Long-Term Care and Skilled Nursing FacilityAttachment 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, t*he regulations and guidance described in this attachment appl*y* 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 vaccinationmust 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 priorto 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 exemptionsto 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 statusof 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 thestaff 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, whois not the individual requesting the exemption, and who is acting within their respectivescope 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, butnot limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

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

GUIDANCE

DEFINITIONS

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

"Clinical contraindications" refer to conditions or risks that 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 requireddoses 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 ofthe 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* 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.**
- 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

[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* 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., relatedto 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 doseof 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 notice[4] of their non-compliance with the100% 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 shouldwork 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 tomaintain 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

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[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 theCDC, 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 additionalCDC-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 whetherthey 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 vaccinebooster 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, assignedwork 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 grantedexemptions 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 investigatingconcerns related to COVID-19 vaccination of staff. Surveyors should focus investigations on staffthat 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 vaccinationpolicies 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 updateassociated 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 determinewhich 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 theinformation 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 incorrectdoes 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 levelof 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 theirpolicy 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 representthe 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 vaccinationwere 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 <u>less than</u> 25% of staff** are unvaccinated (76% – 99% of staff are vaccinated).
- Pattern**: 25% or more, but <u>less than</u> 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.

<u>Plan of Correction:</u>

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-dosevaccine, 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	**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 P&Ps were not developed and implemented.
Level 4 - Immediate Jeopardy: 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; **or** ○ 1 or more components of the policies and procedures 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.	**J**	**K**	**L**
Level 3 – Actual Harm: ○ 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**
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.	**D**	**E**	**F**
Level 1: No actual harm w/potential for minimal harm: • 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**