



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

Ref: QSO-22-09-ALL
Revised 4/05/22

DATE: January 14, 2022

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: *Revised* Guidance for the Interim Final Rule - Medicare and Medicaid Programs;
Omnibus COVID-19 Health Care Staff Vaccination

Memorandum Summary

- CMS is committed to ensuring America's healthcare facilities respond effectively in an evidence-based way to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On November 05, 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 providing guidance and survey procedures for assessing and maintaining compliance with these regulatory requirements.
- The guidance in this memorandum specifically applies to the following states: Alabama, Alaska, Arizona, Arkansas, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Texas, Utah, West Virginia and Wyoming.
- The guidance in this memorandum does not apply to the following state at this time: Texas.
Surveyors in Texas should not undertake any efforts to implement or enforce the IFC.
- States that are not identified above are expected to continue under the timeframes and parameters identified in the December 28, 2021 memorandum (QSO-22-07-ALL-*Revised*)

Background

Since the beginning of the Public Health Emergency, CMS and the Centers for Disease Control and Prevention (CDC) data show as of mid-October, over 44 million COVID-19 cases, 3 million COVID-19 related hospitalization, and 720,000 COVID-19 deaths have been reported. The CDC has reported that [COVID-19 vaccines are safe and effective](#) at preventing severe illness from COVID-19 and limiting the spread of the virus that causes it. On [December 11, 2020](#), the Advisory Committee in Immunization Practices (ACIP) recommended, as interim guidance, that both 1) health care personnel, and 2) residents of long-term care (LTC) facilities be offered

COVID-19 vaccine in the initial phase of the vaccination program. To support this recommendation, on May 13, 2021, CMS published an interim final rule with comment period (IFC), entitled “Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff” ([86 FR 26306](#)). Also, CMS released guidance for surveyors and LTC facilities in the CMS memo, [QSO-21-19-NH](#), Interim Final Rule - COVID-19 Vaccine Immunization Requirements for Residents and Staff. This rule required all certified LTC facilities (i.e., nursing homes) to educate all residents and staff on the benefits and potential side effects associated with the COVID-19 vaccine, and offer the vaccine.

The regulation was intended to help increase vaccination rates among nursing home residents and staff to reduce the risk of infection and disease associated with COVID-19. Approximately two months after the publication of the rule, about 80 percent of nursing home residents were vaccinated. However, during that same time, roughly 60% of nursing home staff were vaccinated.¹ Therefore, more actions are warranted to increase vaccination rates among staff.

On [August 18, 2021](#), CMS announced that it would be issuing a regulation that all nursing home staff would have to be vaccinated against COVID-19 as a requirement for LTC facilities participating with the Medicare and Medicaid programs. Subsequently, on [September 9, 2021](#), CMS announced that this requirement would be extended to nearly all Medicare and Medicaid-certified providers and suppliers. These actions aim to support increasing vaccination rates among staff working in all facilities, providers, and certified suppliers that participate in Medicare and Medicaid.

Discussion

On November 5, 2021, CMS published an IFC with comment period ([86 FR 61555](#)), entitled “Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination,” revising the infection control requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs. These changes are necessary to protect the health and safety of patients and staff during the COVID-19 public health emergency. The COVID-19 vaccination requirements and policies and procedures required by this IFC must comply with applicable federal non-discrimination and civil rights laws and protections, including providing reasonable accommodations to individuals who are legally entitled to them because they have a disability or sincerely held religious beliefs, practices, or observations that conflict with the vaccination requirement. More information on federal non-discrimination and civil rights laws is available here:

<https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>.

Vaccination Enforcement– Surveying for Compliance

Medicare and Medicaid-certified facilities are expected to comply with all 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 non-compliance for hospitals and certain other acute and continuing care providers is termination; however, CMS’s primary goal is

¹ [COVID-19 Nursing Home Data - Centers for Medicare & Medicaid Services Data \(cms.gov\)](#)

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 by the timeframes specified in the QSO-22-07 unless exempted as required by law, or delayed as recommended by CDC. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.** Non-compliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance. Consistent with CMS's existing enforcement processes, this guidance will help surveyors determine the severity of a noncompliance deficiency finding at a facility when assigning a citation level. These enforcement action thresholds are as follows:

Within 30 days after issuance of this memorandum², if a facility demonstrates that:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; **and**
- 100% of staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule;** **or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice³ of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

Within 60 days after the issuance of this memorandum⁴, if the facility demonstrates that:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple-dose vaccine series), or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**

² If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

³ This information will be communicated through the CMS Form-2567, using the applicable Automated Survey Process Environment (ASPEN) federal tag.

⁴ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

- Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple-dose vaccine series, or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule**. The facility will receive notice⁵ of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

Within 90 days and thereafter following issuance of this memorandum, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.

Federal, state, Accreditation Organization, and CMS-contracted surveyors will begin surveying for compliance with these requirements as part of initial certification, standard recertification or reaccreditation, and complaint surveys 30 days following the issuance of this memorandum.

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 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 should be used in conjunction with the information in this memo.

- 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

⁵ This information will be communicated through the CMS Form-2567, using the applicable Automated Survey Process Environment (ASPEN) tag.

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. The effective dates of the specific actions are specified above.

/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

Outpatient Physical Therapy (OPT) Attachment
Revised

This attachment is a supplement to and should be used in conjunction with the following memoranda: *QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-Revised effective December 28, 2021, QSO-22-09-ALL- *Revised* effective January 14, 2022, *or* QSO-22-11-ALL-*Revised* effective January 20, 2022.

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 [CDC](https://www.cdc.gov/vaccines/imz/downloads/pdf/16-0101.pdf), 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 contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, 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:

All OPTs are required to achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the OPT and/or its patients.

There may 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 will begin surveying *facilities from states identified in each memorandum* for compliance 30 days after issuance of the *applicable* memorandum. 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 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 this memorandum unless exempted as required by law. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.**

Within 30 days following the issuance of the *applicable* memorandum¹, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 60 days following the issuance of the *applicable* memorandum³, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have

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² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule**. The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 within **30 days**⁵ *after the issuance of the applicable memorandum* and address each of the following components:

OPTs 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. This requirement is not explicit and does not specify actions that must be taken; there are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission *examples including*, but *are* not limited to:

- Reassigning staff who have not completed their primary vaccination series to non-patient care areas, to duties that can be performed remotely (i.e., telework), or to duties which limit exposure to those most at risk (e.g., assign to patients who are not immunocompromised, unvaccinated);
- Requiring staff who have not completed their primary vaccination series to follow additional, [CDC-recommended precautions](#), such as adhering to universal source control

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and physical distancing measures in areas that are restricted from patient access (e.g., staff meeting rooms, kitchen), even if the facility or service site is located in a county with low to moderate community transmission.

- Requiring at least weekly testing for exempted staff, and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community transmission in addition to following [CDC recommendations](#) for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients.

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

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. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the OPT's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of the applicable memorandum:** 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 Plan

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 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 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
 - A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations
 - 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 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 yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (f)(3)(x)), including deadlines for staff to be vaccinated.
- The OPT will provide a list of all staff and their vaccine status.
 - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
 - The OPT must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The OPT must also identify newly hired staff (hired in the last 60 days).
 - The OPT must indicate the position or role of each staff member
- *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 policy and procedure to ensure all components are present.
- Surveyors will review any contingency plan 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%2F%2Finfo-by-product%2Fclinical-considerations.html

Level of Deficiency

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below:

- **Immediate Jeopardy:**

- 40% or more of staff remain unvaccinated creating a likelihood of serious harm

OR

- Did not meet the 100% staff vaccination rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.

- **Condition Level-**

- Did not meet the 100% staff vaccination rate standard; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

- 21-39% of staff remain unvaccinated creating a likelihood of serious harm.

- **Standard Level:**

- 100% of staff are vaccinated and all new staff have received at least one dose; **and**

- 1 or more components of the policies and procedures were not developed and implemented

OR,

- Did not meet the 100% staff vaccination rate standard, but are making good faith efforts toward vaccine compliance.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The OPT has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).
- OR,**
- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement.
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The OPT has not met the requirement of staff vaccinated, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, including a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

- If the OPT has no or has limited access to vaccine, and the OPT has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- If the OPT provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

Enforcement Actions

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

ICF/IID Attachment

Revised

This attachment is a supplement to and should be used in conjunction with *the following memoranda: QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-Revised effective December 28, 2021, QSO-22-09-ALL-Revised effective January 14, 2022, or QSO-22-11-ALL-Revised effective January 20, 2022.

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 the [CDC](https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf), 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 contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, 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 other arrangement. This also includes individuals under contract or 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

All ICF/IID are required to achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the ICF/IID and/or its clients.

There may be many infrequent services and tasks performed in or for a health care ICF/IID that is conducted by “one-off” vendors, volunteers, and professionals. ICF/IID 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. ICF/IIDs should consider the frequency of presence, services provided, and proximity to clients and staff.

Surveying for Compliance

Surveyors will begin surveying *facilities from states identified in each memorandum* for compliance 30 days after issuance of the *applicable* memorandum, through a full survey for recertification, federal initial surveys, or a complaint survey. Surveyors should focus on the staff that regularly work in the ICF/IID (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.,

suspension, or out on Family and Medical Leave Act (FMLA) leave, or Worker's Compensation Leave, would not count as unvaccinated staff for the 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% constitute non-compliance under the rule.**

Within 30 days following the issuance of the *applicable* memorandum¹, if the facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or client contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule ; or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination).

Within 60 days following the issuance of the *applicable* memorandum³, if the facility demonstrates:

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple vaccine series, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% and has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to an enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plan of correction, termination).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 within **30 days⁵** *after the issuance of this memorandum* and address each of the following components:

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. There are

⁴ This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

⁵ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission examples include, but are not limited to:

- Reassigning staff who have not completed their primary vaccination series 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 staff who have not completed their primary vaccination series to follow additional, CDC-recommended precautions, such as adhering to universal source control and physical distancing measures in areas that are restricted from 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.
- Requiring at least weekly testing for exempted staff and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community transmission, in addition to following CDC recommendations for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with clients.

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

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 ICF/IID to the Equal Employment Opportunity Commission (EEOC) Compliance Manual on Religious Discrimination (<https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination>) for information 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, the health care ICF/IID covered by this IFC can address those individually. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and clients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the ICF/IID's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see the CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of the applicable memorandum:** 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 Plan

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 clinical precautions and considerations. 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 ICF/IID and/or its clients;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the ICF/IID continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the ICF/IID, 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
 - A process for which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations
 - 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 ICF/IID'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 yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (f)(3)(x)), including deadlines for staff to be vaccinated.
- The ICF/IID will provide a list of all staff and their vaccine status.
 - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
 - The ICF/IID must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The ICF/IID must also identify newly hired staff (hired in the last 60 days).
 - The ICF/IID must indicate the position or role of each staff member
- *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 policy and procedure to ensure all components are present.
- Surveyors will review any contingency plan developed to mitigate the spread of COVID-19 infections by the ICF/IID to include:
 - Requiring unvaccinated staff to follow [CDC-recommended clinical 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) 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 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 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 of 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 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

Level of Deficiency

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below:

- **Immediate Jeopardy:**
 - 40% or more of staff remain unvaccinated creating a likelihood of serious harm

OR

 - Did not meet the 100% staff vaccination rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.
 - .
- **Condition Level-**
 - Did not meet the 100% staff vaccination rate standard; **and**

- 1 or more components of the policies and procedures were not developed and implemented

OR,

- 21-39% of staff remain unvaccinated creating a likelihood of serious harm.

- **Standard Level:**

- 100% of all staff vaccinated and all new staff have received at least one dose; **and**
- 1 or more components of the policies and procedures were not developed and implemented

OR,

- Did not meet the 100% staff vaccination rate standard, but are making good faith efforts toward vaccine compliance.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The ICF/IID has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).

OR,

- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement.
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The ICF/IID has not met the requirement of staff vaccinated, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions above to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

- a. If the ICF/IID has no or has limited access to vaccine, and the ICF/IID has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- b. If the ICF/IID provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

Enforcement Actions

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

Community Mental Health Centers (CMHC) Attachment
Revised

This attachment is a supplement to and should be used in conjunction with the following memoranda: *QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-Revised effective December 28, 2021, QSO-22-09-ALL- *Revised* effective January 14, 2022, or QSO-22-11-ALL-*Revised* effective January 20, 2022.

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 [CDC](https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf), 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 contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, 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:

All CMHCs are required to achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the CMHC and/or its clients.

There may be many infrequent services and tasks performed in or for a 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 will begin surveying *facilities from states identified in each memorandum* for compliance 30 days after issuance of the *applicable* memorandum. 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 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 this memorandum unless exempted as required by law. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.**

Within 30 days following the issuance of the *applicable* memorandum¹, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule;**
- or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 60 days following the issuance of the *applicable* memorandum³, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g.,

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**

- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule**. The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 within **30 days⁵** *after the issuance of the applicable memorandum* and address each of the following components:

CMHCs 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. This requirement is not explicit and does not specify actions that must be taken; there are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission *examples including*, but *are* not limited to:

⁴ This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

⁵ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

- Reassigning staff who have not completed their primary vaccination series 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 staff who have not completed their primary vaccination series to follow additional, [CDC-recommended precautions](#), such as adhering to universal source control and physical distancing measures in areas that are restricted from 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.
- Requiring at least weekly testing for exempted staff, and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community transmission in addition to following [CDC recommendations](#) for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with clients.

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

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. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the CMHC's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of the applicable memorandum:** 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 Plan

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 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 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
 - A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other reasonable accommodations
 - 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 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 yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (c)(3)(x)), including deadlines for staff to be vaccinated.
- The CMHC will provide a list of all staff and their vaccine status.
 - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
 - The CMHC must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The CMHC must also identify newly hired staff (hired in the last 60 days).
 - The CMHC must indicate the position or role of each staff member
- *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 policy and procedure to ensure all components are present.
- Surveyors will review any contingency plan 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.*
- For each individual identified by the CMHC as vaccinated, surveyors will:
 - Review CMHC 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 CMHC as unvaccinated, surveyors will
 - Review CMHC 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 CMHC 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 CMHC 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

Level of Deficiency

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below:

- **Immediate Jeopardy:**
 - 40% or more of staff remain unvaccinated creating a likelihood of serious harm
- OR**
- Did not meet the 100% staff vaccination rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.
- **Condition Level-**
 - Did not meet the 100% staff vaccination rate standard; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

- 21-39% of staff remain unvaccinated creating a likelihood of serious harm.

- **Standard Level:**

- 100% of staff are vaccinated and all new staff have received at least one dose; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

- Did not meet the 100% staff vaccination rate standard, but are making good faith efforts toward vaccine compliance.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The CMHC has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).

OR,

- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement.
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The CMHC has not met the requirement of staff vaccinated, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

- a. If the CMHC has no or has limited access to vaccine, and the CMHC has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- b. If the CMHC provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

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 is a supplement to and should be used in conjunction with *the following memoranda: QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-Revised effective December 28, 2021, QSO-22-09-ALL- Revised effective January 14, 2022, or QSO-22-11-ALL-Revised effective January 20, 2022.

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 the [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 contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, 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 other arrangement. This also includes individuals under contract or 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

All HHAs are required to achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the HHA and/or its patients.

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, 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 will begin surveying *facilities from states identified in each memorandum* for compliance 30 days after issuance of the *applicable* memorandum, through a full survey for recertification or reaccréditation, federal initial surveys, or a complaint survey. Surveyors should focus on the staff that regularly work in the HHA (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., suspension, or out on Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave, would not count as unvaccinated staff for the 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 this memorandum unless exempted as required by law. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.**

Within 30 days following the issuance of the *applicable* memorandum¹, if the facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule;**
- or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to an enforcement action. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, termination).

Within 60 days following the issuance of the *applicable* memorandum³, if the facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple vaccine series, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to an enforcement action. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, termination.).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 within **30 days**⁵ of *issuance of the applicable memorandum* and address each of the following components:

HHAs 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. There are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission examples include, but are not limited to:

- Reassigning staff who have not completed their primary vaccination series to non-patient care areas, to duties that can be performed remotely (i.e., telework), or to duties which limit exposure to those most at risk (e.g., assign to patients who are not immunocompromised, unvaccinated);

⁴ This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

⁵ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

- Requiring staff who have not completed their primary vaccination series to follow additional, [CDC-recommended precautions](#), such as adhering to universal source control and physical distancing measures in areas that are restricted from patient access (e.g., staff meeting rooms, kitchen), even if the facility or service site is located in a county with low to moderate community transmission.
- Requiring at least weekly testing for exempted staff and staff who have not completed their primary vaccination series, until regulatory requirements are met, regardless of whether the facility or service site is located in a county with low to moderate community transmission, in addition to following CDC recommendations for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

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 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 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 HHA 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 HHA covered by this IFC can address those individually. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the provider or supplier's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see the CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of the applicable memorandum:** 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 Plan

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 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 HHA and/or its patients;
 - A process for ensuring that all required staff are fully vaccinated;
 - A process for ensuring that the HHA continues to follow all standards of infection prevention and control practice, for reducing the transmission and spread of COVID-19 in the HHA, 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
 - A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations
 - 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 HHA'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 yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (d)(3)(x)), including deadlines for staff to be vaccinated.
- The HHA will provide a list of all staff and their vaccine status.
 - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff. The HHA must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The HHA must also identify newly hired staff (hired in the last 60 days).
 - The HHA must indicate the position or role of each staff member
- *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 policy and procedure 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
 - 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) 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 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 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

Level of Deficiency

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below:

- **Immediate Jeopardy:**
 - 40% or more of staff remain unvaccinated creating a likelihood of serious harm
- OR**
- Did not meet the 100% staff vaccination rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.
- **Condition Level:**
 - Did not meet the 100% staff vaccination rate standard; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

- 21-39% of staff remain unvaccinated creating a likelihood of serious harm.
 - **Standard Level:**
 - 100% of staff are vaccinated and all new staff have received at least one dose; **and**
 - 1 or more components of the policies and procedures were not developed and implemented
- OR,**
- Did not meet the 100% staff vaccination rate standard, but are making good faith efforts toward vaccine compliance.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The HHA has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).
- OR,**
- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The HHA has not met the requirement of staff vaccinated, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

- a. If the HHA has no or has limited access to vaccine, and the HHA has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).

- b. If the HHA provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

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.

Psychiatric Residential Treatment Facility (PRTF) Attachment
Revised

This attachment is a supplement to and should be used in conjunction with *the following memoranda: QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-Revised effective December 28, 2021, QSO-22-09-ALL- Revised effective January 14, 2022, *or* QSO-22-11-ALL-Revised effective January 20, 2022

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 the [CDC](https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf), 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 contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. For COVID-19 vaccines, according to the CDC, is clinically contraindicated 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

All PRTFs are required to achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the PRTF and/or its residents.

There may be many infrequent services and tasks performed in or for a PRTF that is 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, 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 will begin surveying *facilities* for compliance 30 days after issuance of the applicable memorandum, through a full survey for recertification, federal initial surveys, or a complaint survey. Surveyors will be guided to focus on the vaccination status and PRTF policies to address vaccination for staff that regularly work in the PRTF (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended or moved to a role where they are no longer “providing care, treatment, or other services to the facility (e.g., suspension, or out on Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave), would not count as unvaccinated staff for the 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% constitute non-compliance under the rule.**

Within 30 days following the issuance of the *applicable* memorandum¹, if the facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule;**
- or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the facility is non-compliant under the rule. The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% and has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination).

Within 60 days following the issuance of the *applicable* memorandum³, if the facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g.,

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**

- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple vaccine series, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% and has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to an enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plan of correction, termination).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 PRTF policies and procedures must be implemented within **30 days⁵ after issuance of the *applicable memorandum*** and address each of the following components:

PRTFs must have a process for ensuring that all 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. There are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission examples include, but are not limited to:

- Reassigning staff who have not completed their primary vaccination series to non-resident care areas, to duties that can be performed remotely (i.e., telework), or to duties

⁴ This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

⁵ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

which limit exposure to those most at risk (e.g., assign to residents who are not immunocompromised, unvaccinated);

- Requiring staff who have not completed their primary vaccination series to follow additional, [CDC-recommended precautions](#), such as adhering to universal source control and physical distancing measures in areas that are restricted from 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.
- Requiring at least weekly testing for exempted staff and staff who have not completed their primary vaccination series, until the regulatory requirements are met, regardless of whether the facility or service site is located in a county with low to moderate community transmission, in addition to following CDC recommendations for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with residents.

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

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 should include 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 an 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 how the PRTF should evaluate and respond 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 PRTF covered by this IFC can address those individually. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and residents, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the PRTF's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see the CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of the applicable memorandum:** 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 Plan

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 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 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
 - A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations
 - 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 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 that are not yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (c)(c)(x)), including deadlines for staff to be vaccinated.
- The PRTF will provide a list of all staff and their vaccine status.
 - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
 - The PRTF must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The PRTF must also identify newly hired staff (hired in the last 60 days).
 - The PRTF must indicate the position or role of each staff member
- *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 policy and procedure to ensure all components are present.
- Surveyors will review any contingency plan 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
 - 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 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.) 2 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) 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 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 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 of 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 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

Level of Deficiency

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below:

- **Immediate Jeopardy:**
 - 40% or more of staff remain unvaccinated creating a likelihood of serious harm

OR

 - Did not meet the 100% staff vaccinate rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.
- **Condition Level-**
 - Did not meet the 100% staff vaccination rate standard; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

 - 21-39% of staff remain unvaccinated creating a likelihood of serious harm.

- **Standard Level:**
 - 100% of staff are vaccinated and all new staff have received at least one dose; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

- Did not meet the 100% staff vaccination rate standard, but are making good faith efforts toward vaccine compliance.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The PRTF has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).
- OR,**
- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement.
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The PRTF has not met the requirement of staff vaccinated, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

- a. If the PRTF has no or has limited access to vaccine, and the PRTF has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- b. If the PRTF provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

Enforcement Actions

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

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

This attachment is a supplement to and should be used in conjunction with *the following memoranda: QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment apply to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-Revised effective December 28, 2021, QSO-22-09-ALL-Revised effective January 14, 2022, or QSO-22-11-ALL-Revised effective January 20, 2022.

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 will begin surveying *facilities from states identified in each memorandum* for compliance 30 days from the date of issuance of *the applicable* memorandum. 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% constitute non-compliance under the rule.** Non-compliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance.

Within 30 days after the issuance of the *applicable* memorandum¹, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule.**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

² This information will be communicated through the CMS Form-2567, using the Automated Survey Process Environment(ASPEN) tag F888.

is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to an enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

Within 60 days after the issuance of the *applicable* memorandum³ if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule.**
- Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple vaccine series, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to an enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination, etc.).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to enforcement action.

Policies and Procedures:

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

Requirements which must be implemented within **30 days of the issuance of the *applicable* memorandum:**

§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

³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

⁴ This information will be communicated through the CMS Form-2567, using the Automated Survey Process Environment (ASPEN) tag F888

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. There are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission including, *examples include* but *are* not limited to:

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

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive and represent actions that can be implemented. However, facilities can choose other precautions 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. This can be used to determine how unvaccinated staff are assigned, to determine if additional precautions have been implemented to prevent COVID-19 transmission.

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. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the facility's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

§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.

Regulatory Provisions implemented **60 days after the issuance of the *applicable* memorandum***:
§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.

* If 60 days falls on a weekend or designated Federal Holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

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 resident and 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 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. Surveyors will review for compliance with this requirement on all initial certification, standard recertification surveys, as well as all complaint 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. For Life Safety Code (LSC)-only complaint or LSC-only follow-up surveys, staff vaccination requirements are not required to be investigated.*

Offsite Preparation – CDC NHSN Data Verification:

Surveyors should verify facility reporting of vaccine data to NHSN as a part of offsite preparation prior to going onsite for any initial, certification, or complaint survey. This will help them determine if there are inaccuracies in the facility's vaccine NHSN reporting or with the facility's process for tracking and securely documenting the COVID-19 vaccination status for all staff [per §483.80(i)(3)(iv)]. Surveyors can obtain the percent of staff who received a completed COVID-19 vaccination for any facility by accessing the file through [this link](#), which is also posted on the [COVID-19 Nursing Home Data - Centers for Medicare & Medicaid Services Data \(cms.gov\)](#) webpage (click on the link in the section that states "Listing of vaccination rates for individual nursinghomes").

In the file, each nursing home's percent of staff vaccinated as reported to NHSN is listed in the column titled, "Recent Percentage of Staff who are Fully Vaccinated".

The percent of staff vaccinated as reported through NHSN and as identified through the onsite survey should be reasonably consistent, although the numbers may not be exactly the same. For example, there is a time lag between when facilities submit data to NHSN and when the data is posted publicly. Therefore, the information presented to the surveyor may differ from the data posted publicly.

- If the percent of staff vaccinated from both sources (NHSN and onsite) is reasonably consistent (e.g., within 10% of each other), no further investigation is required for data tracking or reporting.
- If the percent of staff vaccinated differs between both sources (e.g., greater than 10% variation), surveyors should interview the facility and review the documentation to determine which source is incorrect, and the facility's explanation for the discrepancy.
 - If the surveyor determines that the information presented to the surveyor is incorrect (and NHSN is correct), or both sources are incorrect, this likely demonstrates the facility's failure to have a process for tracking and securely documenting the COVID-19 vaccination status for all staff [per §483.80(i)(3)(iv)], and F-888 should be cited.
 - If the surveyor determines that the information reported to NHSN is incorrect (and the information reviewed onsite is correct), the surveyor should instruct the facility to immediately correct the information in the NHSN system. If the surveyor identifies that a data field is blank, instruct facilities to obtain additional information on submitting data to NHSN by emailing NH_COVID_Data@cms.hhs.gov.

NOTE: Surveyors should be aware that the determination that one source is incorrect does not automatically infer that the other source is correct.

Citing Noncompliance - Scope and Severity:

Facility staff vaccination rates under 100% constitute non-compliance under the rule. The level of severity will be cited based on the level of harm, or likelihood of harm for residents. For example, facilities with a high percentage of unvaccinated staff, several COVID-19 infections, and gaps in their policy and procedures, represent a higher risk of harm to residents. Therefore, these facilities would be cited at a higher level of severity than facilities with few unvaccinated staff, no COVID-19 infections, and compliant policy and procedures.

NOTE: Failure of contract staff to provide evidence of vaccination status reflects noncompliance and should be cited at F888 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 at 483.80(i)(3)(ii).

Note: The descriptions below addressing the “expected minimum threshold of staff vaccinated” do not include the 14-day waiting period as identified by CDC for full vaccination. Rather they represent the completed vaccine series (i.e., one dose of a single-dose vaccine, or the final dose of a two-dose vaccine series). From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these scope and severity determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds yet pose a threat to patient health and safety not otherwise addressed by the criteria below.

Severity will be based on the following criteria:

- Level 4 - Immediate Jeopardy (IJ)
- **Noncompliance resulting in serious harm or death:**
 - Did not meet the requirement of staff vaccinated **or** has no policies and procedures developed or implemented; **and**
 - 3 or more resident infections in the last 4 weeks resulting in at least one resident experiencing hospitalization (i.e., serious harm) or death.

OR,

Noncompliance resulting in a likelihood for serious harm or death:

- Did not meet the requirement of staff vaccinated; **and**
- 3 or more resident infections in the last 4 weeks that did not result in serious harm or death; **and**
- One of the following:
 - Any observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE so F880 would also be cited); **or**
 - 1 or more components of the policies and procedures to ensure staff vaccination were not developed or implemented.

OR,

- More than 40% of staff are unvaccinated **and** there is evidence of a lack of effort to increase staff vaccination rates.

- Level 3: Actual Harm that is not IJ
 - Did not meet the requirement of staff vaccinated; **and**
 - 3 or more resident infections in the last 4 weeks which did not result in hospitalization (i.e., serious harm) or death, or the likelihood for IJ for one or more residents; **and**
 - 1 or more components of the policies and procedures were not developed and implemented.
- Level 2: No actual harm w/potential for more than minimal harm that is not IJ

- Did not meet the requirement of staff vaccinated; **and**
 - No resident *infections*
 - OR,**
 - Did not meet the requirement of staff vaccinated; **and**
 - 1 or more components of the policies and procedures were not developed and implemented.
- Level 1:
 - Met the requirement of staff vaccinated; **and**
 - 1 or more components of the policies and procedures to ensure staff vaccination were not developed and implemented (must be cited as widespread (“C”).

Scope:

Scope is based on the percent of staff vaccinated because lower vaccination rates are associated with higher numbers of COVID-19 resident cases. For example, a study of how the vaccine prevents COVID-19 outbreaks (<https://emergency.cdc.gov/han/2021/han00447.asp>) found that:

- Nursing homes where vaccination coverage of staff is 75% or lower experienced higher rates of preventable COVID infection; and
- The COVID-19 resident case rate in nursing homes with 45-59% of staff vaccinated was approximately twice as high as facilities with over 60% of staff vaccinated.

In other words, for facilities with few staff unvaccinated, we expect the facility to be at a lower risk for an isolated number of resident infections. Conversely, in facilities with a higher percentage of staff unvaccinated (e.g., >40%), there is an increased risk of widespread resident infections through the facility. Therefore, the scope will be based on the following criteria:

- Isolated: **1% or more, but less than 25% of staff** are unvaccinated (76% – 99% of staff are vaccinated).
- Pattern: **25% or more, but less than 40% of staff** are unvaccinated (61% – 75% of staff are vaccinated).
- Widespread: **40% or more of staff are unvaccinated** (0% - 60% of staff are vaccinated), OR 1 or more components of the policies and procedures listed above were not developed and implemented.

Note: Facilities that have met the requirement for staff vaccination will not be cited unless there is noncompliance with the development or implementation of policies and procedures. However, facilities may still be cited for noncompliance with other requirements, such as failure to implement an effective infection prevention and control program contributing to resident COVID-19 infections (F-880). To view this information in the Severity/Scope Grid, see Table 1 below.

Plan of Correction:

To Qualify for Substantial Compliance and Clear the Citation:

- The facility has met the requirement of staff vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff); **or**
- The combined number of staff that are vaccinated (have received a single dose of a single-dose vaccine, or all doses of a multiple vaccine series) or have received at least one dose of a

multiple vaccine series meet the requirement of staff vaccinated.

- Staff that have received at least one dose of a multiple vaccine series must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Level 1 (“C”):

- The facility has not met the requirement of staff vaccinated but has provided evidence that some of the unvaccinated staff have obtained their first dose, **and** other unvaccinated staff are scheduled for their first dose. For example, the citation at Level 1 would continue if there is evidence that 50% of staff who were identified as unvaccinated have received one dose of a multiple vaccine series with their second dose scheduled, or are scheduled to receive one dose of a single-dose vaccine series.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal:

Plans of correction or Immediate Jeopardy removal plans for noncompliance at F888 should be reviewed to ensure they include the following:

- Correcting any gaps in the facility’s policies and procedures.
- Implementation of the facility’s contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions (see §483.80(i)(3)(iii)) to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the scope and severity of a citation and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the scope, severity, and/or enforcement is adjusted).

- a) 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 health department and pharmacies).
- b) 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 facility staff vaccination rate is 90% or more, there is no resident outbreak in the previous 4 weeks, and all policies and procedures were developed and implemented, per Table 1 this would be cited “D”. However, if the facility provides evidence that it has made a good faith effort by taking aggressive steps to get all staff vaccinated, surveyors may lower the citation to “A”.

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

Table 1: Scope and Severity Grid

Severity & Scope for F888	<u>ISOLATED</u> 1% <u>or more</u> , but <u>less than 25%</u> of staff are unvaccinated (76% – 99% of staff are vaccinated).	<u>PATTERN</u> 25% <u>or more</u> , but <u>less than 40%</u> of staff are unvaccinated (61% – 75% of staff are vaccinated).	<u>WIDESPREAD</u> 40% <u>or more</u> of staff are unvaccinated (0% - 60% of staff are vaccinated), OR 1 or more components of the P&Ps were not developed and implemented.
<p>Level 4 - Immediate Jeopardy: Noncompliance resulting in serious harm or death:</p> <ul style="list-style-type: none"> Did not meet the requirement of staff vaccinated <i>or has no policies and procedures developed or implemented</i>; and 3 or more resident infections in the last 4 weeks resulting in at least one resident experiencing hospitalization (i.e., serious harm) or death. <p>OR, Noncompliance resulting in a likelihood for serious harm or death:</p> <ul style="list-style-type: none"> Did not meet the requirement of staff vaccinated; and 3 or more resident infections in the last 4 weeks that did not result in serious harm or death; and One of the following: <ul style="list-style-type: none"> Any observations of noncompliant infection control practices by staff; or 1 or more components of the policies and procedures were not developed or implemented. <p>OR,</p> <ul style="list-style-type: none"> More than 40% of staff are unvaccinated and there is evidence of a lack of effort to increase staff vaccination rates. 	J	K	L
<p>Level 3 – Actual Harm:</p> <ul style="list-style-type: none"> Did not meet the requirement of staff vaccinated; and 3 or more resident infections in the last 4 weeks which did not result in hospitalization (i.e., serious harm) or death, or the likelihood for IJ for one or more residents; and 1 or more components of the policies and procedures were not developed and implemented 	G	H	I
<p>Level 2: No actual harm w/potential for more than minimal harm that is not IJ:</p> <ul style="list-style-type: none"> Did not meet the requirement of staff vaccinated; and No resident infections <p>OR,</p> <ul style="list-style-type: none"> Did not meet the <i>requirement</i> of staff vaccinated; and 1 or more components of the policies and procedures were not developed and implemented. 	D	E	F
<p>Level 1: No actual harm w/potential for minimal harm:</p> <ul style="list-style-type: none"> Met the requirement of staff vaccinated; and 1 or more components of the P&Ps were not developed and implemented (cited as widespread (“C”). 	A	B	C

Ambulatory Surgical Centers (ASC) Attachment
Revised

This attachment is a supplement to and should be used in conjunction with *the following memoranda: QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-Revised effective December 28, 2021, QSO-22-09-ALL-Revised effective January 14, 2022, or QSO-22-11-ALL-Revised effective January 20, 2022.

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

All ASCs are required to achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the ASC and/or its patients.

There may be many infrequent services and tasks performed in or for a health care ASC that is 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 will begin surveying *facilities from states identified in each memorandum* for compliance 30 days after the issuance of the *applicable* memorandum. Surveyors *should* focus on the staff that regularly work in the ASC (e.g., weekly), using a phased-in approach as described below.

NOTE: Facility staff who have been suspended or on extended leave e.g., Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave, would not count as unvaccinated staff for the 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 memorandum unless exempted as required by law. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.**

Within 30 days following the issuance of the *applicable* memorandum¹, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 60 days following the issuance of the *applicable* memorandum³, if the facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

doses of a multiple vaccine series, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule**. The facility will receive notice of their non-compliance with the 100% standard. The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% and has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to an enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plan of correction, termination).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 within **30 days⁵ after the issuance of the *applicable memorandum*** and address each of the following components:

ASCs 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. There are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission *examples include* but *are* not limited to:

- Reassigning staff who have not completed their primary vaccination series to non-patient care areas, to duties that can be performed remotely (i.e., telework), or to duties which limit exposure to those most at risk (e.g., assign to patients who are not immunocompromised, unvaccinated);
- Requiring staff who have not completed their primary vaccination series to follow additional, [CDC-recommended precautions](#), such as adhering to universal source control

⁴ This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

⁵ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

and physical distancing measures in areas that are restricted from patient access (e.g., staff meeting rooms, kitchen), even if the facility or service site is located in a county with low to moderate community transmission.

- Requiring at least weekly testing for exempted staff and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community in addition to following CDC recommendations for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

The ASCs 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;
- 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. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the ASC's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of the applicable memorandum:** 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 Plan

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.

* If the 60 days falls on a weekend or designated Federal Holiday, CMS will use enforcement discretion to initiate enforcement on the following business day.

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 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 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
 - A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations;
 - 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 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 yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (c)(3)(x)), including deadlines for staff to be vaccinated.
- The ASC will provide a list of all staff and their vaccine status.
 - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
 - The ASC must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The ASC must also identify newly hired staff (hired in the last 60 days).
 - The ASC must indicate the position or role of each staff member.
- *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 policy and procedure 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
 - 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 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 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 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

Level of Deficiency

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below:

- **Immediate Jeopardy:**
 - 40% or more of staff remain unvaccinated creating a likelihood of serious harm
- OR**
- Did not meet the 100% staff vaccination rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.
- **Condition Level:**
 - Did not meet the 100% staff vaccination rate standard ; **and**
 - 1 or more components of the policies and procedures were not developed and implemented.
- OR,**
- 21-39% of staff remain unvaccinated creating a likelihood of serious harm.

- **Standard Level:**

- 100% of staff are vaccinated and all new staff have received at least one dose; **and**
 - 1 or more components of the policies and procedures were not developed and implemented.

OR,

- Did not meet the 100% staff vaccination rate standard, but are making good faith efforts toward vaccine compliance.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The ASC has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff)
- OR,**
- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) requirement.
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The ASC has not met the requirement of staff vaccinated, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

- a. If the ASC has no or has limited access to vaccine, and the ASC has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).

- b. If the ASC provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

Enforcement Actions

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

Hospice Attachment
Revised

This attachment is a supplement to and should be used in conjunction with *the following memoranda: QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-*Revised* effective December 28, 2021, QSO-22-09-ALL- *Revised* effective January 14, 2022, *or* QSO-22-11-ALL-*Revised* effective January 20, 2022.

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 [CDC](https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf), 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 contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, 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>)

Background

All hospices are required to achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the hospice and/or its patients.

There may be many infrequent services and tasks performed in or for a hospice that is 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 will begin surveying *facilities from states identified in each memorandum* for compliance 30 days after issuance of the *applicable* memorandum, through a full survey for recertification or reaccreditation, federal initial surveys, or a complaint survey. 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 are on extended leave (e.g., suspension, or out on Family and Medical Leave Act (FMLA) leave, or Worker’s Compensation Leave, would not count as unvaccinated staff for the 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% constitute non-compliance under the rule.**

Within 30 days following the issuance of the *applicable* memorandum¹, if the facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule;** **or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination).

Within 60 days following the issuance of the *applicable* memorandum³, if the facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

³ ³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**

- Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple vaccine series, or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule**. The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% and has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to an enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plan of correction, termination).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 within **30 days⁵** *after issuance of the applicable memorandum* and address each of the following components:

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. There are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission examples include, but are not limited to:

- Reassigning staff who have not completed their primary vaccination series to non-patient care areas, to duties that can be performed remotely (i.e., telework), or to duties which limit exposure to those most at risk (e.g., assign to patients who are not immunocompromised, unvaccinated);

⁴ This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

⁵ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

- Requiring staff who have not completed their primary vaccination series to follow additional, [CDC-recommended precautions](#), such as adhering to universal source control and physical distancing measures in areas that are restricted from patient access (e.g., staff meeting rooms, kitchen), even if the facility or service site is located in a county with low to moderate community transmission.
- Requiring at least weekly testing for exempted staff and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community transmission, in addition to following CDC recommendations for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

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 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 hospices 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, the hospice covered by this IFC can address those individually. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the hospice's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of the applicable memorandum:** 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 Plan

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 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 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
 - A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations;
 - 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 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 that are not yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (d)(3)(x)), including deadlines for staff to be vaccinated.
- The hospice will provide a list of all staff and their vaccine status.
 - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
 - The hospice must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The hospice must also identify newly hired staff (hired in the last 60 days).
 - The hospice must indicate the position or role of each staff member
- *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 policy and procedure to ensure all components are present.
- Surveyors will review any contingency plan developed to mitigate the spread of Covid-19 infections by the hospice may include:
 - Requiring unvaccinated staff to follow additional, [CDC-recommended precautions](#), such 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) 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 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 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 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

Level of Deficiency

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below:

- **Immediate Jeopardy:**
 - 40% or more of staff remain unvaccinated creating a likelihood of serious harm

OR

 - Did not meet the 100% staff vaccination rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) and 1 or more components of the policies and procedures were not developed or implemented.
- **Condition Level-**
 - Did not meet the 100% staff vaccination rate standard; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

 - 21-39% of staff remain unvaccinated creating a likelihood of serious harm.
- **Standard Level:**

- 100% of staff are vaccinated and all new staff have received at least one dose; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

- Did not meet the 100% staff vaccination rate standard, but are making good faith efforts toward vaccine compliance.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The hospice has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).

OR,

- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement.
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The hospice has not met the requirement of staff vaccinated, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

- a. If the hospice has no or has limited access to vaccine, and the hospice has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- b. If the hospice provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

Enforcement Actions

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

Hospital Attachment

Revised

This attachment is a supplement to and should be used in conjunction with the following memoranda: *QSO-22-07-ALL-Revised*, *QSO-22-09-ALL-Revised*, and *QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. *Implementation of this guidance will occur according to the* timeframes and parameters identified in either *QSO-22-07-ALL-Revised* effective December 28, 2021, *QSO-22-09-ALL- Revised* effective January 14, 2022, or *QSO-22-11-ALL-Revised* effective January 20, 2022.

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 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 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 [CDC](https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf), 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 contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, 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

All hospitals are required to achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the hospital and/or its patients.

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

Surveying for Compliance

Surveyors will begin surveying facilities from states identified in each memorandum for compliance 30 days after the issuance of the *applicable* memorandum.. 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 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.

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 memorandum unless exempted as required by law. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.** Non-compliance does not necessarily lead to termination, and facilities will generally be given opportunities to return to compliance.

Within 30 days following the issuance of the *applicable* memorandum¹, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule.**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to an enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and/or termination).

Within 60 days following the issuance of the *applicable* memorandum³, if the facility demonstrates--

- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule.**
- Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple vaccine series, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice⁴ of their non-compliance with

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

⁴ This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to an enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and/or termination).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 within **30 days⁵** after the issuance of the *applicable* memorandum and address each of the following components:

Hospitals 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. This requirement is not explicit and does not specify actions that must be taken; there are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission examples, including, but not limited to:

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

⁵ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

whether the facility or service site is located in a county with low to moderate community transmission, in addition to following CDC recommendations for testing unvaccinated in facilities located in counties with substantial to high community transmission.

- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

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, 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 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 hospitals 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. An example of an accommodation for an unvaccinated employee with a qualifying exemption could

include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the hospital's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of the applicable memorandum:** 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 Plan

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 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 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
 - A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations;
 - 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 yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (g)(3)(x)), including deadlines for staff to be vaccinated.
- The hospital will provide a list of all staff and their vaccine status:

- Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
 - The provider or supplier must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The hospital must also identify newly hired staff (hired in the last 60 days).
 - The hospital must indicate the position or role of each staff member
- *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 policy and procedure to ensure all components are present.
- Surveyors will review any contingency plan 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 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 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

Level of Deficiency

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below:

- **Immediate Jeopardy:**
 - 40% or more of staff remain unvaccinated creating a likelihood of serious harm
OR
 - Did not meet the 100% staff vaccination rate standard ; observations of noncompliant infection control practices by staff (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.
- **Condition Level:**
 - Did not meet the 100% staff vaccination rate standard; **and**
 - 1 or more components of the policies and procedures were not developed and implemented.
 - OR,**
 - 21-39% of staff remain unvaccinated creating a likelihood of serious harm.
- **Standard Level:**
 - 100% of staff are vaccinated and all new staff have received at least one dose; **and**
 - 1 or more components of the policies and procedures were not developed and implemented.
 - OR,**
 - Did not meet the 100% staff vaccination rate standard, but are making good faith efforts toward vaccine compliance.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The hospital has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).

OR

- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement.
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The hospital has not met the requirement, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

- a. If the hospital has no or has limited access to vaccine, and the hospital has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- b. If the hospital provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

Enforcement Actions

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

Critical Access Hospitals (CAH) Attachment
Revised

This attachment is a supplement to and should be used in conjunction with the following memoranda: *QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-*Revised* effective December 28, 2021, QSO-22-09-ALL- Revised effective January 14, 2022, *or* QSO-22-11-ALL-*Revised* effective January 20, 2022.

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 [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 contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, 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:

All CAHs are required to achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the CAH and/or its patients.

There may be many infrequent services and tasks performed in or for a CAH that is conducted by “one-off” vendors, volunteers, and professionals. CAHs are not required to ensure the vaccination of individuals who very infrequently provide ad hoc non-healthcare services (such as annual elevator inspection), 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 will begin surveying *facilities from states identified in each memorandum* for compliance 30 days after issuance of the *applicable* memorandum. 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 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 this memorandum unless exempted as required by law. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.**

Within 30 days following the issuance of the *applicable* memorandum¹, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule;** **or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 60 days following the issuance of the *applicable* memorandum³, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule**. The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 within **30 days**⁵ *after the issuance of the applicable memorandum* and address each of the following components:

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. This requirement is not explicit and does not specify actions that must be taken; there are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission *examples including*, but *are* not limited to:

- Reassigning staff who have not completed their primary vaccination series to non-patient care areas, to duties that can be performed remotely (i.e., telework), or to duties which limit exposure to those most at risk (e.g., assign to patients who are not immunocompromised, unvaccinated);
- Requiring staff who have not completed their primary vaccination series to follow additional, [CDC-recommended precautions](#), such as adhering to universal source control and physical distancing measures in areas that are restricted from patient access (e.g.,

⁴ This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

⁵ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

staff meeting rooms, kitchen), even if the facility or service site is located in a county with low to moderate community transmission.

- Requiring at least weekly testing for exempted staff, and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community transmission in addition to following [CDC recommendations](#) for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients.

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

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 exemption an 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. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the CAH's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of the applicable memorandum:** 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 Plan

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 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 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
- A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations;
- 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 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
- Contingency plans for staff that are not yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a

temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (f)(3)(x)), including deadlines for staff to be vaccinated.

- The CAH will provide a list of all staff and their vaccine status.
 - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
 - The CAH must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The CAH must also identify newly hired staff (hired in the last 60 days).
 - The CAH must indicate the position or role of each staff member
- *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 policy and procedure to ensure all components are present.
- Surveyors will review any contingency plan 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):
 - 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 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

Level of Deficiency

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below

- **Immediate Jeopardy:**
 - 40% or more of staff remain unvaccinated creating a likelihood of serious harm

OR

 - Did not meet the 100% staff vaccination rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.
- **Condition Level-**
 - Did not meet the 100% staff vaccination rate standard; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

 - 21 to 39% of staff remain unvaccinated creating a likelihood of serious harm.
- **Standard Level:**
 - Met the expected minimum threshold of staff are vaccinated and all new staff have received at least one dose; **and**

- 1 or more components of the policies and procedures were not developed and implemented

OR,

- Did not meet the 100% staff vaccination rate standard, but are making good faith efforts toward vaccine compliance.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The CAH has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).
- OR**
- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement.
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The CAH has not met the requirement of staff vaccinated, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions see to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

- a. If the CAH has no or has limited access to vaccine, and the CAH has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- a. If the CAH provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

Enforcement Actions

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

End-Stage Renal Disease Facility (ESRD) Facility Attachment
Revised

This attachment is a supplement to and should be used in conjunction with *the following memoranda: QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-*Revised* effective December 28, 2021, QSO-22-09-ALL- *Revised* effective January 14, 2022, *or* QSO-22-11-ALL-*Revised* effective January 20, 2022.

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 [CDC](https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf), 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 contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, 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:

All ESRD Facilities are required to achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the ESRD Facility and/or its patients.

There may be many infrequent services and tasks performed in or for a 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 will begin surveying *facilities from states identified in each memorandum* for compliance 30 days after issuance of the *applicable* memorandum. 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 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 this memorandum unless exempted as required by law. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.**

Within 30 days after issuance of the *applicable* memorandum¹, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient contact, are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule;** **or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 60 days after issuance of the *applicable* memorandum³, if the facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule;** **or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant**

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

under the rule. The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 within **30 days⁵ *after the issuance of the applicable memorandum*** and address each of the following components:

ESRD Facilities 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. This requirement is not explicit and does not specify actions that must be taken; there are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission *examples including*, but *not* limited to:

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

⁴ This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

⁵ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

- Requiring at least weekly testing for exempted staff, and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community, in addition to following [CDC recommendations](#) for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients.

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

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. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the ESRD's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of the applicable memorandum:** 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 Plan

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 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 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
- A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations
- 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 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 yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (b)(3)(x)), including deadlines for staff to be vaccinated.

- The ESRD Facility will provide a list of all staff and their vaccine status.
 - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
 - The ESRD Facility must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The ESRD Facility must also identify newly hired staff (hired in the last 60 days).
 - The ESRD Facility must indicate the position or role of each staff member

○ *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 policy and procedure to ensure all components are present.
- Surveyors will review any contingency plan 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.*

Non-direct care contracted workers are not to be included in the staff vaccination rate calculations.

- *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

Level of Deficiency

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below:

- **Immediate Jeopardy:**
 - 40% or more of staff remain unvaccinated creating a likelihood of serious harm

OR

 - Did not meet the 100% staff vaccination rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.
- **Condition Level:**
 - Did not meet the 100% staff vaccination rate standard; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

 - 21-39% of staff remain unvaccinated creating a likelihood of serious harm.
- **Standard Level:**

- 100% of staff are vaccinated and all new staff have received at least one dose; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

- Did not meet the 100% staff vaccination rate standard, but are making good faith efforts toward vaccine compliance.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The ESRD Facility has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).
- OR,**
- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement.
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The ESRD Facility has not met the requirement of staff vaccinated, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

- a. If the ESRD Facility has no or has limited access to vaccine, and the ESRD Facility has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- b. If the ESRD Facility provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

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 is a supplement to and should be used in conjunction with *the following memoranda: QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-Revised effective December 28, 2021, QSO-22-09-ALL-Revised effective January 14, 2022, or QSO-22-11-ALL-Revised effective January 20, 2022.

§ 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 [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 contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, 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:

All HITs achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the HIT and/or its patients.

There may be many infrequent services and tasks performed in or for a HIT that is 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 will begin surveying *facilities from states identified in each memorandum* for compliance 30 days after issuance of the *applicable* memorandum. 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 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 this memorandum unless exempted as required by law. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.**

Within 30 days after issuance of the *applicable* memorandum¹, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule;** **or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 60 days after the issuance of the *applicable* memorandum³, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to additional enforcement action. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 within **30 days**⁵ *after the issuance of the applicable memorandum* and address each of the following components:

HITs 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. This requirement is not explicit and does not specify actions that must be taken; there are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission *examples including*, but *are* not limited to:

- Reassigning staff who have not completed their primary vaccination series to non-patient care areas, to duties that can be performed remotely (i.e., telework), or to duties

⁴ This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

⁵ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

which limit exposure to those most at risk (e.g., assign to patients who are not immunocompromised, unvaccinated);

- Requiring staff who have not completed their primary vaccination series to follow additional, [CDC-recommended precautions](#), such as adhering to universal source control and physical distancing measures in areas that are restricted from patient access (e.g., staff meeting rooms, kitchen), even if the facility or service site is located in a county with low to moderate community transmission.
- Requiring at least weekly testing for exempted staff, and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community transmission in addition to following [CDC recommendations](#) for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients.

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

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. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the HIT's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of the applicable memorandum:** 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 Plan

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 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
 - A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations
 - 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 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 that are not yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (c)(3)(x), including deadlines for staff to be vaccinated.
- The HIT will provide a list of all staff and their vaccine status.
 - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
 - The HIT must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The HIT must also identify newly hired staff (hired in the last 60 days).
 - The HIT must indicate the position or role of each staff member
- *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 policy and procedure to ensure all components are present.
- Surveyors will review any contingency plan 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
 - 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 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

Level of Deficiency

For instances of non-compliance with accreditation standards identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%.

- **Immediate Jeopardy:**

- 40% or more of staff remain unvaccinated creating a likelihood of serious harm

OR

- Did not meet the 100% staff vaccination rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.

- **Condition Level or equivalent:**

- Did not meet the 100% staff vaccination rate standard; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

- 21-39% of staff remain unvaccinated creating a likelihood of serious harm.

- **Standard Level or equivalent:**

- 100% of staff are vaccinated and all new staff have received at least one dose; **and**

- 1 or more components of the policies and procedures were not developed and implemented

OR,

- Did not meet the 100% staff vaccination rate standard, but are making good faith efforts toward vaccine compliance.

Plan of Correction

To Qualify for Substantial Compliance with accreditation standards and Clear the Deficiency:

- The HIT has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).
- **OR,**
- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement.
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance with accreditation standards, but the Deficiency Remains at Standard Level or Equivalent:

- The HIT has not met the requirement of staff vaccinated, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for the correction of deficiencies should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the level of deficiency and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: a noncompliance is still identified, only the deficiency level and enforcement is adjusted).

- a. If the HIT has no or has limited access to vaccine, and the HIT has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- b. If the HIT provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

Enforcement Actions

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

Comprehensive Outpatient Rehabilitation Facilities Attachment
Revised

This attachment is a supplement to and should be used in conjunction with the following memoranda: *QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-Revised effective December 28, 2021, QSO-22-09-ALL-Revised effective January 14, 2022, or QSO-22-11-ALL-Revised effective January 20, 2022.

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 [CDC](https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf), 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 contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, 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:

All CORFs are required to achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the CORF and/or its patients.

There may 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 will begin surveying *facilities from states identified in each memorandum* for compliance 30 days after issuance of the *applicable* memorandum. 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 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 this memorandum unless exempted as required by law. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.**

Within 30 days following the issuance of the *applicable* memorandum¹, if the facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule.;**
or
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

Within 60 days following the issuance of the *applicable* memorandum³, if the facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule; or**
- Less than 100% of all staff have received at least one dose of a single-dose vaccine, or all doses of a multiple vaccine series, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule**. The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% and has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to an enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plan of correction, termination).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 within **30 days⁵** *after the issuance of the applicable memorandum* and address each of the following components:

CORF's 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.

^{3 3} If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

⁴ This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

⁵ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

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. This requirement is not explicit and does not specify actions that must be taken; there are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission *examples including*, but *are* not limited to:

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

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

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 s 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. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the CORF's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of the applicable memorandum:** 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 Plan

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 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 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
 - A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations
 - 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 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 yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (n)(3)(x)), including deadlines for staff to be vaccinated.
- The CORF will provide a list of all staff and their vaccine status.
 - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
 - The CORF must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The CORF must also identify newly hired staff (hired in the last 60 days).
 - The CORF must indicate the position or role of each staff member
- *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 policy and procedure to ensure all components are present.
- Surveyors will review any contingency plan 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

Level of Deficiency

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below:

- **Immediate Jeopardy:**
 - 40% or more of staff remain unvaccinated creating a likelihood of serious harm
- OR**
- Did not meet the 100% staff vaccination rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.
- **Condition Level-**

- Did not meet the 100% staff vaccination rate standard; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

- 21-39% of staff remain unvaccinated creating a likelihood of serious harm.

• **Standard Level:**

- 100% of staff are vaccinated and all new staff have received at least one dose; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

- Did not meet the 100% staff vaccination rate standard, but are making good faith efforts towards compliance.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The CORF has met the requirements of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).
- **OR,**
- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement.
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The CORF has not met the requirement of staff vaccinated, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

- a. If the CORF has no or has limited access to vaccine, and the CORF has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- b. If the CORF provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

Enforcement Actions

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

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

This attachment is a supplement to and should be used in conjunction with *the following memoranda: QSO-22-07-ALL-Revised, QSO-22-09-ALL-Revised, and QSO 22-11-ALL-Revised* memorandum: Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination.

While the memoranda noted above apply to specific states, the regulations and guidance described in this attachment applies to all states. Implementation of this guidance will occur according to the timeframes and parameters identified in either QSO-22-07-ALL-Revised effective December 28, 2021, QSO-22-09-ALL-Revised effective January 14, 2022, or QSO-22-11-ALL-Revised effective January 20, 2022.

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 [CDC](https://www.cdc.gov/vaccines/imz/downloads/#vaccine-booster), 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 contraindication” refers to conditions or risks that precludes the administration of a treatment or intervention. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, 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:

All RHCs/FQHCs achieve a 100% vaccination rate for their staff through the development of a policy to address vaccination applicable to all staff who provide any care, treatment, or other services for the RHC/FQHC and/or its patients.

There may be many infrequent services and tasks performed in or for a 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 will begin surveying *facilities from states identified in each memorandum* for compliance 30 days after issuance of the *applicable* memorandum. 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 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 this memorandum unless exempted as required by law. **Facility staff vaccination rates under 100% constitute non-compliance under the rule.**

Within 30 days after issuance of the *applicable* memorandum¹, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received at least one dose of COVID-19 vaccine or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule;** **or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant under the rule.** The facility will receive notice² of their non-compliance with the 100% standard. A facility that is above 80% **and** has a plan to achieve a 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 60 days after issuance of the *applicable* memorandum³, if a facility demonstrates:

- Policies and procedures are developed and implemented for ensuring all facility staff, regardless of clinical responsibility or resident contact are vaccinated for COVID-19, including all required components of the policies and procedures specified below (e.g., related to tracking staff vaccinations, documenting medical and religious exemptions, etc.); **and**
- 100% of staff have received the necessary doses to complete the vaccine series (i.e., one dose of a single-dose vaccine or all doses of a multiple vaccine series) or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is compliant under the rule;** **or**
- Less than 100% of all staff have received at least one dose of COVID-19 vaccine, or have a pending request for, or have been granted a qualifying exemption, or are identified as having a temporary delay as recommended by the CDC, the **facility is non-compliant**

¹ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

² This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

³ If 60 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day.

under the rule. The facility will receive notice⁴ of their non-compliance with the 100% standard. A facility that is above 90% **and** has a plan to achieve a 100% staff vaccination rate within 30 days would not be subject to additional enforcement action. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety. Facilities that do not meet these parameters could be subject to additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction and termination.).

Within 90 days and thereafter following issuance of the *applicable* memorandum, facilities failing to maintain compliance with the 100% standard may be subject to 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 within **30 days⁵ after the issuance of the *appropriate memorandum*** and address each of the following components:

RHCs/FQHCs 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. **This requirement is not explicit and does not specify actions that must be taken;** there are a variety of actions or job modifications a facility can implement to potentially reduce the risk of COVID-19 transmission *examples including*, but *are* not limited to:

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

⁴ This information will be communicated through the CMS Form-2567, using the appropriate Automated Survey Process Environment (ASPEN).

⁵ If 30 days falls on a weekend or designated federal holiday, CMS will use enforcement discretion to initiate compliance assessments the next business day

- Requiring at least weekly testing for exempted staff, and staff who have not completed their primary vaccination series, until the regulatory requirement is met, regardless of whether the facility or service site is located in a county with low to moderate community transmission, in addition to following [CDC recommendations](#) for testing unvaccinated in facilities located in counties with substantial to high community transmission.
- Requiring staff who have not completed their primary vaccination series to use a NIOSH-approved N95 or equivalent or higher-level respirator for source control, regardless of whether they are providing direct care to or otherwise interacting with patients.

NOTE: This requirement is not explicit and does not specify which actions must be taken. The examples above are not all inclusive, and represent actions that can be implemented. However, facilities can choose other precautions 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.

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. An example of an accommodation for an unvaccinated employee with a qualifying exemption could include mandatory routine COVID-19 testing in accordance with OSHA and CDC guidelines, physical distancing from co-workers and patients, re-assignment or modification of duties, teleworking, or a combination of these actions. Accommodations can be addressed in the RHC/FQHC's policies and procedures.

Staff who have been granted an exemption to COVID-19 vaccination requirements should adhere to national infection prevention and control standards for unvaccinated health care personnel. For additional information see CDC's [Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 \(COVID-19\) Pandemic](#) webpage.

Regulatory Provisions implemented **60 days after issuance of this memorandum:** 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 Plan

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 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 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 ensuring all staff obtain any recommended booster doses, and any recommended additional doses for individuals who are immunocompromised, in accordance with the recommended timing of such doses;
- A process by which staff may request a vaccine exemption from the COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws, such as religious beliefs or other accommodations
- 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 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 yet vaccinated for COVID-19 (and without an exemption for medical contraindications or without a temporary delay in vaccination due to clinical considerations as recommended by the CDC and as specified in paragraph (id(3)(x))), including deadlines for staff to be vaccinated.

- The RHC/FQHC will provide a list of all staff and their vaccine status.
 - Including the percentage of unvaccinated staff, excluding those staff that have approved exemptions
 - If any concerns are identified with the staff vaccine status list, surveyors should verify the percentage of vaccinated staff.
 - The RHC/FQHC must identify any staff member remaining unvaccinated because it's medically contraindicated or has a religious exemption.
 - The RHC/FQHC must also identify newly hired staff (hired in the last 60 days).
 - The RHC/FQHC must indicate the position or role of each staff member
- *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 policy and procedure to ensure all components are present.
- Surveyors will review any contingency plan 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

Level of Deficiency

For instances of non-compliance identified through the survey process, the level of deficiency will be determined based on the following criteria: From 30-60 days following issuance of this memorandum, the expected minimum threshold for use in these determinations will be 80%. From 60-90 days following issuance of this memorandum, the expected minimum threshold will be 90%. From 90 days on, the expected minimum threshold will be 100%. States should work with their CMS location for cases that exceed these thresholds, yet pose a threat to patient health and safety not otherwise addressed by the criteria below:

- **Immediate Jeopardy:**
 - 40% or more of staff remain unvaccinated creating a likelihood of serious harm

OR

 - Did not meet the 100% staff vaccination rate standard; observations of noncompliant infection control practices by staff, (e.g., staff failed to properly don PPE) **and** 1 or more components of the policies and procedures were not developed or implemented.
- **Condition Level-**
 - Did not meet the 100% staff vaccination rate standard; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

 - 21-39% of staff remain unvaccinated creating a likelihood of serious harm.
- **Standard Level:**
 1. 100% of staff vaccinated and all new staff have received at least one dose; **and**
 - 1 or more components of the policies and procedures were not developed and implemented

OR,

 - Did not meet the 100% staff vaccination rate standard of staff are not vaccinated, but are making good faith efforts toward vaccine compliance.

Plan of Correction

To Qualify for Substantial Compliance and Clear the Citation:

- The RHC/FQHC has met the requirement of staff fully vaccinated (either by staff obtaining additional doses, or replacing unvaccinated staff with vaccinated staff).
- OR,**
- The combined number of staff that are vaccinated (have received a single dose of a vaccine or all of the doses in the multiple dose vaccine series or have received at least one dose of a multiple vaccine series) meet the requirement.
 - Staff that has received at least one dose must also have their second dose scheduled.

To Qualify for Substantial Compliance, but the Citation Remains at Standard Level:

- The RHC/FQHC has not met the requirement of staff vaccinated, but has provided evidence of the unvaccinated staff that have obtained their first dose, AND the remainder of the unvaccinated staff are scheduled for their first dose.

Components of a Plan of Correction AND/OR Actions Required for IJ Removal

Plans of correction or Immediate Jeopardy removal plans for noncompliance should be reviewed to ensure they include the following:

- Correcting any gaps in the facility's policies and procedures.
- Implementation of the facility's contingency plan, that should include a deadline for each unvaccinated staff to have received their first dose of a vaccine.
- Implementation of additional precautions to mitigate the spread of COVID-19 by unvaccinated staff.

Good-Faith Effort:

Surveyors and CMS may lower the citation level and/or enforcement action if they identify that any of the following have occurred **prior to the survey** (note: noncompliance is still cited, only the citation level and enforcement is adjusted).

- a. If the RHC/FQHC has no or has limited access to vaccine, and the RHC/FQHC has documented attempts to obtain vaccine access (e.g., contact with health department and pharmacies).
- b. If the RHC/FQHC provides evidence that they have taken aggressive steps to have all staff vaccinated, such as advertising for new staff, hosting vaccine clinics, etc.

Enforcement Actions

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