, weight loss (or gain) is a guide in determining nutritional status. An analysis of weight loss or gain should consider the individual's former lifestyle as well as the current diagnosis.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Determine if residents selected for a comprehensive or focused review as appropriate, have maintained acceptable parameters of nutritional status.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

weight or desirable body weight range and electrolyte balance, unless the resident's clinical condition demonstrates that this is not possible or resident preferences indicate otherwise.

(2) Is offered sufficient fluid intake to maintain proper hydration and health.

(3) Is offered a therapeutic diet when there is a nutritional problem and the health care provider orders a therapeutic diet.

(4) A resident who has been able to eat enough alone or with assistance is not fed by enteral methods unless the resident's clinical condition demonstrates that enteral feeding was clinically indicated and consented to by the resident.

(5) A resident who is fed by enteral means receives the appropriate treatment and services to restore, if possible, oral eating skills and to prevent complications of enteral feeding including but not limited to aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers.

§483.25(g)(1-5)
§485.645(d)(8) Tag C-1626

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

11.10.01 Quality of life

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Quality of life is a fundamental principle that applies to all care and services provided to facility residents. Each resident must receive, and the facility must provide, the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, consistent with the resident's comprehensive assessment and plan of care.

(a) Based on the comprehensive assessment of a resident and consistent with the resident's needs and choices, the facility must provide the necessary care and services to ensure that a resident's abilities in activities of daily living do not diminish unless circumstances of the individual's clinical condition demonstrate that such diminution was unavoidable. This includes the facility ensuring that:

(1) A resident is given the appropriate treatment and services to maintain or improve his or her ability to carry out the activities of daily living, including those specified in paragraph (b) of this section,

(2) A resident who is unable to carry

No additional information.

DOCUMENT REVIEW

Verify that medical records reflect:

- Treatments appropriate to the needs of the resident including vision and hearing.
- The resident receives services consistent with professional standards of practice related to:
  - Care to prevent pressure ulcers.
  - Foot care.
  - Appropriate diet and fluids.
  - Appropriate pain management.
  - Respiratory care, as appropriate.
  - Services to maintain continence and prevent the use of an indwelling catheter.
  - Services to prevent accidents.
- The resident has not developed a pressure ulcer or experienced a reduction in range of motion, unless unavoidable.
- Attempts to use alternatives prior to installing a side or bed rail.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene, and

(3) Personnel provide basic life support, including CPR, to a resident requiring such emergency care prior to the arrival of emergency medical personnel and subject to related physician orders and the resident's advance directives.

(b) Activities of daily living. The facility must provide care and services in accordance with paragraph (a) of this section for the following activities of daily living:

(1) Hygiene—bathing, dressing, grooming, and oral care,

(2) Mobility—transfer and ambulation, including walking,

(3) Elimination—toileting,

(4) Dining—eating, including meals and snacks,

(5) Communication, including

(i) Speech,

(ii) Language,

(iii) Other functional communication systems.

§483.24
§483.24(a-b)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

§485.645(d)(5) Tag C-1620

11.11.01 Quality of Care

Quality of care is a fundamental principle that applies to all treatment and care provided to facility residents. Based on the comprehensive assessment of a resident, the facility must ensure that residents receive treatment and care in accordance with professional standards of practice, the comprehensive person-centered care plan, and the resident's choices, including but not limited to the following:

(a) Vision and hearing. To ensure that residents receive proper treatment and assistive devices to maintain vision and hearing abilities, the facility must, if necessary, assist the resident—

(1) In making appointments, and

(2) By arranging for transportation to and from the office of a practitioner specializing in the treatment of vision or hearing impairment or the office of a professional specializing in the provision of vision or hearing assistive devices.

(b) Skin integrity—

(1) Pressure ulcers. Based on the comprehensive assessment of a

☐ Compliant ☐ Not Compliant

No additional information.

This standard is not met as evidenced by:

DOCUMENT REVIEW

- The facility provides sufficient staff to direct the care to the residents.
- The facility provides evidence of staff competencies and skills sets, consistent with requirements, including:
  - □ Caring for residents with mental and psychosocial disorders or post-traumatic stress disorder (PTSD).
  - □ Use of non-pharmacological interventions.
- The medical record reflects the resident receives appropriate treatment and care when the assessment identifies a diagnosis of dementia, mental disorder, or psychosocial adjustment difficulties.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

resident, the facility must ensure that—

(i) A resident receives care, consistent with professional standards of practice, to prevent pressure ulcers and does not develop pressure ulcers unless the individual's clinical condition demonstrates that they were unavoidable; and

(ii) A resident with pressure ulcers receives necessary treatment and services, consistent with professional standards of practice, to promote healing, prevent infection and prevent new ulcers from developing.

(2) Foot care. To ensure that residents receive proper treatment and care to maintain mobility and good foot health, the facility must—

(i) Provide foot care and treatment, in accordance with professional standards of practice, including to prevent complications from the resident's medical condition(s) and

(ii) If necessary, assist the resident in making appointments with a qualified person, and arranging for transportation to and from

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

such appointments.

(c) Mobility.

(1) The facility must ensure that a resident who enters the facility without limited range of motion does not experience reduction in range of motion unless the resident's clinical condition demonstrates that a reduction in range of motion is unavoidable; and

(2) A resident with limited range of motion receives appropriate treatment and services to increase range of motion and/or to prevent further decrease in range of motion.

(3) A resident with limited mobility receives appropriate services, equipment, and assistance to maintain or improve mobility with the maximum practicable independence unless a reduction in mobility is demonstrably unavoidable.

(d) Accidents. The facility must ensure that—

(1) The resident environment remains as free of accident hazards as is possible; and

(2) Each resident receives adequate supervision and assistance devices to prevent accidents.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(e) Incontinence. *(1) The facility must ensure that a resident who is continent of bladder and bowel on admission receives services and assistance to maintain continence unless his or her clinical condition is or becomes such that continence is not possible to maintain.* *(2) For a resident with urinary incontinence, based on the resident's comprehensive assessment, the facility must ensure that—* *(i) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary;* *(ii) A resident who enters the facility with an indwelling catheter or subsequently receives one is assessed for removal of the catheter as soon as possible unless the resident's clinical condition demonstrates that catheterization is necessary, and* *(iii) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections*		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

and to restore continence to the extent possible.

(3) For a resident with fecal incontinence, based on the resident's comprehensive assessment, the facility must ensure that a resident who is incontinent of bowel receives appropriate treatment and services to restore as much normal bowel function as possible.

(f) Colostomy, urostomy, or ileostomy care. The facility must ensure that residents who require colostomy, urostomy, or ileostomy services, receive such care consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

(h) Parenteral fluids. Parenteral fluids must be administered consistent with professional standards of practice and in accordance with physician orders, the comprehensive person-centered care plan, and the resident's goals and preferences.

(i) Respiratory care, including tracheostomy care and tracheal suctioning. The facility must ensure that a resident who needs respiratory care, including tracheostomy care and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

tracheal suctioning, is provided such care, consistent with professional standards of practice, the comprehensive person-centered care plan, the residents' goals and preferences, and §483.65 of this subpart.

(j) Prostheses. The facility must ensure that a resident who has a prosthesis is provided care and assistance, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences, to wear and be able to use the prosthetic device.

(k) Pain management. The facility must ensure that pain management is provided to residents who require such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

(l) Dialysis. The facility must ensure that residents who require dialysis receive such services, consistent with professional standards of practice, the comprehensive person-centered care plan, and the residents' goals and preferences.

(m) Trauma-informed care. The facility must ensure that residents who are

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
trauma survivors receive culturally-competent, trauma-informed care in accordance with professional standards of practice and accounting for residents' experiences and preferences in order to eliminate or mitigate triggers that may cause re-traumatization of the resident. *(n) Bed rails. The facility must attempt to use appropriate alternatives prior to installing a side or bed rail. If a bed or side rail is used, the facility must ensure correct installation, use, and maintenance of bed rails, including but not limited to the following elements.* *(1) Assess the resident for risk of entrapment from bed rails prior to installation.* *(2) Review the risks and benefits of bed rails with the resident or resident representative and obtain informed consent prior to installation.* *(3) Ensure that the bed's dimensions are appropriate for the resident's size and weight.* *(4) Follow the manufacturers' recommendations and specifications for installing and maintaining bed rails.* §483.25 §483.25(a-f)		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

§483.25(h-n)
§485.645(d)(5) Tag C-1620

11.12.01 Behavioral health services

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Each resident must receive, and the facility must provide, the necessary behavioral health care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. Behavioral health encompasses a resident's whole emotional and mental well-being, which includes, but is not limited to, the prevention and treatment of mental and substance use disorders.

(a) The facility must have sufficient staff who provide direct services to residents with the appropriate competencies and skills sets to provide nursing and related services to assure resident safety and attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident, as determined by resident assessments and individual plans of care and considering the number, acuity and diagnoses of the facility's resident population in accordance with §483.70(e).

No additional information.

DOCUMENT REVIEW

- The facility provides sufficient staff to direct the care to the residents.
- The facility provides evidence of staff competencies and skills sets, consistent with requirements, including:
  - Caring for residents with mental and psychosocial disorders or post-traumatic stress disorder (PTSD)
  - Use of non-pharmacological interventions
- The medical record reflects the resident receives appropriate treatment and care when the assessment identifies a diagnosis of dementia, mental disorder, or psychosocial adjustment difficulties.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

These competencies and skills sets include, but are not limited to, knowledge of and appropriate training and supervision for:

(1) Caring for residents with mental and psychosocial disorders, as well as residents with a history of trauma and/or post-traumatic stress disorder, that have been identified in the facility assessment conducted pursuant to §483.70(e), and

(2) Implementing non-pharmacological interventions.

(b) Based on the comprehensive assessment of a resident, the facility must ensure that—

(1) A resident who displays or is diagnosed with mental disorder or psychosocial adjustment difficulty, or who has a history of trauma and/or post-traumatic stress disorder, receives appropriate treatment and services to correct the assessed problem or to attain the highest practicable mental and psychosocial well-being;

(2) A resident whose assessment did not reveal or who does not have a diagnosis of a mental or psychosocial adjustment difficulty or a documented history of trauma

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

and/or post-traumatic stress disorder does not display a pattern of decreased social interaction and/or increased withdrawn, angry, or depressive behaviors, unless the resident's clinical condition demonstrates that development of such a pattern was unavoidable; and

(3) A resident who displays or is diagnosed with dementia receives the appropriate treatment and services to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being.

(c) If rehabilitative services such as but not limited to physical therapy, speech-language pathology, occupational therapy, and rehabilitative services for mental disorders and intellectual disability, are required in the resident's comprehensive plan of care, the facility must—

(1) Provide the required services, including specialized rehabilitation services as required in §483.65; or

(2) Obtain the required services from an outside resource (in accordance with §483.70(g) of this part) from a Medicare and/or Medicaid provider of specialized rehabilitative services.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(d) 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 §485.645(d)(5) Tag C-1620		

12

DISTINCT PART REHABILITATION UNITS

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

☐ N/A. This chapter is not applicable. The facility has no Distinct Part Rehabilitation Unit.

12.00.00 CONDITION OF PARTICIPATION: Distinct Part Rehabilitation Unit/ Prospective Payment System Excluded Unit	☐ Compliant ☐ Not Compliant	This condition is not met as evidenced by:
Rehabilitation units seeking exclusion from the Medicare Prospective Payment System (PPS) must comply with all standards consistent with the following CFR codes: ▪ §482 – Conditions of Participation for Hospitals; AND ▪ §412.25 Excluded hospital units: "Common Requirements" (refer to standards 12.00.02 through 12.00.32) AND ▪ §412.29 Excluded Rehabilitation Units: "Additional Requirements" (refer to standards 12.02.00 through 12.02.10). §485.647	These are the criteria for a PPS excluded rehabilitation unit in a critical access hospital. Failure to meet the CoP will result in notification to CMS with removal of approval for this unit.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Score this CoP Not Compliant if a preponderance of deficiencies are identified in: □ Standards 12.00.02 through 12.00.32. □ Standards 12.02.00 through 12.02.10. ▪ If PPS excluded unit, is the space containing the rehabilitation beds separate from the beds on other units of the hospital?

12.00.01 For future use		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.02 Basis for exclusion *In order to be excluded from the prospective payment systems as specified in §412.1(a)(1) and be paid under the inpatient rehabilitation facility prospective payment system as specified in §412.1(a)(3), a rehabilitation unit must meet the following requirements:* *Be part of an institution that—* (i) *Has in effect an agreement under §489 to participate as a hospital;* (ii) *Prior to October 1, 2019, is not excluded in its entirety from the prospective payment systems; and* (iii) *Unless it is a unit in a critical access hospital, the hospital of which an IRF is a unit must have at least 10 staffed and maintained hospital beds that are paid under the applicable payment system under which the hospital is paid, or at least 1 staffed and maintained hospital bed for every 10 certified inpatient rehabilitation facility beds, whichever number is greater.* *Otherwise, the IRF will be classified as an IRF hospital, rather than an IRF unit. In the case of an inpatient psychiatric facility unit, the*	☐ Compliant ☐ Not Compliant ACHC will verify with the CMS Location (Regional Office) that the hospital has a current agreement to participate in the Medicare program and that the hospital is not already excluded in its entirety from PPS.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The hospital has a current 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. □ See standard 01.04.01 for size limitations for the unit and score there.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
hospital must have enough beds that are paid under the applicable payment system under which the hospital is paid to permit the provision of adequate cost information, as required by §413.24(c). §412.25(a) §412.25(a)(1)(i-iii)		
12.00.03 Admission criteria	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
In order to be excluded from the Medicare PPS System, the unit must… ▪ *Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.* §412.25(a)(2)	No additional information.	**DOCUMENT REVIEW** Verify: ▪ Written admission criteria are in place. ▪ Through review of open and closed records, that the approved admission criteria are consistently applied for all patients.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.04 Separate medical records	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
In order to be excluded for the Medicare PPS System, the unit must… ▪ *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)	Distinct Part Units have separate medical records that are not commingled with other hospital records. These records are readily available for review.	**OBSERVATION** ▪ Confirm that the medical records for the Rehab DPU are not commingled with other hospital records; these are readily available for review.
12.00.05 Availability of clinical records and information	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
In order to be excluded for the Medicare PPS System, the unit must… ▪ *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)	The hospital has a written policy that specifies the clinical information that accompanies the patient when transferred to the exempt rehabilitation unit.	**DOCUMENT REVIEW** Verify: ▪ A policy details the prompt transfer of clinical information for patients transferred to the rehabilitation unit. ▪ Medical records reflect that clinical information is promptly transferred with the record.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.06 State licensure requirements *In order to be excluded for the Medicare PPS System, the unit must…* ▪ *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: ▪ 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.
12.00.07 Utilization review requirements *In order to be excluded for the Medicare PPS System, the unit must…* ▪ *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: ▪ The hospital has a utilization review plan that includes the review of rehabilitation services, either internally or through the QIO. ▪ The UR standards are applied to the care offered in the rehab unit.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.08 Distinct unit structure	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
In order to be excluded for the Medicare PPS System, the unit must… ▪ *Have beds physically separate from (that is, not commingled with) the hospital's other beds*. §412.25(a)(7)	The Distinct Part Unit rehabilitation beds are physically separate from the beds in other units of the hospital. If the unit doesn't have enough patients to fill those beds, the beds must be left empty or the unit can decrease the number of beds in the unit after the hospital has notified CMS of its intent.	**OBSERVATION** ▪ Verify that the DPU rehabilitation beds are physically separate from the beds in other units of the hospital. □ The beds on the rehab unit do not belong to the medical/surgical patients; these beds are dedicated to rehab patients only.
12.00.09 Distinct unit structure: Fiscal intermediary	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
In order to be excluded from the Medicare PPS System, the unit must… ▪ *Be serviced by the same fiscal intermediary as the hospital.* §412.25(a)(8)	No additional information.	**DOCUMENT REVIEW** ▪ Verify that the DPU uses the same fiscal intermediary as the hospital.
12.00.10 Distinct unit structure: Separate cost center	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
In order to be excluded from the Medicare PPS System, the unit must… ▪ *Be treated as a separate cost center for cost finding and apportionment purposes.* §412.25(a)(9)	No additional information.	**DOCUMENT REVIEW** ▪ Verify that the DPU is treated as a separate cost center for cost finding and apportionment purposes.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.11 Distinct unit structure: Allocate costs	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
In order to be excluded from the Medicare PPS System, the unit must… ▪ *Use an accounting system that properly allocates costs.* §412.25(a)(10)	No additional information.	**DOCUMENT REVIEW** ▪ Verify that the DPU uses an accounting system that properly allocates costs.
12.00.12 Distinct unit structure: Statistical data	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
In order to be excluded from the Medicare PPS System, the unit must… ▪ *Maintain adequate statistical data to support the basis of allocation.* §412.25(a)(11)	No additional information.	**DOCUMENT REVIEW** ▪ Verify that the DPU maintains adequate statistical data to support the basis of allocation.
12.00.13 Distinct unit structure: Cost report	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
In order to be excluded from the Medicare PPS System, the unit must… ▪ *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)	No additional information.	**DOCUMENT REVIEW** ▪ Verify that the DPU reports its costs per the standard**.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.14 Distinct unit structure: Requirements on the first day of the first cost reporting period *In order to be excluded from the Medicare PPS System, the unit must…* ▪ *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 or rehabilitation care regardless of whether there are any inpatients in the unit on that date.* §412.25(a)(13)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the DPU is fully equipped and staffed to provide hospital inpatient rehabilitation care.
12.00.15 Change in 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*	☐ Compliant ☐ Not Compliant A request to add or decrease the number of beds or square footage may occur at any time during the cost report period but the change must remain in effect for the remainder of the cost report period. No changes can be made without notifying both CMS Location (regional office) and the FI/MAC at least 30 days prior to the change.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ If the DPU has had a change in the number of beds or a change in square footage during this accreditation cycle, verify that the facility notified the Medicare contractor and CMS 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
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 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)		
12.00.16 Change in status of hospital units *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 below in §412.25(c)(1) and (c)(2).* *(1) The status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW AND INTERVIEW** ▪ Has the DPU had a change of status during this accreditation cycle? □ If yes, has the facility notified the fiscal intermediary and the CMS Location in writing at least 30 days before the change?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
reporting period, it cannot be excluded from the prospective payment systems before the start of 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)		
12.00.17 <u>Number of excluded units</u> *Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems specified in §412.1(a)(1). A hospital excluded from the prospective*	☐ Compliant ☐ Not Compliant The hospital may have one PPS excluded rehabilitation unit.	This standard is not met as evidenced by: **<u>OBSERVATION AND INTERVIEW</u>** ▪ Verify that there is only one PPS excluded rehabilitation unit in this facility.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
payment systems as specified in §412.1(a)(1) may not have an excluded unit (psychiatric or rehabilitation) that is excluded on the same basis as the hospital. §412.25(d)		
12.00.18 Satellite facilities: Definition *For purposes of §412.25(e)(2) through (e)(5), a satellite facility is:* (1) *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)(1)	☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that the satellite facility: ▪ Provides inpatient services consistent with requirement. ▪ Is located consistent with requirement.
12.00.19 Satellite facilities: Criteria *Except as provided below in §412.25(e)(3) and (e)(6), 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:*	☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period 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.* *(B) For a psychiatric unit, the requirements under §412.27(a).* §412.25(e)(2) §412.25(e)(2)(i-ii)(A-B)		number of state-licensed and Medicare-certified beds on the last day of the unit's last cost reporting period.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.20 Satellite facility: Separate governing body *The satellite facility meets all the following requirements except as provided in §412.25(e)(2)(iv):* ▪ *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 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)	☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The governing body/CEO of the satellite facility is different than that for the hospital. ▪ Care provided is not under control of the hospital medical staff and chief medical officer.
12.00.21 Satellite facility: Admission and discharge records ▪ [The satellite facility] *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 ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ The satellite facility maintains admission and discharge records separate from those of the hospital. ▪ These records are readily available.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.22 Satellite facility: Beds are physically separate ▪ [The satellite facility] *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 ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify that the beds of the satellite facility are physically separate from the beds of the hospital.
12.00.23 Satellite facility: Fiscal intermediary ▪ [The satellite facility*] 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 ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the satellite facility uses the same fiscal intermediary as the hospital of which it is a part.
12.00.24 Satellite facility: Separate cost center ▪ [The satellite facility] *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 ☐ Not Applicable (no satellite facility) 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.25 Satellite facility: Accounting system ▪ *For cost reporting and apportionment purposes,* [the satellite facility] *uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation*. §412.25(e)(2)(iii)(F)	☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility) 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 allocation.
12.00.26 Satellite facility: Hospital cost report ▪ [The satellite facility] *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 ☐ Not Applicable (no satellite facility) 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.
12.00.27 Satellite facility: Exception ▪ *Effective for cost reporting periods beginning on or after October 1, 2019, the requirements of §412.25 (e)(2)(iii)(A), do not apply to a satellite facility of a unit that is part of a hospital excluded from the prospective payment systems specified in*	☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documents to determine the satellite facility meets this requirement. ▪ Determine whether this unit was structured as a satellite facility on September 30, 1999, and excluded from

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§412.1(a)(1) that does not furnish services in a building also used by another hospital that is not excluded from the prospective payment systems specified in §412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is not excluded from the prospective payment systems specified in §412.1(a)(1). ▪ *Except as specified below in §412.25(e)(4) and (e)(5), the provisions of §412.25(e)(2) 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 considered to be part of the unit at the satellite facility on September 30, 1999.* §412.25(e)(2)(iv) §412.25(e)(3)		the prospective payment systems on that date. □ 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.28 Satellite facility: Increase/ decrease square footage or decrease beds *In applying the provisions of §412.25 (e)(3), 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 ☐ Not Applicable (no satellite facility An increase/decrease in the square footage or a decrease in the number of beds is acceptable for the following reasons: 1. To permit construction or renovation necessary for compliance with federal, state, or local law. 2. Due to a catastrophic event.	This standard is not met as evidenced by: **OBSERVATION AND INTERVIEW** If the satellite facility increased/decreased the square footage or decreased the number of beds, verify that these changes were: ▪ To permit construction or renovation necessary for compliance with federal, state, or local law. ▪ Due to a catastrophic event.
12.00.29 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 §412.25(e)(3) —* *(i) Any unit structured as a satellite facility on September 30, 1999, may increase the square footage of the unit*	☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **OBSERVATION AND INTERVIEW** ▪ Determine if the unit was a structure of satellite facility on September 30, 1999. If yes: □ Was the increase/decrease in square

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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 §412.25(b)(2) (see above), without affecting the provisions of §412.25(e)(3) (see above); *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 §412.25(b)(2) (see above), 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 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)		footage of the satellite facility or the decrease in the number of beds consistent with the requirement?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.00.30 Satellite facility: Inpatient rehabilitation facility *The provisions in §412.25(e)(2)(i)—* ▪ *Do not apply to any inpatient rehabilitation facility that is subject to the inpatient rehabilitation facility prospective payment system under subpart P of §412, effective for cost reporting periods beginning on or after October 1, 2003.* §412.25(e)(6)	☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Confirm that the satellite facility is compliant with this requirement.
12.00.31 Changes in classification of hospital units *For purposes of exclusions from the prospective payment system under this section—* ▪ *The classification of a hospital unit is effective for the unit's entire cost 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)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documents to verify whether the DPU 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
12.00.32 CAH units not meeting applicable requirements *If a psychiatric or rehabilitation unit of a CAH does not meet the requirements of §485.647 with respect to a cost reporting period,* ▪ *No payment may be made to the CAH for services furnished in that unit for that period.* ▪ *Payment to the CAH for services in the unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of §485.647.* §412.25(g)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Confirm that the unit is compliant with this requirement.
12.01.00 CONDITION OF PARTICIPATION: Psychiatric and rehabilitation distinct part units *If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of §482, the common requirements of §412.25(a)(2) through (f) for hospital units excluded from the prospective payments systems, and the additional requirements of §412.29 and §412.30 related specifically*	☐ Compliant ☐ Not Compliant No additional information.	This condition is not met as evidenced by: **DOCUMENT REVIEW** ▪ Confirm that the facility is compliant with this requirement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

to rehabilitation units.

(b) *Eligibility requirements.*

(1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a).

(3) The average annual 96-hour length of stay requirement specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in §485.647(b)(1), and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in §485.620.

§485.647(a)(2)
§485.647(b)
§485.647(b)(1-3)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.02.00 Additional requirements *Classification criteria for payment under the inpatient rehabilitation facility prospective payment system.* ▪ *To be excluded from the prospective payment systems described in §412.1(a)(1) and to be paid under the prospective payment system specified in §412.1(a)(3), an inpatient rehabilitation hospital or 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: **INTERVIEW AND DOCUMENT REVIEW** ▪ Score as noncompliant if a preponderance of standards 12.02.01 through 12.02.10 fail to meet requirements.
12.02.01 Provider agreement *An inpatient rehabilitation unit must:* ▪ *Have (or be part of a hospital that has) a provider agreement under §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 the facility has an agreement to participate in the Medicare program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.02.02 Inpatient population requirement *Except in the case of a "new" IRF or "new" IRF beds, as defined below in §412.29(c), 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 below at §412.29 (b)(2).* *A patient with a comorbidity, as defined at §412.602, may be included in the inpatient population that counts toward the required applicable percentage if—* *(i) The patient is admitted for inpatient rehabilitation for a condition that is not one of the conditions specified in*	☐ Compliant ☐ Not Compliant ☐ N/A. This is a new IRF or new IRF beds. No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that for the most recent consecutive 12-months, 60% of the patients were admitted for intensive rehabilitation services as defined in the standard.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

§412.29 (b)(2);

(ii) The patient has a comorbidity that falls in one of the conditions specified in §412.29 (b)(2); 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 §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)

(vii) Brain injury

(viii) Neurological disorders, including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease

(ix) Burns

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(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, 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*		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. (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.)*		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(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)(C)		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.02.03 Written certification for new IRFs *In the case of new IRFs (as defined in §412.29(c)(1)) or new IRF beds (as defined in §412.29(c)(2)), the IRF must provide a written certification that the inpatient population it intends to serve meets the requirements of §412.29(b).* *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 §412 for at least 5 calendar years. A new IRF will be considered new from the 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 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*	☐ Compliant ☐ Not Compliant ☐ N/A The rehabilitation facility has submitted a written attestation statement as well as Form CMS 4378 (rehabilitation hospital worksheet) to the state agency as a part of the application packet, or as determined by CMS to maintain the IPPS excluded status. **NEW IRFS** If an IRF unit has been closed for five years, it can open its doors as a new unit. **NEW IRF BEDS** If the hospital added beds to its IRF unit, the hospital must have approval (certificate of need or state license) before adding beds, if such approval is required. The hospital must receive written CMS Location approval before adding any new beds to its IRF unit. The hospital's IRF may not have more than one increase in beds during a single cost reporting period. If the hospital's IRF unit decreased beds, it did not thereafter add beds unless a full 12-month cost reporting period had elapsed. **CHANGE OF OWNERSHIP OR LEASING** IRF status is lost if a hospital is acquired and the new owners reject assignment of the previous owner's Medicare provider assignment. Only entire hospitals may be sold or leased. IRF units may not be sold or leased separately from the hospital of which it is a part.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Note: This requirement applies only for "new" inpatient rehabilitation facilities or "new" rehabilitation beds. For new units, verify that: ▪ The rehabilitation unit has not been paid under PPS for at least five calendar years. ▪ The attestation statement and IRF unit worksheet have been submitted to the state agency. For new IRF beds, verify that: ▪ The hospital received state approval (certificate of need or state licensure), if approval is required by the state, prior to IRF unit bed increase. ▪ The hospital received written approval from the CMS Location before any new beds were added to the IRF unit. ▪ If the IRF unit decreased beds, it did not add beds unless a full 12-month cost reporting period had elapsed. ▪ The IRF unit did not have more than one increase in beds during a single cost reporting period.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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 and the addition of new IRF beds to that 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 §412.29 (b) from the 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 §489.18f, 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 IRF continues to meet all of the requirements for payment under the*	**MERGERS** As with the change of ownership, the owner of the merged hospital must accept assignment of the hospital's (with the IRF unit) provider agreement to ensure uninterrupted reimbursement. If the owner of the hospital to be merged doesn't accept assignment of the previous owner(s) Medicare provider agreement, the new owner(s) will not be eligible for reimbursement until the new owner(s) reapplies to the Medicare program to operate a new hospital and has been granted IRF status.	If the hospital has undergone a change of ownership or a merger: ▪ Ensure that the new owners have accepted assignment of the previous Medicare provider agreement, if assignment was not accepted, the facility cannot request continued participation as a PPS excluded rehab unit.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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 IRF prospective payment system.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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)		
12.02.04 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 hospital 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 The purpose of the preadmission screening tool is to reduce the rate of hospital readmission by ensuring the patients accepted to the IRF will benefit from the intensive rehabilitation services. The IRF consistently applies the screening procedure.	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 that address whether the patient is likely to benefit significantly from an intensive inpatient program or assessment. □ The medical records indicate that the preadmission screen is applied to all patients admitted to the rehabilitation unit.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.02.05 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 Hospital policy defines: 1. Required medical supervision for patients, including at least three face-to-face visits per week. 2. Special training and experience requirements for inpatient rehabilitation medical staff.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Hospital policy addresses the required elements. ▪ Through review of five patient records that each record contains documentation of a minimum of three face-to-face visits per week by a licensed physician with specialized training and experience in inpatient rehabilitation.
12.02.06 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.* §412.29(f)	☐ 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 and follows a procedure to evaluate and document that personnel are qualified and competent, consistent with state law.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Policies establish the qualifications for personnel providing rehabilitation services. ▪ Licenses for the professional staff are current and issued by the state in which the personnel are providing services.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ The hospital ensures that its personnel are qualified and competent.
12.02.07 Director – requirements *An inpatient rehabilitation unit must have a director of rehabilitation who—* *(1) 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;* *(2) Is a doctor of medicine or* doctor of osteopathic medicine; *(3) Is licensed under State law to practice medicine or surgery; and* *(4) Has had, after completing a one-year hospital internship, at least 2 years of training or experience in the medical-management of inpatients requiring rehabilitation services.* §412.29(g) §412.29(g)(1-4)	☐ 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 AND FILE REVIEW** Verify: ▪ The rehabilitation unit has a medical director of rehabilitation. The director is an MD or DO. ▪ The medical director's license is current and issued by the state in which the service is being provided. ▪ The medical director has met the criteria for internship plus two years of training or experience. ▪ The medical director provides at least 20 service hours per week providing a combination of patient services and administration for the rehab unit.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
12.02.08 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 Each plan of treatment includes the patient's medical prognosis and the anticipated interventions, functional outcomes, and discharge destination from the IRF stay. Interventions detailed in the overall plan of care include: ▪ Expected intensity (number of hours per day). ▪ Frequency (number of days per week). ▪ Duration (total number of days during the IRF stay) of physical, occupational, speech-language pathology, and prosthetic/ orthotic therapies required by the patient. The treatment plan includes measurable long term and short-term goals with estimated time frames for achieving these 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 of closed records. Sample volumes as appropriate to evaluate both inpatient and outpatient records to verify: ▪ Each patient has a plan of treatment in their medical record. ▪ A 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.)
12.02.09 Coordinated multidisciplinary 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 appropriateness of treatment.*	☐ Compliant ☐ Not Compliant The facility has a written policy that addresses the functioning of the interdisciplinary team approach, including: 1. Planning patient care. 2. Establishing goals. 3. Discharge planning. 4. Documentation requirements. 5. Frequency of team meetings.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Policies address the required elements. ▪ Medical records contain periodic clinical entries related to achievement of goals, consistent with facility policy. ▪ An interdisciplinary team approach is used for the rehabilitation of each patient.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§412.29(i)		▪ At least weekly team conferences are held to determine appropriateness of treatment in relation to goal achievement.
12.02.10 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 §412.29(c), but the inpatient population actually treated during that period does not meet the requirements of §412.29(b), Medicare adjusts payments to the IRF retroactively in accordance with the provisions in §412.130.* §412.29(j)	☐ Compliant ☐ Not Compliant ☐ N/A. This is a new IRF or new IRF beds. New IRFs must meet the requirements of this section to receive retroactive payment.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Confirm that facility policies address the required elements.
12.03.00 Multidisciplinary team The Rehabilitation Program uses an integrated, multidisciplinary approach to patient care. The Program's core team may include, but is not necessarily limited to: ▪ Physician	☐ Compliant ☐ Not Compliant The disciplines represented in the core team will vary depending upon the mission and objective of the facility. Other healthcare workers may be included as appropriate, such as: ▪ Psychologist ▪ Psychiatrist ▪ Neuropsychologist	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the organizational chart for the integrated, multidisciplinary rehabilitation services program to verify that it meets the requirement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ Rehabilitation RN ▪ Speech Therapist ▪ Occupational Therapist ▪ Social Worker ▪ Physical Therapist ▪ Therapeutic Recreational Specialist for inpatient facilities **§412.29(i)**	▪ Orthotist ▪ Prosthetist ▪ Exercise physiologist ▪ Vocational rehabilitation counselor ▪ Audiologist	
12.03.01 Organizational plan There should be a written description of the Rehabilitation Program which includes, but need not be limited to the following: ▪ The scope of services provided and how these services relate to each other. ▪ Services specific to inpatient or outpatient programs including: □ Admission criteria □ The assessment and evaluation process □ 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** ▪ Verify the plan for the Rehabilitation Program is available for review. The plan includes all elements in the standard.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§412.25(a)		
12.03.02 Quality assessment performance improvement (QAPI) Rehabilitation services are integrated into the facility-wide QAPI plan. **§485.641(b)(1)** **§485.641(b)(2)** **§482.21(c)(2)**	☐ 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. ▪ 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.

13

DISTINCT PART PSYCHIATRIC UNITS

CHAPTER 13 | DISTINCT PART PSYCHIATRIC UNIT/PROSPECTIVE PAYMENT SYSTEM (PPS) EXCLUDED UNIT

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

☐ N/A. This chapter is not applicable. The facility has no Distinct Part Psychiatric Unit.

13.00.00 CONDITION OF PARTICIPATION: Distinct Part Psychiatric Unit/Prospective Payment System Excluded Unit

☐ Compliant ☐ Not Compliant

This condition is not met as evidenced by:

Psychiatric units seeking exclusion from the Medicare Prospective Payment System (PPS) must comply with all standards consistent with the following CFR codes:

- §482 – Conditions of Participation for Hospitals;

AND

- §412.25 Excluded hospital units: "Common Requirements" **(refer to standards 13.00.02 through 13.00.32)**

AND

- §412.29 Excluded Psychiatric Units: "Additional Requirements" **(refer to standards 13.02.00 through 13.02.35)**

§485.647

These are the criteria for a PPS excluded psychiatric unit in a critical access hospital.

Failure to meet the CoP will result in notification to CMS with removal of approval for this unit.

OBSERVATION AND DOCUMENT REVIEW

- Score this CoP Not Compliant if a preponderance of deficiencies are identified in:
  - Standards 13.00.02 through 13.00.32.
  - Standards 13.02.00 through 13.02.35.
- If PPS excluded unit, is the space containing the rehabilitation beds separate from the beds on other units of the hospital?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.00.01 Participation requirements *Section 1861(f) of the Social Security Act provides that an institution participating in Medicare as a psychiatric hospital must meet certain specified requirements imposed on hospitals under section 1861(e), must be primarily engaged in providing, by or under the supervision of a physician, psychiatric services for the diagnosis and treatment of mentally ill persons, must maintain clinical records and other records that the Secretary finds necessary, and must meet staffing requirements that the Secretary finds necessary to carry out an active program of treatment for individuals who are furnished services in the hospital.* *A distinct part of an institution can participate as a psychiatric hospital if the institution meets the specified 1861(e) requirements and is primarily engaged in providing psychiatric services, and if the distinct part meets the records and staffing requirements that the Secretary finds necessary.* §482.1(a)(2)	☐ Compliant ☐ Not Compliant No additional information.	This condition is not met as evidenced by: **DOCUMENT REVIEW, INTERVIEW, AND OBSERVATION** ▪ Verify through full chapter review that the facility is functioning within the requirements of a distinct part psychiatric unit.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.00.02 Basis for exclusion	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
In order to be excluded from the prospective payment systems as specified in §412.1(a)(1) and be paid under the inpatient psychiatric facility prospective payment system as specified in §412.1(a)(2), a psychiatric unit must meet the following requirements: *Be part of an institution that—* (i) *Has in effect an agreement §489 to participate as a hospital;* (ii) *Prior to October 1, 2019, Is not excluded in its entirety from the prospective payment systems; and* (iii) *Unless it is a unit in a critical access hospital, the hospital of which an IRF is a unit must have at least 10 staffed and maintained hospital beds that are paid under the applicable payment system under which the hospital is paid, or at least 1 staffed and maintained hospital bed for every 10 certified inpatient rehabilitation facility beds, whichever number is greater. Otherwise, the IRF will be classified as an IRF hospital, rather than an IRF unit. In the case of an inpatient psychiatric facility unit, the hospital must have enough beds that*	ACHC will verify with the CMS Location (Regional Office) that the hospital has a current agreement to participate in the Medicare program and that the hospital is not already excluded in its entirety from PPS.	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The hospital has a current 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. □ See standard 01.04.01 for size limitations for the unit and score there.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
are paid under the applicable payment system under which the hospital is paid to permit the provision of adequate cost information, as required by §413.24(c). §412.25(a) §412.25(a)(1)(i-iii)		
13.00.03 Admission criteria *In order to be excluded from the Medicare PPS System, the unit must…* ▪ *Have written admission criteria that are applied uniformly to both Medicare and non-Medicare patients.* §412.25(a)(2)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Written admission criteria are in place. ▪ Through review of open and closed records, that the approved admission criteria are consistently applied for all patients.
13.00.04 Separate medical records *In order to be excluded for the Medicare PPS System, the unit must meet…* ▪ *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 Distinct Part Units have separate medical records that are not commingled with other hospital records. These records are readily available for review.	This standard is not met as evidenced by: **OBSERVATION** ▪ Confirm that the medical records for the psychiatric DPU are separate and not commingled with other hospital records; these are readily available for review.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.00.05 Availability of clinical records and information *In order to be excluded for the Medicare PPS System, the unit must…* ▪ *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 accompanies the patient when transferred to the exempt psychiatric unit.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ A policy details the prompt transfer of clinical information for patients transferred to the psychiatric unit. ▪ Medical records reflect that clinical information is promptly transferred with the record.
13.00.06 State licensure requirements *In order to be excluded for the Medicare PPS System, the unit must…* ▪ *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: ▪ Applicable state licensure laws are met, including any special licensing requirements issued by the state.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.00.07 Utilization review requirements *In order to be excluded for the Medicare PPS System, the unit must…* ▪ *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: ▪ The hospital has a utilization review plan that includes the review of psychiatric services, either internally or through the QIO. ▪ The UR standards are applied to the care offered in the psychiatric unit.
13.00.08 Distinct unit structure *In order to be excluded for the Medicare PPS System, the unit must…* ▪ *Have beds physically separate from (that is, not commingled with) the hospital's other beds*. §412.25(a)(7)	☐ Compliant ☐ Not Compliant The Distinct Part Unit psychiatric beds are physically separate from the beds in other units of the hospital. If the unit does not have enough patients to fill those beds, the beds must be left empty, or the unit can decrease the number of beds in the unit after the hospital has notified CMS of its intent.	This standard is not met as evidenced by: **OBSERVATION** ▪ Verify that the DPU psychiatric beds are physically separate from the beds in other units of the hospital. □ The beds on the psychiatric unit do not belong to the medical/surgical patients; these beds are dedicated to psychiatric patients only.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.00.09 Distinct unit structure: Fiscal intermediary *In order to be excluded from the Medicare PPS System, the unit must…* ▪ *Be serviced by the same fiscal intermediary as the hospital.* §412.25(a)(8)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the DPU uses the same fiscal intermediary as the hospital.
13.00.10 Distinct unit structure: Separate cost center *In order to be excluded from the Medicare PPS System, the unit must meet…* ▪ *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 DPU is treated as a separate cost center for cost finding and apportionment purposes.
13.00.11 Distinct unit structure: Allocate costs *In order to be excluded from the Medicare PPS System, the unit must…* ▪ *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 that the DPU uses an accounting system that properly allocates costs.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.00.12 Distinct unit structure: Statistical data *In order to be excluded from the Medicare PPS System, the unit must…* ▪ *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 that the DPU maintains adequate statistical data to support the basis of allocation.
13.00.13 Distinct unit structure: Cost report *In order to be excluded from the Medicare PPS System, the unit must…* ▪ *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 that the DPU reports its costs per the standard.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.00.14 Distinct unit structure: Requirements on the first day of the first cost reporting period	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
In order to be excluded from the Medicare PPS System, the unit must… ▪ *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 or rehabilitation care regardless of whether there are any inpatients in the unit on that date.* §412.25(a)(13)	No additional information.	**DOCUMENT REVIEW** ▪ Verify that the DPU is fully equipped and staffed to provide hospital inpatient psychiatric care.
13.00.15 Change in size of excluded units	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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 request to add or decrease the number of beds or square footage may occur at any time during the cost report period but the change must remain in effect for the remainder of the cost report period. No changes can be made without notifying both CMS Location (regional office) and the FI/MAC at least 30 days prior to the change.	**INTERVIEW AND DOCUMENT REVIEW** ▪ If the DPU has had a change in the number of beds or a change in square footage during this accreditation cycle, verify that the facility notified the Medicare contractor and CMS 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
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 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)		
13.00.16 Change in status of hospital units *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 below in §412.25(c)(1) and (c)(2).* *(1) The status of a hospital unit may be changed from not excluded to excluded 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*	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW AND INTERVIEW** ▪ Has the DPU had a change of status during this accreditation cycle? □ If yes, has the facility notified the fiscal intermediary and the CMS Location in writing at least 30 days before the change?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
from the prospective payment systems before the start of 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)		
13.00.17 Number of excluded units *Each hospital may have only one unit of each type (psychiatric or rehabilitation) excluded from the prospective payment systems specified in §412.1(a)(1). A hospital excluded from the prospective payment systems as specified in §412.1(a)(1) may*	☐ Compliant ☐ Not Compliant The hospital may 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 psychiatric unit in this facility.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
not have an excluded unit (psychiatric or rehabilitation) that is excluded on the same basis as the hospital. §412.25(d)		
13.00.18 Satellite facilities: Definition *For purposes of §412.25(e)(2) through (e)(5), 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)(1)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that the satellite facility: ▪ Provides inpatient services consistent with requirement. ▪ Is located consistent with requirement.
13.00.19 Satellite facilities: Criteria *Except as provided below in §412.25(e)(3) and (e)(6), 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:*	☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(i) In the case of a unit excluded from the prospective payment systems for the most recent cost reporting period 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)(B)		Medicare-certified beds on the last day of the unit's last cost reporting period.
13.00.20 Satellite facility: Separate governing body *The satellite facility meets all the following requirements except as provided in §412.25(e)(2)(iv):* ▪ [The satellite facility] *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 through the use of medical personnel who are not under the control of the medical staff or chief medical*	☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The governing body/CEO of the satellite facility is different than that for the hospital. ▪ Care provided is not under control of the hospital medical staff and chief medical officer.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
officer of the hospital in which it is located. §412.25(e)(2)(iii)(A)		
13.00.21 Satellite facility: Admission and discharge records ▪ [The satellite facility] *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 ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ The satellite facility maintains admission and discharge records separate from those of the hospital. ▪ These records are readily available.
13.00.22 Satellite Facility: Beds are physically separate ▪ [The satellite facility] *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 ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify the beds of the satellite facility are physically separate from the beds of the hospital.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.00.23 Satellite Facility: Fiscal Intermediary ▪ [The satellite facility] *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 ☐ Not Applicable (no satellite facility) 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.
13.00.24 Satellite Facility: Separate Cost Center ▪ [The satellite facility] *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 ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the satellite facility is a separate cost center of the hospital of which it is a part.
13.00.25 Satellite facility: Accounting system ▪ *For cost reporting and apportionment purposes,* [the satellite facility] *uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.* §412.25(e)(2)(iii)(F)	☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the satellite facility uses an accounting system that properly allocates costs and maintains adequate statistical data to support the basis of allocation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.00.26 Satellite facility: Hospital cost report ▪ [The satellite facility] *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 ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify 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.
13.00.27 Satellite facility: Exception ▪ *Effective for cost reporting periods beginning on or after October 1, 2019, the requirements of §412.25 (e)(2)(iii)(A), do not apply to a satellite facility of a unit that is part of a hospital excluded from the prospective payment systems specified in §412.1(a)(1) that does not furnish services in a building also used by another hospital that is not excluded from the prospective payment systems specified in §412.1(a)(1), or in one or more entire buildings located on the same campus as buildings used by another hospital that is not excluded from the prospective payment systems specified in §412.1(a)(1).*	☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility) No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documents to determine 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. □ 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- *Except as specified below in §412.25(e)(4) and (e)(5), the provisions of §412.25(e)(2) 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 considered to be part of the unit at the satellite facility on September 30, 1999.*

§412.25(e)(2)(iv)
§412.25(e)(3)

13.00.28 Satellite facility: Increase/ decrease square footage or decrease beds

☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility)

This standard is not met as evidenced by:

In applying the provisions of §412.25 (e)(3), 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.

An increase/decrease in the square footage or a decrease in the number of beds is acceptable for the following reasons:

1. To permit construction or renovation necessary for compliance with federal, state, or local law.
2. Due to a catastrophic event.

OBSERVATION AND INTERVIEW

If the satellite facility increased/decreased the square footage or decreased the number of beds 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

(ii) *Because of catastrophic events such as fires, floods, earthquakes, or tornadoes.*

§412.25(e)(4)
§412.25(e)(4)(i-ii)

13.00.29 Satellite facility: Structure changes after October 1, 2006

☐ Compliant ☐ Not Compliant ☐ Not Applicable (no satellite facility)

This standard is not met as evidenced by:

For the cost reporting periods beginning on or after October 1, 2006, in applying the provisions of §412.25(e)(3) —

(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 §412.25(b)(2) (see above), without affecting the provisions of §412.25(e)(3) (see above); 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 §412.25(b)(2) (see above), it may subsequently increase the number of beds at the beginning or a cost

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.

OBSERVATION AND INTERVIEW

- Determine if the unit was a structure of the satellite facility on September 30, 1999. If yes:
  - Was the increase/decrease in square footage of the satellite facility or decrease in the number of beds consistent with the requirement?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
reporting period as long as the resulting total number of beds 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)		
13.00.30 For future use		
13.00.31 Changes in classification of hospital units *For purposes of exclusions from the prospective payment system under this section—* ▪ *The classification of a hospital unit is effective for the unit's entire cost 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)	☐ 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
13.00.32 CAH units not meeting applicable requirements *If a psychiatric or rehabilitation unit of a CAH does not meet the requirements of §485.647 with respect to a cost reporting period—* ▪ *No payment may be made to the CAH for services furnished in that unit for that period.* ▪ *Payment to the CAH for services in the unit may resume only after the start of the first cost reporting period beginning after the unit has demonstrated to CMS that the unit meets the requirements of §485.647.* §412.25(g)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Confirm that the satellite facility is compliant with this requirement.
13.01.00 CONDITION OF PARTICIPATION: Psychiatric and Rehabilitation Distinct Part Units *If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of §485, the common requirements of §412.25(a)(2) through (f) for hospital units excluded from the prospective payment systems, and the additional requirements of §412.27 for*	☐ Compliant ☐ Not Compliant No additional information.	This condition is not met as evidenced by: **DOCUMENT REVIEW** ▪ Confirm that the facility is compliant with this requirement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

excluded psychiatric units.

- *Eligibility requirements.*
  - (1) *To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.*
  - (2) *The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in §485.620(a).*
  - (3) *The average annual 96-hour length of stay requirement specified under §485.620(b) does not apply to the 10 beds in the distinct part units specified in §485.647(b)(1), and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in §485.620.*

§485.647(a)(1)
§485.647(b)
§485.647(b)(1-3)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.00 Excluded psychiatric units, additional requirements: Admission criteria *In order to be excluded from the prospective payment system as specified in §412.1(a)(1), and paid under the prospective payment system as specified in §412.1(a)(2), a psychiatric unit must meet the following requirements —* ▪ *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.* §412.27(a)	☐ Compliant ☐ Not Compliant Patients admitted to the Distinct Part Unit have a principal psychiatric diagnosis that requires active inpatient treatment.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that medical records reflect a principal diagnosis that meets the requirement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.01 Scope of service	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
▪ *Furnish, through the use of qualified personnel, psychological services, social work services, psychiatric nursing, occupational therapy and recreational therapy.* §412.27(b)	Personnel may be contracted or on the regular staff. There must be an employed registered nurse supervising care at all times the unit is open and providing care. A psychiatric nurse(s) under an extended contract meets the requirement for an 'employed' registered nurse. The facility defines the required education, training, and experience for the psychiatric nurse. The facility ensures RNs are qualified and experienced in psychiatric nursing. The facility provides orientation to these supplemental staff.	**DOCUMENT REVIEW** Verify: ▪ The scope of service for the unit includes all required services. ▪ An employed RN is on duty supervising care delivery at all times.
13.02.02 Treatment plan	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
▪ *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)	Each patient record contains a treatment plan.	**DOCUMENT REVIEW** ▪ Review the medical records to confirm that there is a current diagnosis and treatment plan in all patient records.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.03 Development of assessment/ diagnostic data	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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)	The facility ensures each patient record contains a psychiatric history including treatment provided for the psychiatric condition.	**DOCUMENT REVIEW** ▪ Verify that all medical records reflect a psychiatric history of findings and treatment.
13.02.04 Legal status	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The medical records must include: ▪ *Identification of the inpatient's legal status.* §412.27(c)(1)(i)	Legal status is defined in state statutes and dictates the circumstances under which the patient is 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.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Interview the facility staff about the terminology they use in defining "legal status." If evaluation and recertification of the patient is required by the state, confirm that legal documentation supporting this status is present. ▪ Verify that any changes in the legal status of the patient are recorded on the medical record with the date.
13.02.05 Admission diagnosis	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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*	The admission or working psychiatric diagnosis (including rule-out diagnoses) is written in accordance with the most current edition of the American Psychiatric Association's Diagnostic and Statistical Manual (DSM) or the	**DOCUMENT REVIEW** ▪ Verify the requirement is met. **Note:** The admitting diagnosis may be found on the face sheet, in the history

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
diagnoses of intercurrent diseases as well as the psychiatric diagnoses. §412.27(c)(1)(ii)	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.	and physical, or in the physician progress notes. □ Were abnormal lab results or H&P findings followed up and justified? □ Are acute physical illnesses requiring immediate treatment managed appropriately? □ Is the diagnosis written in DSM nomenclature? □ If the diagnosis is absent, is there written justification for the omission? (For example, the patient was psychotic on admission and not accompanied by family.) □ Is there an evaluation and treatment plan for identified physical illnesses that may impact the patient's psychiatric outcome?
13.02.06 Patient reason for admission ▪ *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, including the patient (preferably verbatim), with informant identified.	This standard is not met as evidenced by: **DOCUMENT REVIEW AND FILE REVIEW** ▪ Verify that all clinical records reviewed reflect the reason for admission given by the patient, family, or other interested parties.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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.	
13.02.07 Social history and assessment	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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)	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 is completed for all patients. 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. ▪ 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.	**DOCUMENT REVIEW** Review the social service assessment in a sample of open and closed medical records to verify: ▪ Patient participation to the extent possible. Participation of family members or others in providing information. ▪ All three components are included in the assessment. High-risk psychosocial issues should be included in the treatment plan.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ 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 above 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.	
13.02.08 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 neurologic workup or consultation. ▪ At a minimum, the screening neurological exam includes a detailed description of gross testing for cranial nerves II through XII.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.09 Psychiatric evaluation *Each inpatient must receive a psychiatric evaluation.* §412.27(c)(2)	☐ Compliant ☐ Not Compliant 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 for the purpose of determining the patient's diagnosis and treatment. The psychiatric evaluation must include the following components: 1. Chief complaints, reaction to hospitalization. 2. Past history of any psychiatric problems and treatment, including previous precipitating factors, diagnosis, and course for treatment. 3. Past family, educational, vocational, occupational, and social history. A physician signature is required. In those cases where the mental status portion of the psychiatric evaluation is performed by a non-physician, 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** NOTE: Surveyors will score this standard based on the scoring for standards 13.02.10 through 13.02.16. Review a sampling of open and closed medical records to verify: ▪ Complete psychiatric evaluations were performed for all admissions. ▪ Psychiatric evaluations include: □ Chief complaints. □ 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.
13.02.10 Psychiatric evaluation requirements: Timeframe *Each inpatient receives a psychiatric evaluation that must:* ▪ *Be completed with 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** ▪ Verify that open and closed medical records document a complete assessment completed within 60 hours for all admissions.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.11 Psychiatric evaluation requirements: Medical history *Each inpatient receives a psychiatric evaluation that must:* ▪ *Include a medical history.* §412.27(c)(2)(ii)	☐ Compliant ☐ Not Compliant No additional information.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that open and closed medical records document a medical history was completed on all admissions. □ Does the evaluation include any medical conditions that may impact the patient's recovery/remission?
13.02.12 Psychiatric evaluation requirements: Mental status *Each inpatient receives 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** ▪ Verify that open and closed medical records document a psychiatric evaluation that 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.13 Psychiatric evaluation requirements: Onset of illness *Each inpatient receives 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** ▪ Verify that open and closed medical records document a psychiatric evaluation that includes the onset of the illness and the circumstances leading to admission. □ Are the identified problems related to the patient's need for admission?
13.02.14 Psychiatric evaluation requirements: Description of attitudes and behaviors *Each inpatient receives 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** ▪ Verify that open and closed medical records document a psychiatric evaluation that includes a description of attitudes and patient behavior. □ Does the problem statement describe the behavior(s) which require modification in order for the patient to function in a less restrictive environment?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.15 Psychiatric evaluation requirements: Cognition *Each inpatient receives 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** ▪ Verify that open and closed medical records document a psychiatric evaluation that includes intellectual functioning, memory functioning, and orientation.
13.02.16 Psychiatric evaluation requirements: Assets *Each inpatient receives 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** ▪ Verify that open and closed medical records document a psychiatric evaluation that includes 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.17 Treatment plan	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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 treatment team;* □ *adequate documentation to justify the diagnosis and the treatment and* □ *rehabilitation activities carried out.* §412.27(c)(3)(i)	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.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Observe, as available, scheduled treatment program meetings (individual, group, family meetings, therapeutic activities, and therapeutic procedures) and treatment planning meetings. □ Verify that all disciplines required to meet the patient's needs are represented at planning meetings. ▪ Review a select group of treatment plans to verify: □ 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 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		◻ A primary diagnosis is the basis for treatment interventions. 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, there is documentation that less restrictive 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.18 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 population. Active treatment is an essential requirement for inpatient psychiatric care. The patient is hospitalized because it has been determined that they require intensive, 24-hour, specialized psychiatric intervention that cannot be provided outside the psychiatric unit or hospital. 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that open and closed medical records document 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, based on the assessment, evaluation, and plan of care? □ The facility has policies and procedures on therapeutic use of restrictions, such as visitors, mail, and phone calls to validate patient rights are being protected. □ Policies and procedures adequately direct staff on alternatives or less restrictive interventions prior to the use of seclusion and restraints.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.19 Progress notes requirements	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Progress notes must be recorded by the Doctor of Medicine or Doctor of 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 shall contain recommendations for revisions in 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)	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.	**DOCUMENT REVIEW** Verify: ▪ Progress notes are present in open and closed records. □ Select two or more identified problems and goal statements to trace through progress notes. ▪ Entries are dated and signed with the discipline identified. ▪ Frequency of progress note entries appropriately reflects patient acuity. ▪ The content of treatment notes and progress notes align with regard to: □ The treatment plan. □ What the staff is doing to carry out the treatment plan. □ The patient's response to the treatment plan.
13.02.20 Discharge planning and discharge summary	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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	Facility policies establish requirements of the discharge summary which include: ▪ The reason for admission. ▪ Treatment delivered during hospitalization. ▪ A baseline of the psychiatric and social functioning of the patient at the	**DOCUMENT REVIEW** Verify: ▪ Closed patient records include a discharge summary.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
services concerning follow-up or aftercare as well as a brief summary of the patient's condition on discharge. §412.27(c)(5)	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 including identification of relevant community resources. **Note:** Many states have a range of services offered through the department of health. Examples include but are not limited to core mental health services such as counseling, individual and group therapy, medication, and medication monitoring, outpatient residential services, and specialized programs for children and adolescents.	▪ The discharge summary includes: □ The patient's behavioral condition in relation to short- and long-term goals in the treatment plan. □ Concurrent physical problems, treatment administered, 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 illness, strategies to prevent re-hospitalization, and how to improve disease management skills. ▪ The discharge planning process includes participation of multidisciplinary staff and the patient. □ Details of the discharge plan are communicated to the post-hospital treatment entity when possible.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.21 Staffing requirements *The psychiatric 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, as follows:* *(1) Personnel:* *The unit must employ or undertake to provide adequate numbers of qualified professional, technical, and consultative personnel to—* (i) *Evaluate inpatients.* §412.27(d) §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. The program is responsible for organizing its available staff and administrative duties along with patient appointments, treatment plan meetings, treatment sessions, activities, materials, equipment, and patient assignments to wards and groups in such a way that results in patients achieving the maximum therapeutic benefit.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Through observation, interview, and record review, verify that numbers and/or deployment of qualified staff are adequate. □ Review incident reports, medication error reports, and patient and staff injury reports for indications that staffing is an issue. ▪ Review the planned and actual staffing patterns. Review the treatment calendar. Review admission and discharge logs to identify patterns. □ Is there adequate staff to ensure that admission work-ups (assessment, diagnostic data gathering) are completed in a timely manner? □ Is there evidence of continuing evaluation of the patient's progress and response to treatment? ▪ 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.22 Staffing requirements *The psychiatric 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 Members of the patient's treatment team and others responsible for evaluation and assessment contribute their respective data for consideration in the formulation of the treatment plan.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Do staffing problems prevent staff members from attending treatment meetings? ▪ Are the assessments/evaluations absent or delayed to the extent that they are not useful to the treatment team for the purpose of planning individualized treatment?
13.02.23 Staffing requirements *The psychiatric 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 Active treatment interventions are delivered under the direction of a physician and are specific to patient strengths, disabilities, and problems identified in the treatment plan. Treatment interventions and other services are furnished in accordance with accepted standards of professional practice. Patients receive assistance with resolving or ameliorating the problems/ circumstances that led to hospitalization through treatment focused on their unique needs. For example, multiple patients may be referred to an "anger management group," but the focus of discussion and therapeutic intervention may differ depending on the individual patient's particular issue regarding managing anger. The patient's time on the unit is maximized toward the development of appropriate desired outcomes, including but not limited to leisure and recreation.	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. Verify: ▪ Distribution of qualified staff is consistent with particular patient needs. □ Staffing is sufficient to carry out treatment plans including therapies relevant to the identified problems

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

that brought the patient to the hospital.

- Staff absences and/or vacancies do not prevent patients from receiving active treatment.
- Patients do not miss attending therapeutic activities off the unit because there is no staff to escort them.
- Therapeutic groups are available on the unit for patients who are not able to go off the unit?
- Patient care is not observed to be secondary to administrative tasks.
- Active treatment is implemented as the patient's needs emerge during the course of the day and not only at discrete time intervals.

- Patient interviews indicate that patients believe the treatment being provided is helpful.
- Scheduling of activities and their content relate directly to the patient's treatment objectives rather than serving as generalized, non-therapeutic "time-fillers"? Staff can describe how activities relate to the patient's treatment objectives.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ There is a consistent, observable pattern of evidence that hospital staff provide, reinforce, and otherwise implement measures to achieve active treatment objectives.
13.02.24 Staffing requirements *The psychiatric 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 patient together with all relevant professionals caring for the patient should be expected to participate in the discharge planning process. Staffing should be sufficient to facilitate this outcome, to the maximum extent possible.	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. ▪ Do patients participate in their discharge planning process? If not, why? ▪ Do staff interviews confirm that staff working with patients are aware of the discharge plans for those patients? ▪ Do record review and interviews indicate that all relevant staff have participated in discharge planning?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.25 Director of inpatient psychiatric services: Medical Staff *Inpatient psychiatric services must be under the supervision of a clinical director, service chief, or equivalent that is qualified to provide the leadership required for an intensive treatment program.* *The number and qualifications of Doctors of Medicine and* Doctors of Osteopathic Medicine *must be adequate to provide essential psychiatric services.* §412.27(d)(2)	☐ Compliant ☐ Not Compliant The education, training, and experience for the medical director are established. A member of the organized medical staff is designated as clinical (medical) director and this individual is ultimately responsible for the medical and psychiatric care that is provided to patients. 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.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify that: ▪ There is a named clinical (medical) director. ▪ The medical director meets the qualifications established for the role. ▪ There are enough qualified medical staff to provide the services offered 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 medical) director.
13.02.26 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 Neurology or the American Osteopathic Board of Neurology and Psychiatry.* §412.27(d)(2)(i)	☐ Compliant ☐ Not Compliant The 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: **DOCUMENT REVIEW** ▪ Verify that the medical director meets the residency requirements of a psychiatry/neurology program, approved by the ABPN/AOBNP. ▪ Verify his/her board status.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.27 Medical director responsibilities	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The director must monitor and evaluate the quality and appropriateness of services and treatment provided by the medical staff. §412.27(d)(2)(ii)	The medical director is accountable for the oversight of the QAPI plan related to services provided by the unit staff.	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The medical director is accountable for the professional staff QAPI plan for the unit. ▪ The QAPI plan and implementation of education/training for all levels of staff are responsibilities of the medical director. ▪ The unit has 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.
13.02.28 Nursing services	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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.*	See scoring procedure for additional information.	**Note:** This standard is scored based on the results of scoring for standards 13.02.29 and 13.02.30.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

§412.27(d)(3)

13.02.29 Nursing services leadership

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

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 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)

The facility has established the education, training, and experience requirements for the director of psychiatric nursing position.

The duties, functions, and responsibilities of the role are clearly delineated and include:

1. Supervision and evaluation of nursing and paraprofessional staff.
2. Participation in the formulation of patient treatment plans.
3. Medication teaching.
4. Management of therapeutic environments.
5. Provision of mandatory and voluntary in-service training for specialized treatments and therapies, such as individual group and family therapies that require the expertise of the professional psychiatric nurse.

INTERVIEW AND DOCUMENT REVIEW

Verify:

- There is a qualified individual named as the psychiatric nursing director.
- The director meets the established qualifications.

  Note: Education/experience in the care of the mentally ill may be evidenced by:

  - ☐ A master's degree in psychiatric/ mental health nursing.
  - ☐ RN with a related master's degree, such as psychology or nursing education, with two years of psychiatric inpatient nursing care.
  - ☐ A BSN, ADN, or diploma in nursing with at least two years of psychiatric inpatient nursing care and documentation of ongoing education focused on psychiatric nursing, occurring at sufficient intervals to maintain current knowledge.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		◻ Documented clinical consultation/ supervision from a master's prepared psychiatric nurse.
13.02.30 Staffing *The staffing pattern shall ensure the availability of a registered nurse 24 hours each day.* *There shall 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: **DOCUMENT REVIEW AND INTERVIEW** ▪ Verify the availability of at least one RN per shift for each facility unit. ◻ Request calculations regarding planned and actual staffing in raw numbers and full-time equivalencies. ▪ Nurse staffing is not diluted by the performance of non-nursing activities such as housekeeping and escort services. ▪ Nurses are present in group facilitation, 1:1 interventions, etc.
13.02.31 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*	☐ 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** ▪ Determine the number of full-time, part-time, and consulting psychologists. If contractual services are used, determine availability to provide needed services to patients.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
policies and procedures. §412.27(d)(4)		▪ Determine the extent that psychological testing is requested, the response time, and the availability of the results. ▪ Verify that patients in need of psychological therapy or testing receive those services in a timely manner, and with sufficient intensity.
13.02.32 Social services	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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 procedures.* *Social service staff responsibilities shall include, but are not limited to, participating in discharge planning, arranging for follow-up care, and developing mechanisms for exchange of appropriate information with sources outside the hospital.* §412.27(d)(5)	The duties, functions, and responsibilities of the director of social services are 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 findings should result in significant data being available for early integration into the treatment plan and subsequent social work action as indicated. The treatment team should consider the anticipated social work role and expected interventions as recommended in the psychosocial assessment for possible inclusion into the patient's treatment plan. 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 AND DOCUMENT REVIEW** Verify: ▪ There is a qualified individual named as the director of social services. ▪ The director is qualified. ▪ How services are provided to patients through review of medical records and interview. □ Does the director of social services periodically audit the quality of social work services?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.02.33 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: **OBSERVATION AND INTERVIEW** ▪ Verify that a therapeutic activities program provides a variety of activities throughout the week.
13.02.34 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.* §412.27(d)(6)(i)	☐ 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: **OBSERVATION AND INTERVIEW** ▪ Verify the adequacy of activities in providing safe and meaningful outlets that correlate to the identified needs of the patient population. □ Has the unit ensured consistent availability and provision of individualized therapeutic activities and rehabilitative services based on patient's needs?
13.02.35 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 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:	This standard is not met as evidenced by: **OBSERVATION AND INTERVIEW** Verify: ▪ The number of full-time, part time and consulting therapeutic activity staff. ▪ Their roles and responsibilities in

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ An occupational therapist. ▪ A Bachelor of Science (BS)-prepared recreational therapist. ▪ A Bachelor of Science (BS)- or Bachelor of Arts (BA)-prepared music or other related therapist.	accomplishing the philosophy of the program. ▪ There are clearly defined monitoring and evaluation mechanisms to conduct consistent and timely review of the quality and appropriateness of therapeutic and rehabilitative services.
13.03.00 Scope and description of available services There is a written program description which includes, but is not limited to: ▪ The scope of services provided specific to inpatient, partial day, residential and outpatient and aftercare programs and how these programs relate to each other. ▪ Services specific to these programs including: □ Admission criteria, including limitations. □ Assessment/evaluation process. □ Treatment planning processes. □ Therapeutic modalities utilized. □ Provisions for children, adolescent, young adult, adult, geriatric and mentally/developmentally disabled patients.	☐ 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 to verify: ▪ It includes the required elements. ▪ It addresses the ages of patients and the conditions accepted for service.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
□ Staffing, including the roles, responsibilities and supervisory relationships of professional staff as part of the treatment team. □ Integration with the quality assessment and performance improvement (QAPI) Program. **§412.25(a)** **§412.27(a)**		
13.03.01 Physical facilities 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. **§485.608(a)** **§485.614(c)(1)** **§485.614(c)(2)** **§485.623(a)**	☐ Compliant ☐ Not Compliant 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, and etc. Showerheads and other fixtures are designed to reduce the potential of patient injury.	This standard is not met as evidenced by: **OBSERVATION** Verify: ▪ The physical setting promotes reasonable privacy and the dignity for patients. ▪ The environment promotes a sense of safety and security.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.03.02 Patient bedrooms: Safety and security ▪ 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. **§485.614(c)(1)** **§485.614(c)(2)**	☐ 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.	This standard is not met as evidenced by: **OBSERVATION** Verify: ▪ Staff has ready access to patients. ▪ 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. □ Barricading possibilities are considered and risk mitigation strategies are implemented. □ Mirrors and light fixtures are shatter-resistant. □ Light fixtures are secure from tampering.
13.03.03 Patient hygiene needs ▪ Patients are provided with clean towels and bed linens on a regularly scheduled basis, and as required to meet basic hygienic needs.	☐ 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ 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 are oriented to the unit's expectations concerning housekeeping. Access to hazardous cleaning chemicals is minimal and constantly supervised. **§485.614(c)(2)**		□ Does staff assist patients who need help in changing bed linen? ▪ Are "housekeeping" activities promoted as participating in normal activities of daily living behavior? ▪ Are patients oriented to these expectations? Are such duties assigned as discipline or in a punitive fashion? ▪ Verify that reasonable care is taken by staff to limit (or directly supervise) patient access to hazardous chemicals.
13.03.04 <u>Handicapped accessibility</u>	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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. **§412.27(c)(3)(i)** **§482.13(c)(2)** **§485.623(a)**	The facility shall be barrier-free consistent with the current provisions of the Americans with Disabilities Act (ADA).	**<u>OBSERVATION</u>** ▪ While touring the unit, confirm that the area is barrier-free.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
13.03.05 Confidentiality of information Policies and practices protect clinical data and information, which may be described as "unusually sensitive" for psychiatric patients. **§485.614(d)(1)** **§485.638(a)(1)** **§485.638(b)(1)** **§485.638(b)(2)**	☐ 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 records are not routinely forwarded but are made available as needed. 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 AND DOCUMENT REVIEW** Verify: ▪ Policies address the required security and confidentiality of patient information. ▪ Clinical areas do not indicate potential for breaches in security and confidentiality of patient information.

14

LIFE SAFETY

INTRODUCTION

Life Safety primarily pertains to ensuring fire safety, fire protection, and systems that safeguard the well-being and lives of individuals within a building. Considering that these life safety systems, building characteristics, and other related systems are in place to promote and preserve a secure environment, it is important to regard this chapter as a natural continuation of the standards for Physical Environment.

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 Critical Access Hospitals (CAHs) must include healthcare occupancy designations; however, CAHs 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 accommodation for their occupants.

The requirements established by this chapter apply to all CAHs, nursing homes, and limited care facilities.

Examples of Healthcare Occupancies:

- CAHs
- 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 surgical centers
- Diagnostic centers

CMS has determined that all ambulatory surgical centers shall comply with ambulatory health care occupancy requirements regardless of how many patients are incapable of self-preservation.

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.)

This chapter will use the term 'CAH' and 'hospital' interchangeably to refer to all occupancies that are included within the facility that houses the healthcare occupancy. The CAH is expected to be 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 to waive compliance requirements 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 the 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. See §482.41(b)(2); §485.623(d)(2); §485.623(d)(3).

EQUIVALENCIES

After consideration of survey findings, 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 CAH, but only if the equivalency does not adversely affect the health and safety of patients.

Submission of an FSES equivalency request may be made by the CAH after the deficiency has been cited during a survey. The organization identifies the intention to submit an FSES equivalency request on its Plan of Correction as the proposed correction for that particular deficiency.

The FSES equivalency request is submitted to ACHC with any other required Plans of Correction. 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 may approve FSES equivalency requests for Medicare or Medicaid-participating CAHs.

When making a FSES equivalency request, the CAH 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 CAH has an acceptable level of safety based on other features of fire safety, even though the CAH 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: TIME FRAMES

ACHC standard 14.00.06 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'. ACHC has reviewed all of the NFPA standards and developed a standard that everyone can follow to satisfy the intent of the respective 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

ACHC standard 14.00.07 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 Critical Access Hospital creates their own documents or relies on those provided by contractors.

FACILITY DEMOGRAPHIC REPORT

The Facility Demographic Report (FDR) is a document that requests basic information about the facility that must 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 employed by the CAH, or it may be an individual contracted by the CAH to complete the document. Failing to properly answer each question on the FDR will result in a citation.

LIST OF CHAPTER STANDARDS

GENERAL REQUIREMENTS

MEANS OF EGRESS

FIRE ALARM SYSTEMS

FIRE SUPPRESSION SYSTEMS

FIRE SAFETY PROGRAM

BUILDING SERVICES

Fireplaces	03.05.01
Elevator recall	03.05.02
Trash and linen chutes	14.05.03
Generator inspection	14.05.04
Generator monthly load test	14.05.05
Generator three-year load test	14.05.06
Automatic transfer switch test	14.05.07
Health care microgrid systems (HCMS)	**14.05.08**
Medical gas shutoff valves	14.05.09
Utility systems	14.05.10
Medical gas systems and equipment: Maintenance	14.05.11
Cooking hood cleaning	14.05.12
Health Care Facilities Code	**14.05.13**

OPERATING FEATURES

Decorations	14.06.01
Trash receptacles	14.06.02
Portable heaters	14.06.03
Life safety drawings	14.06.04
Alcohol-based handrub dispensers	14.06.05

COMPLIANCE REFERENCES

CMS references	14.07.01

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

GENERAL REQUIREMENTS

14.00.01 Life Safety Code compliance

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Life safety from fire.

(1) Except as otherwise provided in this section—

(i) *The CAH 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.)*

(ii) *Notwithstanding paragraph (d)(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.*

(2) In consideration of a recommendation by the State survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon a CAH, but only if the waiver will not adversely affect the health and safety

All CAHs, 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 is used for CAH business must comply with the Life Safety Code.

The CAH ensures that any necessary life safety features for new construction are not removed or reduced. If the Life Safety Code does not mandate the presence of existing life safety features, they may choose to either maintain or eliminate them.

(For full text, refer to NFPA 101-2012: 4.6.12.2; 4.6.12.3; 18/19.7.9.)

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.

OBSERVATON AND DOCUMENT REVIEW

Verify:

- Through observation that buildings comply with the applicable occupancy chapters of the Life Safety Code and other applicable codes.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

of the patients.

(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

§485.623(c)(1)(i-ii) Tag C-0930
§485.623(c)(2) Tag C-0942
§485.623(c)(3) Tag C-0932

14.00.02 Alternative Life Safety Measures (ALSM): Policy

The CAH 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 as 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 CAH's ALSM policy.

☐ Compliant ☐ Not Compliant

Features of life safety may be compromised or impaired during periods of construction, maintenance, or emergency repairs. During these periods, the CAH 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 features may require compensation, but the ALSM policy must clearly distinguish when and to what extent such measures are implemented.

Examples of alternative measures may include:

- **Implementing a fire watch.**
- **Installing alternative exit signage or covering or removing exit signage that directs to unsafe areas.**
- **Daily inspection to confirm free and unobstructed access to exits.**
- **Temporary but equivalent fire alarm and detection systems.**

This standard is not met as evidenced by:

DOCUMENT REVIEW

Verify:

- The CAH'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
The ALSM policy must identify when a particular compensating measure is required to be implemented and to what extent that measure is implemented.	▪ **Additional firefighting equipment, such as portable fire extinguishers.** ▪ **Temporary, smoke-tight, noncombustible partitions.** ▪ **Increased surveillance of buildings, grounds, and equipment.** ▪ **Storage, housekeeping, and debris removal practices.** ▪ **Enforcement of smoking policies.** ▪ **Enforcement of hot work permits.** ▪ **Additional training for staff in the use of fire equipment, or for construction hazards and temporary measures, or for use of fire extinguishers.** ▪ **Performance of additional fire drills either facility-wide or in areas adjacent to the activity.** **(For full text, refer to NFPA 101-2012: 4.6.10.)**	
14.00.03 Alternative Life Safety Measures (ALSM): Implementation When a Life Safety Code deficiency cannot be corrected the same day it is discovered, the CAH conducts an assessment and implements appropriate measures to compensate for impairments to the Life Safety Code, based on their ALSM policy. The assessment is documented. **§485.623(c)(1)(i-ii)**	☐ Compliant ☐ Not Compliant ☐ N/A When conditions exist that compromise 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. **(For full text, refer to NFPA 101-2012: 4.6.10.)**	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 where a feature of life safety may be compromised, such as construction areas and areas undergoing maintenance.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.00.04 Notification of emergency response forces When a fire alarm system, or parts thereof, are out of service more than four hours in a 24-hour period, the CAH must evacuate the building, evacuate the portion(s) of the building affected by the outage, or establish a fire watch for affected areas. When an automatic *sprinkler system,* or parts thereof, *are out of service for more than ten hours* in a 24-hour period, *the CAH must evacuate the building, evacuate the portion(s) of the building affected by the outage or establish a fire watch* for affected areas. Under these circumstances, the local emergency response force (fire department) must be notified. The fire watch and the notification of are documented. §485.623(c)(6)(i-ii) Tag C-0938	☐ Compliant ☐ Not Compliant ☐ N/A The organization must take appropriate action when the fire alarm system (or parts thereof) is out of service for more than four hours in a 24-hour period, and when the automatic sprinkler system (or parts thereof) is out of service for more than ten hours in a 24-hour period. The phrase 'or parts thereof' refers to circuits or branches of the systems, not a single device. Refer to ACHC standard 14.00.09 for the proper method and procedure to conduct a fire watch. **(For full text, refer to NFPA 101-2012: 9.6.1.6; 9.7.6; NFPA 25-2011: 15.5.2(4).)**	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
14.00.05 Facility demographic report (FDR) The CAH designates an individual to assess the facility's compliance with NFPA 101 *Life Safety Code* (2012 edition), and complete and maintain the Facilities Demographic Report (FDR) and manage all deficiencies. Qualifications and the designation of the responsible individual are documented. 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.	☐ Compliant ☐ Not Compliant 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 CAH must complete the ACHC Facility Demographic Report on at least an annual basis, or more often as needed, for example, when construction or renovations are completed for areas more than 50% of a smoke compartment or 4500 square feet. An FDR must be completed for each facility identified as a healthcare occupancy or as an ambulatory healthcare occupancy and maintain the accuracy of the information. Business occupancies do not require an FDR.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ 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 assessment and maintains the accuracy of the information. Verify that each question was answered accurately.
14.00.06 Testing and inspection: Definition of time periods Unless otherwise stated, the periods of time for testing, inspection and maintenance activities specified within this chapter are: Weekly or 'every 7 days': ▪ The activity is performed and completed anytime during the calendar week.	**Not scored at this standard.** 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.	**DOCUMENT REVIEW** ▪ 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
Monthly or 'every 30 days': ▪ The activity is performed and completed anytime during the calendar month. Quarterly or 'every 3 months': ▪ The activity is performed and completed quarterly, during the third month of the quarterly period. Semi-annually or 'every 6 months': ▪ The activity is performed and completed semi-annually, during the 6th month of the semi-annual period. Annually or 'every 12 months': ▪ The activity is performed and completed annually, during the 12th month of the annual period. 3-Years: ▪ The activity is performed and completed once every 3 years, during the 36th month of the 3-year period. 5-Years: ▪ The activity is performed and completed once every 5 years, during the 60th month of the 5-year period. 6-Years: ▪ The activity is performed and completed once every 6 years, during the 72nd month of the 6-year period.		testing/inspection activity.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.00.07 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.'	**Not scored at this standard.** 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 ACHC standard 14.00.03) 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. **(For full text, refer to NFPA 25-2011: 4.3; 4.4; NFPA 72-2010: 14.2.1; 14.2.2; 14.2.3; 14.2.4)**	**DOCUMENT REVIEW** ▪ 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.00.08 Interior finish The interior finish on existing walls and ceilings must be Class A or Class B, except rooms protected with sprinklers 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. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ 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. 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. **(For full text, refer to NFPA 101-2012: Chapter 10.)**	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Review the flame spread rating of 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.
14.00.09 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.	☐ 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	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ Ask to see the documentation of the fire watch. ▪ Check to see that fire watches are performed continuously, without interruption.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.623(c)(1)(i-ii) Tag C-0930	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 more than 30 minutes for one individual to complete one round of the affected area, then additional individuals must be assigned to fire watch duty. 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 A.15.5.2 (4)(b), NFPA 25 *Inspection, Testing, and Maintenance of Water-Based Fire Protection Systems*, 2011 edition. **(For full text, refer to NFPA 25-2011: 15.5.2; NFPA 101-2012: 3.3.104.)**	▪ Determine if the individual(s) performing the fire watch have received fire-response training.

MEANS OF EGRESS

14.01.01 <u>Doors</u> 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. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant Latching devices are necessary to keep patient room doors securely closed in the event of a fire. Positive latching devices are required on all corridor doors **(see 18/19.2.2.2.4; 18/19.2.2.2.5; 18/19.2.2.2.6 of the 2012 edition of the Life Safety Code)**. The use of roller latches will not be allowed on corridor doors in CAHs where corridor doors are required to latch (see ACHC standard 14.00.01). 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.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW AND OBSERVATION</u>** ▪ 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, capable of 'breaking away,' and swing from the side hinges unless the door serves a room with an occupant load under 10 persons.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	Doors must open to a minimum of 90 degrees from its closed position and extend no more than 7 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 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 the door threshold. The depth of the landing is to be at least equal to the width of the widest door leaf **(see 18/19.2.7; 7.1.7; 7.1.10.1; 7.2.5; 7.7.2 of the 2012 edition of the Life Safety Code)**.	▪ Ensure doors in the path of egress open to at least 90 degrees and extend no more than 7 inches into the corridor when fully opened.
14.01.02 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.	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	**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 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 5 feet of the door, that unlocks the door when depressed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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 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*. **§485.623(c)(1)(i-ii) Tag C-0930**	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 of the 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 clinical needs locks and ensure they are only installed in psychiatric, Alzheimer's, dementia, and substance abuse units. ▪ 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.
14.01.03 <u>Corridor clutter</u> The exit access corridor must be maintained to the full required width. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant Minimum width of exit access corridors for new construction in an acute-care CAH is 8 feet **(see 18.2.3.4 of the 2012 edition of the *Life Safety Code*)**. Minimum width of exit access corridors for new construction in a psychiatric care CAH is 6 feet **(see 18.2.3.5 of the 2012 edition of the *Life Safety Code*)**. 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 **(see 4.6.12.2; 19.2.3.4 of the 2012 edition of the *Life Safety Code*)**.	This standard is not met as evidenced by: **<u>OBSERVATION</u>** ▪ 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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 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*. **(For full text, refer to NFPA 101-2012: 18/19.2.3.4(4); 18/19.2.3.4(5); 18/19.2.5.1; 7.1.10.1; 7.5.1.1.)**	▪ Review the organization's plan to remove the authorized carts from the corridor during a fire emergency.
14.01.04 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	☐ Compliant ☐ Not Compliant ☐ N/A 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	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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. **§485.623(c)(1)(i-ii) Tag C-0930**	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. **(For full text, refer to NFPA 101-2012: 18/19.2.5.7.)**	▪ 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.
14.01.05 <u>Signage</u> 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.	☐ Compliant ☐ Not Compliant All exits must be marked with an approved EXIT sign, except for 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 **(see 7.10.9 of the 2012 edition of the *Life Safety Code*)**. 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 **(see 7.10.8.3 of the 2012 edition of the *Life Safety Code*)**. 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	This standard is not met as evidenced by: **<u>OBSERVATION AND DOCUMENT REVIEW</u>** ▪ 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 ensure all exit signs were inspected.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
This inspection is documented. **§485.623(c)(1)(i-ii) Tag C-0930**	more stories. **(For full text, refer to NFPA 101-2012: 18/19.2.10.1; 7.2.2.5.4; 7.10.2 – 7.10.10.)**	
14.01.06 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. The exit discharge shall be illuminated under both the normal and emergency lighting mode, all the way to the public way. **§485.623(c)(1)(i-ii) Tag C-0930**	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 one-quarter 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 comply with this standard due to the uneven walking surface. Illumination of 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. **(For full text, refer to NFPA 101-2012: 7.7; 7.8.)**	**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.
14.01.07 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	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 of how long they have been installed.	**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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. **§485.623(c)(1)(i-ii) Tag C-0930**	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 **(see 18/19.2.5.2 of the 2012 edition of the *Life Safety Code*)**.	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?
14.01.08 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. **§485.623(c)(1)(i-ii) Tag C-0930**	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 ACHC standard 14.01.03. **(For full text, refer to NFPA 101-2012: 18/19.2.3.4(4); 18/19.2.3.4(5); 18/19.2.5.1; 7.1.10.1; 7.5.1.1.)**	**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.
14.01.09 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	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. **(For full text, refer to NFPA 101-2012: 7.6; 18/19.9.2.6.)**	**OBSERVATION** ▪ During the building tour, examine selected travel distances to exits to ensure they are within the allowable amount.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

travel distance from any point in a room to an exit is 200 feet.

§485.623(c)(1)(i-ii) **Tag C-0930**

14.01.10 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 constructed and maintained in accordance with section 7.1 of the 2012 *Life Safety Code*.

§485.623(c)(1)(i-ii) **Tag C-0930**

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:

- 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.

OBSERVATION

- During the building tour, examine exit enclosures to ensure they do not have openings to unoccupied rooms.
- 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
	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" (see chapter introduction for definition) which permit 7 feet, 0 inches. Stairs and ramps that continue more than one-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. **(For full text, refer to NFPA 101-2012: 18/19.2.2.3; 7.1.3.2.3; 7.2.2.5.3.1.)**	
FIRE DETECTION SYSTEMS		
14.02.01 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. **§485.623(c)(1)(i-ii)** **Tag C-0930**	☐ 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.02.02 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. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant Reliability of the CAH's fire alarm system is critical for the safety of the facilities occupants. This standard does not require the CAH 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 overall 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. 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. **(For further guidance on performing tests, refer to NFPA 72-2010: Table 14.4.5.)**	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 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 CAH 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).

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.02.03 Fire alarm system - 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 premise, to the emergency response force. All results of the tests are documented. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ 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 receives 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 conditions must be tested during fire drills per NFPA 101 *Life Safety Code* (2012 edition), 18/19.7.1.4. **For fire drills, see ACHC standard 03.04.02.** 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review CAH records to determine whether the fire alarm system signal is transmitted annually from the fire alarm panel to the emergency response force. ▪ Review CAH fire drill records to determine whether the fire alarm system signal is transmitted quarterly from the fire alarm panel to the emergency response force when fire drills are conducted.
14.02.04 Fire alarm system: Technician qualifications. 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)	☐ 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Documentation for the individual(s) performing testing, inspection or maintenance of fire alarm system, and their components, must be on file for reviewed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
performing testing, inspecting and maintenance activities on the fire alarm system must be available for review. **§485.623(c)(1)(i-ii) Tag C-0930**	▪ National Institute for Certification in Engineering Technologies (NICET) fire alarm certified. ▪ International Municipal Signal Association (IMSA) fire alarm certified. ▪ Certified by a state or local authority. ▪ Trained and qualified personnel employed 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 CAH staff.	▪ Review documentation that demonstrates compliance with this standard.

FIRE SUPPRESSION SYSTEMS

14.03.01 Water-based fire protection system: Installation and maintenance	☐ Compliant ☐ Not Compliant ☐ N/A	This standard is not met as evidenced by:
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. **§485.623(c)(1)(i-ii) Tag C-0930**	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 **(see 18.3.5.1; 19.3.5.1; 9.7.5 of the 2012 edition of the Life Safety Code. See 5.2.1.1.1; 5.2.1.1.2 of the 2011 edition of NFPA 25. See 6.2.6.2.2; 6.2.7.1 of the 2010 edition of NFPA 13)**.	**INTERVIEW AND OBSERVATION** ▪ 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.03.02 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. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant ☐ N/A Water-based sprinkler systems, including pre-action and dry-pipe systems, are included in this standard. This standard does not require a CAH 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: ▪ Sprinklers **(see NFPA 25-2011: 5.2.1)**. ▪ Piping and hangers **(see NFPA 25-2011: 5.2.2)**. ▪ Control valves, valve components and trim **(see NFPA 25-2011: 5.2.2)**. ▪ Water-flow devices **(see NFPA 72-2010: 14.4.5)**. ▪ Standpipe and hoses **(see NFPA 25-2011: 6.3.1; NFPA 1962-2008: 4.3.2; 4.3.4)**. ▪ Dry-pipe, deluge, and pre-action valves **(see NFPA 25-2011: 13.4.3.2.2; 4.3.2.1)**. ▪ **Private** service mains **(see NFPA 25-2011: 7.3.1)**. ▪ Storage tanks **(see NFPA 25-2011: 9.3; Table 9.1.1.2)**. Control valves are required to be visually inspected monthly to confirm they are still in their designated position. This inspection must be documented.	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. ▪ Verify that the water-based fire protection system documentation fully complies with the frequencies identified in NFPA 25 (2011 edition). Each individual fire alarm device that is tested must be identified as to its location, and whether or not it passed or failed its test. ▪ During the document review session, ensure the sprinkler control valves are inspected monthly.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.03.03 Water-based fire protection system: Control valves, piping and hangers 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 14.02.02. Sprinkler piping and hangers are 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. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant ☐ N/A 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. **(For full text, refer to NFPA 25-2011: 13.3.2.1.1; 5.2.2.2.)**	This standard is not met as evidenced by: **OBSERVATION** ▪ 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.
14.03.04 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.	☐ Compliant ☐ Not Compliant ☐ N/A This standard does not require the installation of fire pumps in the facility. If so equipped, the CAH 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. **(For full text, refer to NFPA 25-2011: 8.3.1; 8.3.2.)**	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ During the document review session, review documentation to ensure fire pump is tested in accordance with NFPA 25.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
The result of all testing is documented. **§485.623(c)(1)(i-ii) Tag C-0930**		
14.03.05 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 result of all testing activities is documented. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant ☐ N/A A CAH 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. 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. **(For full text, refer to NFPA 25-2011: 8.3.3.)**	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ During the document review session, 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
14.03.06 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. The results of all testing activities are documented. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant ☐ N/A 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 **(see NFPA 12A-2009: 7.1.1).** ▪ FM-200 systems **(see NFPA 2001-2012: 7.1.1; 7.1.3).** ▪ Inergen systems **(see NFPA 2001-2012: 7.1.1; 7.1.3).** ▪ CO2 systems **(see NFPA 12-2011: 4.8; 4.8.3.5.1; 4.8.3.2)**.	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.
14.03.07 Water-based standpipes and hoses: Inspection and test 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.	☐ Compliant ☐ Not Compliant ☐ N/A This standard does not require the installation of standpipes or occupant-use fire hoses. If so equipped, the CAH 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 **(see 6.3.1; 6.3.2; Table 6.1.1.2 of the 2011**	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review documentation to ensure wet standpipe systems are water-flow tested at least once every five years in accordance with NFPA 25. ▪ Review documentation to ensure 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. **§485.623(c)(1)(i-ii) Tag C-0930**	**edition of NFPA 25)**. Dry standpipes, including piping in the fire department connection, must by hydrostatic tested once every five years. This standard does not require the installation of occupant-use fire hoses, but if the CAH 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 **(see NFPA 1962-2008: Chapter 7; and NFPA 25-2011: Chapter 6)**.	▪ Review documentation of annual fire hose inspection and when it was last pressure tested or replaced. ▪ Review the documentation from the local or state authority having jurisdiction (AHJ) granting permission to remove occupant-use fire hoses from the facility.
14.03.08 <u>Water-based fire department connections</u> 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. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant ☐ N/A The CAH 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 be obstructed by vehicles, vegetation, or anything else preventing its view from the street.	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review documentation to ensure fire department connections are inspected at least once per quarter. ▪ Observe fire department connections to verify that they are not obscured and are visible from the street.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.03.09 <u>Portable fire extinguishers: Installation, inspection and maintenance</u> 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. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ 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 of the requirements in NFPA 10-2010, chapter 7. The selection of portable fire extinguishers is based on the hazard it is 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 the individual performing the inspection. Electronic documentation is acceptable provided it contains all required data and is retrievable at the time of survey **(see 7.2.2; 7.2.4 of the 2010 edition of NFPA 10)**. **For further guidance on performing tests, refer to NFPA 10-2010: 7.1.2; 7.2.2; 7.2.4; 7.3.1.)**	This standard is not met as evidenced by: **<u>OBSERVATION AND DOCUMENT REVIEW</u>** ▪ 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 4 inches above the floor and the handle is no more than 60 inches above the floor.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.03.10 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. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ 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 **(see 13.5.6.2.1 of the 2011 edition of NFPA 25)**. 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 **(see 13.5.6.2.2 of the 2011 edition of NFPA 25)**.	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
14.03.11 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. **§485.623(c)(1)(i-ii) Tag C-0930**	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. **(For further guidance on performing tests, refer to NFPA 25-2011: 14.2.1)**	**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.
14.03.12 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 area. **§485.623(c)(1)(i-ii) Tag C-0930**	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. ▪ The pressure gauge(s), if provided, shall be inspected physically or electronically to ensure it is in the operable range. ▪ The nozzle blowoff caps, where provided, are intact and undamaged. ▪ Neither the protected equipment nor the hazard has been replaced, modified, or relocated.	**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 compliance with hazardous area requirements.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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.	
FIRE SAFETY SYSTEMS		
14.04.01 Fire-rated barriers The CAH shall ensure that fire-rated barriers are properly rated, appropriate for their purpose, be free from unsealed penetrations, and have the appropriate fire-rated opening protectives. **§485.623(c)(1)(i-ii)** **Tag C-0930**	☐ 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 -

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		rated, self-closing and positive latching.
14.04.02 Smoke barriers The CAH shall assure 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. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant The 2012 edition of the *Life Safety Code* specifies where barriers for smoke compartments 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-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.	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.
14.04.03 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 CAHs. In healthcare facilities not classified as CAHs, fire and smoke dampers must be fully tested and operated one year after installation, and once every four years	☐ 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.	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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
thereafter. The results of all inspection activities are documented. **§485.623(c)(1)(i-ii) Tag C-0930**	▪ 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.	▪ Verify that each fire and smoke damper is documented, and identified as to its location, and whether or not the damper passed or failed its test.
14.04.04 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 NFPA 80 *Standard for Fire Doors and Fire Windows* (2010 edition). The results of all testing and inspection activities are documented. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant ☐ N/A CAHs 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 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.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Documentation demonstrating compliance with NFPA 80 (2010 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.
14.04.05 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	☐ 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.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Examine the Facility Demographic Report to find the facility's construction type. ▪ During building tour, observe number of stories and sprinkler installation to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
maintained according to the UL listing and/or manufacturer's recommendation. **§485.623(c)(1)(i-ii) Tag C-0930**	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.	determine if the construction type listed is correct. ▪ During the building tour, observe the fire-proofing material applied to the structural steel to ensure it is installed and maintained correctly.
14.04.06 Separated occupancies When different occupancies are claimed to be separated in the facility, two-hour fire- rated barriers separate healthcare occupancies from all other occupancies, and one-hour fire-rated barriers separate non-healthcare occupancies. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant ☐ N/A If the organization claims to have separated occupancies in the same building as the healthcare occupancy, then two-hour fire-rated barriers must separate the occupancies. Note that a two-hour fire-rated floor assembly does qualify as an appropriate barrier for occupancy separation but does not qualify as an appropriate building (i.e., construction type) separation. **(For further guidance, refer to NFPA 101-2012: Table 6.1.14.4.1(a).)**	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. ▪ Examine fire-rated barriers to determine if they are free from unsealed penetrations and have appropriately rated doors assemblies.
14.04.07 Fire-rated door assemblies 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.	☐ Compliant ☐ Not Compliant 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	This standard is not met as evidenced by: **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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
The test and inspection are documented. **§485.623(c)(1)(i-ii) Tag C-0930**	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.	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 the door assemblies were tested and inspected on an annual basis.
14.04.08 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 one-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 one-hour fire-rated barriers that extend from the	Hazardous areas must be identified on the organization's life safety drawings. The type of barrier for a hazardous area depends on whether the area is new or existing construction, and whether 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 must meet new construction requirements. Under certain conditions, the space may be able to meet hazardous area requirements for existing conditions. Refer to Chapter 43.7.1.2 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 determine if it meets the requirements listed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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 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. **§485.623(c)(1)(i-ii) Tag C-0930**		
14.04.09 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. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ 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. **(For further guidance, refer to NFPA 101-2012: 3.3.254; 8.4.2(2); 8.4.4.1; 8.5.6.2; 8.5.6.5.)**	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.
14.04.10 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	☐ Compliant ☐ Not Compliant A 30-minute fire-rated wall is defined by NFPA as 3½-inch steel studs with one layer of five-eighths-inch gypsum board on one side. **(For full text, refer to NFPA 101-2012: 8.4.)**	This standard is not met as evidenced by: **OBSERVATION** ▪ During the building tour, examine above the ceilings in corridors in non-

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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 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. **§485.623(c)(1)(i-ii) Tag C-0930**		sprinklered smoke compartments to determine if corridor walls extend to the deck and are free from unsealed penetrations.

BUILDING SERVICES

14.05.01 Fireplaces Direct-vent gas fireplaces are permitted inside smoke compartments containing patient sleeping areas, but not in patient sleeping rooms. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant ☐ N/A 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.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ During the building tour, if a fireplace is observed, determine that is not located in a patient sleeping room.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ 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. **(For full text, refer to NFPA 101-2012: 18/19.5.2.3.)**	
14.05.02 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 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. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant ☐ N/A 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 in alarm. Elevator recall is tested monthly in accordance with the Life Safety Code, regardless of what the Elevator Safety Code requires. **(For full text, refer to NFPA 101-2012: 9.4.3.2; 9.4.6.2.)**	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ During the document review session, review testing documents to ensure the organization is testing recall every month.
14.05.03 Trash and linen chutes 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.	☐ Compliant ☐ Not Compliant ☐ N/A 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.	This standard is not met as evidenced by: **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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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 one-hour fire-rated barriers. **§485.623(c)(1)(i-ii) Tag C-0930**	**Existing linen chutes are permitted to discharge into the same room as trash chutes provided the room is protected with automatic sprinklers.** **(For full text, refer to NFPA 101-2012: 9.5.)**	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 one-hour fire separation requirement.
14.05.04 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 two-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 conductivity test performed.	Routine inspection must be accomplished in accordance with NFPA 110 (2010 edition)**.** For all emergency power generators (regardless of when they were installed) located inside the building, the generator must be installed within a separate room with a minimum of two-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 **(see 7.2.1.1 of the 2010 edition of NFPA 110)**. No other equipment except that which serves the space is permitted to be stored in these rooms **(see 7.2.1.2 of the 2010 edition of NFPA 110)**. 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 **(see 8.3.7: 8.3.7.1; 8.3.7.2 of the**	**OBSERVATION AND INTERVIEW** ▪ Confirm generators located indoors are separated with two-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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
Results of inspection shall be documented. **§485.623(c)(1)(i-ii) Tag C-0930** **§485.623(e)(1-3) Tag C-0950**	**2010 edition of NFPA 110)**. A fuel quality test shall be performed at least annually using tests approved by ASTM standards **(see 8.3.8 of the 2010 edition of NFPA 110)**. 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. **(For further guidance on testing procedures, refer to NFPA 99-2012: 8.3.1; 8.3.3; 8.3.4; 8.4.1.)**	
14.05.05 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 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 CAH 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,	Emergency power generator sets shall be tested in accordance with NFPA 110-**2010: 8.4.** **Spark-ignited generators must be tested in accordance with NFPA 110-2010: 8.4.2.4 and 8.4.9.5.3.** **The owner must determine the date and time of day for mandatory testing, taking into account facility operations.**	**DOCUMENT REVIEW** ▪ Request records to verify that testing is performed as required. Check monthly test dates to ensure no tests 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. **§485.623(c)(1)(i-ii) Tag C-0930** **§485.623(e)(1-3) Tag C-0950**		
14.05.06 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 mover's exhaust gas temperature. Results of tests shall be documented. **§485.623(c)(1)(i-ii) Tag C-0930** **§485.623(e)(1-3) Tag C-0950**	☐ Compliant ☐ Not Compliant Emergency power generator three-year load test shall be tested in accordance with NFPA 110**-2010: 8.4.9.** **A combination test to meet the annual load test requirement and the three-year load test requirement is permitted when tested in accordance with NFPA 110-2010: 8.4.9.6; and 8.4.9.7.**	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Request records to verify that testing is performed as required.
14.05.07 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.	☐ 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: 8.4.9.3**.	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
Results of tests shall be documented. **§485.623(c)(1)(i-ii) Tag C-0930**		
14.05.08 Health Care Microgrid Systems **Health Care Microgrid Systems (HCMS) that comply with NFPA 99-2021 Health Care Facilities Code and NFPA 70-2023 are permitted per CMS QSO-23-11-LSC.**	☐ Compliant ☐ Not Compliant **Health Care Microgrid Systems (HCMS), being small-scale electrical grids, can derive their electricity from various clean energy technologies such as fuel cells, solar power, wind power, energy storage, and more.** **The categorical waiver allows both new and existing health care facilities that are subject to CMS requirements to utilize alternative power sources instead of relying solely on a generator set or battery system only if in accordance with the 2021 edition of the NFPA 99, 2023 edition of the National Electric Code (NFPA 70), and associated references.** **When installed, and used as part of the emergency electrical system, the hospital must indicate during its opening conference, and/or in its Facility Demographic Report, that it has adopted the CMS categorical Waiver for use of an HCMS.** **If not, the Essential Electrical System must be surveyed to NFPA 99-2012 Edition and existing ACHC standards.** **The hospital must have a commissioning report that includes:** ▪ **Description and diagram of the electrical system arrangement, components, sources of power, and building(s) or area(s) served.** ▪ **Documents the results of the HCMS commissioning.** ▪ **Acceptance of the HCMS system and components.** ▪ **If there were issues identified, documentation of correction and retest.**	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ **The organization has adopted the CMS categorical waiver in writing.** ▪ **Request records to verify that testing is performed as required.** ▪ **The commissioning report is available, and any corrections have been addressed and documented.** ▪ **The inspection, testing and maintenance documents meet required intervals.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The hospital must have the equipment in an inspection, testing and maintenance (ITM) program. The system must be tested per manufacturer instructions, or at least annually. **The individuals managing the alternate sources of power, conducting equipment acceptance testing and system commissioning, and performing ITM activities are qualified.**	
14.05.09 <u>Medical gas shutoff valves</u> 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 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. **§485.623(d)(1-2) Tag C-0944**	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 14.05.08.** Medical gas shutoff valves must be accessible and properly labeled to assist in proper routine adjustment of systems and during emergencies. **(For further guidance on medical gas zone valves, refer to NFPA 99-2012: 5.1.4.8; and 5.1.11.2.for valve labeling.)**	This standard is not met as evidenced by: **<u>OBSERVATION</u>** Verify: ▪ 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
14.05.10 Utility systems Utility systems are properly installed and maintained to a fire-safe condition. **§485.623(d)(1-2) Tag C-0944**	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 14.05.09.** Utility systems must be installed and maintained to a fire-safe condition. Access to electrical control panels must not be obstructed **(see NFPA 70-2011, article 110.26)**. 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. **Line Isolation Monitors, if installed, must be tested monthly (auto-test, if equipped, is acceptable) with the LIM test switch and by a manual functional test annually (see 6.3.2; 6.3.3; and 6.3.4 of the 2012 edition of NFPA 99). The test must be documented.**	This standard is not met as evidenced by: **OBSERVATION** Verify: ▪ Electrical control panels have proper clearance, and all circuits labeled. ▪ Electrical junction boxes are properly covered. ▪ Electrical conduits are free of attached wires and cables.
14.05.11 Medical gas systems and equipment: Maintenance There is a routine monitoring and maintenance system for oxygen, compressed air, and vacuum systems and equipment. CAH medical gas systems and equipment must be installed, inspected, tested, and maintained in accordance with NFPA 99 (2012 edition) chapter 5 and chapter 11.	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 14.05.10.** 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. ▪ 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.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Observe the storage areas of compressed medical gas cylinders during building tour. ▪ Review the CAH's policy on inspection, testing and maintenance on medical gas systems, including alarm panels.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
Storage of all medical compressed gas cylinders must comply with NFPA 99, *Standard for Health Care Facilities*, 2012 edition. **§485.623(d)(1-2) Tag C-0944**	▪ Oxidizing gases must be separated from combustibles a minimum of 20 feet in non-sprinklered areas; or 5 feet in sprinklered areas; or in an enclosed cabinet of non-combustible construction having a minimum fire protection rating of one-half 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. ▪ 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.	▪ Examine testing and inspection records for evidence of routine inspections and documentation of the CAH's monitoring and maintenance program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ 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 **(see 5.1.11.1 of the 2012 edition of NFPA 99)**. Medical gas systems, including master alarm panels and branch alarm panels must be inspected, tested, and maintained according to the CAH'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.	
14.05.12 <u>Cooking hoods cleaning</u> Kitchen cooking exhaust hoods and associated equipment are inspected and cleaned on a semi-annual basis.	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 14.05.11.** Kitchen cooking hoods are designed to capture air-borne 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: **11.4**. 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 accordance with their listings. **(For further guidance on testing, refer to NFPA 17A-2009: 7.3.3.)**	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Review documentation to ensure the organization inspected and cleaned their cooking hood exhaust system(s) on a semi-annual basis.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.05.13 Health Care Facilities Code Except as otherwise provided in this section, the CAH 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 CAH. If application of the Health Care Facilities Code required under this section would result in an unreasonable hardship for the CAH, 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. §485.623(d)(1-2) Tag C-0944	☐ Compliant ☐ Not Compliant **Note: This standard was previously numbered 14.05.12.** 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. 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. 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 as defined by Chapter 4 of NFPA 99-2012 are based on the risks to patients and caregivers in the facility.	This standard is not met as evidenced by: **OBSERVATION** **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 ACHC 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

Therefore, a risk assessment is required for certain building systems that the organization has, based on a documented defined procedure. ACHC 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

The following equipment and systems are required to be evaluated in a risk assessment to determine whether each is considered critical equipment and is reflected on the equipment inventory:

- HVAC systems
- Electrical equipment
- Gas equipment

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

OPERATING FEATURES

14.06.01 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:
   a. The decorations do not interfere with the operation of any exit or exit access openings.
   b. 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.

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.

(For further guidance on decorations, refer to NFPA 101-2012: 18/19.7.5.6.)

OBSERVATION

- During the building tour, observe areas for combustible decorations. If CAH 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
c. The decorations do not exceed 30 percent of the wall and ceiling area inside any room or space of a smoke compartment that is protected throughout by automatic sprinklers. d. 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. **§485.623(c)(1)(i-ii) Tag C-0930**		
14.06.02 <u>Trash receptacles</u> Trash receptacles and soiled linen hoppers exceeding 32 gallons capacity must be stored in an approved hazardous room. **§485.623(c)(1)(i-ii) Tag C-0930**	☐ Compliant ☐ Not Compliant 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 of	This standard is not met as evidenced by: **<u>OBSERVATION</u>** ▪ During the building tour, observe if any trash receptacles that exceed 32 gallons are not stored in a hazardous room.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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 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. **(For full text, refer to NFPA 101-2012: 18/19.7.5.7.)**	▪ Where multiple trash receptacles that are less than 32 gallons each are accumulated, determine if they exceed 32 gallons 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.
14.06.03 Portable heaters	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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. **§485.623(c)(1)(i-ii) Tag C-0930**	No additional information. **(For full text, refer to NFPA 101-2012: 19.7.8.)**	**OBSERVATION** ▪ During the building tour, observe under workstations, in storage rooms, and patient rooms for portable space heaters.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.06.04 Life safety drawings	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Basic drawings of the facility indicating the following features are required: ▪ Rated walls and barriers, including their fire rating. ▪ Exit, exit enclosure, horizontal 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. **§485.623(c)(1)(i-ii) Tag C-0930**	Basic life safety drawings are critical to the maintenance of life safety features in the CAH. 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 and cabinets are not desirable. CAH 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 in fully sprinklered smoke compartments; ▪ Hazardous room barriers in existing conditions where the hazardous room is protected with sprinklers.	**OBSERVATION** ▪ Examine the life safety drawings before starting the building tour. The CAH's representatives must be able to interpret the drawings and be able to answer questions that may arise.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
14.06.05 Alcohol based hand-rub dispensers *A CAH may install alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.* Alcohol based hand-rub (ABHR) dispensers are permitted to be installed in compliance with the 2012 *Life Safety Code*. §485.623(c)(5) Tag C-0936	☐ 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 6 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 REFERENCES

14.07.01 CMS References

Not scored at this standard.

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).

§485.623(e)

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 an announcement in the Federal Register.

National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(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.

OBSERVATION

- Score non-compliance with the referenced resource under the appropriate ACHC standard for the element.

15

FOR FUTURE USE

16

RESTRAINTS

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
16.00.00 Restraint and seclusion	☐ Compliant ☐ Not Compliant	This condition is not met as evidenced by:
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.* §485.614(e)	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 contained in this standard apply to all hospital patients when the use of restraint or seclusion becomes necessary, regardless of patient location. The requirements contained in this standard 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 CAHs. ▪ All locations within the CAH (including medical/surgical units, critical care units, forensic units, emergency department, psychiatric units, etc.). ▪ All CAH 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 comprehensive individual patient assessment.	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Review hospital restraint and seclusion policies and procedures to confirm they address, at a minimum: □ Who has the authority to discontinue the use of restraint or seclusion (based on state law and CAH 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 (include both violent or self-destructive patients as well as non-violent, non-self- destructive patients). □ What evidence is there that hospital CAH staff identified the reason for the restraint or seclusion, and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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. However, 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.

CAH 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 their 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 this standard as well as those set forth by State law and hospital policy when the use of restraint or seclusion is necessary.

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 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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 considered a routine part of a Falls Prevention Program. For example:

- A patient is displaying symptoms of Sundowner's Syndrome, in which 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 falling if the patient gets out of bed?
- Is there a way to enable the patient to safely ambulate?

months) to determine any patterns in their use for specific units, shifts, days of the week, etc.

- 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 explained to the patient in understandable terms? Could the patient articulate his/her understanding?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- 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 they 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 would 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 a restraint intervention is needed. If a need for restraint 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 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 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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. CMS does not support the use of weapons by any hospital staff as a means of subduing a patient in order to place that patient in restraint or seclusion. 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, we would expect the situation to be handled as a criminal activity and the perpetrator be 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-CAH employed or contracted law enforcement officials for custody, detention, and public safety reasons are not governed by this rule. The use of such devices are considered law enforcement restraint devices 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 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	officer's prisoner).	
16.00.01 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.* §485.614(e)(1)(i)(A)	☐ Compliant ☐ Not Compliant This restraint 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; or ▪ 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., siderails 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
16.00.02 Chemical restraint *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.* §485.614(e)(1)(i)(B)	☐ Compliant ☐ Not Compliant 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 or not 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 of 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 medical associations or organizations.	This standard is not met as evidenced by: **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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- 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 function in the world around them more effectively or appropriately 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 interact with the world around them effectively or appropriately, 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, a syndrome in which a patient's 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 patient, the sedative is being used inappropriately as a restraint for staff convenience. Such use is not permitted by the regulation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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.

In addition, 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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.	
16.00.03 Non-restraints *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).* §485.614(e)(1)(i)(C)	☐ Compliant ☐ Not Compliant The devices and methods listed here would not be considered restraints, and, therefore, not subject to these requirements. **MEDICAL-SURGICAL CARE DEVICES** ▪ An 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 a mechanical 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; 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 16.00.00 would apply.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Determine whether the hospital's policies and procedures provide 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 siderails 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 siderails.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- 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 this 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, it promotes looking at each patient situation 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

Age or developmentally appropriate protective safety interventions (such as stroller safety belts, swing safety belts, highchair 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, toddler, or preschool-aged child would not be considered restraint or seclusion for the purposes of this regulation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- 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.
- 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 §485.614(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 the patient's will is considered restraint. This includes holds that some member of the medical community may term "therapeutic holds." 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 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- The patient has a right to be free of restraint and, in accordance with §485.614(e), 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.
- In accordance with state law, some patients may be medicated against their will in certain emergency circumstances.

In both circumstances, 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 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 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 the 16.00.00.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- However, side rails are frequently used to restrict the patient's freedom to exit the bed rather than as a method to prevent the patient from falling out of 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 the standard.

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. 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 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- If a patient is not physically able to get out of bed regardless of whether the side rails are raised or not, raising all four side rails for this patient would not be considered restraint because the side rails have no impact on the patient's freedom of movement. In this example, the use of all four side rails would not be considered restraint.

Side rails that are not a restraint

- When a patient is on a bed that constantly moves to improve circulation or prevents skin breakdown, raised side rails are a safety intervention to prevent the patient from falling out of bed and are not viewed as restraint.
- When a patient is placed on seizure precautions and all side rails are raised, the use of side rails would not be considered restraint. The use of padded side rails in this situation should protect the patient from harm; including falling out of bed should the patient have 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.
- The use of a seat belt when transporting a patient in a wheelchair is not considered restraint.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
16.00.04 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.* §485.614(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 the patient chooses.	**OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Determine whether the hospital's policy and procedure 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

16.00.05 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)(16)(ii-v)
§485.614(e)(2-3)

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.

ented 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.

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 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 use is lengthy, look for evidence that the symptoms necessitating the use of restraint or seclusion have persisted.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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 prior to the use of restraint or seclusion. When a patient's behavior presents an immediate and serious danger to him- 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.	▪ 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
16.00.06 Safe application *The CAH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice.* §485.614(e)(4)	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 16.00.08. 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 state law or indication state laws were reviewed and incorporated? ▪ Through review of medical records that include patients who required the use of restraint or seclusion for the management of both violent, self-destructive behaviors, and non-violent, non-self-destructive behaviors. □ After restraints were applied, an assessment was immediately made to ensure that restraints were properly and safely applied. □ CAH policies and procedures were followed. □ Was the use of restraint or seclusion 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
16.00.07 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)(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 reassessments. ▪ The plan addresses the frequency and content of the patient reassessments 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 policy.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review at least five medical records of patients who required restraint or seclusion. ▪ Does the plan of care or treatment reflect a process of assessment, intervention, and evaluation when restraint or seclusion is used? Is there evidence of assessment of the identified problem or of an individual patient assessment? ▪ 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? ▪ Does the patient's plan of care reflect that assessment? □ What was the goal of the intervention? □ What was the described intervention? □ Who is responsible for implementation?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ 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?
16.00.08 Orders for restraint or seclusion *The use of restraint or seclusion must be:* ▪ *In accordance with the order of a physician or other licensed independent practitioner who is responsible for the care of the patient as specified under §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 Note: Prior to updates in 2023, this standard was numbered 16.00.09. CAHs must have policies and procedures for the initiation of restraint or seclusion that identify the categories of licensed independent practitioners (LIP) 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 seclusion has been applied.	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 CAH policy. ▪ The physician or LIP who ordered each use of restraint or seclusion is identified. ▪ 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- 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 is not 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 counter to this philosophy if it sets up the expectation that restraint or seclusion will be used as a routine part of care.

few minutes) after application of the restraint or seclusion.

- Hospital policies and medical staff by-laws 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 have protocols for the use of restraint or seclusion? If so, is the use of protocols consistent with the requirements of the regulation?
- Do a physician's or another LIP's orders specify the reason for restraint or seclusion, the type of restraint, and the duration of restraint or seclusion?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
16.00.09 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 Note: Prior to updates in 2023, this standard was numbered 16.00.10. This regulation 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 was recently released from restraint or seclusion and 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 through the use of restraint or seclusion, a new order would be required. **Note**: A temporary, directly supervised release, however, 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 restraint is not considered to be discontinued because the staff member is present and is serving the same purpose as the restraint or seclusion.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Review a random sample of medical records for patients that have been restrained or secluded. ▪ Review orders, progress notes, flow sheets, and nursing notes to: □ Ensure there are no restraint orders written on a PRN or as standing orders. □ Determine if restraint or seclusion is being improperly implemented on a PRN basis.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

The use of PRN orders for drugs or medications is only prohibited when a drug or medication is being used as a restraint.

- 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 the 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 to be out of bed safely, 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 Lesch-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 the management of violent or self-destructive behavior do not apply.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
16.00.10 Physician notification of restraint and seclusion use *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)	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 16.00.11. The intent of this requirement 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 is aware 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. 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 the 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. ▪ §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 Podiatric Medicine, a chiropractor, or a clinical psychologist.	This standard is not met as evidenced by: **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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- 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 or 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.

16.00.11 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

Note: Prior to updates in 2023, this standard was numbered 16.00.14.

CAHs 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.

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

- Review the CAH 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 policy.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	While hospitals have the flexibility to determine time frames for the renewal of orders for restraint of the non-violent, non-self-destructive patient, renewal order timeframes should support an ongoing evaluation of the need for continued use of restraints. It is recommended that renewal orders are obtained each calendar day.	☐ Does CAH policy align with medical record documentation of restraint duration orders?
16.00.12 Violent restraint 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 nonviolent 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 regulation identifies maximum time limits on the length of each order for restraint or seclusion based on age.	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 time period covered by an order or its renewal exceed 24 hours? ▪ If more restrictive state laws apply, are they being followed? ▪ Is the renewal order for restraint or seclusion based on a comprehensive individual assessment of the patient? ▪ Is there evidence in the medical record that the symptoms necessitating the continued use of restrain or seclusion have persisted?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- The physician or other LIP has the discretion to write the order for a 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 1-hour face-to-face patient evaluation (see standard 16.00.18 and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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 16.00.09 [§482.13(e)(6)].	
16.00.13 Violent restraint 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 independent practitioner who is responsible for the care of the patient as specified under §482.12(c) of this part 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 **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.	This standard is not met as evidenced by: **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 assessments, and a reevaluation 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	EXCEPTION: Repetitive self-mutilating behaviors – see interpretive guidance for standard 16.00.09 [§482.13(e)(6)] for additional information.	
16.00.14 Violent restraint 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.* §482.13 (e)(16)(i) *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 independent practitioner; or* *(B) Registered nurse or physician assistant who has been trained in accordance with the requirements specified in 42 CFR 482.13(f).* §482.13(e)(12) §482.13(e)(12)(i)(A-B)	☐ Compliant ☐ Not Compliant Note: Prior to 2023 updates, elements of this standard were located at 16.00.18, 16.00.20, and 16.00.23. **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 §482.13(f), must see the patient face-to-face within one hour after 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 one hour after the initiation of this intervention. The fact that the patient's behavior warranted the use of a restraint or seclusion 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.	This standard is not met as evidenced by: **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 the one hour face-to-face medical and behavioral evaluation when restraint or seclusion is used to manage violent or self-destructive behavior? ▪ Review CAH policy regarding the one-hour face-to-face evaluation. □ Does the 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 restrictive, apply those requirements

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. §482.13(e)(13)	**EXCEPTION:** Repetitive self-mutilating behaviors: See Explanation for standard 16.00.09. States are free to have requirements that are more restrictive regarding the 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.	instead of those found in this chapter.
16.00.15 Violent restraint and/or seclusion: One-hour face-to-face assessment components *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; and* *(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 Note: Prior to updates in 2023, this standard was numbered 16.00.19. 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 16.00.22-29 [§482.13(f)].	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		assessment of the patient that 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?
16.00.16 Violent restraint and/or seclusion: One-hour face-to-face assessment by a trained RN *If the face-to-face evaluation specified in 42 CFR 482.13 (e)(12) is conducted by a trained registered nurse or physician assistant, the trained registered nurse or physician assistant must consult the attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified under 42 CFR §482.12(c) as soon as possible after the completion of the 1-hour face-to-face evaluation.* §482.13(e)(14)	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 16.00.21. When a trained RN or PA 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: ▪ a discussion of the findings of the one-hour face-to-face evaluation. ▪ the need for other interventions or treatments. ▪ 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 CAH restraint and seclusion policy to verify: ▪ The policy clarifies expectations regarding the requirement, "as soon as possible." ▪ Documentation in 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

16.00.17 Monitoring of the patient

The condition of the patient who is restrained or secluded must be monitored by a physician, other licensed independent practitioner or trained staff that have completed the training criteria specified in 42 CFR 482.13(f) at an interval determined by hospital policy.

§482.13(e)(10)

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Note: Prior to updates in 2023, this standard was numbered 16.00.16.

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

CAH 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.

CAH policies should address:

1. Frequencies of monitoring and assessment as 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 judgment.

DOCUMENT REVIEW

Review CAH policies regarding assessment and monitoring of a patient in restraint or seclusion to verify:

- CAH monitoring policies are put into practice for all restrained or secluded patients.
- Policies identify which categories of staff are responsible for assessing and monitoring the patient.
- Policies include time frames for offering fluids and nourishment, toileting, range of motion, exercise of limbs and systematic release of restrained limbs. Is this documented in the patient's medical record?

Review medical records.

- Was there a valid rationale for the decision regarding the frequency of patient assessment and monitoring documented in the medical record?
  - □ Is documentation consistent, relevant, and reflective of the patient's condition?
  - □ Are time frames described for how often a patient is monitored for vital signs, respiratory and cardiac status, and skin integrity checks?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	For example, placing staff at the bedside of a patient with wrist restraints may be unnecessary. However, 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. CAHs have flexibility in determining which staff perform 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 16.00.21 [§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.	□ 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)?
16.00.18 <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.* §482.13(e)(9)	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 16.00.15. Restraint or seclusion may only be employed while the 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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 include 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.
16.00.19 Simultaneous use of restraint and seclusion *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 patient.* §482.13(e)(15)(i-ii)	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 16.00.22. 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 under standard (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 using both video and audio equipment. **VIDEO AND AUDIO EQUIPMENT** Monitoring with video and audio equipment further requires that staff perform the monitoring near the patient. For the purposes of this requirement, "continually" means ongoing without interruption. The use of video and audio	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** ▪ Review the CAH's policy regarding simultaneous use of restraint and seclusion to determine whether it provides for continual monitoring and otherwise complies with all requirements of §482.13. ▪ Conduct document review and staff interviews to determine if practice is consistent with hospital policy and required uninterrupted audio and visual monitoring is provided as required. ▫ Is the staff member monitoring the patient with video and audio equipment

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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. ▪ If the physical restraint was removed and the patient was still unable to leave the room because the door was locked or staff was 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.	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?
16.00.20 <u>Physician training requirements</u> *Physician and other licensed independent practitioner training requirements must be specified in hospital policy.* *At a minimum, physicians and other licensed independent practitioners authorized to order restraint or seclusion by hospital policy in*	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 16.00.17. 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 regarding application of restraint or	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** Review the policy regarding restraint and seclusion training requirements for physicians and other LIPs. ▪ Are the minimum training requirements addressed? ▪ Review medical staff credentialing and

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
accordance with State law must have a working knowledge of hospital policy regarding the use of restraint or seclusion. §482.13(e)(11)	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. ▪ CAHs 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.	privileging files to determine if physicians or other LIPs involved in restraint and seclusion activities have completed the required training.
16.00.21 Staff training requirements – Use of restraints or seclusion *The patient has the right to safe implementation of restraint or seclusion by trained staff.* §485.614(f)	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 16.00.28. 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: **OBSERVATION AND DOCUMENT REVIEW** ▪ Verify that the CAH 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
16.00.22 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 paragraph;* *(ii) As part of orientation; and* *(iii) Subsequently on a periodic basis consistent with hospital policy.* §482.13(f)(1)(i-iii)	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 16.00.29. All staff designated by the hospital as having direct patient care responsibilities, including contract or agency personnel, must demonstrate the competencies specified in standards 16.00.21-30 [§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. CAHs 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Does the hospital have a documented training program for the use of restraint and seclusion interventions it employs? □ Does the hospital have documented evidence that all levels of staff, including agency or contract staff, with 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

16.00.23 Training content

The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population.

The CAH must provide patient-centered, trauma informed, competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the use of restraint and seclusion.

§485.614(f)(1)
§482.13(f)(2)

☐ Compliant ☐ Not Compliant

The training requirements include all staff that applies restraint or seclusion, monitor, assess, or otherwise provide care for patients in restraint or seclusion.

All staff, including contract or agency personnel, designated by the hospital as having direct patient care responsibilities is 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 require 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 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.

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

- Does the CAH's educational program include techniques related to the specific patient populations being served?
- Does the 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 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

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.

Training for an RN to conduct the one-hour face-to-face evaluation would include all the training requirements in standards (§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:

- complete review of systems assessment.
- behavioral assessment.
- review and assessment of the patient's history, medications, most recent lab results, etc.

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.

16.00.24 Training requirements: Alternate interventions

The hospital must require appropriate staff to have education, training, and demonstrated knowledge based on the specific needs of the patient population.

The training must include alternatives to the use of restraint/seclusion.

☐ Compliant ☐ Not Compliant

Note: Prior to updates in 2023, this standard was numbered 16.00.31.

Although there may be circumstances in which the use of restraint or seclusion may be 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

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

- Does the CAH's training program address the use of alternative interventions?
- Interview staff to assess their alternate intervention skills.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.614(f)(2) §482.13(f)(2)	otherwise help the patient maintain self-control and avert escalation. The use of alternate interventions 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 interventions can be implemented during the course of treatment based upon the assessment of an individual patient's responses.	
16.00.25 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 Note: Prior to updates in 2023, this standard was numbered 16.00.32. 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 condition is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Does the CAH 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 educational program address how to conduct an assessment of a patient's medical and behavioral conditions? ▪ Does the 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 that they can demonstrate the abilities addressed in this requirement.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
16.00.26 <u>Training requirements: Safe application</u> *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 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)	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 16.00.33. 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: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** ▪ Is all staff identified by the CAH as 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 CAH's educational program address recognition and response to patient signs of physical and psychological distress? □ Are staff members able to identify signs of physical and psychological distress in a timely manner? □ Are staff members able to respond to and appropriately treat signs of physical and psychological distress? ▪ Review hospital data (e.g., incident reports, patient injury or death reports, etc.) to identify any patterns that may indicate that staff are not adequately trained to recognize and respond to patient signs of physical and psychological distress.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
16.00.27 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:* ▪ *Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.* §482.13(f)(2)(v)	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 16.00.34. 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 their ability to identify specific patient behavioral changes that may indicate that restraint or seclusion is no longer necessary and can be safely discontinued.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Does the CAH's educational program address identification of specific behavioral changes that may indicate that restraint or seclusion is no longer necessary? ▪ Interview staff to determine if they can demonstrate the abilities addressed in this requirement.
16.00.28 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 1-hour face-to-face evaluation.* §482.13(f)(2)(vi)	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 16.00.35. No additional information.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Does the CAH's educational 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ Does the educational program address the specific requirements for the training of RNs and PAs that the hospital authorizes to conduct the one-hour face-to- face evaluation? ▪ Interview staff to determine if they can demonstrate the competencies addressed in the regulation.
16.00.29 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 Note: Prior to updates in 2024, this standard was numbered 16.00.36. When restraint or seclusion techniques are used, patients are placed at a higher risk for injuries or even death. CAH 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.▪ CAHs are not required to use a 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 CAH's educational program address first aid techniques? ▪ Does the educational program include, or provide for, staff training and certification in cardiopulmonary resuscitation (including provisions for recertification)? ▪ Is appropriate staff certified in cardiopulmonary resuscitation?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
16.00.30 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 Note: Prior to updates in 2024, this standard was numbered 16.00.37. ▪ CAHs 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 qualify them to teach the staff? ▪ Are they qualified to identify and meet the needs of the patient population(s) being served? ▪ Does the CAH have a system for documenting and ensuring that the individuals providing education and training have the appropriate qualifications required by this regulation?
16.00.31 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 Note: Prior to updates in 2023, this standard was numbered 16.00.38. 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 CAH policy.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review a sample of personnel records, including contract or agency staff, to verify that training and demonstration of competency have been completed during orientation and periodically, consistent with hospital policy.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

16.00.32 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, 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 (1) 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*

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

Note: Prior to updates in 2023, this standard was numbered 16.00.40.

"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 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 §482.13(g)(1) must be submitted to the CMS Location by telephone, facsimile, or electronically (as determined by the Location) 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.

DOCUMENT REVIEW

- Does the hospital have restraint/seclusion death reporting policies and procedures that address 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?

If Yes:

- Review the report and medical records to determine whether they:
  - ☐ met the criteria for reporting to CMS.
  - ☐ were submitted timely to CMS.
  - ☐ were complete.
  - ☐ noted the date and time the death reported to CMS was entered into the patient's medical record.

If No:

- Ask the hospital how it ensures that there were no reportable restraint/seclusion-associated deaths.
- If the hospital's system relies on staff identification of reportable deaths,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

prolonged periods of time, or death related to chest compression, restriction of breathing or asphyxiation.

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.*
3) *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 of this standard; or*
   - ii) *Recorded in the internal log or other system for deaths described in item 2) of this standard.*
4) *For deaths described in item 2 of this standard, entries into the internal log or other system must be documented as follows:*

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 PROCESS

After reviewing the submitted information, the CMS Location 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.

CAH 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.

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.

- 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 recordkeeping requirements?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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, and name of attending physician or other licensed independent practitioner who is responsible for the care of the patient as specified in standards 01.00.18 – 01.00.21, 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.* §485.614(g)(1-4)(i-iii)	▪ 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 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 CAH 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 CAH 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	▪ 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 died 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 on 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 regulation.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		▪ 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?

17

EMERGENCY MANAGEMENT

INTRODUCTION

ACHC Emergency Management Standards establish requirements to ensure adequate planning for both natural and man-made disasters. CAHs must coordinate compliance with these standards with other regulatory requirements that the CAH follows.

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; the 2012 edition of the NFPA 99 Health Care Facilities 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.

While it is important that CAHs consider mitigation, recovery, and business continuity while planning for emergencies, the scope and focus of the Emergency Management Standards is the continuity of operations during and immediately after the emergency.

WHAT IS MEANT BY "PROGRAM"?

A program is the overall coordination of policies, procedures, and activities related to a specific function. The Emergency Preparedness Program (also known as the Emergency Management Program) consists of multiple policies, plans, and components. Some of these are to be shared with the CAH's community emergency response agency, including the Hazard Vulnerability Analysis (HVA), the Emergency Operations Plan (EOP), and the Evacuation Plan.

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

Risk Assessment and Emergency Planning	The CAH must assess risk using 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).
Policies and Procedures	The CAH must develop and implement policies and procedures that support execution of its EOP. These policies and procedures may be part of the EOP, or they may be maintained separately. If separately maintained, the EOP must reference where they are located to facilitate access.
Communication Plan	The CAH must develop and maintain an emergency preparedness communication plan. The communication plan may be part of the EOP, or it may be maintained separately. If separate from the EOP, the EOP must reference the location of the plan to facilitate access.

Training and Testing	The CAH must 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.

CLARIFICATIONS AND DEFINITIONS (Provided for reference.)

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 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 include acute care hospitals, critical access hospitals (CAH), inpatient hospices, inpatient substance abuse facilities, long-term care facilities, psychiatric hospitals, skilled nursing facilities (SNF), and specialty hospitals.

Community Partners: Community partners may include:

- **Local, tribal, regional, state, and federal emergency preparedness officials**
- **Local emergency planning committee**
- **Emergency response agencies (fire, police, emergency medical services)**
- **The department of public health, or public safety**

- **Local municipality representatives**
- **Community organizations**
- **Other health care organizations**

For full-scale and community-based exercises, community partners are any emergency management officials (fire, police, emergency medical services, etc.).

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 overall 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 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 that 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, directions, 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 drills 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.

LIST OF STANDARDS

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

PLANNING

17.00.01 CONDITION OF PARTICIPATION: Emergency preparedness

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

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

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

§485.625 Tag C-0950

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The CAH must have an emergency preparedness program that includes:

1. Planning
2. Procedures
3. Communication
4. Training and 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 should ensure their Emergency Preparedness Programs are aligned with their

INTERVIEW AND DOCUMENT REVIEW

Verify:

- The Emergency Preparedness Program was developed based on an all-hazards approach.
- The program is documented in writing.
- The program includes the four key elements described.
  - ☐ The program is reviewed every two years (*biennially*).
  - ☐ The program is retained for a period of two years.
- Facility leadership can describe the facility's Emergency Preparedness Program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	state and local emergency plans/pandemic plans. ▪ The emergency preparedness program must be reviewed every two years (*biennially*)**.**	
17.00.02 Hazard Vulnerability Analysis (HVA) *The CAH 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.* The CAH 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 CAH's Hazard Vulnerability Analysis (HVA) must be shared with the community's emergency response agencies. The CAH must identify likely 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	☐ Compliant ☐ Not Compliant Prior to establishing an emergency operations plan, the CAH 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 CAHs will have the capacity and capability to address a broad range of related emergencies. The CAH may choose to create a single hazard vulnerability analysis (HVA) that applies to all the sites of the CAH, or an individual hazard vulnerability analysis (HVA) for each of their locations. The CAH 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 CAH will have a copy of this risk assessment and to work with that entity that developed it to ensure that the CAH 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 CAH may not own but where they provide treatment for their patients. Some remote locations may have different hazards and therefore a separate HVA would be appropriate. CAHs must prioritize the potential hazards to their organization, and these priorities are documented in the HVA. **The CAH shares the details of the HVA with one or more community partners as defined in the clarifications and**	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Verify that the hazard vulnerability analysis (HVA) is reviewed by the organization and updated every two years (biennially) by the emergency management committee. ▪ **The CAH has shared its HVA with one or more community partners.** **Note: Evidence of communication beyond making the HVA available to these entities is not required.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
accidents, other likely mass casualties, unforeseen widespread communicable diseases, etc.) and develop appropriate responses that will assure that safety and wellbeing of patients. The HVA is documented and reviewed by the oversight committee on emergency management for relevancy and accuracy on a biennial basis. §485.625(a) Tag C-0950 §485.625(a)(1)	**definitions.** 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), CAHs must consider the following: 1. Identification of all business functions essential to the CAH's operations should be considered during an emergency. 2. Identification of all risks or emergencies that the CAH may reasonably expect to confront. 3. Identification of all contingencies for which the CAH should plan. 4. Consideration of the CAH's location, including all locations where the CAH delivers patient care or services, or has business operations. 5. Assessment of the extent to which natural or man-made emergencies may cause the CAH to cease or limit operations. 6. Determination of what arrangements with other CAHs, other 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.	

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	□ Home-based healthcare settings. □ Physical environment, including but not limited to changes needed to achieve distancing, isolation, or capacity/surge.	
17.00.03 Emergency Operations Plan A written Emergency Operations Plan (EOP) is developed, maintained, and available to the staff for crisis preparation and response. *The Emergency* Operations *Plan must include strategies for addressing emergency events identified by the risk assessment.* The EOP is based on the priorities established in the current Hazard Vulnerability Analysis (HVA) to determine the strategies and activities designed to reduce the risk associated with emergency events. The EOP is reviewed with the community's emergency response agencies to synchronize responses to common emergency events. The CAH 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.	☐ Compliant ☐ Not Compliant The written emergency operations plan (EOP) and associated procedures address situations for each department and/or service within the CAH 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 individual EOPs for each location. **The CAH shares the details of the EOP with one or more community partners as defined in the clarifications and definitions.** The CAH assesses the community's abilities to meet the needs of the CAH during an emergency event. This involvement with the community and the assessment of the community's abilities is documented. The written EOP includes a plan for a widespread infection outbreak or pandemic. The EOP is integrated into the facility-wide Quality Assurance Performance Improvement (QAPI) Program. 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.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The EOP applies to the potential emergencies identified in the Hazard Vulnerability Analysis (HVA). ▪ 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 ensure improvement in outcomes/ results. ▪ The EOP provides for an influx of patients during an emergency. ▪ Does the CAH share its plans and abilities with the local authority in community emergency preparedness during the planning phase as well as the implementation phase?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. §485.625(a) Tag C-0950 §485.625(a)(1-2)	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 □ 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 (EID) such as Influenza, Ebola, Zika Virus, COVID-19 or SARS-CoV-2 and others. □ 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 (EID)** The type of infectious diseases to consider or the care-related emergencies that are a result of infectious diseases are not specified. Adding EID 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 EID may include but are not limited to: ▪ Potentially infectious bio-hazardous waste. ▪ Bioterrorism. ▪ Pandemic influenza.	▪ Facility leadership can identify the hazards (e.g., natural, man-made, facility, geographic, EID, etc.) that were identified in the facility's risk assessment and how the risk assessment was conducted. ▪ 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. ▪ **The CAH has shared their EOP with one or more community partners.** **Note: Evidence of communication beyond making the EOP available to these entities is not required.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- Highly communicable diseases (such as Ebola, Zika Virus, SARS, or novel COVID-19 or SARS-CoV-2)
  EID 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

CAHs must have policies and procedures which include emergency staffing strategies and plan for emergencies resulting in a surge of patients. 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 burden on the healthcare system.

Surge Planning During Natural Disasters

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.

Surge Planning for Infectious Diseases/Pandemics

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:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Reduce morbidity and mortality. ▪ Minimize disease transmission. ▪ Protect healthcare personnel. **Preserving CAH/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. ▪ 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.	
17.00.04 <u>Patient population</u> *The Emergency* Operations *Plan* (EOP) *must address patient population, including but not limited to persons at-risk.* §485.625(a)(3) Tag C-0950	☐ Compliant ☐ Not Compliant When creating the EOP, emergency response considerations should be given to at-risk populations within the CAH, 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	This standard is not met as evidenced by: **<u>INTERVIEW AND DOCUMENT REVIEW</u>** Verify: ▪ The EOP addresses specific patient populations. □ The EOP identifies a plan for at-risk patient groups according to their needs.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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.	
17.00.05 Services *The Emergency* Operations *Plan* (EOP) *must address the type of services the CAH has the ability to provide in an emergency.* The EOP also addresses services needed that cannot be provided by the facility during an emergency as part of continuity of operations and services. §485.625(a)(3) Tag C-0950	☐ Compliant ☐ Not Compliant When creating the EOP, the type of services that the CAH has the ability to 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 emergency events. If specific equipment is required for services listed, as in radiological diagnostic services as an example, the plan must state how equipment will be made available under emergency power.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The EOP identifies the types of services that the CAH has the ability to provide during an emergency. ▪ The EOP addresses plan for services needed that cannot be provided during an emergency? ▪ Check the services to be provided. If specific equipment is required, 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
17.00.06 Continuity of operations *The Emergency* Operations *Plan* (EOP) *must address the continuity of operations, including delegations of authority and succession plans.* §485.625(a)(3) Tag C-0950	☐ Compliant ☐ Not Compliant When creating the EOP, considerations should be given to: ▪ How the CAH will continue to operate during the emergency event. ▪ Who is delegated as the authority during the emergency event. ▪ 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 ICS is 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 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 CAH. 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 can assume 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."	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The EOP provides for the continuity of operations. □ The EOP addresses how the CAH plans to continue to provide these services during an emergency. □ The EOP addresses the delegation of authority during emergency events, and the succession of that authority.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
17.00.07 Collaboration *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, including documentation of the CAH's efforts to contact such officials and, when applicable, its participation in collaborative and cooperative planning efforts.* §485.625(a)(4) Tag C-0950	☐ Compliant ☐ Not Compliant 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 CAH 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 officials or authorities listed within the plan.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The EOP provides for collaboration with the authorities during the planning process for emergency management.

PROCEDURES

17.01.01 Policies and procedures *The CAH 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.	☐ Compliant ☐ Not Compliant The format of the EOP and the policies and procedures (P&P) that a facility uses are at their discretion. ACHC does not prescribe or specify whether the EOP includes the content of the P&P or they are separate documents. However, the facility must address all requirements for the EOP and all requirements for the P&P. If P&P are not included in the EOP, then the EOP must reference where they be located.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The P&P described in standards 17.01.02 through 17.01.14 are established. ▪ If relevant P&P are separate from the EOP, they are referenced in the EOP with locations noted.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. *Entities providing services under arrangement; Patient's physicians; other CAHs and hospitals, Volunteers, Federal, State, tribal, regional, and local emergency preparedness staff; and other sources of assistance shall be updated on an annual basis.* §485.625(b) Tag C-0950 §485.625(c) §485.625(d)(2)	Contracts with vendors and suppliers are to be renewed annually or when vendors/suppliers are changed. Real-time electronic tracking systems of current and former 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 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.	▪ Relevant P&P have been reviewed and updated every two years per 17.01.01. Score timeline issues under the 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
17.01.02 Nutritional services *The policy and procedure 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 17.01.01 by the emergency management oversight committee. §485.625(b)(1)(i) Tag C-0950 §485.625(d)(2)	☐ Compliant ☐ Not Compliant The policy and procedures (P&P) for nutritional services describe the strategies for ensuring nutritional needs are met during situations in which CAH 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: ▪ 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. 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 17.01.01. The CAH 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 CAH stores 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.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The P&P for nutritional services address methods for ensuring the nutritional needs of patients and personnel are met during emergencies, including major facilities disruption. ▪ The plan and calculations used to determine the quantity of drinking water and food adequately meets the needs of all the staff and inpatients during an emergency event. ▪ Policies and procedures have been reviewed and updated every two years per Standard 17.01.01. ▪ Written agreements with vendors and/or suppliers have been updated annually.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

17.01.03 Supplies

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The policy and procedure 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 CAH 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 **at least annually.**

These policies and procedures must be reviewed and updated per standard 17.01.01 by the emergency management oversight committee.

§485.625(b)(1)(i) Tag C-0950

The CAH identifies in written policies and procedures the medical supplies, pharmaceutical supplies, and general equipment it will need to potentially meet the needs of patients and staff 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 storage of the supplies and equipment to ensure their safety (protection against theft or damage, contamination, or deterioration) and availability when needed.

The CAH makes provisions to ensure the availability of those supplies when needed.

The CAH 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.

INTERVIEW AND DOCUMENT REVIEW

Verify:

- Medical supplies, pharmaceutical supplies, and general equipment are inventoried and stored for the immediate response of an emergency, as confirmed by interview with the person in charge of emergency management.
- The organization has reviewed and updated the inventory of emergency response supplies **per policy in accordance with state and/or federal requirements, or at least annually**.
- P&P provide for the supplies and equipment needed in the initial phase of an emergency event.
- P&P have been reviewed and updated per standard 17.01.01.
- The organization has a policy that includes the anticipation of 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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** CAH 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 communicable diseases. ▪ 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 CAH determines the types and quantities of equipment, supplies, and medications needed for continuity of patient care. While stockpiling is not required, the CAH determines the quantities of supplies needed for a one-month period of time: ▪ PPE: Procedure masks, gowns, gloves, ventilator masks (such as N95 respirators). ▪ Hand sanitizer and hand soap. ▪ Cleaning chemicals and supplies. ▪ Paper products, such as toilet paper, paper towels. ▪ Other. **PERPETUAL INVENTORY** During a widespread communicable disease outbreak or pandemic, a shortage of supplies should be anticipated.	▪ 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
	The CAH has a process to update the Incident Command Center regarding available equipment and supplies, such as: ▪ Patient beds. ▪ ICU beds. ▪ Mechanical ventilators. ▪ PPE: Procedure masks, gowns, gloves, ventilator masks (such as N95 respirators). ▪ IV infusion pumps. ▪ Quantities of medications used to treat the communicable diseases. The organization **includes a process for a more frequent inventory of supplies during this type of event and** 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.	
17.01.04 Utilities	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The policy and procedure for alternate sources of energy must address the 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.*	The CAH must ensure the continuation of operation of strategic utilities during an emergency event, including: ▪ emergency power. ▪ fuel for generators and boilers. ▪ medical air, gas, and vacuum. ▪ sewage and waste disposal. The CAH must document which areas of the facility are served by emergency power and which 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. Policies and	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ 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 every two years per 17.01.01.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ *Fire detection, extinguishing, and alarm systems.* ▪ *Sewage and waste disposal.* The policy and procedure 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 17.01.01 by the emergency management committee. §485.625(b)(1)(ii)(A) Tag C-0950 §485.625(b)(1)(ii)(B-D)	procedures must address how the CAH determined which HVAC units (if any) are connected to emergency power. The CAH 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 CAH 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 CAH 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 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 the capability to replenish the fuel supply before it is exhausted. The CAH maintains documentation of its fuel supply needs and its procedures for fuel replenishment in times of emergency. If the CAH uses the same fuel supply for multiple uses, (heating, hot water, generator, etc.) the CAH must maintain fuel supplies to address its total needs and to address periods where re-	▪ Utility supplies for emergency power, fuel, medical air, gas, vacuum, and non-potable water are appropriate for the size of the CAH, the services provided, and the number of staff and inpatients. ▪ The CAH's risk assessment includes the facility's 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
	supply may be limited (i.e., snow, flooding, transportation disruption, etc.). CAHs 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 connect electrical equipment in the facility to a portable and mobile generator.	
17.01.05 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 CAH's care during an emergency. *If on-duty staff and sheltered patients are relocated during an emergency, the CAH must document the specific name and location of the receiving facility or other location.*	CAHs must have policies and procedures in place to track the location of staff and patients in the CAH's care during an emergency. Tracking patients after an emergency is not a requirement of this standard.	**INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ P&P are in place regarding the tracking of on-duty staff and sheltered patients in the CAH's care during an emergency. ▪ P&P have been reviewed and updated every two years per 17.01.01. ▪ Written agreements with vendors and/or suppliers are updated annually.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
These policies and procedures must be reviewed and updated per ACHC standard 17.01.01 by the emergency management committee. §485.625(b)(2) Tag C-0950		
17.01.06 Evacuation *The policies and procedures must address the safe evacuation from the CAH, which includes consideration of care and treatment needs of evacuees; staff responsibilities; transportation; identification of evacuation location(s); and primary and alternate means of communication with external sources of assistance.* The policies and procedures provide for a written emergency evacuation plan which identifies when and how the 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 17.01.01 by the emergency management committee. §485.615(b)(3) Tag C-0950	☐ Compliant ☐ Not Compliant 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. CAHs 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 resources. A written Emergency Evacuation Plan identifies when and how the CAH will evacuate patients from the CAH 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 CAHs) 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. **The CAH shares the details of the Evacuation Plan with one or more community partners as defined in the clarifications and definitions.**	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ P&P provide for an emergency evacuation plan. ▪ The P&P consider multiple transportation options for patient evacuation needs. ▪ How staff would handle a situation in which a patient refused to evacuate. ▪ P&P have been reviewed and updated every two years per 17.01.01. ▪ **The CAH has shared their Evacuation Plan with one or more community partners.** **Note: Evidence of communication beyond making the Evacuation Plan available to these entities is not required.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
17.01.07 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 17.01.01 by the emergency management committee. §485.625(b)(4) Tag C-0950	☐ Compliant ☐ Not Compliant The CAH must have policies and procedures in place that addresses 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 to ensure their safety. CAHs 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 every two years per standard 17.01.01.
17.01.08 Medical documentation *The 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 17.01.01 by the emergency management committee. §485.625(b)(5)	☐ Compliant ☐ Not Compliant CAH 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 CAH to have the same system as other healthcare providers in their region.	This standard is not met as evidenced by: **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 the patient medical records available during emergency events? ▪ P&P are reviewed and updated every two years per 17.01.01.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
17.01.09 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 emergency event. *These policies and procedures must be reviewed and updated* per ACHC standard 17.01.01 by the emergency management committee. §485.625(b)(6) Tag C-0950	☐ Compliant ☐ Not Compliant **During an emergency event, the CAH has the authority to assign disaster-related responsibilities to volunteer practitioners who do not possess independent practitioner licenses but are mandated by law and regulations to hold a valid license, certification, or registration.** If facilities use volunteers as part of their emergency staffing strategy, policies and procedures should clearly outline what type(s) of volunteers would be accepted during an emergency and what role(s) these volunteers might play. **Note: Volunteers as referenced in this standard indicate the integration of designated healthcare professionals. The intent of this standard is to facilitate the process of identifying and verifying licenses, certifications, or registrations to ensure protection against substandard care in times of emergencies or disasters.** The volunteer management plan may be part of EOP or it may be separate. If separate, the EOP must reference where to find the volunteer management plan. The plan must include verification of each volunteer's identity, license, credentials, certifications, malpractice insurance, and CAH privileges through federal, state, or local systems and within 72 hours of activating the Incident Command Center, when possible. The volunteer's identity and evidence of state professional license must be verified prior to providing patient care. 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 policy and procedure.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The P&P include a volunteer management plan if volunteers are used. ▪ If no volunteers are used, does the facility have other emergency staffing strategies? ▪ There is a P&P that addresses surge needs during an emergency. ▪ P&P are reviewed and updated every two years per standard 17.01.01.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
17.01.10 Continuity of services *The policies and procedures must address the development of arrangements with other CAHs 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 17.01.01 by the emergency management committee. §485.625(b)(7) Tag C-0950	☐ Compliant ☐ Not Compliant A transfer agreement must be signed with other CAHs 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 support: ▪ Physicians and facilities in the treatment of trauma patients. ▪ Timely transfer of patients and information necessary to their care. ▪ Continuity of the care and treatment appropriate to the needs of the trauma patients. ▪ Use 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: **DOCUMENT REVIEW** Verify: ▪ P&P identify the CAHs with which there are transfer agreements. ▪ Transfer agreements are completed and signed by representatives from each organization. ▪ P&P are reviewed and updated every two years per standard 17.01.01.
17.01.11 Invoking the 1135 Waiver *The policies and procedures must address the role of the CAH 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.* *These policies and procedures must be reviewed and updated* per ACHC standard 17.01.01 by the emergency management	**(a)** ☐ Compliant ☐ Not Compliant 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 CAHs that provide such services in good faith to be reimbursed and exempted from sanctions (absent any determination of fraud or abuse).	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ P&P include the role of the CAH under an 1135 Waiver. ▪ P&P identify the alternate care site identified by the state or local emergency management officials. ▪ P&P are reviewed and updated every two years per standard 17.01.01.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
committee. §485.625(b)(8) Tag C-0950	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 Regional Office with a copy to ACHC. CMS has stated that they expect that 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.	
17.01.12 Security 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 17.01.01 by the emergency management committee.	☐ Compliant ☐ Not Compliant 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 the following: 1. The differing needs of each location where the CAH operates. 2. The special needs of patient populations treated at the CAH (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 CAH's emergency plans.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ P&P reflect a comprehensive plan to ensure the security and wellbeing of patients during emergency situations. ▪ Policies describe how supplemental security forces are obtained in the event of a disaster. ▪ P&P and systems are in place to provide emergency security services. ▪ P&P are reviewed and updated every two years per standard 17.01.01.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
17.01.13 Decontamination	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The policies and procedures must address how the CAH arranges for the chemical, biological and radioactive decontamination. These policies and procedures must be reviewed and updated per ACHC standard 17.01.01 by the emergency management committee.	Decontamination procedures must be in place for internal and external accidents. The CAH 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 notification of the appropriate authorities based on the size and severity of the spill and CAH resources available.	**DOCUMENT REVIEW** Verify: ▪ P&P address decontamination activities. ▪ P&P are reviewed and updated every two years per standard 17.01.01.
17.01.14 Incident command center	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The policies and procedures must address the identification where the CAH'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 17.01.01.	There is a reference in the policies and procedures to the location of the command center for directing and controlling CAH emergency response functions. **Hospitals can incorporate a virtual command center (VCC) into their Emergency Operations Plan (EOP), tailored to the nature of the event response. Activation would be at the discretion of the Incident Commander. The VCC plan should specify a designated point of contact and outline a strategy for regular briefings, to be scheduled as decided by the Incident Commander.** 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.	**DOCUMENT REVIEW** Verify: ▪ P&P identify the location of the command center. ▪ P&P Include a setup process for the Incident Command Center. ▪ P&P are reviewed and updated every two years per standard 17.01.01. ▪ There is a process for providing updates to the ICC regarding availability of equipment/supplies.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

COMMUNICATION

17.02.01 Communication plan

Section 1.02 ☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The CAH must develop and maintain an emergency communication plan that complies with Federal, State, and local laws, and must be reviewed and updated per ACHC standard 17.01.01.

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 CAH designated spokespersons to the media.

§485.625(c) Tag C-0950

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 CAH units and departments must include a process to initiate the call back of staff on each unit. Staff must be able to make external 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 CAH or away from the CAH whenever the Incident Command System is activated **and where it is located**.

The staff call-back roster is dated and is updated semi-annually.

The communication plan identifies the location where the media will be briefed.

INTERVIEW AND DOCUMENT REVIEW

Verify:

- The staff call-back roster has been updated semi-annually.
- Collaboration takes place with federal, state, and local officials to ensure the communication plan complies with requirements as confirmed through interview with the leadership or designee responsible for emergency management.
- The communication plan is reviewed and updated every two years per standard 17.01.01.

17.02.02 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 CAHs and hospitals*

Emergency preparedness officials may include, but are not limited to, emergency management agencies which may be local to the community and local officials who support the Incident Command Center depending on the nature of the disaster (e.g., fire, police, public health, etc.).

Additionally, emergency management officials also include state public health departments, federal emergency preparedness officials (FEMA, ASPR, DHS, CMS, etc.), and tribal emergency officials, as applicable.

DOCUMENT REVIEW

Verify:

- The emergency communications plan includes the names and contact information of the individuals noted.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
▪ *Volunteers* ▪ *Federal, State, tribal, regional, and local emergency preparedness staff* ▪ *Other sources of assistance.* §485.625(c)(1) Tag C-0950 §485.625(c)(1)(i-v) §485.625(c)(2)(i-ii)	Facilities have discretion in formatting 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 and current. Any changes to information for entities on the contact list are updated when changes are discovered and at a minimum as follows (reference 17.01.01): ▪ 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.	▪ Verify that the facility has contact information for the State Survey Agency and/or public health departments.
17.02.03 Primary and alternate means of communication *The communication plan must include primary and alternate means for communication with the following:* ▪ *The CAH's staff* ▪ *Federal, State, tribal, regional, and local emergency management agencies.* §485.625(c)(3) Tag C-0950 §485.625(c)(3)(i) §485.625(c)(3)(ii)	☐ Compliant ☐ Not Compliant Reliable communication must be maintained by the CAH 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)	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the emergency communications plan to verify that it meets the requirement for primary and alternate communication means with staff and outside agencies.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ 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 how the CAH communicates with staff and outside agencies that have a functional role with the CAH's response and recovery phases during an emergency event.	
17.02.04 Information sharing *The communication plan must include a method for sharing information and medical documentation for patients under the CAH's care, as necessary, with other health care providers to maintain the continuity of care.* §485.625(c)(4) Tag C-0950	☐ 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 must 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 time frame 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, including 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	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the emergency communications plan addresses the CAH's plan on sharing patient information with other healthcare providers.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	or electronic) for how facilities are to share the required information.	
17.02.05 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).* §485.625(c)(5) Tag C-0950 §485.625(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 §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 §164.510. The requirements in paragraphs (b)(2), (b)(3), or (b)(5) of §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** ▪ Verify that the emergency communications plan includes the necessary means to provide patient information to family members, personal representative, or other individuals responsible for the care of the patient.
17.02.06 CAH information *The communication plan must include a means of providing information about the CAH's occupancy, needs, and its ability to provide assistance, to the authorities having jurisdiction, the Incident Command Center, or designee.* §485.625(c)(7) Tag C-0950	☐ Compliant ☐ Not Compliant Communicating critical information to the authorities having jurisdiction regarding the CAH during an emergency is vital to a well-organized response to an emergency. The CAH 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** ▪ Verify that the emergency communications plan addresses how the CAH will communicate its needs and abilities during an emergency to the appropriate authorities.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

REPORTING FACILITY 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 THE 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.), and wheelchairs and beds.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

TRAINING AND TESTING

17.03.01 Emergency training

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The CAH must develop and maintain a training program that is based on the Emergency Operations Plan (EOP), the Hazard Vulnerability Assessment (HVA), the Policies & Procedures, and the communication plan.

The CAH must do all of the following:

- *Provide initial training in emergency preparedness policies and procedures, including prompt reporting and extinguishing of fires, protection, and where necessary, evacuation of patients, personnel, and guests, fire prevention, and cooperation with firefighting and disaster authorities, to all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles.*
- 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 emergency preparedness training program may be part of the EOP or it may be separate. If separate, the EOP must reference where to find the training program.

The CAH must provide initial training in emergency preparedness policies and procedures to all new and existing staff, including individuals providing services under arrangement, volunteers, and physicians, consistent with their expected role.

The CAH must provide emergency preparedness training to all staff at least every two years. The CAH must maintain documentation of the training. The CAH 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 patient population, such as triage processes and transfer/discharge during mass casualty or surge events. Furthermore, the facility must train staff based on

INTERVIEW AND DOCUMENT REVIEW

Verify:

- The training program ensures all staff are educated on the Emergency Preparedness Program.
  - □ Refer to the facility's risk assessment to determine if the training and testing program reflects risks and hazards identified within the facility's program.
- Staff (including physicians and contract workers) receive training on emergency preparedness every two years.
- Documentation is available and accurate for training and testing.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
The training program must be reviewed and updated biennially or every two years. §485.625(d) Tag C-0950 §485.625(d)(1)(i-v)	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 this may include proper use of PPE, assessing patient needs and how to screen patients and provide care based on the facility's capacity and capabilities and communication including reporting and providing information on patient status to caregivers and family members. Facilities must also be able to demonstrate additional training when the emergency plan is significantly updated. CAHs that have changed their EOP should plan to conduct initial training for 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.	
17.03.02 Emergency exercises *The CAH must develop and maintain a testing program* (exercises) *that is based on the Emergency* Operations *Plan* (EOP), the Hazard Vulnerability Assessment (HVA), *the Policies & Procedures, and the communication plan*.	☐ Compliant ☐ Not Compliant The purpose of the emergency exercises is to demonstrate the effectiveness of the CAH's emergency plan and to use the results of the exercises to improve the CAH'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.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Review the after-action reports of the emergency exercises and any actual events.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

The training and testing program must be reviewed and updated at least every two years.

All CAH facilities associated with providing healthcare 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 CAH must conduct two exercises per year, to test the emergency plan:

1. *The CAH 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 CAH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the CAH is exempt from engaging its next required full-scale community-based or individual facility-based full-scale exercise following the onset of the actual event.*
2. *The CAH must participate in a second exercise of their choice:*
   a. *an individual facility-based functional exercise*
   b. *a mock disaster drill*

Each implementation (either an actual emergency or an exercise) 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 CAH's capability to respond to emergencies, and to improve the EOP. The emergency committee submits reports to CAH leadership, and as appropriate, state, and federal entities.

The areas of evaluation in the after-action report include, but is not limited to:

- **Activation process and succession.**
- **Coordination of services and patients.**
- **Utilization of resources and communications.**
- **Areas of effectiveness.**
- **Areas for improvement.**

The scenario for tabletop exercises cannot be related to 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 activities must 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. For the latter, the facilitator must have specialty experience or education in emergency preparedness operations.

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

Verify:

- All after-action report items have been documented in meeting minutes of the oversight committee on emergency management and the Quality Assurance Performance Improvements (QAPI) committee.
- After-action reports are available for the past three years.
- Each exercise is based on one of the identified HVA hazards.
- Buildings classified as healthcare occupancy or ambulatory healthcare occupancy participated in at least two emergency exercises within the past calendar year.
- Buildings classified as business occupancies that provide patient care activities participated in at least one emergency exercise within the past calendar year.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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 CAH completes an after-action report.* *The CAH must analyze the CAH's response to and maintain documentation of all drills, tabletop exercises and emergency events, and revise the CAH's emergency plan, as needed.* §485.625(d) Tag C-0950 §485.625(d)(2)(i-iii)	facility-based level and is testing a particular clinical area, staff in this clinical area should participate to develop a clear understanding of their roles and responsibilities. Facilities can review which members of staff participated in the previous exercise to ensure participation in the 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 to require activation of the relevant emergency plans meets the full-scale exercise requirement and exempts the facility from the next community-based full-scale exercise or individual, facility-based exercise following the actual event. Facilities must be able to demonstrate this through written documentation that may include, but is not limited to, an 1135 waiver issued to the facility (time limited and event-specific); documentation alerting staff of the emergency; documentation of facility closures; meeting minutes addressing event-specific information. The facility must also complete an after-action report and integrate corrective actions into their emergency preparedness program. Example: If a CAH 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 CAH 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.	

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

OPERATIONAL REQUIREMENTS

17.04.01 Emergency power

☐ Compliant ☐ Not Compliant

This standard is not met as evidenced by:

The CAH must implement emergency power systems based on the Emergency Operations *Plan (*EOP) in the 'Planning' section (see standard 09.00.01), *and the Policies & Procedures* in the 'Procedures' section (see standard 17.01.01).

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 CAH must implement the emergency power inspection, testing, and maintenance requirements found in NFPA 99-2012, NFPA 101-2012, and NFPA 110-2010.

The CAH 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 CAH

NFPA 99 covers emergency power requirements for lighting, fire detection systems, extinguishing systems, and alarm systems. But 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 CAHs should accommodate any additional electrical loads the facility determines to be necessary to meet all subsistence needs required by emergency preparedness plans, policies, and procedures, unless the facility's emergency plans, policies and procedures define that the CAH 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.

OBSERVATION AND DOCUMENT REVIEW

Note: Generator inspection and testing requirements are scored in the Life Safety chapter.

Verify:

- The CAH's plan to keep the generator operational during an emergency.
- Newly installed generators (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 newer; alternately, the date can be verified on testing documentation for annual or 3-yr/4-hr generator load testing.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

decides to evacuate.

§485.625(e)(1-3) Tag C-0950
§485.623(a)

17.04.02 Integrated healthcare systems

☐ Compliant ☐ Not Compliant ☐ NA

This standard is not met as evidenced by:

If a CAH 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 CAH 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 services offered.*
3. *Demonstrate that each separately certified facility is capable of actively using the unified and integrated*

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.

INTERVIEW AND DOCUMENT REVIEW

- If elected, review the CAH's plan on how it will provide a unified and integrated approach to emergency preparedness to all separately certified healthcare facilities.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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 a training and testing program that meets the requirements set forth on the Testing & Training section of this chapter.*

§485.625(f)(1-5) Tag C-0950

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

PROGRAM EVALUATION

17.05.01 Evaluating the Emergency Preparedness Program

An evaluation of the Emergency Preparedness Program is completed at least every two years.

The evaluation is documented.

☐ **Compliant** ☐ **Not Compliant**

The Emergency Preparedness Program is the overall 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.

The documented annual evaluation for the Emergency Preparedness program includes an assessment of:

- **Objectives – assess whether the program objectives require changes, based on changes to standards, regulations, the facility, or operations. Objectives of a program represent the output or what you want to accomplish and provide direction and purpose with the program.**
- **Scope – assess whether the program scope requires changes, based on changes to standards, regulations, the facility, or operations. Identify any new processes needed, or whether any can be deleted. The scope of a program defines the boundaries represented and what is included in the program.**
- **Plan effectiveness – assess whether the program met the objectives. Use ongoing monitoring of performance to demonstrate whether the program was effective or if opportunities for improvement were identified.**
  - **Effectiveness includes the results of:**
    - **» Review of the HVA.**
    - **» Review of the EOP.**
    - **» Review of procedures and the communication plan.**
    - **» Training and testing**

This standard is not met as evidenced by:

INTERVIEW AND DOCUMENT REVIEW

- **An evaluation of the Emergency Preparedness Program has been completed within the last two years.**
- **The evaluation has been reviewed by the Emergency Management Committee and/or the Safety Committee and documented in the meeting minutes.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

- **Plan for improvement – based on the evaluation of the objectives,**
- **scope, and effectiveness, identify recommendations for improvement and/or revisions to program policies for the next cycle.**
  - **Plan for improvement includes updates or changes to:**
    - **Policies and procedures.**
    - **Training and testing.**

COMPLIANCE RESOURCES

17.06.01 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).

§485.625(g)

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.

(1) National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1.617.770.3000.

(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.*

18

INFECTION PREVENTION AND CONTROL & ANTIBIOTIC STEWARDSHIP PROGRAMS

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.00.00 CONDITION OF PARTICIPATION: Infection Prevention and Control and Antibiotic Stewardship Programs *The CAH must have active facility-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 coordination with the facility-wide quality assessment and performance improvement (QAPI) program.* §485.640 Tag C-1200	☐ Compliant ☐ Not Compliant The hospital develops, implements, and maintains an active, hospital-wide program for the prevention, control, and investigation of infections and communicable diseases. To demonstrate compliance, the critical access hospital has implemented a formal infection control program that is hospital-wide, includes all locations, all campuses, all departments, and services. The Infection Prevention and Control (IPC) Program includes a formal hospital-wide Antibiotic Stewardship Program, including all departments and locations. 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 IPC 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 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	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** This CoP will be cited as deficient when there are cumulative or severe deficiencies identified in this chapter.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

(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 CAH's program must include an active surveillance component that covers both CAH patients and personnel working in the CAH. Surveillance includes infection detection, data collection and analysis, monitoring, and evaluation of preventive interventions.

The CAH 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 CAH's various locations or departments. The CAH must document its surveillance activities, including the measures selected for monitoring, and the collection and analysis methods. Surveillance activities should be conducted in accordance with recognized infection control practices, such as 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 Program includes processes to reduce the risk of growth and spread of legionella and other opportunistic pathogens in building water systems.

The CAH's IPC Program must be integrated into its Quality Assurance and Performance Improvement (QAPI) Program. (See §482.42(b)(1).)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.00.01 Responsibilities of the governing body	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The governing body, or responsible individual, 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 CAH's QAPI leadership.* §485.640(c)(1) §485.640(c)(1)(i) Tag C-1225 §485.640(c)(1)(ii) Tag C-1229	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.	**INTERVIEW AND DOCUMENT REVIEW** ▪ Interview members of leadership to discuss the implementation issues of the IPC Program and Antibiotic Stewardship Program. ▪ Determine whether the hospital's IPC Program is integrated with its hospital-wide QAPI program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.00.02 Infection prevention and control program leadership *The CAH 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, or responsible individual, 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.* §485.640(a)(1) Tag C-1204	☐ 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 these roles, hospitals should assure that the designated individuals 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 of recognized professional societies, such as APIC and SHEA. The number of infection preventionist(s)/infection control officer(s) that must be devoted to the IPC Program are not quantified. However, resources must be adequate to accomplish the tasks required for the 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 IPC Program; how to prevent infectious/communicable diseases; and how to report infectious/communicable diseases to the program.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that an infection preventionist(s)/infection control officer(s): □ is designated and has the responsibility for the infection prevention and control program. □ has developed and implemented hospital infection control policies. ▪ Review the personnel file of the infection preventionist(s)/infection control officer(s) to verify that he/she is qualified through ongoing education, training, experience, or certification to oversee the infection control program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.00.03 Responsibilities of the infection 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 CAH's QAPI program on infection prevention and control issues.* *(iv) Competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, 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 policies and procedures by CAH*	☐ Compliant ☐ Not Compliant The job description for the infection prevention and control professional(s) describes all requirements listed in the standard. The CAH provides evidence of the required policies, surveillance reports, and staff training. Infection prevention and control issues are integrated into the CAH's QAPI Program. 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. 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	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ The job description for the infection prevention and control professional reflects the required elements of this standard. ▪ The written infection prevention and control policies of the CAH reference national guidelines.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
personnel. *(vi) Communication and collaboration with the antibiotic stewardship program.* §485.640(c)(2) §485.640(c)(2)(i) Tag C-1231 §485.640(c)(2)(ii) Tag C-1235 §485.640(c)(2)(iii) Tag C-1237 §485.640(c)(2)(iv) Tag C-1239 §485.640(c)(2)(v) Tag C-1240 §485.640(c)(2)(vi) Tag C-1242	preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks. 9. Complying with the reportable disease requirements of the local health authority.	
18.00.04 Infection prevention and control policies *The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the CAH and between the CAH and other healthcare settings.* §485.640(a)(2) Tag C-1206	☐ Compliant ☐ Not Compliant The CAH has a written infection control plan approved as part of the IPC Program that includes policies for the implementation and evaluation 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 control policies should be specific to each department, service, and location, including off-site locations, and be evaluated and revised when indicated. The policies and procedures are based on national guidelines. The IPC Program provides for approval of all cleaning products and dilution ratios used in the hospital prior to implementation and maintains a current inventory/list of all cleaning products used in the organization. The list is updated as new products are introduced into the facility.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify that: ▪ There are facility-wide policies and procedures for preventing and controlling the transmission of infection. ▪ The policies and procedures have been correctly implemented in an active infection control program. ▪ There is approval for all cleaning products and the associated dilution ratios. ▪ A cleaning product inventory is in place and is current.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.00.05 Scope and complexity of services *The infection prevention and control program reflects the scope and complexity of the CAH services provided.* §485.640(a)(4) Tag C-1210	☐ 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 IPC Program is hospital-wide and program-specific in gathering and assessing infection and communicable disease data.
18.00.06 For future use		
18.00.07 Acute respiratory illness reporting, including influenza virus, influenza-like illness, COVID-19, severe acute respiratory infection, and other acute infectious illness *During a Public Health Emergency, as defined in §400.200 the CAH 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.* §485.640**(d)(1)(i-ii)** §485.640**(d)(2)**	☐ Compliant ☐ Not Compliant ☐ **Not Applicable** Medicare and Medicaid participation requires that hospitals report data critical to the management and mitigation of acute infectious disease. While subject to change as specified by the Secretary of HHS, required data include: ▪ **Confirmed infections for a respiratory illnesses, including but not limited to influenza, COVID-19, and RSV, among newly admitted and hospitalized patients.** ▪ **Total bed census and capacity, including for critical hospital units and age groups.** ▪ **Specified patient demographic information, including but not limited to age.** **NOTE: While this reporting is required on an ongoing basis, compliance will be determined by CMS independently from surveys performed by state survey agencies or accreditation organizations (AO). In the event of a**	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** ▪ Interview members of the leadership team to discuss the reporting process. Verify: ▪ The CAH can provide details of the reporting process. ▪ The CAH has implemented its **process** for reporting data in accordance with the frequency and format defined by the Secretary, HHS. **NOTE: This standard is scored N/A unless a PHE declaration is in effect.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	related PHE, CMS may reassign assessment responsibility to AOs.	
18.00.08 Unified multi-hospital Infection Prevention and Control Program	☐ Compliant ☐ Not Compliant ☐ Not Applicable	This standard is not met as evidenced by:
If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities 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 CAHs meets all of the requirements of this section. Each separately certified CAH 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 CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH;* 2. *The unified and integrated infection*	The governing body ensures the 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.	**DOCUMENT REVIEW** Verify: ▪ 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.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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 CAHs, 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 CAHs are duly considered and addressed.* §485.640(g)(1-3)		
18.00.09 <u>Unified multi-hospital Infection Prevention and Control Program leadership</u> *A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the CAH 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*	☐ Compliant ☐ Not Compliant ☐ Not Applicable 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: **<u>DOCUMENT REVIEW</u>** Verify: ▪ Information about the hospital's IPC and Antibiotic Stewardship Programs is communicated to the governing body.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to CAH staff. § 485.640(g)(4)		
18.01.01 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 CAH's infection prevention and control and QAPI programs, on antibiotic use issues.* *(iv) Competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAHs, on the*	☐ 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

practical applications of antibiotic stewardship guidelines, policies, and procedures.

§485.640(c)(3)
§485.640(c)(3)(i) Tag C-1244
§485.640(c)(3)(ii) Tag C-1246
§485.640(c)(3)(iii) Tag C-1248
§485.640(c)(3)(iv) Tag C-1250

18.01.02 Antibiotic Stewardship Program leadership

The CAH must demonstrate that:

An individual (or individuals), who is 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.

§485.640(b)(1) Tag C-1212

☐ Compliant ☐ Not Compliant

The CAH must designate in writing an individual to lead its antibiotic stewardship program.

The CAH 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 Preventionist/ Infection Control Officer responsible for the infection control program of the facility.

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.
- Verify the appointment is based on the recommendations of the medical staff leadership and pharmacy leadership.

18.01.03 Facility-wide Antibiotic Stewardship Program

The facility-wide antibiotic stewardship program:

☐ Compliant ☐ Not Compliant

The CAH implements an Antibiotic Stewardship Program to help reduce inappropriate antibiotic use and antimicrobial resistance in the facility.

This standard is not met as evidenced by:

DOCUMENT REVIEW

Verify:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
(i) Demonstrates coordination among all components of the CAH 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 services of the CAH; and* *(iii) Documents any improvements, including sustained improvements, in proper antibiotic use.* §485.640(b)(2) §485.640(b)(2)(i) Tag C-1218 §485.640(b)(2)(ii) Tag C-1219 §485.640(b)(2)(iii) Tag C-1220	The CAH plays an important role in combatting antimicrobial resistance through implementation of a robust stewardship program that follows nationally recognized guidelines for appropriate antibiotic use.	▪ 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. ▪ Program improvements are documented.
18.01.04 <u>Antibiotic stewardship guidelines</u> *The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use.* §485.640(b)(3) Tag C-1221	☐ Compliant ☐ Not Compliant The CAH'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 CAH 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	This standard is not met as evidenced by: **<u>DOCUMENT REVIEW</u>** ▪ Verify the program bases antibiotic use on nationally recognized guidelines.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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 allowing for flexibility to adapt policies and procedures in concert with any updates in the guidelines the hospital has elected to follow.	
18.01.05 Scope and complexity of the Antibiotic Stewardship Program *The antibiotic stewardship program reflects the scope and complexity of the services CAH provided.* §485.640(b)(4) Tag C-1223	☐ Compliant ☐ Not Compliant The Antibiotic Stewardship Program covers all departments of the facility and all outpatient areas.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The Antibiotic Stewardship Program is hospital-wide. ▪ The Antibiotic Stewardship Program identifies all hospital locations and policies and procedures take these into account.
18.02.01 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*	☐ Compliant ☐ Not Compliant The IPC 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	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ The hospital maintains a sanitary environment. ▪ The hospital develops and implements infection control measures related to

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
for preventing and controlling the transmission of infections within the hospital and between the hospital and other institutions and settings. **§485.640(a)(2)**	revised when indicated. 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: **MAINTENANCE OF A SANITARY PHYSICAL ENVIRONMENT** ▪ 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 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 its personnel.	▪ Risks associated with patient infections present upon admission are mitigated. ▪ Risks contributing to healthcare-associated infections are mitigated (for example, observe whether staff exhibit good hand washing hygiene). ▪ Active surveillance. ▪ Coordination occurs as required by law with federal, state, and local emergency preparedness and health authorities to address communicable disease threats, bioterrorism, and outbreaks. ▪ Compliance with the reportable disease requirements of the local health authority.

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 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 that cannot be removed from corrugated boxes, stratifying the risk of potential infection against that of loss or damage to the 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

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:
   - □ 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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.	
18.02.02 Surveillance *The infection prevention and control program 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.* §485.640(a)(3) Tag C-1208	☐ Compliant ☐ Not Compliant The CAH 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 to 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.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ 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 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 authorities, as required by law, regarding reportable diseases

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		and other infection control issues.
18.02.03 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. **§485.640(a)(2)** **§485.640(a)(3)**	☐ 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 the sanitary condition of the environment of care, noting the 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 active surveillance program to determine whether it is suitable to the scope and complexity of the hospital's services. Verify: ▪ **Environmental surveillance reports are being sent to the following committees: Medical Staff, Safety, and Infection Control.** ▪ Meeting minutes include evidence that summaries of such surveillance have been discussed. ▪ Environmental surveillance activities are included in the hospital-wide QAPI program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.02.04 Personal protective equipment (PPE)	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
The CAH, in accordance with nationally recognized standards of practice (OSHA, CDC, APIC), must: ▪ Define in policies and procedures the 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. **§485.640(a)(2)**	Personal protective equipment (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 CAH, in accordance with nationally recognized 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 personal protective equipment (PPE) use (e.g., 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.	**OBSERVATION AND DOCUMENT REVIEW** ▪ Observe staff donning and removing PPE. Verify: ▪ Policies and procedures are based on national guidelines. ▪ Training for PPE occurs in orientation and periodically thereafter. ▪ Monitoring occurs for proper use of PPE.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Transport of patients. ▪ Textiles and laundry. ▪ Waste disposal. ▪ Dishware and eating utensils. ▪ Adjunctive measures such as post exposure chemoprophylaxis. ▪ Management of visitors. ▪ Monitoring use of PPE.	
18.02.05 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. **§485.640(a)(2)**	☐ 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: ▪ Use of alcohol-based hand rubs (ABHR). ▪ Surgical hand antisepsis. ▪ Elimination of the use of artificial nails for ALL staff working in intensive care units and operating rooms. ▪ Natural nail tips limited to ¼ inch in length. ▪ 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 that 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, the elements listed. ▪ Observe hand hygiene technique throughout the organization in all areas where patient care is delivered to determine if organization policies are being followed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

18.02.06 Reduce risk of legionella in water systems

The infection control program includes processes to reduce the risk of growth and spread of legionella and other opportunistic pathogens in building water systems including:

The infection control leader collaborates with a multi-disciplinary team to reduce the risk of growth and spread of legionella and other opportunistic pathogens in the water systems.

§485.640 Tag C-1200

☐ Compliant ☐ Not Compliant

Legionnaire's disease, a severe and sometimes fatal pneumonia, can occur in persons who inhale aerosolized droplets of water contaminated with the bacterium legionella.

Outbreaks generally are linked to 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

This standard is not met as evidenced by:

DOCUMENT REVIEW

Note: Facilities unable to demonstrate measures to minimize the risk of Legionnaire's disease are at risk of citation for non-compliance at the Condition-level in a state survey.

Verify:

- The CAH implements a Water Management Program that considers the ASHRAE industry standard and the CDC 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

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ cooling towers ▪ medical devices (such as 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 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 plan 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 plan has been implemented, a communication plan is developed and shared with the staff on a routine basis as established by the hospital policy.	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 the water management program.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.02.07 Prevention of infections: Central venous catheters The organization adopts nationally recognized clinical practice standards that are identified as effective in improving patient safety through 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. **§485.640(a)(2)**	☐ 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. 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. ▪ Prompt removal of the catheter as soon as it is no longer essential.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify the facility has taken actions to prevent central line-associated bloodstream infection by implementing evidence-based practices. ▪ Review the policy for central catheter insertion and care. It must: □ Reflect evidence-based strategies for infection reduction. □ Define a process to monitor compliance and infection rates. Review patient records to determine compliance with the policy.
18.02.08 For future use		

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.02.09 Recall process There is a process for the recall and disposal or reprocessing of outdated or contaminated patient care supplies/ equipment. **§485.640(a)(2)**	☐ 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. Confirm that the policy addresses: □ The provision for physician notification. □ The removal of products from patient care.
18.03.01 Staff orientation and training There is a hospital-wide plan for staff orientation and ongoing training in infection prevention and control. **§485.640(a)(2)**	☐ 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 covered in orientation and during annual education programs.
18.03.02 Employee health policies The Infection Control Committee establishes and evaluates employee health	☐ 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	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Review the Infection Control Committee

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
policies. **§482.42** **§485.640(a)(2)**	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."	minutes or the medical staff minutes when it acts as a committee-of-the-whole to verify the facility has an employee health plan, approved annually by the Infection Control Committee (function).
18.03.03 Employee Health: Vaccines for healthcare workers Vaccinations will be made available to all healthcare workers in accordance with state and federal law. The vaccination status of all employees will be maintained. There is a process in place ensuring all employees are vaccinated as required by hospital policy or have been granted an exemption. **§482.42** **§485.640(a)(2)**	☐ 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. 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.	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 the Centers for Disease Control and Prevention (CDC). ▪ Employee health policies and procedures include: □ Vaccinations are made available to all healthcare workers. □ There is a process in place to ensure all employees are vaccinated or have been granted an exemption.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ COVID-19 (see Standard 18.03.04) 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).	□ All employees have been offered the recommended vaccinations. □ The vaccination status of all employees is maintained. □ For vaccines required by state and federal law, records of employee exemption from vaccination are maintained.
18.04.01 Decontamination and 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 that have been approved by the Infection Control Committee (function). **§485.640(a)(2)**	☐ Compliant ☐ Not Compliant Policies and procedures are written for all types of activities relating to decontamination of supplies and equipment to protect the staff and visitors. The CAH infection control policies shall be approved by the Infection Control Committee/function at least annually. The hospital shall comply with these policies. A policy identifies when sterilization, low-level, high-level disinfection, or chemical disinfection is acceptable and delineates the steps of each disinfection process 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, 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 and training/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	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ Policies and procedures address disinfection and sterilization procedures. ▪ Documentation that the Infection Control Committee has reviewed, at least annually, the departmental policies regarding disinfection and sterilization. ▪ Practices are consistent with CDC guidelines, OSHA, state, and local laws, and evidence-based guidelines. ▪ Through observation and interview, that staff are familiar with policies and procedures and follow them.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	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.	
18.04.02 <u>Decontamination of reusable items and reuse of single use devices</u> If reuse is approved within the organization, the FDA Reuse of Single Use Devices Guidelines must be followed. There are approved policies for collecting, receiving, decontaminating, cleaning, disinfecting, and sterilizing of reusable instruments. **§485.640(a)(2)**	☐ Compliant ☐ Not Compliant Sterilization may be provided through 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 the hospital assures: 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: **<u>OBSERVATION AND DOCUMENT REVIEW</u>** 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 for reuse of single use items, if applicable. ▪ Through observation and discussion with staff, confirm that the reuse policy is implemented.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.04.03 <u>High level disinfection/sterilization and processing of endoscopes</u> 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. **§485.640(a)(2)**	☐ Compliant ☐ Not Compliant The hospital has policies and procedures **addressing comprehensive practices for processing flexible and semi-rigid endoscopes using high-level disinfection or sterilization. These are written in accordance with nationally recognized standards from** CDC, APIC, AAMI, FDA etc., and manufacturer's IFU to include: □ **Point of use treatment.** □ Transporting instruments. □ **Hand-off communication.** □ Leak testing. □ **Decontamination/cleaning**. □ **Packaging (when applicable)**. □ **High-level disinfection**. □ **Sterilization**. □ **Safe storage.** □ **The physical design and functional layout of the endoscope processing areas**. □ **Personnel education, training, and competency verification**. □ **QAPI activities for flexible and semi-rigid endoscopes**. **At a minimum, hospital policies also address:** ▪ **Classifying the endoscope inventory as critical, semi-critical, and non-critical devices in accordance with nationally recognized classification guidelines.** ▪ **Cleaning, disinfection, and sterilization processes according to the device classification.** **An annual risk assessment is performed if the cleaning, disinfection, and sterilization processes of all hospital flexible and semi-rigid endoscopes**	This standard is not met as evidenced by: **<u>OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW</u>** **Verify:** ▪ **The hospital policies address the safe processing of endoscopes including point of use treatment, transporting endoscopes, hand-off communication, leak testing, decontamination and cleaning, packaging when applicable, high-level disinfection, sterilization, safe storage, the physical design of the endoscope processing areas, education, training, and competency verification of personnel including the frequency, and the Flexible and Semi-rigid Endoscope Quality Program.** ▪ 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. ▪ **The endoscope processing areas meet the minimum requirements for safe processing.**

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	is not done in accordance with the recommendations. New endoscope purchases are classified immediately, and an interim risk assessment is completed if the cleaning, disinfection, and sterilization processes are not followed according to the device classification. ▪ **The workflow, room design, decontamination, inspection, and disinfection is in accordance with nationally recognized standards.** □ **Unidirectional workflow procedures are established for device processing.** □ **Floors, walls, and ceilings should be monolithic, smooth, and cleanable.** □ **Air flow meets requirements.** □ **Hand hygiene, standard precautions, PPE, attire, and the scope cleaning process are defined.** □ **Required lighting and magnification for scope inspection.** □ **The use of instrument air for drying; a defined permissible upper limit is identified. Medical air is not permitted to be used.** □ **Water quality plan.** □ **Cleaning verification testing.** □ **Processing of endoscopic accessories.** □ **Documentation and record keeping.** □ **Borescopic inspection may be used but is not required.**	▪ **Hospital policies and procedures are written in accordance with recommendations from nationally recognized guidelines and standards as well as equipment Instructions for Use (IFU).**
18.04.04 <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: Prior to updates in 2023, this standard was numbered 18.04.03. 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	This standard is not met as evidenced by: **<u>OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW</u>** ▪ Review the infection control plan to confirm that the program is consistent

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
§485.640(a)(2)	formerly known as "flash sterilization." 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** Policies 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. 2. Identification of devices NOT compatible with IUSS. 3. Identification, for each IUSS cycle, the appropriate physical monitors (time, temperature, pressure). 4. The policy identifies: □ indications for use of a Chemical Indicator (CI). □ indications for use of a Biological Indicator (BI). □ sterilization procedure. □ use of labels. □ frequency of testing.	with the national standards of practice. ▪ Verify that the infection control plan has eliminated use of "flash sterilization" and has adopted the term "Immediate Use Steam Sterilization" (IUSS). **Note:** If the answer to any of the following questions is "no," a citation under the appropriate infection control Condition is warranted. ▪ Is IUSS reserved for immediate use needs (e.g., used only emergently), when a 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 necessary time, equipment,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE

supplies and facilities available.

- □ Have been trained and are able to correctly follow the manufacturer's IFU regarding IUSS with respect to each instrument, sterilizer, container, and all 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 the sterilizer cycle being used for IUSS matches the device manufacturer's IFU?
- Are physical monitors used documenting 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 the manufacturer labeling?
- Is the rigid sterilization container being used for the load consistent with manufacturer's recommendations for IUSS (e.g., load weight, configuration of instruments)?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.04.05 Sterilization and decontamination devices Policies and/or procedures describe the use of devices to monitor sterilization or decontamination results in compliance with manufacturer's instructions. **§485.640(a)(2)**	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 18.04.04. Policies and procedures are consistent with manufacturer's instructions and national guidelines such as CDC, CDC-HICPAC, AORN, AAMI, etc. Practice reflects implementation of the policies. Chemical indicators can be any of several types to demonstrate the product has gone through a sterilization process. Vendor contracts must 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/sterilization-medical-devices.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** 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.
18.04.06 Sterilization data requirements Appropriate documentation, including temperature and pressure readings, is recorded and maintained for every	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 18.04.05. A policy requires that for each sterilizer load (e.g., low temperature sterilization devices, such as equipment for cleaning endoscopes and	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** ▪ Observe the load control mechanism. ▪ Verify:

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
sterilized load. **§485.640(a)(2)**	reprocessing equipment), readings are maintained and specifies how long the documentation is retained. The readings may be automatically printed values or handwritten, including the Person's name or initials, timed, and dated. The load control numbers documentation includes identification of the equipment used, the sterilization cycle, and date for each sterilized item.	□ Policy addresses requirements. □ Implementation via the quality control logs.
18.04.07 Preparing, assembling, 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. **§485.640(a)(2)**	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 18.04.06. 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.	This standard is not met as evidenced by: **OBSERVATION, INTERVIEW, AND DOCUMENT REVIEW** Verify: ▪ Policies are in place describing all five processes. ▪ Policies are enforced.
18.04.08 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. **§485.640(a)(2)**	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 18.04.07. 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** Verify: ▪ Policy describes how long each type of package is considered sterile. □ It must address 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
18.04.09 Environmental requirements in decontamination rooms The physical environment of areas used for final decontaminating, cleaning, and/or sterilizing equipment or supplies provides for each of the following: 1. Adequate space. 2. A double sink. 3. Air flow in the direction from the clean area toward the dirty area. 4. An air exchange rate of at least six in the clean area and at least ten in the dirty area. **§485.640(a)(2)**	☐ Compliant ☐ Not Compliant Note: Prior to updates in 2023, this standard was numbered 18.04.08. 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.
18.05.01 Housekeeping There are policies and procedures periodically approved as part of the Infection Prevention and Control function/leadership relating to the description of the scope and practices of Housekeeping, Linen Services and the hospital's environment. **§485.640(a)(2)**	☐ Compliant ☐ Not Compliant The current approved policies are available to the staff. Practices are consistent with policies. Policies include, but are not limited to: 1. High-risk cleaning procedures. 2. Air supply and return grills. 3. Maintenance of ceilings. 4. Hand-washing sinks. 5. Maintenance of housekeeping and laundry equipment. 6. Waste disposal.	This standard is not met as evidenced by: **OBSERVATION AND DOCUMENT REVIEW** Verify: ▪ 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
18.05.02 High-risk cleaning procedures	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
There are policies and procedures for cleaning areas in the hospital deemed high risk due to their special functions. These would include, but are not limited to: ▪ Surgery. ▪ Labor and delivery. ▪ Cardiac catheterization lab. ▪ Bone marrow rooms. ▪ Central sterile processing. ▪ Newborn nursery. ▪ Linen processing. **§485.640(a)(2)**	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. ▪ High-risk cleaning policies have been approved by the Infection Control Committee (function) at least every three years.
18.05.03 Air supply and return grilles	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Air supply and return grilles are clean. **§485.640(a)(2)**	The HVAC grilles do not have a build-up of dust or debris.	**OBSERVATION** ▪ Observe grilles for build-up of dust/ debris. (Special care is taken to observe in the ICU, OR, delivery room, food preparation areas, etc.)
18.05.04 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	Care is taken to reduce the potential that dust and other contaminants may fall from ceiling spaces into food service or patient care areas.	**OBSERVATION** ▪ In the sensitive areas noted above,

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
tiles do not have moisture stains/mildew. **§485.640(a)(2)**	Ceiling tiles are exchanged when they are moistened to minimize the potential for bacterial growth.	determine the risk of contamination from ceilings. ▪ Verify that ceiling tiles are clean with no evidence of dust or other contaminates. ▪ Ceiling tiles are not stained.
18.05.05 <u>Maintenance of housekeeping and laundry equipment</u>	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Policies and procedures govern the care and cleaning of housekeeping and laundry equipment. **§485.640(a)(2)**	There are written procedures describing processes for decontaminating cleaning equipment. These include, but are not limited to: ▪ The frequency with which the equipment is cleaned. ▪ The cleaning products used on each type of equipment. ▪ Where and how the equipment is to be stored to reduce re-contamination.	**<u>OBSERVATION AND DOCUMENT REVIEW</u>** ▪ Review policies and observe practice to determine whether the hospital is following current accepted practices of the industry.
18.05.06 <u>Waste disposal</u>	☐ 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. **§485.640(a)(2)**	There are written procedures which describe methods of holding, handling, transporting, storage, and disposal of all types of waste.	**<u>OBSERVATION AND DOCUMENT REVIEW</u>** ▪ Review policies and observe practice to determine if acceptable methods are being used in the hospital for trash storage and disposal.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.06.01 Soiled linen management	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Contaminated linen will be 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 are not used for storage or transport of clean linen. The dirty portion of the laundry area has negative pressure to prevent airborne contamination, in accordance with state and federal guidelines for healthcare laundry facilities. **§485.640(a)(2)**	Soiled linen is stored in nonabsorbent, covered devices. Measures are taken to reduce the potential for particles becoming airborne, exposed, and/or liquids dripping from, or absorbing into, 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.	**OBSERVATION** Verify: ▪ Policies address each element of the Standard and are approved by the Infection Control Committee (function). ▪ 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.
18.06.02 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. **§485.640(a)(2)**	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.	**OBSERVATION AND INTERVIEW** ▪ Observe the storage and transport of clean linen. Verify: ▪ Transport carts are enclosed.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	The lowest shelf of the clean linen storage and transportation carts are enclosed and not open to the spread of dust and other potential contaminants.	▪ Clean linen storage shelves and transportation carts do not have open grating as the lowest shelf.
18.07.01 Extermination program There is a pest extermination program to control the presence and reproduction of pests. The pest control program must be safe for use. **§485.640(a)(2)**	☐ 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. The pest control program addresses the exterior and interior of the building(s). Measures are taken to reduce the opportunities for insects and other pests to have access into the facilities. All openings to the outside of the physical hospital are protected to effectively reduce the potential of the entrance of pests into the hospital. 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. There is an ongoing pest extermination process within the hospital. This can be by provided by hospital employees or by a contracted outside service. 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** Verify: ▪ Records of pest control. ▪ Availability of MSDS precautions for any chemicals. ▪ Observe for exposure of patients and staff to hazardous conditions. ▪ Measures are taken to prevent pest entry.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
Contaminated linen collection bags or containers will be labeled and/or color coded to communicate that the contents contain infectious materials. Soiled linen containers are not used for storage or transport of clean linen. The dirty portion of the laundry area has negative pressure to prevent airborne contamination, in accordance with state and federal guidelines for healthcare laundry facilities. **§485.640(a)(2)**	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.	□ Contaminated containers are sanitized before use to transport clean linen.
18.06.02 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. **§485.640(a)(2)**	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 are enclosed and not open to the spread of dust and other potential contaminants.	**OBSERVATION AND INTERVIEW** ▪ Observe the storage and transport of clean linen. Verify: ▪ Transport carts are enclosed. ▪ Clean linen storage shelves and transportation carts do not have open grating as the lowest shelf.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
18.07.01 Extermination program	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
There is a pest extermination program to control the presence and reproduction of pests. The pest control program must be safe for use. **§485.640(a)(2)**	There is an ongoing pest extermination process within the hospital. This can be by provided by hospital employees or by a contracted outside service. The pest control program addresses the exterior and interior of the building(s). Measures are taken to reduce the opportunities for insects and other pests to have access into the facilities. All openings to the outside of the physical hospital are protected to effectively reduce the potential of the entrance of pests into the hospital. 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. There is an ongoing pest extermination process within the hospital. This can be by provided by hospital employees or by a contracted outside service. 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.	**OBSERVATION** Verify: ▪ Records of pest control. ▪ Availability of MSDS precautions for any chemicals. ▪ Observe for exposure of patients and staff to hazardous conditions. ▪ Measures are taken to prevent pest entry.

19

DISCHARGE PLANNING

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
19.00.00 CONDITION OF PARTICIPATION: Discharge Planning *A Critical Access Hospital (CAH) 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 the CAH to post-discharge care, and reduce the factors leading to preventable CAH and hospital readmissions.* §485.642 Tag C-1400	☐ Compliant ☐ Not Compliant Discharge planning is a process to determine the most appropriate post-acute destination for a patient and the resources required for a smooth and safe transition to this destination.	This standard is not met as evidenced by: **DOCUMENT REVIEW** ▪ Verify that the hospital has written policies and procedures for discharge planning. **Note:** Evaluate compliance with each standard. Depending on the nature and degree of deficiencies identified related to specific discharge planning standards, determine whether deficiencies rise to the level of substantial, i.e., condition-level, noncompliance with this CoP.
19.00.01 Discharge planning process *The CAH'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*	☐ Compliant ☐ Not Compliant The CAH must evaluate patients 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:** See also standard 19.00.05.	This standard is not met as evidenced by: **INTERVIEW AND DOCUMENT REVIEW** Verify: ▪ Policy requires identification at an early stage of hospitalization those patients who are likely to suffer adverse health consequences upon discharge or readmission if there is inadequate

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
as well as for other patients upon the request of the patient, patient's representative, or patient's physician. §485.642(a) Tag C-1404		discharge planning. ▪ Policy addresses the procedure for providing a discharge planning evaluation at the request of the patient, patient's representative, or patient's physician. ▪ Staff can demonstrate the procedure for discharge planning evaluation.
19.00.02 Timeliness of Assessment *Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-CAH care will be made before discharge and to avoid unnecessary delays in discharge.* §485.642(a)(1) Tag C-1406	☐ Compliant ☐ Not Compliant When 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, timely evaluation is completed. "Timely" means there is sufficient opportunity 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 primarily due to the delay in making appropriate arrangements.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Policy addresses the timely completion of the discharge planning evaluation. ▪ Medical records reflect timely discharge planning evaluation. □ Examples of the date and time 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)

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
		and/or is the delay due to the hospital's failure to develop timely discharge planning evaluations?
19.00.03 Discharge planning evaluation *A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate post-CAH services, including, but not limited to, hospice care services, post-CAH 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.* §485.642(a)(2) Tag C-1408	☐ Compliant ☐ Not Compliant For every inpatient identified as at potential risk of adverse health consequences without a discharge plan, a discharge planning evaluation must be completed. In addition, an evaluation must also be completed if the patient, or the patient's representative, or the patient's attending physician requests one. The CAH has a process for making patients, including the patient's representative, and attending physicians aware that they may request a discharge planning evaluation. The evaluation is a detailed review of the individual patient's post-discharge needs, in order to identify the specific areas that must be addressed in the discharge plan. The evaluation identifies whether there are community-based services available to meet the patient's needs while allowing the patient to live at home. **Upon discharge, the goal is for a patient to be able to return to the setting in which they were living prior to admission. The evaluation must consider social determinants of health and what the patient's care needs will be immediately upon discharge, and whether those needs are expected to remain constant or lessen over time.** Such health care services include, but are not limited to: ▪ Home health or attendant care, and other community-based services. ▪ Hospice or palliative care. ▪ Respiratory therapy.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Medical records with discharge planning evaluations include assessment of: □ The patient's post-acute care needs. □ The patient's ability to perform activities of daily living (personal hygiene and grooming, dressing, and undressing, feeding, control over bowel and bladder, ambulation, etc.). □ The patient's or family/other support person's ability to provide needed care. □ The need for medical equipment or home modification. □ Identification of available community-based services, if needed. □ The patient's insurance coverage (if applicable) and how that coverage might or might not provide for services post-hospitalization. □ For patients admitted from a

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
	▪ Rehabilitation services (PT, OT, speech, etc.). ▪ End Stage Renal Dialysis services. ▪ 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. Hospitals are expected to have knowledge of the capabilities and capacities of long-term care facilities and of various types of service providers in the area where most of the patients it serves receive post-hospital care. This includes familiarity with available Medicaid home and community-based services (HCBS).	nursing facility, skilled nursing facility or assisted living facility, assessment of that facility's capability to provide necessary post-hospital services to the patient.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
19.00.04 Documentation in medical record	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
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). §485.642(a)(3) Tag C-1410	The medical record includes documentation of the discharge planning evaluation discussed with the patient or patient's representative, even 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 that the 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.	**DOCUMENT REVIEW** Verify: ▪ Discharge planning evaluation results are included in the medical record. ▪ The evaluation results were discussed with the patient or the patient's representative.
19.00.05 Physician request for discharge planning	☐ Compliant ☐ Not Compliant	This standard is not met as evidenced by:
Upon the request of a patient's physician, the CAH must arrange for the development and initial implementation of a discharge plan for the patient. §485.642(a)(4) Tag C-1412	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.	**DOCUMENT REVIEW** Verify: ▪ The hospital has a process for notifying physicians that they may request a discharge plan and that the hospital will develop and implement a plan upon request.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
19.00.06 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, a registered nurse, social worker, or other appropriately qualified personnel.* §485.642(a)(5) Tag C-1417	☐ Compliant ☐ Not Compliant 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.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The hospital establishes the qualifications for developing or supervising development of the discharge planning evaluation. ▪ If the policy permits someone other than an RN or social worker to be responsible for developing or supervising such evaluations, the required qualifications of those individuals to perform this function are specified.
19.00.07 Re-evaluation of patient condition *The CAH's discharge planning process must require regular re-evaluation 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.* §485.642(a)(6) Tag C-1420	☐ Compliant ☐ Not Compliant Changes in a patient's condition may warrant adjustments to the discharge plan. Hospitals either routinely reassess all plans or defines a process for triggering reassessment when the patient's condition changes.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Policy addresses the reassessment of the discharge plan as indicated for changes in the patient's condition.

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
19.00.08 Assess the discharge planning process *The CAH 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.* §485.642(a)(7) Tag C-1422	☐ Compliant ☐ Not Compliant The hospital must reassess the effectiveness of its discharge planning process on an ongoing basis. The reassessment process reviews 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 or not the discharge was followed by a preventable readmission. 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. 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, but other intervals are permissible. 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 on an ongoing basis, i.e., at least quarterly. Hospitals may employ various methodologies to identify potentially preventable readmissions. There are proprietary products that, for example, use claims data to identify such cases. The hospital documents its methodology for tracking readmission rates.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ Policy addresses reassessing the discharge planning process including collection and analysis of readmissions data. ▪ The discharge planning process reassessment is addressed in the QAPI Program, including: □ Rate of re-admissions □ Effectiveness of the discharge planning process relative to patient readmissions. ▪ The assessment of readmissions includes 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?

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
19.00.09 Selection of a post-acute care provider *The CAH 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 CAH 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.* §485.642(a)(8) Tag C-1425	☐ Compliant ☐ Not Compliant The CAH may, but is not required to, include a list of home health agencies (HHAs), skilled nursing facilities (SNFs), IRFs, or LTCHs in the discharge plan. The CAH is required to assist patients, their families, or their caregivers or support persons in selecting a post-acute care provider and must do so by using and sharing data that includes but is not limited to HHA, SNF, IRF, or LTCH data on quality measures and resource use measures.	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The CAH maintains or can easily access data on quality and resource use measures in post-acute care options for discharge planning. ▪ If the hospital 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 this is clearly stated clearly on the lists. ▪ (Through interview) Current patients or their family, they were presented with information to support their choice of post-acute care options. □ 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
		▪ 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?
19.01.01 Transmission of patient's medical information *Discharge of the patient and provision and transmission of the patient's necessary medical information.* *The CAH 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*	☐ Compliant ☐ Not Compliant The hospital must arrange, as applicable, transfer to appropriate facilities or referrals to follow-up ambulatory care services. Medical information must be provided for patients being transferred and for those being discharged home, to make the patient's physician aware of the outcome of hospital treatment or follow-up care needs. Increasing use of hospitalists in the inpatient hospital setting means the patient's personal physician may have had no interaction with the patient during the inpatient stay. Prompt provision of medical information creates opportunity for the patient's physician to discuss with the hospital care team changes to the patient's	This standard is not met as evidenced by: **DOCUMENT REVIEW** Verify: ▪ The hospital has identified the specific medical information and timeframe for forwarding this at discharge. ▪ For patients discharged home, the necessary medical information was sent to a practitioner with which the patient has an established relationship prior to the first post-discharge appointment or

STANDARD	REQUIRED ELEMENTS/ADDITIONAL INFORMATION	SCORING PROCEDURE
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. §485.642(b) Tag C-1430	preadmission medication regimen or other elements of the post-discharge care plan about which the physician may have questions.	within seven days of discharge, whichever comes first. ▪ For patients without an established relationship with a practitioner, the necessary information was provided on potential primary care providers, such as health clinics, if available. ▪ For patients transferred to another inpatient facility, the necessary medical information was ready at time of transfer and sent to the receiving facility with the patient.

APPENDIX

INSTRUCTIONS FOR THE FACILITY DEMOGRAPHIC REPORT

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.

On the following pages are updated documents 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
- 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
- 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 assessed 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: