



CMS and OSHA Vaccine and Testing Mandates

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COVID-19 Vaccine and Testing Mandates

Two rules issued in the Federal Register November 5, 2021

- CMS IFR: Omnibus COVID-19 Health Care Staff Vaccination (comments due January 4, 2022)
- OSHA COVID-19 Vaccination and Testing; Emergency Temporary Standard (comments due December 6, 2021)

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CMS COVID-19 Vaccine Mandate

- Effective November 5, 2021
- Applies to all Medicare and Medicaid certified providers and supplier (Home Health and Hospice)
- Compliance dates
- Phase I December 6, 2021
- Phase II January 4, 2022

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CMS COVID-19 Vaccine Mandate

Phase 1- December 6, 2021

- All staff receive the first dose, or only dose as applicable, of a COVID-19 vaccine, or have requested or been granted an exemption to the vaccination requirements of this IFC. All policies and procedures established.

Phase II -January 4, 2022

- The primary vaccination series has been completed and that staff are fully vaccinated, except for those staff have been granted exemptions, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by CDC, due to clinical precautions and considerations.
 - Initial implementation will not require 2 week waiting period after completed vaccination.

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CMS COVID-19 Vaccine Mandate

Policies and Procedures

- Ensuring all staff “fully” vaccinated (2 week or more from complete vaccination)
- Exemption for religious and medical reasons
- Precautions for unvaccinated
- Tracking and documenting vaccination status and reasons for exemption
- Contingency plan for unvaccinated

CMS COVID-19 Vaccine Mandate

§ 484.70 Condition of participation: Infection prevention and control.

The HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases.

.....

d) Standard: COVID–19 Vaccination of Home Health Agency staff.

The home health agency (HHA) 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.

CMS COVID-19 Vaccine Mandate

§ 418.60 Condition of participation: Infection control.

.....

(d) Standard: COVID–19 Vaccination of facility staff. The hospice 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

CMS COVID-19 Vaccine Mandate

§484.70(d)(1)

Application:

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following HHA staff, who provide any care, treatment, or other services for the HHA and/or its patients:

- (i) HHA employees;
- (ii) Licensed practitioners;
- (iii) Students, trainees, and volunteers; and
- (iv) Individuals who provide care, treatment, or other services for the HHA and/or its patients, under contract or by other arrangement.

CMS COVID-19 Vaccine Mandate

§484.70(d)(2)

(2) The policies and procedures of this section do not apply to the following HHA staff:

- (i) Staff who exclusively provide telehealth or telemedicine services outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (d)(1) of this section; and
- (ii) Staff who provide support services for the HHA that are performed exclusively outside of the settings where home health services are directly provided to patients and who do not have any direct contact with patients, families, and caregivers, and other staff specified in paragraph (d)(1) of this section.

CMS COVID-19 Vaccine Mandate

§484.70(d)(3)(i)

Policies and procedures:

(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) 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 HHA and/or its patients.

Exceptions to vaccination:

- Pending requests for, or who have been granted, exemptions to the vaccination requirements
 - Federal law, such as the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964.
- Staff for whom COVID-19 vaccination must be temporarily delayed

Applies to Phase I - may have limited application.

CMS COVID-19 Vaccine Mandate

§484.70(d)(3)(ii)

Fully vaccinated

(ii) A process for ensuring that all staff specified in paragraph (d)(1) of this section are fully vaccinated for COVID–19

Exceptions:

- granted exemptions to the vaccination requirements
 - Federal law, such as the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964.
- staff for whom COVID–19 vaccination must be temporarily delayed (per CDC for clinical considerations)

CMS COVID-19 Vaccine Mandate

§484.70(d)(3)(iii)

Additional precautions

(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 (i.e. OSHA Healthcare ETS)

CMS COVID-19 Vaccine Mandate

§484.70(d)(3)(iv)

Tracking and documenting vaccination status

(iv) A process for tracking and securely documenting the COVID–19 vaccination status of all staff specified in paragraph (d)(1) of this section

- Policy includes types of acceptable documentation
- Confidential medical records
- Include exempt personnel

CMS COVID-19 Vaccine Mandate

§484.70(d)(3)(v)

Tracking boosters

(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.

- Will require ongoing tracking and employee compliance

CMS COVID-19 Vaccine Mandate

§484.70(d)(3)(vi)

Exemptions

(vi) A process by which staff may request an exemption from the staff COVID–19 vaccination requirements based on an applicable Federal law.

- Federal law, such as the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964

–How, Who, and What criteria

CMS COVID-19 Vaccine Mandate

§484.70(d)(3)(vii)

Tracking and documenting exemptions

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the HHA has granted, an exemption from the staff COVID–19 vaccination requirements.

- Information provided by the employee
- Decisions for or against exemption and why
- Any special accommodations made

CMS COVID-19 Vaccine Mandate

§484.70(d)(3)(viii)

Medical exemption

(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 HHA's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

CMS COVID-19 Vaccine Mandate

§484.70(d)(3)(ix)

Delayed vaccinations

(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.

- Might permit the application for (d)(3)(1)

CMS COVID-19 Vaccine Mandate

§484.70(d)(3)(x)

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

- Disaster planning and emergency preparedness
- Temporary utilization of unvaccinated personnel
- Staffing agencies
- (d)(3)(1)

CMS COVID-19 Vaccine Mandate

CMS expects the requirements to remain relevant for some time beyond the end of the formal PHE. Depending on the future nature of the COVID–19 pandemic, may retain these provisions as a permanent requirement.

CMS COVID-19 Vaccine Mandate

IFC preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader exemptions than provided for by Federal law and are inconsistent with this IFC.

Resources

- 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-clinicalconsiderations.pdf>.
- Equal Employment Opportunity Commission's website at <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eo-laws>.
- COVID–19 vaccination religious exemption template [Request For A Religious Exception To The Covid-19 Vaccination Requirement - Template](#) (saferfederalworkforce.gov)

OSHA ETS

- OSHA “Healthcare” ETS - June 21, 2021
- OSHA COVID-19 Vaccine and Testing ETS
- Intended to work in tandem to close gaps in employee protections.
 - “OSHA’s intent was to leave no coverage gaps between section 1910.502 and this ETS”

OSHA ETS

Employees not subject to the “Healthcare” ETS are covered under the COVID vaccine ETS

- Whole entities
- Individual employees

“...it will be necessary for employers with employees covered by section 1910.502 to determine if they also have employees covered by this ETS”

OSHA COVID VACCINE/TESTING

- Phase I
 - Comply with all requirements of this ETS by December 6, 2021, except section (g) which outlines the COVID testing requirements.
- Phase II
 - January 4, 2022 compliance with testing for unvaccinated staff that do not meet an exemption.

OSHA COVID VACCINE/TESTING

- Scope and application.
- Definitions
- Employer policy on vaccination.
- Determination of employee vaccination status.
- Employer support for employee vaccination
- COVID-19 testing for employees who are not fully vaccinated.
- Employee notification to employer of a positive COVID-19 test and removal
- Face coverings.
- Information provided to employees
- Compliance dates
- Reporting COVID-19 fatalities and hospitalizations to OSHA.
- Availability of records.

OSHA COVID VACCINE/TESTING

Applicability and Scope

- All employers with 100 or more employees
- Except :
 - Workplaces covered under the Safer Federal Workforce Task Force COVID–19 Workplace Safety: Guidance for Federal Contractors and Subcontractors; or
 - **Settings where any employee provides healthcare services or healthcare support services when subject to the requirements of § 1910.502.**
 - The requirements of this section do not apply to the employees of covered employers;
 - Who do not report to a workplace where other individuals such as coworkers or customers are present;
 - while working from home; or who work exclusively outdoors.

OSHA COVID VACCINE/TESTING

Definitions:

Fully vaccinated

- Fully vaccinated means: (i) A person's status 2 weeks after completing primary vaccination with a COVID–19 vaccine with, if applicable, at least the minimum recommended interval between doses in accordance with the approval, authorization, or listing that is: (A) Approved or authorized for emergency use by the FDA; (B) Listed for emergency use by the World Health Organization (WHO); or (C) Administered as part of a clinical trial at a U.S. site, if the recipient is documented to have primary vaccination with the active (not placebo) COVID–19 vaccine candidate, for which vaccine efficacy has been independently confirmed (e.g., by a data and safety monitoring board) or if the clinical trial participant at U.S. sites had received a COVID–19 vaccine that is neither approved nor authorized for use by FDA but is listed for emergency use by WHO; or (ii) A person's status 2 weeks after receiving the second dose of any combination of two doses of a COVID–19 vaccine that is approved or authorized by the FDA, or listed as a two-dose series by the WHO (i.e., a heterologous primary series of such vaccines, receiving doses of different COVID–19 vaccines as part of one primary series). The second dose of the series must not be received earlier than 17 days (21 days with a 4-day grace period) after the first dose.

Face covering

- (i)(A) completely covers the nose and mouth; (B) Is made with two or more layers of a breathable fabric that is tightly woven (i.e., fabrics that do not let light pass through when held up to a light source); (C) Is secured to the head with ties, ear loops, or elastic bands that go behind the head. If gaiters are worn, they should have two layers of fabric or be folded to make two layers; (D) Fits snugly over the nose, mouth, and chin with no large gaps on the outside of the face; and (E) Is a solid piece of material without slits, exhalation valves, visible holes, punctures, or other openings

OSHA COVID VACCINE/TESTING

Employer policy on vaccination

- The employer must establish, implement, and enforce a written mandatory vaccination policy,
 - Permitted exemptions to the vaccination requirements
 - Federal law, such as the Americans with Disabilities Act (ADA) and Title VII of the Civil Rights Act of 1964.
- or, Establishes, implements, and enforces a written policy allowing any employee not subject to a mandatory vaccination policy to choose either to be fully vaccinated against COVID-19 or provide proof of regular testing for COVID-19.

OSHA COVID VACCINE/TESTING

Determination of employee vaccination status.

- Employer must determine the vaccination status of each employee, whether fully vaccinated, and provide acceptable proof of vaccination status
- List of acceptable documents or attestation
- Maintain a roster of vaccinated employees

OSHA COVID VACCINE/TESTING

Employer support for employee vaccination

- Provide up to 4 hours paid time, including travel time, at the employee's regular rate of pay (employer cost)
- Provide reasonable time and paid sick leave to recover from side effects experienced following any primary vaccination dose to each employee for each dose (approx. 2 days)
 - May use employee sick leave, if no accrued sick leave, employer cost.

OSHA COVID VACCINE/TESTING

COVID-19 testing for employees who are not fully vaccinated

- Must tested for COVID-19 at least once every 7 days
- Provide documentation of the most recent COVID-19 test result to the employer no later than the 7th day following the date on which the employee last provided a test result or removed from the workplace
- Employees with irregular schedules or who don't report to the workplace regularly must be tested for COVID-19 within 7 days prior to returning to the workplace
- Documentation of that test result to the employer upon return to the workplace
- Maintain confidential record of each test
- Cost of testing is to the employee, unless prohibited by other laws or arrangements(collective bargaining)

OSHA COVID Tests

<https://www.osha.gov/coronavirus/ets2/faqs> Question 6J

Cleared, approved, or authorized, including in an Emergency Use Authorization (EUA), by the U.S. Food and Drug Administration (FDA) to detect current infection with the SARS-CoV-2 virus (e.g., a viral test); administered in accordance with the authorized instructions; and not both self-administered and self-read unless observed by the employer or an authorized telehealth proctor.

Diagnostic tests for current infection fall into two categories: nucleic acid amplification tests (NAATs) and antigen tests. NAATs are a type of molecular test that detect genetic material (nucleic acids); NAATs for COVID-19 identify the ribonucleic acid (RNA) sequences that comprise the genetic material of the virus. Most NAATs need to be processed in a laboratory with variable time to receive results (approximately 1–2 days), but some NAATs are point-of-care tests with results available in about 15–45 minutes.

Antigen tests may also meet the definition of COVID-19 test under this standard. Antigen tests indicate current infection by detecting the presence of a specific viral antigen. Most can be processed at the point of care with results available in about 15–30 minutes. Antigen tests generally have similar specificity to, but are less sensitive than, NAATs.

Antigen tests are the only type of diagnostic tests that can be self-administered.

OSHA COVID VACCINE/TESTING

Employee notification to employer of a positive COVID-19 test and removal.

- Employee to promptly notify the employer when they receive a positive COVID-19 test or are diagnosed with COVID-19 by a licensed healthcare provider
- Immediately remove from the workplace until:
 - Receives a negative result on a COVID-19 nucleic acid amplification test (NAAT) following a positive result on a COVID-19 antigen test if the employee chooses to seek a NAAT test for confirmatory testing;
 - Meets CDC return to work criteria, or
 - Cleared by a licensed healthcare provider

OSHA COVID VACCINE/TESTING

Face coverings

- Employees not fully vaccinated wears a face covering when indoors and when occupying a vehicle with another person for work purposes except;
 - When alone in a room with floor to ceiling walls and a closed door
 - While the employee is eating or drinking at the workplace or for identification purposes
 - When wearing a respirator or facemask.
 - Mini respirator program
 - When infeasible related to tasks or hazard risk for the employee
- An employer may not prohibit employees or customers from wearing a face covering

OSHA COVID VACCINE/TESTING

Information provided to employees

The employer must inform each employee, in a language and at a literacy level the employee understands, about:

- The requirements of this ETS and associated policies and procedures
- COVID-19 vaccine efficacy, safety, and the benefits of being vaccinated, by providing the document, “Key Things to Know About COVID-19 Vaccines,” available at <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/keythingstoknow.html>;
- The requirements of 29 CFR 1904.35(b)(1)(iv), which prohibits the employer from discharging or in any manner discriminating against an employee for reporting a work-related injuries or illness, and section 11(c) of the OSH Act, which prohibits the employer from discriminating against an employee for exercising rights under, or as a result of actions that are required by, this section. Section 11(c) also protects the employee from retaliation for filing an occupational safety or health complaint, reporting a work-related injuries or illness, or otherwise exercising any rights afforded by the OSH Act; and
- The prohibitions of 18 U.S.C. 1001 and of section 17(g) of the OSH Act, which provide for criminal penalties associated with knowingly supplying false statements or documentation.

OSHA COVID VACCINE/TESTING

Reporting COVID-19 fatalities and hospitalizations to OSHA

- Each work-related COVID-19 fatality within 8 hours of the employer learning about the fatality.
- Each work-related COVID-19 in-patient hospitalization within 24 hours of the employer learning about the in-patient hospitalization
- When reporting COVID-19 fatalities and in-patient hospitalizations to OSHA in accordance with paragraph (j)(1) of this section, the employer must follow the requirements in 29 CFR part 1904.39, except for 29 CFR part 1904.39(a)(1) and (2) and (b)(6).

* OSHA requirements for reporting fatalities and hospitalizations under 29 CFR 1904.39. The only difference is that under the ETS, employers are required to report a COVID-19 in-patient hospitalization or fatality that occurs at any time after a work-related incident (i.e., exposure). Under 1904.39, employers are only required to report fatalities that occur within 30 days of the work related incident and in-patient hospitalizations that occur within 24 hours of the work-related incident

OSHA COVID VACCINE/TESTING

Availability of records

- By the end of the next business day after a request, the employer must make available, for examination and copying, the individual COVID-19 vaccine documentation and any COVID-19 test results for a particular employee to that employee and to anyone having written authorized consent of that employee.
- By the end of the next business day after a request by an employee or an employee representative, the employer must make available to the requester the aggregate number of fully vaccinated employees at a workplace along with the total number of employees at that workplace.
- The employer must provide to the Assistant Secretary for examination and copying:
 - Within 4 business hours of a request, the employer's written policy required by paragraph (d) of this section, and the aggregate numbers of fully vaccinated employees at a workplace along with the total number of employees at that workplace, and
 - By the end of the next business day after a request, all other records and other documents required to be maintained by this ETS .

Resources

OSHA COVID-19 Vaccination and Testing website

- Policy Templates
 - [Mandatory Vaccination Sample](#)
 - [Vaccination or Testing and Face Covering Sample](#)
- Fact Sheets
 - [Workers' Rights \(Spanish\)](#)
 - [Penalties for Knowingly Supplying False Information \(Spanish\)](#)
 - [Reporting COVID-19 Fatalities and In-Patient Hospitalizations](#)

[FAQs](#)

- <https://www.osha.gov/coronavirus/ets2>

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COVID1-19 Vaccination and Testing Mandates

Medicare certified home care providers

- COVID-19 Healthcare ETS
- COVID-19 Vaccination and Testing ETS (>100 employees)
- CMS Vaccination Mandate
 - CMS COVID -19 Vaccination IFR covers many of the requirements as in the OSHA Vaccine/Testing mandate, but not all.
 - Information to employees
 - Fatality and hospitalization reporting for office staff
 - Records to OSHA are different
 - Payment for vaccination slightly different

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COVID-19 Vaccination and Testing Mandates

Non-certified home care providers

- OSHA Healthcare ETS
- OSHA COVID-19 Vaccination and Testing ETS
 - (>100 employees)

Future Considerations

- OSHA Healthcare ETS expires 12/21/2021
- Renew?
- Permanent?
- Expire?

**COVID-19 Vaccination and Testing
Mandates**

QUESTIONS????

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