

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

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

### **F888**

#### **§483.80 Infection control**

**§483.80(i) COVID-19 Vaccination of facility staff.** The facility must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

- (1) Regardless of clinical responsibility or resident contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its residents:**
  - (i) Facility employees;**
  - (ii) Licensed practitioners;**
  - (iii) Students, trainees, and volunteers; and**
  - (iv) Individuals who provide care, treatment, or other services for the facility and/or its residents, under contract or by other arrangement.**
- (2) The policies and procedures of this section do not apply to the following facility staff:**
  - (i) Staff who exclusively provide telehealth or telemedicine services outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (i)(1) of this section; and**
  - (ii) Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with residents and other staff specified in paragraph (i)(1) of this section.**
- (3) The policies and procedures must include, at a minimum, the following components:**
  - (i) A process for ensuring all staff specified in paragraph (i)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multidose 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 COVID19 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-clinicalconsiderations.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 xrays outside of the facility, while the x-ray technician who performed the x-ray onsite will be subject to these requirements.

The vaccine may be offered and provided directly by the facility or, if unavailable at the facility, staff must obtain COVID-19 vaccines through a pharmacy partner, local health department, or other appropriate health entity. See requirements at 42 CFR §483.80(d)(3), at F887.

**Surveying for Compliance:**

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

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

**Vaccination Enforcement:**

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

**Policies and Procedures:**

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

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

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

to identify other actions that can potentially reduce the risk of COVID-19 transmission from unvaccinated staff.

**§483.80(i)(3)(iv)-(v) and (ix) Process for tracking staff vaccine status:** The facility must track and securely document:

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

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

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

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

Facilities must have a process by which staff may request exemption from COVID-19 vaccination based on an applicable Federal law. This process should clearly identify how an exemption is requested, and to whom the request must be made. Additionally, facilities must have a process for collecting and evaluating such requests, including the tracking and secure documentation of information provided by those staff who have requested exemption, the facility's determination of the request, and any accommodations that are granted.

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

**Medical Exemptions:**

Certain allergies or recognized medical conditions may provide grounds for a medical exemption. With regard to recognized clinical contraindications to receiving a COVID-19 vaccine, facilities should refer to the CDC informational document, *Summary Document for Interim Clinical*

*Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States*, accessed at <https://www.cdc.gov/vaccines/covid-19/downloads/summary-interim-clinical-considerations.pdf>. In general, CDC considers a history of a severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the COVID-19 vaccine, or an immediate (within 4 hours of exposure) allergic reaction of any severity to a previous dose, or known (diagnosed) allergy to a component of the COVID-19 vaccine, to be a contraindication to vaccination with COVID-19 vaccines.

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

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

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

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

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

**Accommodations of Unvaccinated Staff with a Qualifying Exemption:**

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

**§483.80(i)(3)(x) Contingency Plans:**

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

**§483.80(i)(3)(ii):** Requires facilities to have a process for ensuring that all staff specified in paragraph (i)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by CDC, due to clinical precautions and considerations.

#### **INVESTIGATIVE PROCEDURES**

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

#### **Survey Process Updates for tag F888:**

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

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

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

**CDC NHSN Data Verification:**

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

**Citing Noncompliance - Scope and Severity:**

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

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

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

**Plan of Correction and Good Faith Effort:**

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

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

**POTENTIAL TAGS FOR ADDITIONAL INVESTIGATION**

- F658: for concerns related to professional standards of practice for the provision of vaccines;
- F880: for concerns related to infection prevention and control;



- F887: for concerns related to educating and offering COVID-19 vaccination to residents and staff.

**Contact:** For questions regarding LTC requirements, please email: [DNH\\_TriageTeam@cms.hhs.gov](mailto:DNH_TriageTeam@cms.hhs.gov)