

OHCA Vaccine Mandate Toolkit for Skilled Nursing Facilities

Key Dates

- Rule: [CMS Interim Final Rule: Omnibus COVID-19 Health Care Staff Vaccination](#)
- CMS frequently-asked questions ([FAQs](#))
- Effective Date: November 5, 2021
- Phase 1 – February 14, 2022
 - Policies and procedures established AND
 - All staff have received first dose or have a pending request for, or have been granted a qualifying exemption, or identified as having a temporary delay as recommended by the CDC OR
 - 80% of staff have received first dose and the facility has a plan to achieve full vaccination within 60 days. These providers will receive a notice of non-compliance (Form 2567) but will NOT have enforcement actions.
 - From survey guidance: “States should work with CMS for cases that exceed these thresholds, yet pose a threat to health and safety. Facilities that do not meet these parameters could be subject to additional Enforcement Actions such as plans of correction, civil money penalties, etc.”
- Phase 2 – March 15, 2022
 - Policies and procedures established AND
 - Primary vaccination series completed on all staff who have not been granted an exemption or had vaccination delayed due to clinical precautions as specified by CDC.
 - 90% of staff have received first dose and the facility has a plan to achieve full vaccination within 30 days. These providers will receive a notice of non-compliance (Form 2567) but will NOT have enforcement actions.
 - From Survey Guidance: “States should work with CMS for cases that exceed these thresholds, yet pose a threat to health and safety. Facilities that do not meet these parameters could be subject to additional Enforcement Actions such as plans of correction, civil money penalties, etc.”
- CMS final enforcement date – April 14, 2022
Providers who do not have 100% staff compliance (completion of primary vaccination series or granted an exemption) will be subject to enforcement actions.

Required Policies and Procedures

- Ensuring all staff are fully vaccinated (received the first vaccination series)
 - Exception for those that telework 100% of the time. These individuals must be identified in the documentation. (483.80(i)(3)(i))
 - Surveyors will check if providers have a process for ensuring all staff obtain any recommended booster doses at the recommended timing as well.
- Exemption for religious reasons (483.80(i)(3)(vi-ix))
 - [EEOC Guidance on Religious Discrimination](#)
 - [EEOC Religious Discrimination Compliance Manual](#)
 - EEOC Religious Exemptions [Template Form](#)
 - Federal Contractors Religious Exemption [Template Form](#)

- Surveyors will NOT evaluate the details of the request for a religious exemption or the rationale for acceptance or denial. Instead, they will ensure that providers have an effective process for staff to request a religious exemption.
- Exemptions for medical reasons (483.80(i)(3)(vi-ix))
 - Documentation requirements:
 - Must be signed and dated by a licensed practitioner, other than the individual requesting the exemption, who is acting within their scope of practice.
 - Must specify which of the authorized COVID–19 vaccines are clinically contraindicated for the staff member. CDC guidance (below) must be used for clinical contraindications.
 - Must state the recognized clinical reasons for the contraindications.
 - Must include a statement by the practitioner recommending the exemption based on recognized clinical contraindications.
 - [CDC guidance](#) giving recognized medical conditions contraindicating COVID-19 vaccine.
- Precautions for unvaccinated personnel (483.80(i)(3)(iii))
 - Can include things like required weekly testing, N95 masking, physical distancing, and removing staff from patient care work
 - [CDC Guidance](#): Interim Infection Prevention and Control Recommendations for Healthcare Personnel During the Coronavirus Disease 2019 (COVID-19) Pandemic
- Tracking and documenting vaccination status and exemption reasons, detailing the following: (483.80(i)(3)(iv-vi)), (483.80(d)(3))
 - The vaccination status of all covered staff. This should include their CDC COVID-19 vaccination record, documentation of vaccination from a healthcare provider, or state immunization system record.
 - The vaccination status of any staff members who have had booster doses [recommended by CDC](#).
 - The vaccination status of staff members for whom vaccination must be temporarily delayed, as [recommended by CDC](#), due to clinical precautions and considerations.
 - Information provided by staff members who have been granted exemptions.
 - Providers should be able to provide surveyors a list of all staff, vaccination status, and identified new hires within the last 60 days. The position and role of the staff member should be clearly identified on this list as well.
- Contingency plan for unvaccinated personnel (483.80(i)(3)(x))
 - Disaster planning and emergency preparedness.
 - Temporary utilization of unvaccinated personnel. Staff with at least one round of vaccination should be prioritized, per CMS guidance.
 - Staffing agencies or position posting if staff are unable to meet vaccination deadlines.

Requirements of Participation

- Tag: F888 - § 483.80 Infection control.
 - (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 patient contact, the policies and procedures must apply to the following facility staff, who provide any care, treatment, or other services for the facility and/or its residents:
 - (i) Facility employees;
 - (ii) Licensed practitioners;
 - (iii) Students, trainees, and volunteers;
 - (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 settings where facility services are provided to residents and who do not have any direct contact with residents, patient families and caregivers, and other staff specified in paragraph (d)(1) of this section;
 - (ii) Staff who provide support services for the facility that are performed exclusively outside of the settings where facility services are provided to residents and who do not have any direct contact with residents, patient families and caregivers, and other staff specified in paragraph (d)(1) of this section.
- (3) The policies and procedures must include, at a minimum, the following components:
 - (i) A process for ensuring all staff specified in paragraph (d)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID–19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID–19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its residents;
 - (ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;
 - (iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID–19, for all staff who are not fully vaccinated for COVID–19;
 - (iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (d)(1) of this section;
 - (v) A process for tracking and securely documenting the COVID–19 vaccination status of any staff who have obtained any booster doses as recommended by 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;
 - (B) A statement by the authenticating practitioner recommending that the staff member be exempted from the facility’s COVID–19 vaccination requirements for staff based on the recognized clinical contraindications;
 - (ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID–19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID–19, and individuals who received monoclonal antibodies or convalescent plasma for COVID–19 treatment; and
 - (x) Contingency plans for staff who are not fully vaccinated for COVID–19.
- Tag: F887 - § 483.80 Infection control.
 - (3) COVID-19 immunizations. The LTC facility must develop and implement policies and procedures to ensure all the following:
 - (i) When COVID-19 vaccine is available to the facility, each resident and staff member is offered the COVID-19 vaccine unless the immunization is medically contraindicated or the resident or staff member has already been immunized;
 - (ii) Before offering COVID-19 vaccine, all staff members are provided with education regarding the benefits and risks and potential side effects associated with the vaccine;
 - (iii) Before offering COVID-19 vaccine, each resident or the resident representative receives education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine
 - (iv) In situations where COVID-19 vaccination requires multiple doses, the resident, resident representative, or staff member is provided with current information regarding those additional doses, including any changes in the benefits or risks and potential side effects associated with the COVID-19 vaccine, before requesting consent for administration of any additional doses;

- (v) The resident, resident representative, or staff member has the opportunity to accept or refuse a COVID-19 vaccine, and change their decision;
- (vi) The resident's medical record includes documentation that indicates, at a minimum, the following:
 - (A) That the resident or resident representative was provided education regarding the benefits and potential risks associated with COVID-19 vaccine; and
 - (B) Each dose of COVID-19 vaccine administered to the resident; or
 - (C) If the resident did not receive the COVID-19 vaccine due to medical contraindications or refusal; and
- (vii) The facility maintains documentation related to staff COVID-19 vaccination that includes at a minimum, the following:
 - (A) That staff were provided education regarding the benefits and potential risks associated with COVID-19 vaccine;
 - (B) Staff were offered the COVID-19 vaccine or information on obtaining COVID-19 vaccine; and
 - (C) The COVID-19 vaccine status of staff and related information as indicated by the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN).

Survey Guidance

- Quality, Safety, and Oversight Memo [QSO-22-09-ALL](#) (Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccinations)
- [Long Term Care and Skilled Nursing Facility Attachment](#)
- In addition to the staff vaccination documentation outlined above under policies and procedures, surveyors also will request the number of resident and staff COVID-19 cases over the last 4 weeks. Surveyors will verify facility reporting of vaccine data to NHSN as part of their offsite preparation prior to going onsite for a survey.
 - If percent of staff vaccinated from NHSN and onsite are within 10% of each other, no further investigation (as religious exemptions are not reported to NHSN, they could be a reason for a discrepancy).
 - If percent of staff vaccinated from NHSN and onsite reports are greater than 10%, surveyors will interview facility to explain discrepancy and determine which is correct.
 - If surveyor determines onsite is incorrect and NHSN is correct, will cite F888 due to not having a process to track and document vaccination status accurately.
 - If surveyor determines that onsite is correct and NHSN is incorrect, surveyor will instruct facility to immediately make corrections in NHSN.
- Scope and severity (please see Table 1, Scope and Severity Grid)
 - Immediate jeopardy (level 4)
 - 40% or more of staff unvaccinated AND there is evidence of a lack of effort to increase staff vaccination rates OR
 - Did not meet staff vaccination rate standard OR has no policies procedures developed or implemented; AND 3 or more resident infections in the last 4 weeks resulting in at least one resident experiencing hospitalizations or death.

- Did not meet staff vaccination rate standard AND 3 or more resident infections in the last 4 weeks resulting in at least one resident experiencing hospitalizations or death AND either of the following: any observation of noncompliant infection control practices by staff OR one or components of policies and procedures were not developed and implemented.
 - NOTE: For IJ removal, plans of correction should correct any gaps in policies and procedures identified during survey, implementation of the contingency plan including a deadline for each unvaccinated staff to receive their first vaccine dose and implementation of additional precautions to prevent infection by unvaccinated staff.
 - Level 3 - Did not meet vaccination standard AND 3 or more resident infections in the last 4 weeks which didn't result in hospitalization or death or likelihood of IJ for one or more residents AND one or components of policies and procedures were not developed and implemented.
 - Level 2
 - Did not meet vaccination standard AND no resident outbreaks OR
 - Did not meet vaccination standard AND one or components of policies and procedures were not developed and implemented.
 - Level 1 - Met the requirement of staff vaccination AND one or more components of policies and procedures to ensure vaccination were not developed and implemented.
 - Meeting vaccination standard – it is based on the percentages established for each of the compliance dates specified above.
- Scope
 - Scope is based on the percent of staff vaccinated because lower vaccination rates are associated with higher numbers of COVID-19 resident cases.
 - Isolated: 1% or more, but less than 25% of staff are unvaccinated (76% – 99% of staff are vaccinated).
 - Pattern: 25% or more, but less than 40% of staff are unvaccinated (61% – 75% of staff are vaccinated).
 - Widespread: 40% or more of staff are unvaccinated (0% - 60% of staff are vaccinated), OR
 - 1 or more components of the policies and procedures listed above were not developed and implemented.
- Good-faith effort means that prior to the survey, the provider has had limited access to the vaccine and has documented attempts to obtain vaccine access and the facility has evidence of aggressive steps to have all staff vaccinated, such as hosting vaccine clinics and advertising for new staff. Per the guidance, surveyors and CMS may lower the scope and severity of a citation and/or enforcement action if they identify that the provider made a good-faith effort (note: noncompliance is still cited, only the scope, severity, and/or enforcement is adjusted).
- Plan of Correction
 - To qualify for substantial compliance and clear the citation, providers meet the requirements of staff being fully vaccinated OR the staff that have received their first dose have their second dose scheduled.
 - To qualify for substantial compliance but keep the level 1 citation, providers have not met the requirements of full staff vaccination but has provided evidence that

unvaccinated staff have received their first dose and the remainder of unvaccinated staff have scheduled their first dose.

- Additional Tags for 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.

Table 1: Scope and Severity Grid

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