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; OmnibusCOVID-19 Health Care Staff Vaccination.

*While the memoranda noted above apply to specific states, t*he 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, 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* memorandum[1], 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 notice[2] 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* memorandum[3], 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 notice[4] 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 days**[5] *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:

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[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.