



Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-23-02-ALL

DATE: October 26, 2022

TO: State Survey Agency Directors

FROM: Directors
Quality, Safety & Oversight Group (QSOG) and Survey & Operations
Group (SOG)

SUBJECT: Revised Guidance for Staff Vaccination Requirements

Memorandum Summary

- CMS is committed to taking critical steps to protect vulnerable individuals to ensure America’s health care facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On November 5, 2021, CMS published an interim final rule with comment period (IFC). This rule establishes requirements regarding COVID-19 vaccine immunization of staff among Medicare- and Medicaid-certified providers and suppliers.
- CMS is revising its guidance and survey procedures for all provider types related to assessing and maintaining compliance with the staff vaccination regulatory requirements.
- This memorandum replaces memoranda QSO 22-07-ALL Revised, and QSO 22-09-ALL Revised, and QSO 22-11-ALL Revised to consolidate the information into a single memorandum. The guidance in this memorandum applies to all states.

Background

On November 5, 2021, CMS issued an interim final rule with comment period ([86 FR 61555](#)) titled “Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination” (also referred herein as the “staff vaccination requirement”). This IFC revised the requirements to establish COVID-19 vaccination requirements for staff at applicable Medicare and Medicaid-certified providers and suppliers.

The staff vaccination requirement for all CMS-certified providers and suppliers has been enforced in all states since February 20, 2022. To date, most providers and suppliers surveyed by states have been found to be in substantial compliance with this requirement.

Hospitalizations and deaths from COVID-19 currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local,

and private partners have done to get over 226 million people vaccinated and over 111 million boosted.

Discussion

CMS is replacing QSO memoranda 22-07-ALL Revised, 22-09-ALL Revised, and 22-11-ALL Revised and is revising the interpretive guidance for all provider types found in Attachments A through N. The revisions address frequency of review of the Staff Vaccination requirements, as well as Immediate Jeopardy, Condition-level and actual harm determinations to ensure that deficiency citations recognize good faith efforts by providers/suppliers.

Vaccination Enforcement

Medicare and Medicaid-certified facilities are expected to comply with all applicable regulatory requirements, and CMS has a variety of established enforcement remedies. For nursing homes, home health agencies, and hospice (beginning in 2022), this includes civil monetary penalties, denial of payments, and—as a final measure—termination of participation from the Medicare and Medicaid programs. The sole enforcement remedy for noncompliance for hospitals and certain other acute and continuing care providers is termination; however, CMS’s primary goal is to bring health care facilities into compliance. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.

CMS expects all providers’ and suppliers’ staff to have received the appropriate number of doses of the primary vaccine series unless exempted as required by law, or delayed as recommended by CDC. **Facility staff vaccination rates under 100% constitute noncompliance under the rule.** Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. For example, a facility that is noncompliant and has implemented a plan to achieve compliance would not be subject to an enforcement action.

Review of Staff Vaccination Requirements

While Federal, State agencies (SAs), Accrediting Organization (AOs), and CMS-contracted surveyors may expand any survey to include staff vaccination requirement compliance review, SAs and AOs will only be expected to perform compliance reviews of the staff vaccination requirements as part of initial certification, standard recertification or reaccreditation surveys, and in response to specific complaint allegations related to the staff vaccination requirements. Surveyors may modify the staff vaccination compliance review if the provider/supplier was determined to be in substantial compliance with this requirement within the previous six weeks. Additional information and expectations for compliance can be found at the provider-specific guidance attached to this memorandum.

Provider-Specific Guidance

Guidance specific to provider types and certified suppliers is provided in the following attachments. The provider-specific guidance has been updated, and revised for assigning severity at Immediate Jeopardy, Harm, and Condition levels to align with [QSO-22-17-ALL](#). **State Survey Agencies should reach out to their CMS Location if they are considering citing vaccine requirements at immediate jeopardy, condition or actual harm levels.**

- Attachment A: LTC Facilities (nursing homes)
- Attachment B: ASC
- Attachment C: Hospice
- Attachment D: Hospitals
- Attachment E: PRTF

- Attachment F: ICF/IID
- Attachment G: Home Health Agencies
- Attachment H: CORF
- Attachment I: CAH
- Attachment J: OPT
- Attachment K: CMHC
- Attachment L: HIT
- Attachment M: RHC/FQHC
- Attachment N: ESRD Facilities

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during a survey.

Contact:

DNH_TriageTeam@cms.hhs.gov for questions related to nursing homes;

QSOG_Emergencyprep@cms.hhs.gov for question related to acute and continuing care providers.

Effective Date: This policy should be communicated with all survey and certification staff, their managers, and the State/CMS Location training coordinators immediately.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

cc: Survey and Operations Group Management
Attachments: A through N

Long-Term Care and Skilled Nursing Facility Attachment A-*Revised*

This attachment *provides guidance to surveyors for determining compliance with the Staff Vaccination requirements which apply to all states.*

F888

§483.80 Infection control

§483.80(i) COVID-19 Vaccination of facility staff. The facility 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 2 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 resident contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its residents:

- (i) Facility employees;**
- (ii) Licensed practitioners;**
- (iii) Students, trainees, and volunteers; and**
- (iv) Individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement.**

(2) The policies and procedures of this section do not apply to the following facility staff:

- (i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (i)(1) of this section; and**
- (ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (i)(1) of this section.**

(3) The policies and procedures must include, at a minimum, the following components:

- (i) A process for ensuring all staff specified in paragraph (i)(1) of this section (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 facility and/or its residents;**
- (ii) A process for ensuring that all staff specified in paragraph (i)(1) of this section are fully vaccinated for COVID-19, 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 (i)(1) of this section;**
- (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 facility 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 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:
 - (A) 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**
 - (B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff 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.**

GUIDANCE

DEFINITIONS

“Booster” per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refer to conditions or risks that preclude 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff for whom it has been 2 weeks or more since completion of their primary vaccination series for COVID-19.

“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.

“Staff” refers to individuals who provide any care, treatment, or other services for the facility and/or its residents, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangements. This also includes individuals under contract or by arrangement with the facility, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees, or volunteers. Staff would not include anyone who provides only telemedicine services or support services outside of the facility and who does not have any direct contact with residents and other staff specified in paragraph §483.80(i)(2). Nursing homes 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.

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met. (<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>)

Background

To protect LTC residents from COVID-19, each facility must develop and implement policies and procedures as specified in §483.80(i) to ensure that all LTC staff are fully vaccinated against COVID-19. Per §483.80(i)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who do not enter the facility or have contact with residents or staff of the facility. For example, this may include a telehealth provider who does not visit the facility, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the facility or, if unavailable at the facility, staff

must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity. See requirements at 42 CFR §483.80(d)(3), at F887.

Surveying for Compliance:

Surveyors should focus on staff that regularly work in the facility (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended or are on extended leave e.g., Family and Medical Leave Act (FMLA) leave, or Worker's Compensation Leave, would not count as unvaccinated staff for determining compliance with this requirement.

Vaccination Enforcement:

CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the memorandum unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute noncompliance under the rule.** Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action. See Citing Noncompliance – Scope and Severity below for additional information.*

Policies and Procedures:

The facility's policies and procedures must address each of the components specified in §483.80(i)(3).

§483.80(i)(3)(i): Requires the facility to have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series, or have a pending, or have been granted a qualifying exemption, or identified as having a delay as recommended by the CDC, prior to providing any care, treatment, or other services for the facility and/or its residents.

§483.80(i)(3)(iii): Requires facilities to ensure those staff who are not yet fully vaccinated, or who have a pending or been granted an exemption, or who have a temporary delay as recommended by the CDC, adhere to additional precautions that are intended to mitigate the spread of COVID-19. Facilities *have discretion to* choose *which additional* precautions *to implement* that align with the intent of the regulation which is intended to “mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.” 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.

§483.80(i)(3)(iv)-(v) and (ix) Process for tracking staff vaccine status:

The facility must track and securely document:

- each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);

- staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation);
- requirements by the facility; **and**
- staff for whom COVID-19 vaccination must be temporarily delayed. For temporary delays, facilities should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of resident care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with residents. This includes staff who are contracted, volunteers, or students. The survey team will provide a vaccine matrix that may be used by the facility.

NOTE: See requirements at §483.80(d)(3) in F887 for verification and maintenance of documentation related to staff COVID-19 vaccination.

§483.80(i)(3)(vi) - (viii) Vaccination Exemptions:

Facilities must have a process by which staff may request exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies or recognized medical conditions may provide grounds for a medical exemption. 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements based on the medical

contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

Facilities must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with applicable federal law and each facility's policies and procedures. We direct providers and suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the facility's acceptance or denial of the request. Rather, surveyors will review to ensure the facility has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided that is not legally required or if it is requested solely to evade vaccination. For individual staff members that have valid reasons for exemption, the facility can address those individually. Accommodations can be addressed in the facility's policies and procedures.

§483.80(i)(3)(x) Contingency Plans:

Facilities are required to have contingency plans for staff who are not fully vaccinated. Contingency plans should include actions that the facility would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption. Contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions required at §483.80(i)(3)(iii). Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multi-dose vaccine. The plans should also indicate the actions the facility will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

§483.80(i)(3)(ii): Requires facilities to have a process for ensuring that all staff specified in paragraph(i)(1) of this section are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

INVESTIGATIVE PROCEDURES

Use the Infection Prevention, Control & Immunizations Facility Task, along with the above interpretive guidance, when determining if the facility meets the requirements for, or investigating concerns related to COVID-19 vaccination of staff. Surveyors should focus investigations on staff that provide services in the facility on a regular (e.g., weekly) basis.

Survey Process Updates for tag F888:

To determine compliance with §483.80(i), surveyors will request the facility's COVID-19 vaccination policies and procedures, the number of staff COVID-19 cases over the last 4 weeks, a list of all staff (see note below regarding sampling contracted staff), their vaccination status, and information on how the facility ensures that their contracted staff are compliant with the vaccination requirement. The staff list must include the position or role of each staff member, including staff (facility staff, volunteers, or students) who are or are likely to be in contact with residents or other staff, regardless of frequency.

NOTE: The list of vaccinated staff maintained by the facility, or the Staff Vaccine Matrix are used for sampling staff. Please refer to the Long-Term Care Survey Process Procedure Guide and/or CMS 20054, Infection Prevention, Control & Immunization for instructions for sampling contracted staff.

CMS will update the CMS-20054: "Infection Prevention, Control & Immunizations" Facility Task to include the new requirement at F888 for staff COVID-19 vaccination. Additionally, CMS will update associated survey documents, which will be found under the "Survey Resources" link in the Downloads Section of the CMS Nursing Homes website. The updated documents will also be added to the Long-Term Care Survey Process software application. *Per [QSO-22-17-ALL](#), surveyors will review for compliance with this requirement on all initial certification, standard recertification surveys, and only for complaint surveys specifically alleging noncompliance with this requirement.* Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

CDC NHSN Data Verification:

Surveyors have the discretion to verify the accuracy of NHSN data on surveys based on a complaint report or if concerns are identified. We note that CMS and CDC conduct quality checks of facility NHSN data submissions each week in an effort to identify trends or indicators of data reporting issues. Procedures for conducting this review may be found in the [Surveyor Resources folder](#) and LTCSP procedure guide.

Citing Noncompliance - Scope and Severity:

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 226 million people vaccinated and over 111 million boosted. Therefore, CMS is directing that the level of severity and scope for noncompliance at F888 will be cited at severity level 1, with a scope of widespread, or "C." Noncompliance is based on the failure to implement policies and procedures at 483.80(i)(3)(ii).

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at severity level 2, with a scope of widespread, or “F.” Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or no policies or procedures as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

NOTE: *Regardless of a facility’s compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices at F880 to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices are in place, which are designed to minimize transmission of COVID-19.*

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If the* facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).
- *If the* facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the ***POC demonstrates that*** the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be ***considered a good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.***

POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION

- F658: for concerns related to professional standards of practice for the provision of vaccines;
- F880: for concerns related to infection prevention and control;
- F887: for concerns related to educating and offering COVID-19 vaccination to residents and staff.

Contact: For questions regarding LTC requirements, please email:
DNH_TriageTeam@cms.hhs.gov

Ambulatory Surgical Centers (ASC) Attachment
Revised

This attachment *provides guidance to surveyors for determining compliance with the Staff Vaccination requirements, which apply to all states.*

Q-0246

§ 416.51 Condition for coverage—Infection control.

(c) *Standard: COVID-19 vaccination of staff.* The ASC 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 2 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 center staff, who provide any care, treatment, or other services for the center and/or its patients:

- (i) Center employees;**
- (ii) Licensed practitioners;**
- (iii) Students, trainees, and volunteers; and**
- (iv) Individuals who provide care, treatment, or other services for the center and/or its patients, under contract or by other arrangement.**

(2) The policies and procedures of this section do not apply to the following center staff:

- (i) Staff who exclusively provide telehealth or telemedicine services outside of the center setting and who do not have any direct contact with patients and other staff specified in paragraph (c)(1) of this section; and**
- (ii) Staff who provide support services for the center that are performed exclusively outside of the center setting and who do not have any direct contact with patients and other staff specified in paragraph (c)(1) of this section.**

(3) The policies and procedures must include, at a minimum, the following components:

- (i) A process for ensuring all staff specified in paragraph (c)(1) of this section (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 center and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section 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 (c)(1) of this section;

(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 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:

(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.

GUIDANCE

DEFINITIONS

“Booster,” per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refer to conditions or risks that preclude 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“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.

“Staff” refers to individuals who provide any care, treatment, or other services for the ASC and/or its patients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the ASC and/or its patients, under contract or by other arrangement. This also includes individuals under contract or by arrangement with the ASC, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **Staff would not include anyone who provides only telemedicine services or support services outside of the ASC and who does not have any direct contact with patients and other staff specified in paragraph (c)(1).**

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including *known* COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met

(<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>)

Background

To protect ASC patients from COVID-19, each ASC must develop and implement policies and procedures as specified in §416.51(c) to ensure that all ASC staff are fully vaccinated against COVID-19. Per §416.51(c)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who do not enter the ASC or have contact with patients or staff of the facility. For example, this may include a telehealth provider who does not visit the facility, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the ASC or, if unavailable at the facility, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may also be many infrequent services and tasks performed in, or for, an ASC that are conducted by “one-off” vendors, volunteers, and professionals. ASCs are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), services that are performed exclusively off-site, and are 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. ASCs should consider the frequency of presence, services provided, and proximity to patients and staff.

Surveying for Compliance

Surveyors should focus on staff that regularly work in the ASC (e.g., weekly), using a phased-in approach described below.

NOTE: Facility staff who have been suspended, or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave or Worker’s Compensation Leave), would not count as unvaccinated staff for determining compliance.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

ASCs will be expected to meet the following:

Vaccination Enforcement

CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule.**

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single-dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures

The ASC policies and procedures must be implemented and address each of the following components:

The ASC must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series, prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to “mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.” The requirement is not explicit and does not specify which actions must be taken.

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.

The ASC must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation) requirements by the ASCs; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:

Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies or recognized medical conditions, may provide grounds for exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, ASCs 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the ASC's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

ASCs must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the

COVID-19 vaccination due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each ASC's policies and procedures. We direct providers and suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the ASC's acceptance or denial of the request. Rather, surveyors will review to ensure the ASC has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption facility can address those individually. Accommodations can be addressed in the ASC's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the ASC must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.

Contingency plans should include actions that the ASC would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the ASC will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference

- Surveyors will ask ASCs to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:
 - 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 ASC and/or its patients;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the ASC continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the ASC, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
 - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
 - 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;
 - A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
 - 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;
 - A process for ensuring that 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 ASC's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
 - 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, or individuals who received

monoclonal antibodies or convalescent plasma for COVID-19 treatment;
and

- Contingency plans for staff that are not fully vaccinated for COVID-19.
- The ASC will provide their process for how the ASC ensures that their contracted staff are compliant with the vaccination requirement.

2. Record Review, interview, and observations:

- Surveyors will review the policies and procedures to ensure all components are present.
- Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the ASC that may include:
 - Requiring unvaccinated staff 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.
 - Reassigning unvaccinated staff 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 at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission; and
 - Requiring unvaccinated staff 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.
- Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):
 - Direct care staff, including contracted staff meeting the definition of staff (vaccinated and unvaccinated);
 - Contracted staff; and
 - Direct care staff with an exemption
- There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay). Two of the direct care staff sampled should be contractors.
- The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.

- Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.
- For each individual identified by the ASC as vaccinated, surveyors will:
 - Review ASC records to verify vaccination status. 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, or
 - State immunization information system record.
 - Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay.

- For each individual identified by the ASC as unvaccinated, surveyors will
 - Review ASC records.
 - Determine if they have been educated and offered vaccination.
 - Interview staff and ask if they plan to get vaccinated if they have declined to get vaccinated and if they have a medical contraindication or religious exemption.
 - Request and review documentation of the medical contraindication.
 - Request to see employee record of the staff education on the ASC policy and procedure regarding unvaccinated individuals.
 - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.
- For each individual identified by the ASC as unvaccinated due to a medical contraindication:
 - Review and verify that all required documentation 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.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

***NOTE:** Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.*

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).*
- *If the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all*

policies and procedures were developed and implemented, this would be considered a good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.

Hospice Attachment
Revised

This attachment *provides guidance to surveyors for determining compliance with the Staff Vaccination requirements, which apply to all states.*

L-900

§ 418.60 Condition of participation: Infection control.

(d) Standard: COVID-19 Vaccination of facility staff. The hospice 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 2 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 hospice staff, who provide any care, treatment, or other services for the hospice and/or its patients:

- (i) Hospice employees;**
- (ii) Licensed practitioners;**
- (iii) Students, trainees, and volunteers; and**
- (iv) Individuals who provide care, treatment, or other services for the hospice and/or its patients, under contract or by other arrangement.**

(2) The policies and procedures of this section do not apply to the following hospice staff:

- (i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where hospice services are provided to patients and who do not have any direct contact with patients, patient families and caregivers, and other staff specified in paragraph (d)(1) of this section; and**
- (ii) Staff who provide support services for the hospice that are performed exclusively outside of the settings where hospice services are provided to patients and who do not have any direct contact with patients, patient families and caregivers, and other staff specified in paragraph (d)(1) of this section.**

(3) The policies and procedures must include, at a minimum, the following components:

- (i) A process for ensuring all staff specified in paragraph (d)(1) of this section (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 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 hospice and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section 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 (d)(1) of this section;

(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 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 hospice 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 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:

(A) 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

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the hospice's COVID-19 vaccination requirements for staff 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.

GUIDANCE

DEFINITIONS

“Booster,” per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refer 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“Primary Vaccination Series” refers to staff who have received a single-dose vaccine or all doses of a multi-dose vaccine for COVID-19.

“Staff” refers to individuals who provide any care, treatment, or other services for the hospice and/or its patients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the hospice and/or its patients, under contract or other arrangement. This also includes individuals under contract or arrangement with the hospice, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **Staff would not include anyone who provides only telemedicine services or support services outside of the hospice and who does not have any direct contact with patients and other staff specified in paragraph (d)(1).**

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

[\(<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>\)](https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf)

Background

To protect hospice patients from COVID-19, each hospice must develop and implement policies and procedures as specified in §418.60(d) to ensure that all hospice staff are fully vaccinated against COVID-19. Per §418.60(d)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who are outside of the settings where hospice services are provided to patients and who do not have any direct contact with patients, patient families and caregivers, and other staff. For example, this may include a telehealth provider who does not visit the settings where hospice services are provided to patients, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of those settings.

The vaccine may be offered and provided directly by the hospice or, if unavailable through the hospice, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may also be many infrequent services and tasks performed in, or for, a hospice that are conducted by “one-off” vendors, volunteers, and professionals. Hospices are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), 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. Hospices should consider the frequency of presence, services provided, and proximity to patients and staff.

Surveying for Compliance

Surveyors should focus on the staff that regularly work in the hospice (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended, or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave), would not count as unvaccinated staff for determining compliance.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

Hospices will be expected to meet the following:

Vaccination Enforcement

CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule.**

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures

The hospice policies and procedures must be implemented and address each of the following components:

The hospice must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series, prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to “mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.” The requirement is not explicit and does not specify which actions must be taken.

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.

The hospice must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include type of exemption and supporting documentation) requirements by the hospice; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:

Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies, or recognized medical conditions may provide grounds for exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, hospices 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the hospice's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

Hospices must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical considerations, including known COVID-19 infection

until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each hospice's policies and procedures. We direct providers and suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the hospice's acceptance or denial of the request. Rather, surveyors will review to ensure the hospice has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption, a facility can address those individually. Accommodations can be addressed in the hospice's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the hospice must develop contingency plans for staff who have not completed the primary vaccination series for COVID-

Contingency plans should include actions that the hospice would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the hospice will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference

- Surveyors will ask hospices to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:
 - 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 hospice and/or its patients;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the hospice continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the hospice, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
 - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
 - 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;
 - A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on an applicable Federal law;
 - A process for tracking and securely documenting information provided by those staff who have requested, and for whom the hospice has granted, an exemption from the staff COVID-19 vaccination requirements;
 - A process for ensuring that 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 hospice's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
 - 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, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

- Contingency plans for staff who are not fully vaccinated for COVID-19.
 - The hospice will provide their process for how the hospice ensures that their contracted staff are compliant with the vaccination requirement.
2. Record Review, interview, and observations:
- Surveyors will review the policies and procedures to ensure all components are present.
 - Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the hospice that may include:
 - Requiring unvaccinated staff 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.
 - Reassigning unvaccinated staff 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 at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission; and
 - Requiring unvaccinated staff 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.
 - Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):
 - Direct care staff, including those contracted staff meeting the definition of staff (vaccinated and unvaccinated);
 - Contracted staff; and
 - Direct care staff with an exemption
 - There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay.) Two of the direct care staff sampled should be contractors.
 - The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.

- Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.
- For each individual identified by the hospice as vaccinated, surveyors will:
 - Review hospice records to verify vaccination status. 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, or
 - State immunization information system record.
 - Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay.

- For each individual identified by the hospice as unvaccinated, surveyors will
 - Review hospice records
 - Determine, if they have been educated and offered vaccination
 - Interview staff and ask if they plan to get vaccinated, if they have declined to get vaccinated, and if they have a medical contraindication or religious exemption.
 - Request and review documentation of medical contraindication.
 - Request to see employee record of the staff education on the hospice policy and procedure regarding unvaccinated individuals.
 - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.
- For each individual identified by the hospice as unvaccinated due to a medical contraindication:
 - Review and verify that all required documentation 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.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

***NOTE:** Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.*

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).*
- *If the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.*

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.

Hospital Attachment

Revised

This attachment *provides guidance to surveyors for determining compliance with the Staff Vaccination requirements, which apply to all states.*

A-0792

§ 482.42 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

- (g) ***Standard: COVID-19 Vaccination of hospital staff.*** The hospital must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 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 hospital staff, who provide any care, treatment, or other services for the hospital and/or its patients:**
- (i) **Hospital employees;**
 - (ii) **Licensed practitioners;**
 - (iii) **Students, trainees, and volunteers; and**
 - (iv) **Individuals who provide care, treatment, or other services for the hospital and/or its patients, under contract or by other arrangement.**
- (2) **The policies and procedures of this section do not apply to the following hospital staff:**
- (i) **Staff who exclusively provide telehealth or telemedicine services outside of the hospital setting and who do not have any direct contact with patients and other staff specified in paragraph (g)(1) of this section; and**
 - (ii) **Staff who provide support services for the hospital that are performed exclusively outside of the hospital setting and who do not have any direct contact with patients and other staff specified in paragraph (g)(1) of this section.**
- (3) **The policies and procedures must include, at a minimum, the following components:**

(i) A process for ensuring all staff specified in paragraph (g)(1) of this section (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 CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the hospital and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (g)(1) of this section are fully vaccinated for COVID-19, 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 (g)(1) of this section;

(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 hospital 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 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:

(A) 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

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the hospital’s COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(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.

GUIDANCE

DEFINITIONS

“Booster,” per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refer to conditions or risks that preclude 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“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.

“Staff” refers to individuals who provide any care, treatment, or other services for the hospital and/or its patients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the hospital and/or its patients, under contract or by other arrangement. This also includes

individuals under contract or arrangement with the hospital, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **Staff would not include anyone who provides only telemedicine services or support services outside of the hospital and who does not have any direct contact with patients and other staff specified in paragraph (g)(1).**

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met (<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>)

Background

To protect hospital patients from COVID-19, each hospital must develop and implement policies and procedures as specified in §482.42(g) to ensure that all hospital staff are fully vaccinated against COVID-19. Per §482.42(g)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who do not enter the hospital or have contact with patients or staff of the facility. For example, this may include a telehealth provider who does not visit the facility, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the hospital or, if unavailable at the facility, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may also be many infrequent services and tasks performed in, or for a hospital, that are conducted by “one-off” vendors, volunteers, and professionals. Hospitals are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), or services that are performed exclusively off-site, and are not at, or adjacent to, any site of patient care (such as accounting services), but they may choose to extend COVID-19 vaccination requirements to them if feasible. Hospitals should consider the frequency of presence, services provided, and proximity to patients and staff.

Surveying for Compliance

Surveyors should focus on the staff that regularly work in the hospital (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended, or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave), would not count as unvaccinated staff for determining compliance.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

Hospitals will be expected to meet the following:

Vaccination Enforcement:

CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule.**

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures

The hospital policies and procedures must be implemented and address each of the following components:

The hospital must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series, prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to “mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.” The requirement is not explicit and does not specify which actions must be taken.

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.

The hospital must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation) requirements by the hospital; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:

Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies, or recognized medical conditions may provide grounds for exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, Hospitals 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the hospital's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

Hospitals must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the

COVID-19 vaccination due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including (Religious) Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each hospital's policies and procedures. We direct providers and suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the hospital's acceptance or denial of the request. Rather, surveyors will review to ensure the hospital has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption facility can address those individually. Accommodations can be addressed in the hospital's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the hospital must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.

Contingency plans should include actions that the hospital would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the hospital will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference

- Surveyors will ask hospitals to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:
 - A process for ensuring all required staff have received, at a minimum, the first dose of a multi-dose COVID-19 vaccine, or a one-dose COVID-19 vaccine, before staff provide any care, treatment, or other services for the hospital and/or its patients;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the hospital continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the hospital, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
 - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
 - 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;
 - A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
 - 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; A process for 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;
 - A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws, and for further ensuring that such documentation contains:
 - all information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and
 - a statement by the authenticating practitioner recommending that the staff member be exempted from the hospital's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
 - 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, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

- Contingency plans for staff that are not fully vaccinated for COVID-19.

- The hospital will provide their process for how the hospital ensures that their contracted staff are compliant with the vaccination requirement.

2. Record Review, interview, and observations:

- Surveyors will review the policies and procedures to ensure all components are present.
- Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the hospital that may include:
 - Requiring unvaccinated staff 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.
 - Reassigning unvaccinated staff 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 at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission
 - Requiring unvaccinated staff 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.
- Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):
 - Direct care staff, including contracted staff meeting the definition of staff (vaccinated and unvaccinated)
 - Contracted staff
 - Direct care staff with an exemption
- There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay). Two of the direct care staff sampled should be contractors.

- The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.
- Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.
- For each individual identified by the hospital as vaccinated, surveyors will:
 - Review hospital records to verify vaccination status. 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, or
 - State immunization information system record.
 - Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay.

- For each individual identified by the hospital as unvaccinated, surveyors will
 - Review hospital records.
 - Determine if they have been educated and offered vaccination.
 - Interview staff and ask if they plan to get vaccinated if they have declined to get vaccinated and if they have a medical contraindication or religious exemption.
 - Request and review documentation of the medical contraindication.
 - Request to see employee record of the staff education on the hospital policy and procedure regarding unvaccinated individuals.
 - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.
- For each individual identified by the hospital as unvaccinated due to a medical contraindication:
 - Review and verify that all required documentation 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.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

NOTE: Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If* the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).
- *If* the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a

good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.

Psychiatric Residential Treatment Facility (PRTF) Attachment

Revised

This attachment *provides guidance* to *surveyors for determining compliance* with *the Staff Vaccination requirements, which* apply to *all states*.

N-0120

§ 441.151 General requirements.

(c) COVID-19 Vaccination of facility staff. The facility 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 2 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 resident contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its residents:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (c)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the center setting and who do not have any direct contact with residents and other staff specified in paragraph (c)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (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 facility and/or its residents;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated for COVID-19, 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 that the facility follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19, and which must include the implementation of additional precautions 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 (c)(1) of this section;

(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 facility 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 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:

(A) 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

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff 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.

GUIDANCE

DEFINITIONS

“Booster,” per Centers for Disease Control and Prevention (CDC), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refer 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“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.

“Staff” refers to individuals who provide any care, treatment, or other services for the PRTF and/or its residents, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the PRTF and/or its residents, under contract or by other arrangement. This also includes individuals under contract or by arrangement with the PRTF, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **Staff would not include anyone who provides only telemedicine services or support services outside of the PRTF and does not**

have any direct contact with residents, nor contact with staff that do have direct contact with residents and other staff specified in paragraph (c)(1).

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met. (<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>)

Background

To protect PRTF residents from COVID-19, each PRTF must develop and implement policies and procedures as specified in §441.151(c) to ensure that all PRTF staff are fully vaccinated against COVID- 19. Per §441.151(c)(2), the requirements in this section do not apply to individuals who provide support services that are performed exclusively outside of the facility setting and who do not have any direct contact with residents and other staff. For example, this may include a telehealth provider who does not visit the facility, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the hospice or, if unavailable at the facility, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may also be many infrequent services and tasks performed in, or for, a PRTF that are conducted by “one-off” vendors, volunteers, and professionals. PRTFs are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), services that are performed exclusively off-site, and are not at or adjacent to any site of resident care (such as accounting services), but they may choose to extend COVID-19 vaccination requirements to them if feasible. PRTFs should consider the frequency of presence, services provided, and proximity to residents and staff.

Surveying for Compliance

Surveyors should focus on staff that regularly work in the PRTF (e.g., weekly), using a phased-in approach described below.

NOTE: Facility staff who have been suspended, or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave), would not count as unvaccinated staff for determining compliance.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

PRTFs will be expected to meet the following:

Vaccination Enforcement

CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule.**

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

NOTE: Facility staff who have been suspended, or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker's Compensation Leave), would not count as unvaccinated staff for determining compliance with this requirement.

Policies and Procedures

The PRTF policies and procedures must be implemented and address each of the following components:

The PRTF must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series, prior to providing any care, treatment, or other services for the facility and/or its residents.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to "mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated." The requirement is not explicit and does not specify which actions must be taken.

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.

The PRTF must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation) requirements by the PRTF;
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of resident care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with residents. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:

Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies, or recognized medical conditions may provide grounds for exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, PRTFs 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the PRTF's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

PRTFs must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical considerations, including known COVID-19 infection

until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each PRTF's policies and procedures. We direct PRTFs to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the PRTF's acceptance or denial of the request. Rather, surveyors will review to ensure the PRTF has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption, the facility can address those individually. Accommodations can be addressed in the PRTF's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the PRTF must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19

Contingency plans should include actions that the PRTF would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the PRTF will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference

- Surveyors will ask PRTFs to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:
 - 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 PRTF and/or its residents;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the PRTF continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the PRTF, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
 - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
 - 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;
 - A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law; A process for tracking and securely documenting information provided by those staff who have requested, and for whom the facility has granted, an exemption from the staff COVID-19 vaccination requirements;
 - A process for ensuring that 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 PRTF's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
 - 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, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and
 - Contingency plans for staff who are not fully vaccinated for COVID-19.

- - The PRTF will provide their process for how the PRTF ensures that their contracted staff are compliant with the vaccination requirement.
2. Record Review, interview, and observations:
- Surveyors will review the policies and procedures to ensure all components are present.
 - Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the PRTF that may include:
 - Requiring unvaccinated staff to follow additional, [CDC-recommended precautions](#), such as adhering to universal source control and physical distancing measures in areas that are restricted from resident 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.
 - Reassigning unvaccinated staff to non-resident 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 residents who are not immunocompromised, unvaccinated);
 - Requiring at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission; and
 - Requiring unvaccinated staff 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 residents.
 - Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):
 - Direct care staff, including contracted staff meeting the definition of staff (vaccinated and unvaccinated);
 - Contracted staff; and
 - Direct care staff with an exemption
 - There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6- person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay.) Two of the direct care staff sampled should be contractors
 - The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.

- Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.
- For each individual identified by the PRTF as vaccinated, surveyors will:
 - Review PRTF records to verify vaccination status. 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, or
 - State immunization information system record.
 - Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay/

- For each individual identified by the PRTF as unvaccinated, surveyors will
 - Review PRTF records
 - Determine, if they have been educated and offered vaccination
 - Interview staff and ask if they plan to get vaccinated, if they have declined to get vaccinated, and if they have a medical contraindication or religious exemption.
 - Request and review documentation of the medical contraindication.
 - Request to see employee record of the staff education on the PRTF policy and procedure regarding unvaccinated individuals.
 - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.
- For each individual identified by the PRTF as unvaccinated due to a medical contraindication:
 - Review and verify that all required documentation 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.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

NOTE: Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If* the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).
- *If* the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a

good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.

Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IIDs) Attachment
Revised

This attachment *provides guidance* to *surveyors for determining compliance* with *the Staff Vaccination requirements, which* apply to *all states*.

W-0508

§ 483.430 Condition of Participation: Facility staffing.

(f) Standard: COVID-19 Vaccination of facility staff. The facility 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 2 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 client contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its clients:

- (i) Facility employees;**
- (ii) Licensed practitioners;**
- (iii) Students, trainees, and volunteers; and**
- (iv) Individuals who provide care, treatment, or other services for the facility and/or its clients, under contract or by other arrangement.**

(2) The policies and procedures of this section do not apply to the following facility staff:

- (i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with clients and other staff specified in paragraph (f)(1) of this section; and**
- (ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with clients and other staff specified in paragraph (f)(1) of this section.**

(3) The policies and procedures must include, at a minimum, the following components:

- (i) A process for ensuring all staff specified in paragraph (f)(1) of this section (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 facility and/or its clients;

(ii) A process for ensuring that all staff specified in paragraph (f)(1) of this section are fully vaccinated for COVID-19, 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 (f)(1) of this section;

(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 facility 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 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:

(A) 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

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff 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.

§ 483.460 Condition of participation: Health care services.

(a) * * *

(4) * * *

- (v) The client, or client’s representative, has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision;

GUIDANCE

DEFINITIONS

“Booster”: per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refer 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“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.

“Staff” refers to individuals who provide any care, treatment, or other services for the ICF/IID and/or its clients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the ICF/IID and/or its clients, under contract or by other arrangement. This also includes individuals under contract or by arrangement with the ICF/IID, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **Staff would not include anyone who provides only telemedicine services or support services outside of the ICF/IID and who does not have any direct contact with clients and other staff specified in paragraph (f)(1).**

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>

Background

To protect ICF/IID patients from COVID-19, each ICF/IID must develop and implement policies and procedures as specified in §483.430(f) to ensure that all ICF/IID staff are fully vaccinated against COVID-19. Per §483.430(f)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who do not enter the ICF/IID or have contact with clients or staff of the facility. For example, this may include a telehealth provider who does not visit the facility, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the ICF/IID or, if unavailable at the facility, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There also may be many infrequent services and tasks performed in, or for, a health care ICF/IID that are conducted by “one-off” vendors, volunteers, and professionals. ICF/IIDs are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), services that are performed exclusively off-site, and are 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. ICF/IIDs should consider the frequency of presence, services provided, and proximity to clients and staff.

Surveying for Compliance

Surveyors should focus on staff that regularly work in the ICF/IID (e.g., weekly), using a phased-in approach described below.

NOTE: Facility staff who have been suspended, or who are on extended leave (e.g.,

Family and Medical Leave Act (FMLA) leave, or Worker's Compensation Leave), would not count as unvaccinated staff for determining compliance.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

ICF/IIDs will be expected to meet the following:

Vaccination Enforcement

CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule.**

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures

The ICF/IID policies and procedures must be implemented and address each of the following components:

The ICF/IID must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series, prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to "mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated." The requirement is not explicit and does not specify which actions must be taken.

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.

The ICF/IID must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation) requirements by the ICF/IID; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of client care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with clients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:

Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies, or recognized medical conditions may provide grounds for an exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, ICF/IIDs 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for

the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the ICF/IID's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

ICF/IIDs must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each ICF/IID's policies and procedures. We direct providers and suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the ICF/IID's acceptance or denial of the request. Rather, surveyors will review to ensure the ICF/IID has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption facility can address those individually. Accommodations can be addressed in the ICF/IID's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the ICF/IID must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.

Contingency plans should include actions that the ICF/IID would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption. but contingency plans

should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the ICF/IID will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference

- Surveyors will ask ICF/IIDs to provide vaccination policies and procedures. At a minimum, the policy and procedures must provide:
 - 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 HIT and/or its patients;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the HIT continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the HIT, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
 - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
 - 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;
 - A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
 - 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;
 - A process for ensuring that 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 HIT's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
 - 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, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and
 - Contingency plans for staff who are not fully vaccinated for COVID-19.
- The ICF/IID will provide their process for how the ICF/IID ensures that their contracted staff are compliant with the vaccination requirement.

2. Record Review, interview, and observations:

- Surveyors will review the policies and procedures to ensure all components are present.
- Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the ICF/IID to include:
 - Requiring unvaccinated staff to follow additional, [CDC-recommended precautions](#), such as adhering to universal source control and physical distancing measures in areas that are restricted from client 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.
 - Reassigning unvaccinated staff to non-client 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 clients who are not immunocompromised, unvaccinated);
 - Requiring at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission; and
 - Requiring unvaccinated staff 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 clients.
- Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):
 - Direct care staff, including contracted staff meeting the definition of staff (vaccinated and unvaccinated);

- Contracted staff; and
 - Direct care staff with an exemption
- There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay). Two of the direct care staff sampled should be contractors.
 - The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.
 - Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.
 - For each individual identified by the ICF/IID as vaccinated, surveyors will:
 - Review ICF/IID records to verify vaccination status. 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, or
 - State immunization information system record.
 - Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay.

- For each individual identified by the ICF/IID as unvaccinated, surveyors will
 - Review ICF/IID records
 - Determine, if they have been educated and offered vaccination
 - Interview staff and ask if they plan to get vaccinated, if they have declined to get vaccinated, and if they have a medical contraindication or religious exemption.
 - Request and review documentation of the medical contraindication.
 - Request to see employee record of the staff education on the ICF/IID policy and procedure regarding unvaccinated individuals.

- Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.
- For each individual identified by the ICF/IID as unvaccinated due to a medical contraindication:
 - Review and verify that all required documentation 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.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

***NOTE:** Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.*

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If* the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).
- *If* the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.

Home Health Agency (HHA) Attachment

Revised

This attachment *provides guidance to surveyors for determining compliance with the Staff Vaccination requirements, which apply to all states.*

G-687

§ 484.70 Condition of Participation: Infection Prevention and Control.

(d) Standard: COVID-19 Vaccination of Home Health Agency staff. The home health agency (HHA) 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 2 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 HHA staff, who provide any care, treatment, or other services for the HHA and/or its patients:

- (i) HHA employees;**
- (ii) Licensed practitioners;**
- (iii) Students, trainees, and volunteers; and**
- (iv) Individuals who provide care, treatment, or other services for the HHA and/or its patients, under contract or by other arrangement.**

(2) The policies and procedures of this section do not apply to the following HHA staff:

- (i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (d)(1) of this section; and**
- (ii) Staff who provide support services for the HHA that are performed exclusively outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (d)(1) of this section.**

(3) The policies and procedures must include, at a minimum, the following components:

- (i) A process for ensuring all staff specified in paragraph (d)(1) of this section (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 HHA and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID-19, 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 (d)(1) of this section;

(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 HHA 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 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

(A) 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

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the HHA's COVID-19 vaccination requirements for staff 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.

GUIDANCE

DEFINITIONS

“Booster,” per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refer 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“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.

“Staff” refers to individuals who provide any care, treatment, or other services for the HHA and/or its patients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the HHA and/or its patients, under contract or by other arrangement. This also includes individuals under contract or by arrangement with the HHA, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **Staff would not include anyone who provides only telemedicine services or support services outside of the HHA and who does not have any direct contact with patients and other staff specified in paragraph (d)(1).**

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>

Background

To protect HHA patients from COVID-19, each HHA must develop and implement policies and procedures as specified in §484.70(d) to ensure that all HHA staff are fully vaccinated against COVID-19. Per §484.70(d)(2), the requirements in this section do not apply to individuals who provide support services that are performed exclusively outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff. For example, this may include a telehealth provider who does not visit the settings where HHA services are provided to patients, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of those settings.

The vaccine may be offered and provided directly by the HHA or, if unavailable through the HHA, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may be many infrequent services and tasks performed in or for a HHA that is conducted by “one-off” vendors, volunteers, and professionals. HHAs are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), services that are performed exclusively off-site, and are 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. HHAs should consider the frequency of presence, services provided, and proximity to patients and staff.

Surveying for Compliance

Surveyors should focus on staff that regularly work in the HHA (e.g., weekly), using a phased-in approach described below.

NOTE: Facility staff who have been suspended, or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave), would not count as unvaccinated staff for determining compliance.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

HHAs will be expected to meet the following:

Vaccination Enforcement

CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule.**

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures

The HHA policies and procedures must be implemented and address each of the following components:

The HHA must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series, prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to “mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.” The requirement is not explicit and does not specify which actions must be taken.

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.

The HHA must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation) requirements by the HHA; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:

Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies, or recognized medical conditions may provide grounds for an exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, HHAs 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the HHA's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

HHAs must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical considerations, including known COVID-19 infection

until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met..

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each HHA’s policies and procedures. We direct providers and suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the HHA’s acceptance or denial of the request. Rather, surveyors will review to ensure the HHA has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption, the facility can address those individually. Accommodations can be addressed in the provider or supplier’s policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the HHA must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.

Contingency plans should include actions that the HHA would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the HHA will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference

- Surveyors will ask HHAs to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:
 - 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 HIT and/or its patients;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the HIT continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the HIT, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
 - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
 - 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;
 - A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
 - 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;
 - A process for ensuring that 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 HIT's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
 - 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, or individuals who received

monoclonal antibodies or convalescent plasma for COVID-19 treatment;
and

- Contingency plans for staff who are not fully vaccinated for COVID-19.

- The HHA will provide their process for how the HHA ensures that their contracted staff are compliant with the vaccination requirement.

2. Record Review, interview, and observations:

- Surveyors will review the policies and procedures to ensure all components are present.
- Surveyors will review any contingency plan developed to mitigate the spread of COVID-19 infections by the ASC that may include:
 - Requiring unvaccinated staff 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.
 - Reassigning unvaccinated staff 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 at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission; and
 - Requiring unvaccinated staff 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
- Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):
 - Direct care staff, including contracted staff meeting the definition of staff (vaccinated and unvaccinated);
 - Contracted staff; and
 - Direct care staff with an exemption
- There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay). Two of the direct care staff sampled should be contractors.

- The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.
- Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.

- For each individual identified by the HHA as vaccinated, surveyors will:
 - Review HHA records to verify vaccination status. 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, or
 - State immunization information system record.
 - Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay.

- For each individual identified by the HHA as unvaccinated, surveyors will
 - Review HHA records
 - Determine, if they have been educated and offered vaccination
 - Interview staff and ask if they plan to get vaccinated if they have declined to get vaccinated and if they have a medical contraindication or religious exemption.
 - Request and review documentation of the medical contraindication.
 - Request to see employee record of the staff education of the HHA policy and procedure regarding unvaccinated individuals.
 - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.

- For each individual identified by the HHA as unvaccinated due to a medical contraindication:
 - Review and verify that all required documentation 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.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

***NOTE:** Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.*

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).*
- *If the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a*

good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey. Home Health providers may be subject to alternative sanctions for non-compliance with this regulation based on current enforcement authority.

Comprehensive Outpatient Rehabilitation Facilities Attachment
Revised

This attachment *provides guidance to surveyors for determining compliance with the Staff Vaccination requirements, which apply to all states.*

I-549

§ 485.58 Condition of participation: Comprehensive rehabilitation program.

(d) * * *

(4) The services must be furnished by personnel that meet the qualifications of § 485.70 and the number of qualified personnel must be adequate for the volume and diversity of services offered. Personnel that do not meet the qualifications specified in § 485.70(a) through (m) may be used by the facility in assisting qualified staff. When a qualified individual is assisted by these personnel, the qualified individual must be on the premises, and must instruct these personnel in appropriate patient care service techniques and retain responsibility for their activities.

I-630

§ 485.70 Personnel qualifications.

(n) The CORF 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 2 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 facility staff, who provide any care, treatment, or other services for the facility and/or its patients:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (n)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (n)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (n)(1) of this section (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 facility and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (n)(1) of this section are fully vaccinated for COVID-19, 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 fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (n)(1) of this section;

(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 facility 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 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

(A) 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

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff 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.

GUIDANCE

DEFINITIONS

“Booster”: per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to a primary vaccine is likely to have waned over time.

“Clinical contraindications” refer to conditions or risks that preclude 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“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.

“Staff” refers to individuals who provide any care, treatment, or other services for the CORF and/or its patients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the CORF and/or its patients, under contract or other arrangement. This also includes individuals under contract or arrangement with the CORF, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **Staff would not include anyone who provides only telemedicine services or support services outside of the CORF and who does not have any direct contact with patients and other staff specified in paragraph (n)(1).**

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met (<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>)

Background:

To protect CORF patients from COVID-19, each CORF must develop and implement policies and procedures as specified in §485.70(n) to ensure that all CORF staff are fully vaccinated against COVID-19. Per §485.70(n)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who do not enter the CORF or have contact with patients or staff of the facility. For example, this may include a telehealth provider who does not visit the facility, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the CORF or, if unavailable at the facility, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may also be many infrequent services and tasks performed in, or for, a health care CORF that is conducted by “one-off” vendors, volunteers, and professionals. CORFs are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), 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. CORFs should consider the frequency of presence, services provided, and proximity to patients and staff.

Surveying for Compliance

Surveyors should focus on the staff that regularly work in the CORF (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker's Compensation Leave), would not count as unvaccinated staff for determining compliance with this requirement.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

CORFs will be expected to meet the following:

Vaccination Enforcement

CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule.**

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures

The CORF policies and procedures must be implemented and address each of the following components:

The CORF must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to "mitigate the transmission and spread of

COVID-19 for all staff who are not fully vaccinated.” The requirement is not explicit and does not specify which actions must be taken.

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.

The CORF must track and securely document:

- Each staff member’s vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation) requirements by the CORF; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility’s policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities’ tracking mechanism should clearly identify each staff’s role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:

Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies, or recognized medical conditions may provide grounds for an exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, CORFs 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate

(within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the CORF's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

CORFs must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each CORF's policies and procedures. We direct CORFs to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the CORF's acceptance or denial of the request. Rather, surveyors will review to ensure the CORF has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption facility can address those individually. Accommodations can be addressed in the CORF's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the CORF must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.

Contingency plans should include actions that the CORF would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the CORF will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference

- Surveyors will ask CORFs to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:
 - 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 CORF and/or its patients;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the CORF continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the CORF, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
 - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
 - 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;
 - A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
 - 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;
 - A process for ensuring that 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 CORF's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
 - 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, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and
 - Contingency plans for staff that are not fully vaccinated for COVID-19.
- The CORF will provide their process for how the CORF ensures that their contracted staff are compliant with the vaccination requirement.

2. Record Review, interview, and observations:

- Surveyors will review the policies and procedures to ensure all components are present.
- Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the CORF that may include:
 - Requiring unvaccinated staff 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.
 - Reassigning unvaccinated staff 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 at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission
 - Requiring unvaccinated staff 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
- Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):

- Direct care staff, including those contracted staff meeting the definition of staff (vaccinated and unvaccinated)
 - Contracted staff
 - Direct care staff with an exemption
- There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay.). Two of the direct care staff sampled should be contractors.
 - The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.
 - Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.
 - For each individual identified by the CORF as vaccinated, surveyors will:
 - Review CORF records to verify vaccination status. 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, or
 - State immunization information system record.
 - Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay.

- For each individual identified by the CORF as unvaccinated, surveyors will
 - Review CORF records
 - Determine if they have been educated and offered vaccination
 - Interview staff and ask if they plan to get vaccinated if they have declined to get vaccinated and if they have a medical contraindication or religious exemption.
 - Request and review documentation of medical contraindication.
 - Request to see employee record of the staff education on CORF policy and procedure regarding unvaccinated individuals.

- Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.
- For each individual identified by the CORF as unvaccinated due to a medical contraindication:
 - Review and verify that all required documentation 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.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

***NOTE:** Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.*

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If* the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).
- *If* the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.

Critical Access Hospital (CAH) Attachment
Revised

This attachment *provides guidance to surveyors for determining compliance with the Staff Vaccination requirements, which apply to all states.*

C-1260

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

(f) *Standard: COVID-19 Vaccination of CAH 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 2 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 (f)(1) of this section; 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 (f)(1) of this section.**

(3) The policies and procedures must include, at a minimum, the following components:

- (i) A process for ensuring all staff specified in paragraph (f)(1) of this section (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 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 (f)(1) of this section are fully vaccinated for COVID-19, 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 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 (f)(1) of this section;

(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 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 CAH has granted, an exemption from the staff COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws;

(viii) A process for ensuring that 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

(A) 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

(B) 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;

(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.

GUIDANCE

DEFINITIONS

“Booster” per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refer to conditions or risks that preclude 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“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.

“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, and volunteers; and individuals who provide care, treatment, or other services for the CAH and/or its patients, under contract or by other arrangement. This also includes individuals under contract or by arrangement with the CAH, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **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 paragraph (f)(1).

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met (<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>)

Background:

To protect CAH patients from COVID-19, each CAH must develop and implement policies and procedures as specified in §485.640(f) to ensure that all CAH staff are fully vaccinated against COVID- 19. Per §485.640(f)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who do not enter the CAH or have contact with patients or staff of the facility. For example, this may include a telehealth provider who does not visit the facility, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the CAH or, if unavailable at the facility, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may also 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), 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.

Surveying for Compliance

Surveyors should focus on the staff that regularly work in the CAH (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave), would not count as unvaccinated staff for determining compliance with this requirement.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

CAHs will be expected to meet the following:

Vaccination Enforcement

CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule.**

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures

The CAH policies and procedures must be implemented and address each of the following components:

The CAH must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to “mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.” The requirement is not explicit and does not specify which actions must be taken.

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.

The CAH must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation) requirements by the CAH; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:

Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies, or recognized medical conditions may provide grounds for an exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, CAHs 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the CAH's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

CAHs must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each CAH's policies and procedures. We direct providers and suppliers to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the CAH's acceptance or denial of the request. Rather, surveyors will review to ensure the CAH has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption facility can address those individually. Accommodations can be addressed in the CAH's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the CAH must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.

Contingency plans should include actions that the CAH would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the CAH will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference

- Surveyors will ask CAHs to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:
 - 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;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the CAH continues to follow all standards of infection prevention and control practices, 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;
 - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
 - 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;
 - A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
 - 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;
 - A process for ensuring that 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;
 - 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, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

- o Contingency plans for staff that are not fully vaccinated for COVID-19.
- The CAH will provide their process for how the CAH ensures that their contracted staff are compliant with the vaccination requirement

2. Record Review, interview, and observations:

- Surveyors will review the policies and procedure to ensure all components are present.
- Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the CAH that may include:
 - Requiring unvaccinated staff 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.
 - Reassigning unvaccinated staff 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 at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission
 - Requiring unvaccinated staff 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
- Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):
 - o Direct care staff, including those contracted staff meeting the definition of staff (vaccinated and unvaccinated)
 - o Contracted staff
 - o Direct care staff with an exemption
- There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay.). Two of the direct care staff sampled should be contractors.
- The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.

- Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.
- For each individual identified by the CAH as vaccinated, surveyors will:
 - Review CAH records to verify vaccination status. 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, or
 - State immunization information system record.
 - Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay.

- For each individual identified by the CAH as unvaccinated, surveyors will
 - Review CAH records.
 - Determine if they have been educated and offered vaccination. Interview staff and ask if they plan to get vaccinated if they have declined to get vaccinated and if they have a medical contraindication or religious exemption.
 - Request and review documentation of medical contraindication.
 - Request to see employee record of the staff education of the CAH policy and procedure regarding unvaccinated individuals.
 - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.
- For each individual identified by the CAH as unvaccinated due to a clinical contraindication:
 - Review and verify that all required documentation is:
 - Signed and dated by physician or advanced practice provider
 - States the specific vaccine that is contraindicated
 The recognized clinical reason for the contraindication with a statement recommending exemption.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

***NOTE:** Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.*

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).*
- *If the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.*

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.

Outpatient Physical Therapy (OPT) Attachment
Revised

This attachment provides guidance to surveyors for determining compliance with the Staff Vaccination requirements, which apply to all states.

I-172

§ 485.725 Condition of participation: Infection control.

(f) Standard: COVID-19 vaccination of organization staff. The organization that provides outpatient physical therapy 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 2 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 organization staff, who provide any care, treatment, or other services for the organization and/or its patients:

- (i) Organization employees;**
- (ii) Licensed practitioners;**
- (iii) Students, trainees, and volunteers; and**
- (iv) Individuals who provide care, treatment, or other services for the organization and/or its patients, under contract or by other arrangement.**

(2) The policies and procedures of this section do not apply to the following organization staff:

- (i) Staff who exclusively provide telehealth or telemedicine services outside of the organization setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section; and**
- (ii) Staff who provide support services for the organization that are performed exclusively outside of the organization setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section.**

(3) The policies and procedures must include, at a minimum, the following components:

- (i) A process for ensuring all staff specified in paragraph (f)(1) of this section (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 organization and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (f)(1) of this section are fully vaccinated for COVID-19, 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 for all staff specified in paragraph (f)(1) of this section;

(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 organization 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 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

(A) 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

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the organization's COVID-19 vaccination requirements for staff 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.

GUIDANCE

DEFINITIONS

“Booster” per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refers to conditions or risks that preclude 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“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.

“Staff” refers to individuals who provide any care, treatment, or other services for the OPT and/or its patients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the OPT and/or its patients, under contract or other arrangement. This also includes individuals under contract or arrangement with the OPT, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **Staff would not include anyone who provides only telemedicine services or support services outside of the OPT and who does not have any direct contact with patients and other staff specified in paragraph (f)(1).**

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met (<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>)

Background:

To protect OPT patients from COVID-19, each OPT must develop and implement policies and procedures as specified in §485.725(f) to ensure that all OPT staff are fully vaccinated against COVID-19. Per §485.725(f)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who do not enter the OPT or have contact with patients or staff of the facility. For example, this may include a telehealth provider who does not visit the facility, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the OPT or, if unavailable at the facility, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may also be many infrequent services and tasks performed in, or for, an OPT that is conducted by “one-off” vendors, volunteers, and professionals. OPTs are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), services that are performed exclusively off-site, and are 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. OPTs should consider the frequency of presence, services provided, and proximity to patients and staff.

Survey for Compliance

Surveyors should focus on the staff that regularly work in the OPT (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended, or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave), would not count as unvaccinated staff for determining compliance with this requirement.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

OPTs will be expected to meet the following:

Vaccination Enforcement

CMS expects all facilities’ staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination**

rates under 100% of unexcepted staff constitute non-compliance under the rule.

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures

The OPT policies and procedures must be implemented and address each of the following components:

The OPT must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to “mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.” The requirement is not explicit and does not specify which actions must be taken.

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.

The OPT must track and securely document:

- Each staff member’s vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation) requirements by the OPT; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility’s policies and procedures, but those individuals

are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:

Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies, or recognized medical conditions may provide grounds for an exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, OPTs 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the OPT's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

OPTs must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each OPT's policies and procedures. We direct OPT to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the OPT's acceptance or denial of the request. Rather, surveyors will review to ensure the OPT has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption facility can address those individually. Accommodations can be addressed in the OPT's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the OPT must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.

Contingency plans should include actions that the OPT would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the OPT will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference
 - Surveyors will ask OPTs to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:

- 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 OPT and/or its patients;
- A process for ensuring that all required staff are fully vaccinated;
- A process for ensuring that the OPT continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the OPT, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
- A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
- 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;
- A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
- 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;
- A process for ensuring that 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 OPT’s COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
- 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, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

Contingency plans for staff that are not fully vaccinated for COVID-19.

- The OPT will provide their process for how the OPT ensures that their contracted staff are compliant with the vaccination requirement.

2. Record Review, interview, and observations:

- Surveyors will review the policies and procedures to ensure all components are present.
- Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the OPT that may include:
 - Requiring unvaccinated staff 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.
 - Reassigning unvaccinated staff 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 at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission
 - Requiring unvaccinated staff 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
- Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):
 - Direct care staff, including those contracted staff meeting the definition of staff (vaccinated and unvaccinated)
 - Contracted staff
 - Direct care staff with an exemption
- There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay.). Two of the direct care staff sampled should be contractors.
- The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.
- Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.
- For each individual identified by the OPT as vaccinated, surveyors will:
 - Review OPT records to verify vaccination status. 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, or
 - State immunization information system record.
- Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay.

- For each individual identified by the OPT as unvaccinated, surveyors will
 - Review OPT records
 - Determine if they have been educated and offered vaccination
 - Interview staff and ask if they plan to get vaccinated, if they have declined to get vaccinated, and if they have a medical contraindication or religious exemption.
 - Request and review documentation of the medical contraindication.
 - Request to see employee record of the staff education of the OPT policy and procedure regarding unvaccinated individuals.
 - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.
- For each individual identified by the OPT as unvaccinated due to a medical contraindication:
 - Review and verify all required documentation.
 - Signed and dated by physician or advanced practice provider
 - States the specific vaccine that is contraindicated
The recognized clinical reason for the contraindication with a statement recommending exemption.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

***NOTE:** Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.*

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If* the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).
- *If* the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.

Community Mental Health Center (CMHC) Attachment

Revised

This attachment *provides guidance to surveyors for determining compliance with the Staff Vaccination requirements, which apply to all states.*

M-0114

§ 485.904 Condition of participation: Personnel qualifications.

(c) ***Standard: COVID-19 vaccination of center staff.*** The CMHC must develop and implement policies and procedures to ensure that all center staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 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 client contact, the policies and procedures must apply to the following center staff, who provide any care, treatment, or other services for the center and/or its clients:**

(i) **Center employees;**

(ii) **Licensed practitioners;**

(iii) **Students, trainees, and volunteers; and**

(iv) **Individuals who provide care, treatment, or other services for the center and/or its clients, under contract or by other arrangement.**

(2) **The policies and procedures of this section do not apply to the following center staff:**

(i) **Staff who exclusively provide telehealth or telemedicine services outside of the center setting and who do not have any direct contact with patients and other staff specified in paragraph (c)(1) of this section; and**

(ii) **Staff who provide support services for the center that are performed exclusively outside of the center setting and who do not have any direct contact with patients and other staff specified in paragraph (c)(1) of this section.**

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

(i) **A process for ensuring all staff specified in paragraph (c)(1) of this section (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 CMHC and/or its clients;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated for COVID-19, 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 for all staff specified in paragraph (c)(1) of this section;

(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 CMHC 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 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

(A) 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

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the CMHC's COVID-19 vaccination requirements for staff 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.

GUIDANCE

DEFINITIONS

“Booster”: per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refer to conditions or risks that preclude 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“Primary Vaccination Series” refers to staff who have received a single-dose vaccine or all doses of a multi-dose vaccine for COVID-19.

“Staff” refers to individuals who provide any care, treatment, or other services for the CMHC and/or its clients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the CMHC and/or its clients, under contract or other arrangement. This also includes individuals under contract or arrangement with the CMHC, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **Staff would not include anyone who provides only**

telemedicine services or support services outside of the CMHC and who does not have any direct contact with clients and other staff specified in paragraph (c)(1).

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met (<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>)

Background:

To protect CMHC patients from COVID-19, each CMHC must develop and implement policies and procedures as specified in §485.904(c) to ensure that all CMHC staff are fully vaccinated against COVID- 19. Per §485.904(c)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who do not enter the CMHC or have contact with patients or staff of the facility. For example, this may include a telehealth provider who does not visit the facility, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the CMHC or, if unavailable at the facility, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may also be many infrequent services and tasks performed in, or for, an CMHC that is conducted by “one-off” vendors, volunteers, and professionals. CMHCs are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), services that are performed exclusively off-site, and are not at or adjacent to any site of client care (such as accounting services), but they may choose to extend COVID-19 vaccination requirements to them if feasible. CMHCs should consider the frequency of presence, services provided, and proximity to clients and staff.

Surveying for Compliance

Surveyors should focus on the staff that regularly work in the CMHC (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended, or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave), would not count as unvaccinated staff for determining compliance with this requirement.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

CMHCs will be expected to meet the following:

Vaccination Enforcement

CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule.**

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures

The CMHC policies and procedures must be implemented and address each of the following components:

The CMHC must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to “mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.” The requirement is not explicit and does not specify which actions must be taken.

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.

The CMHC must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation) requirements by the CMHC; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is

remote from sites of resident care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with residents.

Vaccination Exemptions:

Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies, or recognized medical conditions may provide grounds for an exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, CMHCs 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the CMHC's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

CMHCs must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each CMHC's policies and procedures. We direct CMHCs to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the CMHC's acceptance or denial of the request. Rather, surveyors will review to ensure the CMHC has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption facility can address those individually. Accommodations can be addressed in the CMHC's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the CMHC must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.

Contingency plans should include actions that the CMHC would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the CMHC will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference

- Surveyors will ask CMHCs to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:

- 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 CMHC and/or its clients;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the CMHC continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the CMHC, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
 - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
 - 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;
 - A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
 - 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;
 - A process for ensuring that 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 CMHC’s COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
 - 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, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; **and**
 - Contingency plans for staff that are not fully vaccinated for COVID-19.
- The CMHC will provide their process for how the CMHC ensures that their contracted staff are compliant with the vaccination requirement.

2. Record Review, interview, and observations:

- Surveyors will review the policies and procedures to ensure all components are present.
- Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the CMHC that may include:
 - Requiring unvaccinated staff to follow additional, [CDC-recommended precautions](#), such as adhering to universal source control and physical distancing measures in areas that are restricted from client 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.
 - Reassigning unvaccinated staff to non-client 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 clients who are not immunocompromised, unvaccinated);
 - Requiring at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission
 - Requiring unvaccinated staff 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 clients

- Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):
 - Direct care staff, including those contracted staff meeting the definition of staff (vaccinated and unvaccinated)
 - Contracted staff
 - Direct care staff with an exemption

- There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay.) Two of the direct care staff sampled should be contractors.

- The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.

- Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

***NOTE:** Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.*

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).*
- *If the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.*

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.

Home Infusion Therapy (HIT) Attachment

Revised

This attachment *provides guidance to surveyors for determining compliance with the Staff Vaccination requirements, which apply to all states.*

§ 486.525 Required services.

(c) COVID-19 Vaccination of facility staff. The qualified home infusion therapy supplier 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 2 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 qualified home infusion therapy supplier staff, who provide any care, treatment, or other services for the qualified home infusion therapy supplier and/or its patients:

- (i) Qualified home infusion therapy supplier employees;**
- (ii) Licensed practitioners;**
- (iii) Students, trainees, and volunteers; and**
- (iv) Individuals who provide care, treatment, or other services for the qualified home infusion therapy supplier and/or its patients, under contract or by other arrangement.**

(2) The policies and procedures of this section do not apply to the following qualified home infusion therapy supplier staff:

- (i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where home infusion therapy services are provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (c)(1) of this section; and**
- (ii) Staff who provide support services for the qualified home infusion therapy supplier that are performed exclusively outside of the settings where home infusion therapy services are provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (c)(1) of this section.**

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (c)(1) of this section (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 qualified home infusion therapy supplier and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (c)(1) of this section are fully vaccinated for COVID-19, 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 that the facility follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (c)(1) of this section;

(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 qualified home infusion therapy supplier 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 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

(A) 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

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the qualified home infusion therapy supplier's COVID-19 vaccination requirements for staff 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.

GUIDANCE

DEFINITIONS

“Booster” per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refer to conditions or risks that preclude 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“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.

“Staff” refers to individuals who provide any care, treatment, or other services for the HIT and/or its patients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the HIT and/or its patients, under contract or other arrangement. This also includes individuals under contract or arrangement with the HIT, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **Staff would not include anyone who provides only telemedicine services or support services outside of the HIT and who does not have any direct contact with patients and other staff specified in paragraph (c)(1).**

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met (<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>)

Background:

To protect HIT patients from COVID-19, each HIT must develop and implement policies and procedures as specified in §486.525(c) to ensure that all HIT staff are fully vaccinated against COVID-19. Per §486.525(c)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who do not enter the HIT or have contact with patients or staff of the facility. For example, this may include a telehealth provider who does not visit the facility, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the HIT or, if unavailable at the facility, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may also be many infrequent services and tasks performed in, or for, an HIT that are conducted by “one-off” vendors, volunteers, and professionals. HITs are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), services that are performed exclusively off-site, and are 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. HITs should consider the frequency of presence, services provided, and proximity to patients and staff.

Surveying for Compliance

Surveyors should focus on the staff that regularly work in the HIT (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended, or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave), would not count as unvaccinated staff for determining compliance with this requirement.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

HITs will be expected to meet the following:

Vaccination Enforcement

CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule.**

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures

The HIT policies and procedures must be implemented and address each of the following components:

The HIT must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series, prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to “mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.” The requirement is not explicit and does not specify which actions must be taken.

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.

The HIT must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);

- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation) requirements by the HIT; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:

Facilities must have a process by which staff may request exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies, or recognized medical conditions may provide grounds for an exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, HITs 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the HIT's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

HITs must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each HIT's policies and procedures. We direct HIT to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the HIT's acceptance or denial of the request. Rather, surveyors will review to ensure the HIT has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption, the facility can address those individually. Accommodations can be addressed in the HIT's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the HIT must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.

Contingency plans should include actions that the HIT would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also

indicate the actions the HIT will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference

- Surveyors will ask HITs to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:
 - 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 HIT and/or its patients;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the HIT continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the HIT, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
 - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
 - 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;
 - A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
 - 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;
 - A process for ensuring that 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 HIT's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
 - 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, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

- Contingency plans for staff who are not fully vaccinated for COVID-19.

- The HIT will provide their process for how the HIT ensures that their contracted staff are compliant with the vaccination requirement.

2. Record Review, interview, and observations:

- Surveyors will review the policies and procedures to ensure all components are present.
- Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the HIT that may include:
 - Requiring unvaccinated staff 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.
 - Reassigning unvaccinated staff 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 at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission; and
 - Requiring unvaccinated staff 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.
- Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):
 - Direct care staff, including those contracted staff meeting the definition of staff (vaccinated and unvaccinated);
 - Contracted staff; and
 - Direct care staff with an exemption
- There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay). Two of the direct care staff sampled should be contractors.

- The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.
- Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.
- For each individual identified by the HIT as vaccinated, surveyors will:
 - Review HIT records to verify vaccination status. 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, or
 - State immunization information system record.
 - Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay.

- For each individual identified by the HIT as unvaccinated, surveyors will
 - Review HIT records
 - Determine, if they have been educated and offered vaccination
 - Interview staff and ask if they plan to get vaccinated, if they have declined to get vaccinated, and if they have a medical contraindication or religious exemption.
 - Request and review documentation of the medical contraindication.
 - Request to see employee record of the staff education on the HIT policy and procedure regarding unvaccinated individuals.
 - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.
- For each individual identified by the HIT as unvaccinated due to a medical contraindication:
 - Review and verify all required documentation 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.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

***NOTE:** Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.*

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).*
- *If the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a*

good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency identified during the survey.

Rural Health Clinic/Federally Qualified Health Center (RHC/FQHC) Attachment
Revised

This attachment *provides guidance to surveyors for determining compliance with the Staff Vaccination requirements, which apply to all states.*

J-0110

§ 491.8 Staffing and staff responsibilities.

(d) COVID-19 vaccination of staff. The RHC/FQHC 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 2 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 clinic or center staff, who provide any care, treatment, or other services for the clinic or center and/or its patients:

- (i) RHC/FQHC employees;**
- (ii) Licensed practitioners;**
- (iii) Students, trainees, and volunteers; and**
- (iv) Individuals who provide care, treatment, or other services for the clinic or center and/or its patients, under contract or by other arrangement.**

(2) The policies and procedures of this section do not apply to the following clinic or center staff:

- (i) Staff who exclusively provide telehealth or telemedicine services outside of the clinic or center setting and who do not have any direct contact with patients and other staff specified in paragraph (d)(1) of this section; and**
- (ii) Staff who provide support services for the clinic or center that are performed exclusively outside of the clinic or center setting and who do not have any direct contact with patients and other staff specified in paragraph (d)(1) of this section.**

(3) The policies and procedures must include, at a minimum, the following components:

- (i) A process for ensuring all staff specified in paragraph (d)(1) of this section (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 clinic or center and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID-19, 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 that the clinic or center follows nationally recognized infection prevention and control guidelines intended to mitigate the transmission and spread of COVID-19, and which must include the implementation of additional precautions for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status for all staff specified in paragraph (d)(1) of this section;

(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 facility 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 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

(A) 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

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the clinic's or center's COVID-19

vaccination requirements for staff 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

GUIDANCE

DEFINITIONS

“Booster” per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refer to conditions or risks that preclude 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“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.

“Staff” refers to individuals who provide any care, treatment, or other services for the RHC/FQHC and/or its patients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the RHC/FQHC and/or its patients, under contract or other arrangement. This also includes individuals under contract or arrangement with the RHC/FQHC, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or adult students, trainees or volunteers. **Staff would not include anyone who**

provides only telemedicine services or support services outside of the RHC/FQHC and who does not have any direct contact with patients and other staff specified in paragraph (d)(1).

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met (<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>)

Background:

To protect RHC/FQHC patients from COVID-19, each RHC/FQHC must develop and implement policies and procedures as specified in §491.8(d) to ensure that all RHC/FQHC staff are fully vaccinated against COVID-19. Per §491.8(d)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who do not enter the RHC/FQHC or have contact with patients or staff of the facility. For example, this may include a telehealth provider who does not visit the facility, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the RHC/FQHC or, if unavailable at the facility, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may also be many infrequent services and tasks performed in or for an RHC/FQHC that is conducted by “one-off” vendors, volunteers, and professionals. RHCs/FQHCs are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), 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. RHCs/FQHCs should consider the frequency of presence, services provided, and proximity to patients and staff.

Surveying for Compliance

Surveyors should focus on the staff that regularly work in the RHC/FQHC (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended, or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave), would not count as unvaccinated staff for determining compliance with this requirement.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

RHCs/FQHCs will be expected to meet the following:

Vaccination Enforcement

CMS expects all facilities' staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule.**

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures

The RHC/FQHC policies and procedures must be implemented and address each of the following components:

The RHC/FQHC must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: , Facilities can choose which additional precautions to implement that align with the intent of the regulation which is intended to “mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.” This requirement is not explicit and does not specify which actions must be taken.

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.

The RHC/FQHC must track and securely document:

- Each staff member's vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation) requirements by the RHC/FQHC; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility's policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:

Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies, or recognized medical conditions may provide grounds for an exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, RHC/FQHCs 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the RHC/FQHC's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

RHC/FQHCs must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. In addition to medical contraindications, CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical

considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each RHC/FQHC's policies and procedures. We direct RHC/FQHC to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the RHC/FQHC's acceptance or denial of the request. Rather, surveyors will review to ensure the RHC/FQHC has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption, facility can address those individually. Accommodations can be addressed in the RHC/FQHC's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the RHC/FQHC must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.

Contingency plans should include actions that the RHC/FQHC would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the RHC/FQHC will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference

- Surveyors will ask RHCs/FQHCs to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:
 - 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 RHC/FQHC and/or its patients;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the RHC/FQHC continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the RHC/FQHC especially by those staff who are unvaccinated or who are not yet fully vaccinated;
 - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
 - 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;
 - A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
 - 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;
 - A process for ensuring that 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 RHC/FQHC's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
 - 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, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and
 - Contingency plans for staff that are not fully vaccinated for COVID-19.

- The RHC/FQHC will provide their process for how the RHC/FQHC ensures that their contracted staff are compliant with the vaccination requirement
2. Record Review, interview, and observations:
- Surveyors will review the policies and procedures to ensure all components are present.
 - Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the RHC/FQHC that may include:
 - Requiring unvaccinated staff 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.
 - Reassigning unvaccinated staff 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 at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission
 - Requiring unvaccinated staff 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
 - Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindication. The sample should include (as applicable):
 - Direct care staff, including those contracted staff meeting the definition of staff (vaccinated and unvaccinated)
 - Contracted staff
 - Direct care staff with an exemption
 - There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay.). Two of the direct care staff sampled should be contractors.
 - The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.
 - Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.

- For each individual identified by the RHC/FQHC as vaccinated, surveyors will:
 - Review RHC/FQHC records to verify vaccination status. 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, or
 - State immunization information system record.
 - Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay.

- For each individual identified by the RHC/FQHC as unvaccinated, surveyors will
 - Review RHC/FQHC records
 - Determine if they have been educated and offered vaccination
 - Interview staff and ask if they plan to get vaccinated, if they have declined to get vaccinated, and if they have a medical contraindication or religious exemption.
 - Request and review documentation of medical contraindication.
 - Request to see employee record of the staff education of the RHC/FQHC policy and procedure regarding unvaccinated individuals.
 - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.
- For each individual identified by the RHC/FQHC as unvaccinated due to a medical contraindication:
 - Review and verify all required documentation.
 - Signed and dated by physician or advanced practice provider
 - States the specific vaccine that is contraindicated
The recognized clinical reason for the contraindication with a statement recommending exemption.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

***NOTE:** Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.*

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If* the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).
- *If* the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.

End-Stage Renal Disease (ESRD) Facility Attachment

Revised

This attachment *provides guidance to surveyors for determining compliance with the Staff Vaccination requirements, which apply to all states.*

V-0800

§ 494.30 Condition: Infection control.

(b) COVID-19 Vaccination of facility staff. The facility 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 2 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 facility staff, who provide any care, treatment, or other services for the facility and/or its patients:

(i) Facility employees;

(ii) Licensed practitioners;

(iii) Students, trainees, and volunteers; and

(iv) Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following facility staff:

(i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (b)(1) of this section; and

(ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with patients and other staff specified in paragraph (b)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (b)(1) of this section (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 facility and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (b)(1) of this section are fully vaccinated for COVID-19, 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 for all staff specified in paragraph (b)(1) of this section;

(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 facility 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 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:

(A) 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

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements for staff 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.

GUIDANCE

DEFINITIONS

“Booster” per Centers for Disease Control and Prevention ([CDC](https://www.cdc.gov)), refers to a dose of vaccine administered when the initial sufficient immune response to the primary vaccination series is likely to have waned over time.

“Clinical contraindications” refer 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, a vaccine is clinically contraindicated if an individual has a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to component of the COVID-19 vaccine or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine.

“Fully vaccinated” refers to staff who are two weeks or more from completion of their primary vaccination series for COVID-19.

“Good Faith Effort” refers to a provider that has taken aggressive steps toward achieving compliance with staff vaccination requirement **and/or** the provider has no or has limited access to vaccine, and has documented attempts to access to the vaccine.

“Primary Vaccination Series” refers to staff who have received a single-dose vaccine or all doses of a multi-dose vaccine for COVID-19.

“Staff” refers to individuals who provide any care, treatment, or other services for the ESRD Facility and/or its patients, including employees; licensed practitioners; adult students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the ESRD Facility and/or its patients, under contract or other arrangement. This also includes individuals under contract or arrangement with the ESRD Facility, including hospice and dialysis staff, physical therapists, occupational therapists, mental health professionals, licensed practitioners, or students, trainees or volunteers. **Staff would not include anyone who provides only telemedicine services or support services outside of the ESRD Facility and who does not have any direct contact with patients and other staff specified in paragraph (b)(1).**

“Temporarily delayed vaccination” refers to vaccination that must be temporarily deferred, as recommended by CDC, due to clinical considerations, including known COVID-19 infection

until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met (<https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>)

Background:

To protect ESRD patients from COVID-19, each ESRD must develop and implement policies and procedures as specified in §494.30(b) to ensure that all ESRD staff are fully vaccinated against COVID-19. Per §494.30(b)(2), the requirements in this section do not apply to individuals who provide support services from a remote location and who do not enter the ESRD or have contact with patients or staff of the facility. For example, this may include a telehealth provider who does not visit the facility, such as a consultant conducting a telehealth visit, or a radiologist who reads x-rays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the ESRD or, if unavailable at the facility, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity.

There may also be many infrequent services and tasks performed in or for an ESRD Facility that is conducted by “one-off” vendors, volunteers, and professionals. ESRD Facilities are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), services that are performed exclusively off-site, and are 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. ESRD Facilities should consider the frequency of presence, services provided, and proximity to patients and staff.

Surveying for Compliance

Surveyors should focus on the staff that regularly work in the ESRD (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended or who are on extended leave (e.g., Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave), would not count as unvaccinated staff for determining compliance with this requirement.

Surveying for staff vaccination requirements is not required on Life Safety Code (LSC)-only complaints, or LSC-only follow-up surveys. Surveyors may modify the staff vaccination compliance review if the facility was determined to be in substantial compliance with this requirement within the previous six weeks.

ESRD Facilities will be expected to meet the following:

Vaccination Enforcement

CMS expects all facilities’ staff to have received the appropriate number of doses by the timeframes specified in the IFC unless exempted as required by law. **Facility staff vaccination rates under 100% of unexcepted staff constitute non-compliance under the rule.**

Noncompliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. *For example, a facility that is noncompliant and has implemented a plan to achieve a 100% staff vaccination rate would not be subject to an enforcement action.*

Note: The requirements described above do not include the 14-day waiting period as identified by CDC for full vaccination. Rather these requirements are considered met with the completed vaccine series (i.e., one dose of a single dose vaccine, or final dose of a multi-dose vaccine series).

Policies and Procedures

The ESRD Facility policies and procedures must be implemented and address each of the following components:

The ESRD Facility must have a process for ensuring all staff (as defined above) have received at least a single-dose, or the first dose of a multi-dose COVID-19 vaccine series prior to providing any care, treatment, or other services for the facility and/or its patients.

The policy must also ensure those 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, adhere to additional precautions that are intended to mitigate the spread of COVID-19.

NOTE: Facilities have discretion to choose which additional precautions to implement that align with the intent of the regulation which is intended to “mitigate the transmission and spread of COVID-19 for all staff who are not fully vaccinated.” The requirement is not explicit and does not specify which actions must be taken.

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.

The ESRD facility must track and securely document:

- Each staff member’s vaccination status (this should include the specific vaccine received, and the dates of each dose received, or the date of the next scheduled dose for a multi-dose vaccine);
- Any staff member who has obtained any booster doses (this should include the specific vaccine booster received and the date of the administration of the booster);
- Staff who have been granted an exemption from vaccination (this should include the type of exemption and supporting documentation); requirements by the ESRD Facility; and
- Staff for whom COVID-19 vaccination must be temporarily delayed and should track when the identified staff can safely resume their vaccination.

Facilities that employ or contract staff who telework full-time (e.g., 100 percent of their time is remote from sites of patient care and staff who do work at sites of care) should identify these individuals as a part of implementing the facility’s policies and procedures, but those individuals are not subject to the vaccination requirements. Note, however, that these individuals may be subject to other federal requirements for COVID-19 vaccination. Facilities have the flexibility to

use the tracking tools of their choice; however, they must provide evidence of this tracking for surveyor review. Additionally, facilities' tracking mechanism should clearly identify each staff's role, assigned work area, and how they interact with patients. This includes staff who are contracted, volunteers, or students.

Vaccination Exemptions:

Facilities must have a process by which staff may request an exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities 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 determination of the request, and any accommodations that are granted.

Note: Staff who are unable to furnish proper exemption documentation must be vaccinated or the facility must follow the actions for unvaccinated staff.

Medical Exemptions:

Certain allergies, or recognized medical conditions may provide grounds for an exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, ESRD 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*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

Medical exemption documentation must specify which authorized or licensed COVID-19 vaccine is clinically contraindicated for the staff member and the recognized clinical reasons for the contraindication. The documentation must also include a statement recommending that the staff member be exempted from the ESRD Facility's COVID-19 vaccination requirements based on the medical contraindications.

A staff member who requests a medical exemption from vaccination must provide documentation signed and dated by a licensed practitioner acting within their respective scope of practice and in accordance with all applicable State and local laws. The individual who signs the exemption documentation cannot be the same individual requesting the exemption.

ESRD facilities must have a process to track and secure documentation of the vaccine status of staff whose vaccine is temporarily delayed. CDC recommends a temporary delay in administering the COVID-19 vaccination due to clinical considerations, including known COVID-19 infection until recovery from the acute illness (if symptoms were present) and criteria to discontinue isolation have been met.

Non-Medical Exemptions, Including Religious Exemptions:

Requests for non-medical exemptions, such as a religious exemption in accordance with Title VII, must be documented and evaluated in accordance with each ESRD Facility's policies and

procedures. We direct ESRD Facilities to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information on evaluating and responding to such requests.

Note: Surveyors will **not** evaluate the details of the request for a religious exemption, **nor** the rationale for the ESRD Facility's acceptance or denial of the request. Rather, surveyors will review to ensure the ESRD Facility has an effective process for staff to request a religious exemption for a sincerely held religious belief.

Accommodations of Unvaccinated Staff with a Qualifying Exemption:

While accommodations could be appropriate under certain limited circumstances, no accommodation should be provided to staff that is not legally required. For individual staff members that have valid reasons for exemption, facility can address those individually. Accommodations can be addressed in the ESRD's policies and procedures.

Facilities must have a process for ensuring that all staff are fully vaccinated for COVID-19, 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 CDC, due to clinical precautions and considerations.

Contingency Plans

For staff that are not fully vaccinated, the ESRD Facility must develop contingency plans for staff who have not completed the primary vaccination series for COVID-19.

Contingency plans should include actions that the ESRD Facility would take when staff have indicated that they will not get vaccinated and do not qualify for an exemption, but contingency plans should also address staff who are not fully vaccinated due to an exemption or temporary delay in vaccination, such as through the additional precautions. Facilities should prioritize contingency plans for those staff that have obtained no doses of any vaccine over staff that have received a single dose of a multi-dose vaccine. For example, contingency plans could include a deadline for staff to have obtained their first dose of a multiple-dose vaccine. The plans should also indicate the actions the ESRD Facility will take if the deadline is not met, such as actively seeking replacement staff through advertising or obtaining temporary vaccinated staff until permanent vaccinated replacements can be found.

Survey Process

Compliance will be assessed through observation, interview, and record review as part of the survey process.

1. Entrance Conference

- Surveyors will ask ESRD Facilities to provide vaccination policies and procedures. At a minimum, the policies and procedures must provide:
 - 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 ESRD Facility and/or its patients;

- A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the ESRD Facility continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the ESRD Facility, especially by those staff who are unvaccinated or who are not yet fully vaccinated;
 - A process for tracking and securely documenting the COVID-19 vaccination status for all required staff;
 - 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;
 - A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;
 - 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;
 - A process for ensuring that 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 ESRD Facility's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;
 - 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, or individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and
 - Contingency plans for staff that are not fully vaccinated for COVID-19.
- The ESRD Facility will provide their process for how the facility ensures that their contracted staff are compliant with the vaccination requirement

2. Record Review, interview, and observations:

- Surveyors will review the policies and procedures to ensure all components are present.
- Surveyors will review any contingency plans developed to mitigate the spread of COVID-19 infections by the ESRD that may include:
 - Requiring unvaccinated staff 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.
 - Reassigning unvaccinated staff 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 at least weekly testing for unvaccinated staff, regardless of whether the facility or service site is located in a county with low to moderate community transmission
 - Requiring unvaccinated staff 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

- Surveyors will select a sample of staff based on current staff sample selection guidelines. Surveyors should also examine the documentation of each staff identified as unvaccinated due to medical contraindications. The sample should include (as applicable):
 - Direct care staff, including those contracted staff meeting the definition of staff (vaccinated and unvaccinated)
 - Contracted staff
 - Direct care staff with an exemption

- There should be a minimum of 6 direct care/patient engagement staff. This includes direct care contracted staff that are onsite at time of the survey. Of this 6-person sample, 4 should include vaccinated staff/contractors and 2 unvaccinated staff/contractors (1 that is not fully vaccinated and 1 with a medical exemption or temporary delay.) Two of the direct care staff sampled should be contractors.

- The list of vaccinated staff maintained by the facility are used for sampling staff. Please refer to survey process for instructions for sampling contracted staff.

- Surveyors should choose a sample of at least of 2 contracted staff (1 vaccinated and 1 unvaccinated or exempt) who are not included in those direct care contracted staff outlined above.

- For each individual identified by the ESRD Facility as vaccinated, surveyors will:

- Review ESRD Facility records to verify vaccination status. 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, or
 - State immunization information system record.
- Conduct follow-up interviews with staff and administration if any discrepancies are identified. If applicable, determine if any additional doses were provided.

NOTE: Failure for contract staff to provide evidence of vaccination status reflects noncompliance and should be cited under the requirement to have policies and procedures for ensuring that all staff are fully vaccinated, except for those staff who have been granted exemptions or a temporary delay.

- For each individual identified by the ESRD Facility as unvaccinated, surveyors will
 - Review ESRD Facility records
 - Determine if they have been educated and offered vaccination
 - Interview staff and ask if they plan to get vaccinated if they have declined to get vaccinated and if they have a medical contraindication or religious exemption.
 - Request and review documentation of the medical contraindication.
 - Request to see employee record of the staff education on the ESRD Facility policy and procedure regarding unvaccinated individuals.
 - Observe staff providing care to determine compliance with current standards of practice with infection control and prevention.
- For each individual identified by the ESRD Facility as unvaccinated due to a medical contraindication:
 - Review and verify that all required documentation 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.

General Information: https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fvaccines%2Fcovid-19%2Finfo-by-product%2Fclinical-considerations.html

Citing Noncompliance - Level of Deficiency

Hospitalizations and deaths currently remain relatively low nationwide. This is a testament to the tools and protections in place today, particularly the work that federal, state, local, and private

partners have done to get over 225 million people vaccinated and over 110 million boosted.

For instances of noncompliance identified through the survey process, the level of deficiency will be determined based on the threat posed to patient health and safety.

Situations indicating egregious noncompliance, such as a complete disregard for the requirements, should be cited at the condition level. Examples of egregious noncompliance could include more than 50% of staff being unvaccinated (unless exempted, or temporarily delayed), and/or policies and procedures have not been implemented as required. When there are egregious cases of noncompliance, state survey agencies should notify the CMS location of the information.

Examples of when noncompliance should be cited at the standard level could include less than 50% of staff being unvaccinated and/or 1 or more of the policies and procedures have not been implemented as required, but good faith efforts are being made toward compliance with the staff vaccine requirements.

***NOTE:** Regardless of a facility's compliance with the staff vaccination requirements, surveyors should closely investigate infection prevention and control practices to ensure proper practices are in use, such as proper use of personal protective equipment, transmission precautions which reflect current standards of practice, and/or other relevant infection prevention and control practices that are designed to minimize transmission of COVID-19.*

Plan of Correction and Good Faith Effort:

Facilities must submit a plan of correction (POC) demonstrating a good faith effort to correct the noncompliance. Examples of actions which demonstrate a good faith effort include, but are not limited to:

- *If the facility has no or has limited access to the vaccine, and the facility has documented attempts to obtain vaccine access (e.g., contact with the health department and pharmacies).*
- *If the facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc. For example, if the POC demonstrates that the facility staff vaccination rate is 90% or more, and all policies and procedures were developed and implemented, this would be considered a good faith effort and the deficiency could be cleared, with the facility returned to substantial compliance.*

Enforcement Actions

CMS will follow current enforcement procedures based on the level of deficiency cited during the survey.