

Vaccination Mandate Guidance Summary Updated 12/28/2021

On November 4, 2021, the Centers for Medicare and Medicaid Services (CMS) issued an Interim Final Rule establishing COVID-19 vaccination requirements for employees of Medicare and Medicaid-certified providers. In addition, the Occupational Safety and Health Administration (OSHA) released an Emergency Temporary Standard, effective November 5, 2021, outlining COVID-19 vaccination requirements for employers of greater than 100 employees.

Litigation updates:

CMS Interim Final Rule

On November 29 and 30, 2021, two separate federal district courts—the <u>Western District of Louisiana</u> and <u>Eastern District of Missouri</u>—issued injunctions blocking enforcement of the Centers for Medicare and Medicaid Services ("CMS") interim final rule ("vaccine mandate") requiring health care worker vaccinations. In combination, these rulings result in a nationwide preliminary injunction prohibiting CMS from enforcing the vaccine mandate. On December 2, 2021, CMS issued <u>QSO-22-04-ALL</u> stating that the interim final rule was suspended so long as the injunctions remain in effect. Therefore, CMS has 'suspended activities related to the implementation and enforcement of this rule pending future developments in the litigation'. CMS appealed injunctions in both the Fifth and Eighth Circuit Courts in addition to asking the courts to allow enforcement to continue pending the outcome of the appeal process.

On December 15, 2021, the 5th Circuit Court of Appeals narrowed the scope of the district court's nationwide preliminary injunction in Louisiana v. Becerra to the 14 plaintiff states. This left only the states listed as plaintiffs in the two cases (noted above) to be affected by the preliminary injunctions. Iowa, due to participation in the Missouri case, is not subject to the elements of the CMS interim final rule. As of December 16, 2021, 25 states became subject to the CMS vaccination mandate while 25 others remained protected by temporary injunctions. CMS has yet to issue interpretive guidance or begin enforcement actions in any state.

OSHA Vaccination and Testing ETS

On November 12, 2021, the U.S. Court of Appeals for the Fifth Circuit granted a motion to stay OSHA's COVID-19 Vaccination and Testing Emergency Temporary Standard, published on November 5, 2021 (86 Fed. Reg. 61402) ("ETS"). The court ordered that OSHA "take no steps to implement or enforce" the ETS "until further court order." The U.S. Court of Appeals for the Sixth Circuit now has jurisdiction over ETS challenges and Department of Labor has filed a motion to lift the stay. OSHA has suspended activities related to the implementation and enforcement of the ETS pending future developments in the litigation.

On December 17, 2021, the Sixth Circuit Court of Appeals upheld the mandate in a 2-1 ruling, allowing OSHA to move forward with enforcement of the Vaccination and Testing ETS. OSHA updated the timeline for compliance to January 10, 2022, and February 9, 2022.

On December 27, 2021, OSHA withdrew the non-record keeping portions of the health care ETS issued in June. Due to the withdrawal of the June health care ETS, health care employers, including all assisted living, nursing homes or other long term care providers, became subject to OSHA's vaccine mandate ETS.

U.S Supreme Court Hearing (Both CMS and OSHA vaccination mandates)

On December 22, 2021, the Supreme Court of the United States issued orders granting review of legal challenges to the Occupational Safety and Health Administration's COVID-19 Vaccination and Testing Emergency Temporary Standard ("OSHA ETS") and the Centers for Medicare and Medicaid Services Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule ("CMS Vaccine Mandate"). The Supreme Court set an accelerated timeline for the cases, scheduling oral arguments in both cases on January 7, 2022. It is unclear if a ruling will be issued prior to the January 10, 2022, deadline of the OSHA Vaccination and Testing ETS.

Citing the potential reinstatement of the CMS mandate in the state of lowa, the lowa Health Care Association (IHCA) recommends a conservative approach to compliance. There is a risk that CMS could prevail in its appeal and reinstate the mandate with the original deadlines. Modified deadlines for compliance are possible, but not guaranteed. Members are encouraged to enforce all aspects of the vaccine mandate, short of terminating unvaccinated employees that do not have an approved medical or religious waiver. Members should understand that good-faith efforts to comply with the rule, despite the injunction, could offer legal protection in the event of reinstatement with the original deadlines. IHCA is committed to closely monitoring this situation and will communicate changes to members as they occur.

Type of Organization	CMS Interim Final Rule	OSHA VACCINATION ETS
Medicare and/or Medicaid-Certified Nursing Facility or Skilled Nursing Facility with greater than 100 employees	WILL APPLY IF SUSPENSION LIFTED	APPLIES
Medicare and/or Medicaid-Certified Nursing Facility or Skilled Nursing Facility with less than 100 employees	WILL APPLY IF SUSPENSION LIFTED	DOES NOT APPLY
Licensed-Only Nursing Facility (Not Medicare/Medicaid-Certified) with greater than 100 employees	DOES NOT APPLY	APPLIES
Licensed-Only Nursing Facility (Not Medicare/Medicaid-Certified) with less than 100 employees	DOES NOT APPLY	DOES NOT APPLY
Hospital-Based SNF of NF with greater than 100 employees	WILL APPLY IF SUSPENSION LIFTED	APPLIES
Hospital-Based SNF of NF with less than 100 employees	WILL APPLY IF SUSPENSION LIFTED	DOES NOT APPLY
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF-ID) with greater than 100 employees	WILL APPLY IF SUSPENSION LIFTED	APPLIES
Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF-ID) with less than 100 employees	WILL APPLY IF SUSPENSION LIFTED	DOES NOT APPLY
Assisted Living Program with greater than 100 employees	DOES NOT APPLY	APPLIES
Assisted Living Program with less than 100 employees	DOES NOT APPLY	DOES NOT APPLY
Medicaid-Certified Residential Care Facility with greater than 100 employees	WILL APPLY IF SUSPENSION LIFTED	APPLIES
Residential Care Facility with greater than 100 employees	DOES NOT APPLY	APPLIES
Residential Care Facility with less than 100 employees	DOES NOT APPLY	DOES NOT APPLY
Medicare and/or Medicaid-Certified Home Health Agency with greater than 100 employees	WILL APPLY IF SUSPENSION LIFTED	APPLIES
Medicare and/or Medicaid-Certified Home Health Agency with less than 100 employees	WILL APPLY IF SUSPENTION LIFTED	DOES NOT APPLY
Non-Certified Home Health Agency/Home Care with greater than 100 employees	DOES NOT APPLY	APPLIES
Non-Certified Home Health Agency/ Home Care with less than 100 employees	DOES NOT APPLY	DOES NOT APPLY

The Centers for Medicare and Medicaid Services state that its Interim Final Rule only applies to those Medicare and Medicaid-certified provider and supplier types that are subject to CMS health and safety regulations. CMS's health and safety regulations do not cover providers of Home- and Community-Based Services (HCBS). Therefore, assisted living programs and residential care facilities that provide services through the HCBS waiver are not included in the CMS Interim Rule.

IHCA/ICAL/ICHC recommends providers who house different levels of care under the same roof or on the same campus abide by the highest standard consistently across all levels of care.

CMS Interim Final Rule

This rule went effect on November 5, 2021. The regulation requires health care providers to establish a process or policy to fulfill the staff vaccination requirement.

*Note: The CMS interim final rule is pending litigation and a hearing in the U.S. Supreme Court (set for January 7, 2022) and is NOT enforceable in Iowa at this time. However, providers should prepare for compliance should the rule come into effect.

Enforcement thresholds:

CMS identifies that 100% facility staff vaccination rates are required for compliance with the rule.

Within 30 days of issuance of QSO-22-07-ALL, if a facility demonstrates that:

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

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

Policies and procedures are developed and implemented for ensuring all facility staff,

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

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

Included employees

This vaccination requirement applies to eligible staff working at a facility that participates in the Medicare and Medicaid programs, regardless of clinical responsibility or patient contact. The requirement includes all current staff as well as any new staff who provide any care, treatment or other services for the facility and/or its patients. This includes facility employees, licensed practitioners, students, trainees and volunteers. Additionally, this also includes individuals who provide care, treatment or other services for the facility and/or its patients under contract or other arrangements, such as agency personnel, dieticians, mental health professionals, social workers, physicians or contracted therapy staff.

These requirements are not limited to those staff who perform their duties solely within a formal clinical setting, as many health care staff routinely care for patients and clients outside of such facilities (e.g., home health). To ensure maximum patient protection, all staff who interact with other staff, patients, residents or clients in any location beyond the formal clinical setting (such as homes, clinics, other sites of care, administrative offices, off-site meetings, etc.) must be vaccinated. Employees of a health care entity that work solely in an off-site or non-clinical location, such as a corporate office, may not be subject to vaccination requirements if they do not have resident interaction or contact with staff who have resident interaction.

It is important to note that hospice agencies, clinics, dialysis centers, rehabilitation agencies, hospitals, emergency medical services and many other Medicare and Medicaid-certified entities that interact with long-term care (LTC) facilities, assisted living programs, residential care facilities and home health

agencies also fall under this rule. Therefore, the staff of those organizations will be required to comply with vaccination requirements through their employment. Conversations with service providers and partners in care should be initiated to determine compliance efforts within those organizations.

For other services suppliers (such as portable x-ray services, non-medical transport services or durable medical equipment providers), it is important to note that the staff of these entities are indirectly included in the vaccination requirements through their service arrangements with LTC facilities and other providers and suppliers included under this rule. A service arrangement is when these providers have a contract with other providers to furnish services. That contract may require individuals from these organizations to be vaccinated. It is important to note that many of these suppliers may be subject to the other state or federal COVID-19 vaccination requirements, such as those issued by OSHA.

IHCA/ICAL/ICHC recognizes that most members have contracted employees, such as therapists, dieticians, consultants and staff provided though a temporary agency. Members are encouraged to review current contracts held with these partners to ensure the expectations of both parties for vaccination-related information (vaccination status, approved exemptions, etc.) sharing is clear. IHCA has drafted an <u>addendum template</u> that members can use at their discretion to accommodate communication of such expectations. Additionally, CMS has been clear in its direction that facilities covered under the mandate are responsible for having a process to access and review vaccine-related documents for all staff, including contracted employees. Members should also be reminded that they are not required to accept an exemption that was previously approved by the contracting agency and can choose to allow or deny access to their facility based upon what is provided.

Employees who are NOT included

Individuals who provide services 100% remotely and who do not have any direct contact with patients and other staff, such as fully remote telehealth or payroll services, are not subject to the vaccination requirements outlined in this regulation.

Although the details remain unclear at this time, it is unlikely that contractors who visit the facility to provide services on a one-time basis (such as plumber entering to complete repairs) will not be subject to vaccination requirements.

Qualified vaccination types

CMS expects that staff will receive a vaccine licensed or authorized for emergency use by the Food and Drug Administration (FDA), which currently includes the Pfizer-BioNTech COVID-19 Vaccine (interchangeable with the licensed Comirnaty vaccine), Moderna COVID-19 Vaccine and the Janssen (Johnson & Johnson) COVID-19 Vaccine. Facilities will also be in compliance if they allow staff to work who received a vaccine listed by the World Health Organization (WHO) for emergency use that is not approved or authorized by the FDA, or who received a vaccine during their participation in a clinical trial.

CMS expects that vaccine administration will occur within the United States for most staff and that individuals will receive a COVID-19 vaccine authorized for emergency use or licensed by the FDA. However, it is permissible to receive a COVID-19 vaccine outside of the United States. Eligible COVID-19 vaccinations administered to staff outside of the United States include those that are FDA licensed or authorized for emergency use or those that are listed by the WHO for emergency use.

Inclusion of additional doses or booster shots

For purposes of this regulation, CMS currently considers staff fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19. However, staff who have completed the primary series for the vaccine by the Phase 2 (January 4, 2022) implementation date are considered to have met these requirements, even if they have not yet completed the 14-day waiting period required for full vaccination. The completion of a primary vaccination series for COVID-19 is defined in the rule as the administration of a single-dose vaccine (such as the Janssen (Johnson & Johnson) COVID-19 Vaccine), or the administration of all required doses of a multi-dose vaccine (such as the Pfizer-BioNTech COVID-19 Vaccine (interchangeable with the licensed Comirnaty Vaccine) or the Moderna COVID-19 Vaccine). FDA has approved, and CDC has recommended, boosters for certain groups that previously completed a primary vaccination series. Because the science and clinical recommendations around additional doses and boosters is evolving rapidly, members should refer to CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States for additional details.

Staff who have previously had COVID-19 are not exempt from these vaccination requirements. Staff with previous COVID-19 infection should receive the vaccine according to the <u>recommendations</u> set forth by the Centers for Disease Prevention and Control. Additionally, staff who have received treatments for COVID-19 (monoclonal antibodies or convalescent plasma) may not be eligible to receive the vaccination for a period following the administration of the treatment. Staff become subject to the vaccine requirement once the designated period has elapsed.

The preference is that individuals should generally avoid receiving doses of different vaccines to complete a primary COVID-19 vaccination series. Nevertheless, CDC does recognize that, in certain exceptional circumstances (e.g., when the vaccine product given for the first dose cannot be determined or is no longer available), a different vaccine may be used to complete the primary COVID-19 vaccination series. Accordingly, staff may be considered compliant with the requirements within this regulation if they have received any combination of two doses of a vaccine licensed or authorized by the FDA or listed on the WHO emergency use list as part of a two-dose series. Of note, the recommended interval between the first and second doses of a vaccine licensed or authorized by FDA, or listed on the WHO emergency use list, varies by vaccine type. To be compliant with this requirement, the second dose in a two-dose mixed vaccine series must have been received no earlier than 28 days after the first dose.

Staff who have received a COVID-19 vaccination neither licensed or authorized by the FDA nor listed on the WHO emergency use list should receive an FDA licensed or authorized vaccination series. Per CDC

guidelines, staff in this category should wait at least 28 days following the last dose of a non-FDA approved or authorized and non-WHO-listed vaccination to begin a new series. Staff should consult with their doctor or other health care provider if they have questions about their vaccination.

According to the CDC, no additional doses are needed for staff who participated in a clinical trial at a site in the U.S. and received the full series of an "active" vaccine candidate (not placebo) and vaccine efficacy has been independently confirmed (by a data and safety monitoring board).

Staff hired before December 5, 2021, should receive their first dose of a two-dose series or a dose of the single-dose vaccine before December 5, 2021. Staff hired after December 5, 2021, must receive their first dose of a two-dose series or a dose of the single-dose vaccine before they have resident contact. If necessary, the second dose should be administered according to recommendations to maintain compliance.

Is there a testing option for unvaccinated staff?

No. Vaccination is required for all employees unless they meet the requirements for a medical or religious exemption. Nursing facilities should continue to test based upon the requirements outlined in QSO-20-38-NH.

Reporting vaccination status of employees

No new reporting requirements were released with the interim final rule. Reporting staff and resident vaccination status to the National Healthcare Safety Network (NHSN) in nursing facilities remains unchanged. Members are required to track and securely document the vaccination status of each staff member, including those for whom there is a temporary delay in vaccination.

Examples of acceptable forms of vaccine documents include:

- CDC COVID-19 Vaccination record card (or a legible copy of the card)
- Documentation of vaccine administration from a health care provider or electronic medical record
- State immunization information system record (IRIS)
- If vaccinated outside of the U.S., an equivalent to these examples is acceptable

Exemptions

IHCA/ICAL/ICHC has developed a comprehensive <u>toolkit</u> for member use. This toolkit includes a sample policy, medical and religious exemption forms and suggested verbiage for employee handbooks or other organizational policies.

CMS requires facilities to allow for exemptions to staff with recognized medical conditions for which vaccines are contraindicated (as a reasonable accommodation under the Americans with Disabilities Act (ADA) or religious beliefs, observances or practices (established under Title VII of the Civil Rights Act of 1964). Providers and suppliers should establish exceptions as a part of its policies and procedures and in alignment with Federal law. CMS believes that exemptions could be appropriate in

certain limited circumstances, but no exemption should be provided to any staff for whom it is not legally required (under the ADA or Title VII of the Civil Rights Act of 1964) or who requests an exemption solely to evade vaccination.

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.

Iowa recently passed a bill stating that employers must accept medical and religious exemptions without question. The CMS interim final rule takes precedence over state rule due to the Supremacy Clause of the U.S. Constitution. Therefore, any facility or program that is subject to CMS interim final rule is expected to comply with its requirements.

Medical exemptions

Facilities have the flexibility to establish their own processes that permit staff to request a medical exemption from the COVID-19 vaccination requirements. Facilities must ensure that all documentation confirming recognized clinical contraindications to COVID-19 vaccinations for staff seeking a medical exemption are signed and dated by a licensed practitioner, who is not the individual requesting the exemption and is acting within their respective scope of practice based on applicable state and local laws. This documentation must contain 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. Additionally, a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements is also expected.

Religious exemptions

Facilities have the flexibility to establish their own processes that permit staff to request a religious exemption from the COVID-19 vaccination requirements. CMS requires facilities to ensure that requests for religious exemptions are documented and evaluated in accordance with applicable federal law and as a part of a facility's policies and procedures. CMS encourages facilities to review the Equal Employment Opportunity Commission's Compliance Manual on Religious Discrimination for more information on religious exemptions.

Related to religious exemptions, consideration of the following items as outlined in the Civil Rights Act of 1964 (Title VVII) should be given when writing the organization's policy:

Religion is very broadly defined for purposes of Title VII. The presence of a deity (god) or deities
(gods) is not necessary for a religion to receive protection under Title VII. Religious beliefs can
include unique beliefs held by a few or even one individual; however, mere personal
preferences are not religious beliefs. Individuals who do not practice any religion are also
protected from discrimination based on religion or lack thereof. Title VII requires employers to

- accommodate religious beliefs, practices and observances if the beliefs are "sincerely held" and the reasonable accommodation poses no undue hardship on the employer.
- Social, political or economic philosophies, as well as mere personal preferences, are not religious beliefs protected by Title VII.
- Undue hardship is defined as 'something greater than hardship.' This hardship can be found in monetary cost to the employer or in indirect cost to the employer's business, such as the infringement on others' rights or benefits, impairment of workplace safety or causing other workers to carry the accommodated worker's share of the burdensome work.

Members are encouraged to consult with an attorney when considering how to approach exemptions.

Additional measures required for any unvaccinated individual with a qualifying exemption or prior to being fully vaccinated

The regulation requires that facilities develop a process for implementing additional precautions for any staff who are not fully vaccinated to mitigate the transmission and spread of COVID-19.

Accommodations should be addressed in the organization's policies and procedures. Under federal law, including the ADA and Title VII of the Civil Rights Act of 1964, individuals who cannot be vaccinated because of medical conditions or sincerely held religious beliefs, practice or observance may be entitled to an accommodation. Members are encouraged to review the Equal Employment Opportunity Commission's website for additional information about situations that may warrant accommodations. In granting such exemptions or accommodations, employers must ensure that they minimize the risk of transmission of COVID-19 to at-risk individuals, in keeping with their obligation to protect the health and safety of patients.

Potential accommodations can include the following:

- COVID-19 testing (in accordance with OSHA and CDC guidelines)
 - At least weekly testing should be required for exempted or those who are not fully vaccinated regardless of community transmission levels.
- Physical distancing from co-workers and patients/residents
- Reassignment or modification of duties
- Teleworking
- Any combination of the above

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

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.

Enforcement

State survey agencies will integrate compliance measures into complaint and standard (initial certification and recertification/annual) surveys. Surveying for compliance with the vaccination rule will begin January 27, 2022. While onsite, surveyors will review the facility's COVID-19 vaccination policies and procedures, the number of resident and staff COVID-19 cases over the last four weeks and a list of all staff and their vaccination status. This information, in addition to interviews and observations, will be used to determine the compliance of the provider or supplier with these requirements.

Surveyors will specifically be looking for the following items:

- 1. The facility's plan to vaccinate all employees, both current and new.
- 2. The facility's plan to approach exemptions and the accommodations made for those who cannot be vaccinated due to exemption.
- 3. The facility's plan to track and document staff vaccination status.

Medicare- and Medicaid-certified facilities are expected to comply with all regulatory requirements, and CMS has a variety of established enforcement remedies. For nursing homes and home health agencies this includes civil monetary penalties, denial of payment and even termination from the Medicare and Medicaid program, as a final measure. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.

Citing noncompliance - scope and severity:

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

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.

Scope and Severity will be determined as follows:

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; 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
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.	G	н	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 expected minimum threshold of staff vaccinated; and 1 or more components of the policies and procedures were not developed and implemented.	D	E	F
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").	Α	В	С

Occupational Safety and Health Administration's Emergency Temporary Standard

OSHA's Emergency Temporary Standard (ETS) for COVID-19 Vaccination and Testing was released in draft form on November 4, 2021, and made public in the Federal Register on November 5, 2021. The ETS was effective upon publication in the Federal Register.

As of December 27, 2021, due to the withdrawal of the health care ETS issued in June 2021, health care employers with greater than 100 employees became subject to OSHA's Vaccination and Testing ETS.

Instructions to determine if your organization meets the 100-employee threshold:

- Definition of "employee" OSHA has indicated that for the OSHA Vaccine/Testing ETS, "employee" includes all full-time, part-time and seasonal/temporary employees directly employed by the employer. The ETS does not include independent contractors or staffing agency employees.
- All employees are counted regardless of their role in the organization.
- The OSHA Vaccine/Testing ETS requirements do not apply to employees who are 100% remote workers, but those employees still count for purposes of calculating the 100-employee coverage threshold.
- For a single corporate entity with multiple locations, all employees at all locations are counted for purposes of the 100-employee coverage threshold.
- OSHA has indicated that two or more related entities also may be regarded as a single employer for coverage purposes if they handle safety matters as one company. In this case, the employees of all entities making up the integrated single employer must be counted for purposes of the 100-employee coverage threshold.

To comply, employers must ensure provisions are addressed in the workplace by the following dates:

- **January 10, 2022:** All requirements other than testing for employees who have not completed their entire primary vaccination dose(s).
- **February 9, 2022:** Testing for employees who have not received all doses required for a primary vaccination.

Elements for compliance:

- Employer Policy on Vaccination. The ETS requires covered employers to develop, implement
 and enforce a mandatory COVID-19 vaccination policy, with an exception for employers that
 instead establish, implement and enforce a policy allowing employees who are not fully
 vaccinated with a primary series to elect to undergo weekly COVID-19 testing and wear a face
 covering at the workplace.
- 2. **Determination of employee vaccination status.** The ETS requires employers to determine the vaccination status of each employee, obtain acceptable proof of vaccination, maintain records

of each employee's vaccination status and maintain a roster of each employee's vaccination status. If an employee fails to provide acceptable proof of vaccination, that employee should be treated as if they are not fully vaccinated.

Acceptable proof of vaccination:

- Record of immunization from a health care provider or pharmacy
- Copy of COVID-19 vaccination record card
- Copy of medical records documenting the vaccination
- Copy of immunization records from a public health, state or tribal immunization information system
- Copy of other official documentation containing type of vaccine, date(s) of administration and name of health care professional or clinic administering the vaccine
- Signed and dated attestation ONLY where employee has lost or is otherwise unable to produce other acceptable proof
- 3. **Employer support for employee vaccination.** The ETS requires employers to support vaccination by providing employees reasonable time, including up to four hours of paid time, to receive each vaccination dose, and reasonable time and paid sick leave to recover from side effects experienced following each dose.
- 4. COVID-19 testing for employees who are not fully vaccinated. The ETS requires employers to ensure that each employee who is not fully vaccinated is tested for COVID-19 at least weekly (if in the workplace at least once a week) or within seven days before returning to work (if away from the workplace for a week or longer). The ETS does not require employers to pay for any costs associated with testing. However, employer payment for testing may be required by other laws, regulations or collective bargaining agreements or other collectively negotiated agreements. In addition, nothing prohibits employers from voluntarily assuming the costs associated with testing. Employees can be tested outside of the workplace but must provide documentation of the test result to the employer. Employees who have tested positive for COVID-19 or been diagnosed with COVID-19 by a licensed health care provider are exempt from testing for 90 days. Test results are considered part of the employee's medical record and should be maintained as such.
- 5. **Employee notification to employer of a positive COVID-19 test and removal.** The ETS requires employers to: (1) require employees to promptly provide notice when they receive a positive COVID-19 test or are diagnosed with COVID-19; (2) immediately remove any employee from the workplace, regardless of vaccination status, who received a positive COVID-19 test or is diagnosed with COVID-19 by a licensed health care provider; (3) keep removed employees out of the workplace until they meet criteria for returning to work.

- 6. **Face coverings.** The ETS requires employers to ensure that each employee who is not fully vaccinated appropriately wears a face covering when indoors or when occupying a vehicle with another person for work purposes, except in certain limited circumstances. Employers must not prevent any employee, regardless of vaccination status, from voluntarily wearing a face covering unless it creates a serious workplace hazard (e.g., interfering with the safe operation of equipment).
- 7. **Information provided to employees.** The ETS requires employers to provide employees the following in a language and at a literacy level the employees understand: (1) information (here) about the requirements of the ETS and workplace policies and procedures established to implement the ETS; (2) the CDC document "Know About COVID-19 Vaccines"; (3) information about protections against retaliation and discrimination; and (4) information (here) about laws that provide for criminal penalties for knowingly supplying false statements or documentation.
- 8. **Reporting COVID-19 fatalities and hospitalizations to OSHA.** The ETS requires employers to report work-related COVID-19 fatalities to OSHA within eight hours of learning about them, and work-related COVID-19 in-patient hospitalizations within 24 hours of the employer learning about the hospitalization. Reporting instructions found here.
- 9. Availability of records. The ETS requires employers to make available for examination and copying an employee's COVID-19 vaccine documentation and any COVID-19 test results to that employee and to anyone having written authorized consent of that employee. Employers are also required to make available to an employee, or an employee representative, the aggregate number of fully vaccinated employees at a workplace along with the total number of employees at that workplace.

OSHA has addressed some frequently asked questions related to the Vaccination and Testing ETS here.

Comment period

The ETS on Vaccination and Testing also acts as a proposal for a permanent standard. Written comments on any aspect of the ETS must be submitted by January 19, 2022, to www.regulations.gov in Docket number OSHA-2021-0007, which is the only way that OSHA is receiving comments on the ETS.