

NOTICE OF UPDATE



CRITICAL ACCESS HOSPITAL

Please note the following change to *Accreditation Requirements for Critical Access Hospitals*, 2021 edition.

Standard **18.03.04 Employee Health - COVID-19 Vaccination of CAH Staff** has been established per CMS requirements. The change becomes effective for surveys beginning January 27, 2022, in states except: Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Utah, West Virginia and Wyoming where surveys for compliance will begin on February 14, 2022. In Texas, surveys for compliance will begin February 22, 2022.

The Standard, Required Elements, and Scoring Procedure are presented below in entirety.

Standard 07.03.04 Employee Health - COVID-19 Vaccination of Staff

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

1. *Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following CAH staff, who provide any care, treatment, or other services for the CAH and/or its patients:*
 - i. *CAH employees;*
 - ii. *Licensed practitioners;*
 - iii. *Students, trainees, and volunteers; and*
 - iv. *Individuals who provide care, treatment, or other services for the CAH and/or its patients, under contract or by other arrangement.*
2. *The policies and procedures of this section do not apply to the following CAH staff:*
 - i. *Staff who exclusively provide telehealth or telemedicine services outside of the CAH setting and who do not have any direct contact with patients and other staff specified in paragraph 1 above; and*
 - ii. *Staff who provide support services for the CAH that are performed exclusively outside of the CAH setting and who do not have any direct contact with patients and other staff specified in paragraph 1 above.*
3. *The policies and procedures must include, at a minimum, the following components:*
 - i. *A process for ensuring all staff specified in paragraph 1 above (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a*

- multi-dose COVID-19 vaccine, prior to staff providing any care, treatment, or other services for the CAH and/or its patients;*
- ii. A process for ensuring that all staff specified in paragraph 1 above are fully vaccinated, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;*
- iii. A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;*
- iv. A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph 1 above;*
- v. A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;*
- vi. A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable federal law;*
- vii. A process for tracking and securely documenting information provided by those staff who have requested, and for whom the center has granted, an exemption from the staff COVID-19 vaccination requirements;*
- viii. A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable state and local laws, and for further ensuring that such documentation contains:

 - A. All information specifying which of the authorized or licensed COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and*
 - B. A statement by the authenticating practitioner recommending that the staff member be exempted from the center's COVID-19 vaccination requirements based on the recognized clinical contraindications;**
- ix. A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and*
- x. Contingency plans for staff who are not fully vaccinated for COVID-19.*

§485.640(f), §485.640(f)(1), §485.640(f)(1)(i), §482.640(f)(1)(ii), §482.640(f)(1)(iii), §482.640(f)(1)(iv), §482.640(f)(2), §482.640(f)(2)(i), §482.640(f)(2)(ii), §482.640(f)(3), §482.640(f)(3)(i), §482.640(f)(3)(ii), §482.640(f)(3)(iii), §482.640(f)(3)(iv), §482.640(f)(3)(v), §482.640(f)(3)(vi), §482.640(f)(3)(vii), §482.640(f)(3)(viii), §482.640(f)(3)(viii)(A), §482.640(f)(3)(viii)(B), §482.640(f)(3)(viii)(B)(ix), §482.640(f)(3)(viii)(B)(x)

REQUIRED ELEMENTS/ADDITIONAL INFORMATION

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

STAFF SUBJECT TO COVID-19 VACCINATION REQUIREMENTS

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

VACCINATION DEFINITIONS

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

VACCINE EXEMPTIONS

While nothing precludes an employer from requiring employees to be fully vaccinated, there may be some individuals eligible for exemptions from the COVID-19 vaccination requirements

under existing federal law. Accordingly, CAHs must establish and implement a process by which staff may request an exemption from COVID-19 vaccination requirements based on an applicable federal law. Certain allergies, recognized medical conditions, or religious beliefs, observances, or practices, may provide grounds for exemption. CAHs must have a process for collecting and evaluating such requests, including the tracking and secure documentation of information provided by those staff who have requested exemption, the facility's decision on the request, and any accommodations that are provided.

- Employers must follow federal laws protecting employees from retaliation for requesting an exemption on account of religious belief or disability status.
- “Clinical contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States. For staff members who request a medical exemption from vaccination, all documentation confirming recognized clinical contraindications to COVID-19 vaccines which support the staff member's request must be signed and dated by a licensed practitioner who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable state and local laws. Such documentation must contain all information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member and the recognized clinical reason(s) for the contraindications; and a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements based on these recognized clinical contraindications.
- “Temporarily delayed vaccination” refers to vaccination that must be temporarily postponed, as recommended by CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment in the last 90 days.

POLICY & PROCEDURE REQUIREMENTS

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

- Ensuring all required staff have received, at a minimum, the first dose of a multi-dose COVID-19 vaccine, or a one-dose COVID-19 vaccine, before staff provide any care, treatment, or other services for the CAH and/or its patients;
- Ensuring all required staff are fully vaccinated; and the CAH continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the CAH, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
- Tracking and securely documenting the COVID-19 vaccination status for all required staff;
- Tracking and documenting staff who have received any recommended booster doses, or recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
- How staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable federal laws, such as religious beliefs or other accommodations;

- Tracking and securely documenting information confirming recognized clinical contraindications to COVID-19 vaccines provided by those staff who have requested and have been granted a medical exemption to vaccination;
- All documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:
 - » All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and
 - » A statement by the authenticating practitioner recommending that the staff member be exempted from the CAH's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
- Ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and
- Contingency plans for staff that are not yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (g)(3)(x)), including deadlines for staff to be vaccinated.
- All staff are offered and provided education on the COVID-19 vaccination. Education should be documented.

VACCINATION LIST

The CAH must provide a list of all staff and their vaccination status at the time of survey, including:

- The percentage of unvaccinated staff, excluding those staff that have approved exemptions.
- Identification of any staff member remaining unvaccinated because of medical contraindication or religious exemption.
- Identification of newly hired staff (hired in the last 60 days).
- The position or role of each staff member.

DOCUMENTATION OF STAFF VACCINATION

CAHs must track and securely document the vaccination status of each staff member, including those for whom there is a temporary delay in vaccination, such as recent recipients of monoclonal antibodies or convalescent plasma. Vaccine exemption requests and outcomes also must be documented. This documentation will be an ongoing process as new staff are onboarded. While CAH staff may not have personal medical records on file with their employer, all staff COVID-19 vaccines must be appropriately documented by the CAH.

Examples of acceptable forms of proof of vaccination include:

- CDC COVID-19 vaccination record card (or a legible photo of the card).
- Documentation of vaccination from a health care provider or electronic health record.
- State immunization information system record.
- If vaccinated outside of the U.S., a reasonable equivalent of any of the previous examples.

CONTINGENCY PLANNING

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

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

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

Infection Control Measures/Accommodations of Unvaccinated Staff:

Staff who are not yet fully vaccinated, or who have been granted an exemption or accommodation as authorized by law, or who have a temporary delay, must adhere to additional precautions that are intended to mitigate the spread of COVID-19. There are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission including, but not limited to:

- Reassigning staff who have not completed their primary vaccination series to non-patient care areas, to duties that can be performed remotely (i.e., telework), or to duties which limit exposure to those most at risk (e.g., assign to patients who are not immunocompromised, unvaccinated);
- Requiring staff who have not completed their primary vaccination series to follow additional, CDC-recommended precautions, such as adhering to universal source control and physical distancing measures in areas that are restricted from patient access (e.g., staff meeting rooms, kitchen), even if the facility or service site is located in a county with low to moderate community transmission.
- Requiring at least weekly testing for exempted staff and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate

community transmission, in addition to following CDC recommendations for testing unvaccinated in facilities located in counties with substantial to high community transmission.

- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients
- Facilities may also consult with their local health departments to identify other actions that can potentially reduce the risk of COVID-19 transmission from unvaccinated staff.

SURVEY PROCEDURE

Interview and Document Review

Verify:

- Policies and procedures address each required element.
- A list of all staff and their vaccine status is maintained. If any concerns are identified with the staff vaccine status list, verify the percentage of vaccinated staff.
- Documentation by selecting a sample of staff (vaccinated and unvaccinated direct care staff, contracted staff, and staff with an exemption). For each individual identified by the CAH as:
 - » Vaccinated: Review CAH records to verify vaccination status.
 - » Unvaccinated: Review CAH records to determine if they have been educated and offered vaccination. Review documentation of the medical contraindication, as applicable, to verify it is signed and dated by physician or advanced practice provider, states the specific vaccine that is contraindicated and the recognized clinical reason for the contraindication with a statement recommending exemption.

Observe:

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