



Guidance on 2021 Federal COVID-19 CMS and OSHA Vaccine Mandates

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This document should not be interpreted as medical or legal advice. Because the facts pertaining to your situation may fluctuate, or the laws in your jurisdiction might vary, please contact your attorney if you have questions related to your legal or medical obligations or rights, state or federal laws, contract interpretation, or other legal questions.

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I. Introduction

On November 4, 2021, the Biden-Harris Administration announced two major vaccination policies aimed at vaccinating health care workers. The purpose of this paper is to explain these new policies and provide guidance on how they should be interpreted and implemented by health care workers and their employers.

II. The Biden-Harris Administration Announcement

On November 4, 2021, the Biden-Harris Administration announced two major vaccination policies.

From [The White House Vaccination Policy Fact Sheet](#):

First, the Department of Labor's Occupational Safety and Health Administration (OSHA) is announcing the details of a requirement for employers with 100 or more employees to ensure each of their workers is fully vaccinated or tests for COVID-19 on at least a weekly basis. The OSHA rule will also require that these employers provide paid-time for employees to get vaccinated, and ensure all unvaccinated workers wear a face mask in the workplace. OSHA has a strong 50-year record of requiring employers to take common sense actions to prevent workers from getting sick or injured on the job. This rule will cover 84 million employees.

Second, the Centers for Medicare & Medicaid Services (CMS) at the Department of Health and Human Services is announcing the details of its requirement that health care workers at facilities participating in Medicare and Medicaid are fully vaccinated. The rule applies to more than 17 million workers at approximately 76,000 health care facilities, including hospitals, and long-term care facilities.¹

III. The CMS Vaccination Rule

On November 5, 2021, in response to the Biden-Harris Administration announcement, CMS published the [Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule](#) (CMS Vaccination Rule). The CMS Vaccination Rule was published in the [Federal Register](#) and took effect on November 5, 2021.²

1 <https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/fact-sheet-biden-administration-announces-details-of-two-major-vaccination-policies/>

2 <https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicare-programs-omnibus-covid-19-health-care-staff-vaccination>

In their November 4, 2021 [press release](#), CMS provided context for the Vaccination Rule, along with a summary of the document's contents.

The Biden-Harris Administration is requiring COVID-19 vaccination of eligible staff at health care facilities that participate in the Medicare and Medicaid programs. The emergency regulation issued by the Centers for Medicare & Medicaid Services (CMS) today protects those fighting this virus on the front lines while also delivering assurances to individuals and their families that they will be protected when seeking care.

They go on to state:

Facilities covered by this regulation must establish a policy ensuring all eligible staff have received the first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine prior to providing any care, treatment, or other services by December 5, 2021. All eligible staff must have received the necessary shots to be fully vaccinated – either two doses of Pfizer or Moderna or one dose of Johnson & Johnson – by January 4, 2022. The regulation also provides for exemptions based on recognized medical conditions or religious beliefs, observances, or practices. Facilities must develop a similar process or plan for permitting exemptions in alignment with federal law.³

IV. Unpacking the CMS Vaccination Rule

REQUIRED COMPLIANCE

Provider and Supplier Types

The CMS Vaccination Rule applies to Medicare and Medicaid-certified provider and supplier types who are regulated under the Medicare health and safety standards known as [Conditions of Participation and Conditions for Coverage or Requirements](#). Included in this group are the following:

- Ambulatory Surgery Centers
- Community Mental Health Centers
- Comprehensive Outpatient Rehabilitation Facilities
- Critical Access Hospitals
- End-Stage Renal Disease Facilities
- Home Health Agencies
- Home Infusion Therapy Suppliers
- Hospices
- Hospitals
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
- Psychiatric Residential Treatment Facilities
- Programs for All-Inclusive Care for the Elderly Organizations
- Rural Health Clinics
- Federally Qualified Health Centers
- Long Term Care Facilities
- Indian Health Service Facilities

³ <https://www.cms.gov/newsroom/press-releases/biden-harris-administration-issues-emergency-regulation-requiring-covid-19-vaccination-health-care>

Onsite Staff

The CMS Vaccination Rule applies to all new and current staff members who provide any care, treatment, or services for the facility or its patients, regardless of their clinical responsibilities or contact with patients. This includes staff members who provide services under contract or under other arrangements. Examples of these kinds of staff members include facility employees, licensed practitioners, students, trainees, and volunteers. Another example is a physician admitting or treating patients in person within a facility subject to the CMS health and safety regulations is required to be vaccinated for the facility to be compliant with the new vaccine requirement.

Offsite Staff

The CMS Vaccination Rule also applies to staff members who work offsite of a facility (e.g., home health, home infusion therapy, etc.). All staff members must be vaccinated if they interact with other staff, patients, residents, clients, or PACE program participants in any location beyond the formal clinical setting. Such settings include homes, clinics, other sites of care, administrative offices, offsite meeting locations, etc.

CMS DEFINITION OF FULLY VACCINATED

CMS provides the following explanation for what they mean by the term “fully vaccinated.”

From the [CMS Staff Vaccination Requirements – FAQ](#):

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 received by the Phase 2 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). Additionally, staff who receive vaccines listed by the World Health Organization (WHO) for emergency use that are not approved or authorized by the FDA or as a part of a clinical trial are also considered to have completed the vaccination series in accordance with CDC guidelines.⁴

VACCINATION COMPLIANCE DEADLINES AND DOCUMENTATION

Facilities covered by the CMS Vaccination Rule must establish a policy ensuring all eligible staff have received the first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine prior to providing any care, treatment, or other services by **December 5, 2021**. All eligible staff must have received the necessary shots to be fully vaccinated by **January 4, 2022**.

To document employee vaccine compliance, develop a log that includes employee vaccination statuses. You should be able to update this log easily and regularly. The log should be available to surveyors upon request.

4 <https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>

WHERE COMPLIANCE IS NOT REQUIRED

The CMS Vaccination Rule only applies to Medicare and Medicaid-certified facilities. CMS does not have regulatory authority over care settings such as:

- **Assisted living facilities or group homes** – These are not subject to CMS health and safety regulations.
- **Physicians' offices** – These are not subject to CMS health and safety regulations.
- **Medicaid home care services** (e.g., home and community-based services)
- **Schools receiving Medicaid funding** – CMS does not regulate schools.
- **Individuals who provide services 100% remotely** (e.g., telework, telecommuting, and telemedicine) These individuals do not enter the facility or have any direct contact with patients and other staff.

PHYSICIAN PRACTICE REQUIREMENTS

Physician practices are not included in the CMS Vaccination Rule – even though they may accept Medicare and Medicaid insurance. This is because the practices are not regulated by the conditions of participation, conditions of payment, or by CMS requirements.

That said, physician practices are expected to comply with the COVID-19 Healthcare Emergency Temporary Standard issued by Occupational Safety and Health Administration (OSHA) in June 2021. CMS worked closely with OSHA to ensure both of their regulations were complementary, ensured maximum coverage of staff and workers across a multitude of settings, and were not overly duplicative. (More on the OSHA Emergency Temporary Standard in Section VII of this paper.)

V. Exemptions and Accommodations to the CMS Vaccination Rule

REQUESTS FOR EXEMPTIONS

From the [CMS Staff Vaccination Requirements – FAQ](#):

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 their 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.⁵

5 <https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>

While the regulation and requirements do allow for the delay of COVID-19 vaccinations for those who have recently been diagnosed with COVID-19 per the [CDC recommendations](#), there is no exemption for those staff members who show they have antibodies. CDC recommends that all people be vaccinated, regardless of their history of symptomatic or asymptomatic SARS-CoV-2 infection.

MEDICAL EXEMPTION REQUESTS AND DOCUMENTATION

Facilities have the flexibility to establish their own processes and procedures to permit staff to request a medical exemption from the COVID-19 vaccination requirements outlined in the CMS Vaccination Rule. To request a medical exemption, a staff member should provide documentation confirming they have clinical contraindications to the COVID-19 vaccine. They should also provide a statement that they should be exempted from vaccination, signed and dated by an appropriate licensed practitioner acting within their licensed scope of practice.

A licensed practitioner cannot document their own medical exemption.

DISABILITY EXEMPTION REQUESTS AND DOCUMENTATION

Facilities have the flexibility to establish their own processes and procedures to permit staff to request a disability exemption from the COVID-19 vaccination requirements outlined in the CMS Vaccination Rule. The facility must make a good faith effort to confirm whether the employee has a disability protected under the ADA that may exempt them from the vaccination requirements. Documentation confirming the staff member has a disability protected under the ADA, and a statement that they are exempt from the vaccination requirement should be signed and dated by the appropriate person reviewing these exemption requests.

RELIGIOUS EXEMPTION REQUESTS AND DOCUMENTATION

Facilities have the flexibility to establish their own processes and procedures to permit staff to request a religious exemption from the COVID-19 vaccination requirements outlined in the CMS Vaccination Rule.

The U.S. Equal Employment Opportunity Commission (EEOC) created a [Religious Accommodation Request Form](#) staff members may use as a template.

Generally, under Title VII of the Civil Rights Act of 1964 (Title VII), an employer should assume a request for religious accommodation is based on sincerely held religious beliefs. However, if an employer has an objective basis for questioning either the religious nature or the sincerity of a particular belief, the employer would be justified in making a limited factual inquiry and seeking additional supporting information.

An employee who fails to cooperate with an employer's reasonable request for verification of the sincerity or religious nature of a professed belief risks losing any subsequent claim that the employer improperly denied an accommodation.⁶

Documentation confirming the staff member has a religious exemption under Title VII and a statement that they are exempt from the vaccination requirement should be signed and dated by the appropriate person reviewing these exemption requests.

⁶ <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws#L>

ACCOMMODATIONS FOR EXEMPTIONS

Under federal law, including the ADA and Title VII, individuals who cannot be vaccinated because of medical conditions or sincerely held religious beliefs, practices, or observances may be entitled to an accommodation.

To mitigate the transmission and spread of COVID-19, the CMS Vaccination Rule requires facilities to develop a process for implementing additional precautions for any staff who are not vaccinated. CMS encourages facilities to review the EEOC website for additional information about situations that may warrant accommodations. In granting such exemptions or accommodations, employers must ensure 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.

The EEOC's resource, [What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws](#), has a complete explanation of the ADA and religious exemptions to COVID-19 vaccinations and lists reasonable accommodations.

COMPLIANCE DATA REPORTING

The regulations outlined in the CMS Vaccination Rule do not establish any new data reporting requirements. Facilities are expected to continue complying with their facility-specific reporting requirements as set forth in the emergency regulations issued by CMS in May 2020, August 2020, and May 2021, respectively.

OF NOTE: Those facilities participating in the following programs must collect data on the new COVID-19 Vaccination Coverage among Health Care Professionals measure from October 1, 2021, to December 31, 2021, and quarterly thereafter⁷:

- Inpatient Program
- PPS-Exempt Cancer Program
- Long Term Care Hospital Program
- Inpatient Rehabilitation Program
- Inpatient Psychiatric Quality Reporting Program

VI. CMS Enforcement

STATE SURVEY AGENCIES

CMS will work directly with the State Survey Agencies to regularly review compliance with Medicare and Medicaid regulations across multiple health care settings. CMS expects state survey agencies to conduct onsite compliance reviews of these requirements in two ways:

1. State survey agencies will assess all facilities for these requirements during the standard recertification survey.
2. State survey agencies will assess the vaccination status of staff on all complaint surveys. While onsite, surveyors will review the facility's COVID-19 vaccination policies and procedures, the

7 <https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>

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.

Additionally, accrediting organizations will be required to update their survey processes to assess facilities they accredit for compliance with vaccination regulations.

CITATIONS

CMS surveyors cite hospitals and other facilities based on the severity of the deficiency, classified among three levels (from most to least severe): Immediate Jeopardy, Condition, and Standard. In all cases, health care facilities have an opportunity to return to compliance before termination.

Immediate Jeopardy citations indicate a serious scope of non-compliance, failure of the provider to address deficiencies, and close interaction with patients of unvaccinated staff. Termination of the provider type will occur within 23-days following the citation if not immediately addressed.

Condition level citations indicate substantial non-compliance that needs to be addressed to avoid termination.

Standard level citations indicate minor non-compliance where, with respect to this rule, 1) almost all staff are vaccinated, 2) the provider has a reasonable policy in place to educate staff on the vaccinations, and 3) the provider has procedures for tracking and monitoring vaccination rates. CMS generally allows for continued operation subject to the facility's agreement to a CMS-approved plan of correction.

ENFORCEMENT REMEDIES

Medicare and Medicaid-certified facilities are expected to comply with all regulatory requirements. CMS has a variety of established enforcement remedies.

- For nursing homes, home health agencies, and hospice (beginning in 2022), these enforcement remedies include civil monetary penalties, denial of payment, and, as a final measure, termination from Medicare and Medicaid.
- The remedy for non-compliance among hospitals and certain other acute and continuing care providers is termination. However, CMS's goal is to bring health care facilities into compliance. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance.

INTERACTION WITH STATE LAW AND REGULATION

Under the Supremacy Clause of the U.S. Constitution, this regulation pre-empts any state law to the contrary. U.S. Const. art. VI § 2.

VII. OSHA Emergency Temporary Standard Requirements

As stated earlier in section IV of this paper, physician practices are expected to comply with the COVID-19 Emergency Temporary Standard issued by OSHA in June 2021.

OSHA COVID-19 HEALTHCARE EMERGENCY TEMPORARY STANDARD

On June 21, 2021, OSHA issued its [COVID-19 Healthcare Emergency Temporary Standard](#) (OSHA COVID-19 ETS) to protect health care and health care support service workers from occupational exposure to COVID-19. Under OSHA regulations at 29 CFR Subpart U (86 FR 32376), covered health care employers must develop and implement a COVID-19 plan to identify and control COVID-19 hazards in the workplace and implement requirements to reduce transmission of COVID-19 in their workplaces related to the following:

- Patient screening and management
- Standard and transmission-based precautions
- Personal protective equipment (face masks, respirators)
- Controls for aerosol-generating procedures
- Physical distancing of at least six feet when feasible
- Physical barriers, cleaning, and disinfection
- Ventilation
- Health screening training
- Medical management training
- Anti-retaliation
- Record keeping
- Reporting

The OSHA COVID-19 ETS encourages vaccination by requiring employers to provide reasonable time and paid leave for employee vaccinations and any side effects. It exempts certain settings including, but not limited to:

- **Non-hospital ambulatory care settings** – where all non-employees are screened prior to entry, and people with suspected or confirmed COVID-19 are prohibited from entry.
- **Well-defined hospital ambulatory care settings** – where all employees are fully vaccinated, and individuals with possible COVID-19 are prohibited from entry.
- **Home health care settings** – where all employees are fully vaccinated, and there is no reasonable expectation that individuals with COVID-19 will be present.

PHYSICIAN PRACTICES WITH 10 OR FEWER EMPLOYEES

According to the OSHA COVID-19 ETS, a workplace setting is where any employee provides health care services or health care support services. Nonexempt facilities must:

- Conduct a hazard assessment
- Have a written plan to mitigate virus spread
- Provide certain employees with N95 respirators or other personal protective equipment
- Ensure workers can maintain a six-foot distance from each other
- Provide workers with paid time off to get vaccinated, recover from any vaccine side effects, and recover from coronavirus symptoms.

The OSHA COVID-19 ETS exempts fully vaccinated workers in low-risk areas. There are exceptions to various parts of the standard for those health care employers with fewer than 10 employees. For these cases, the OSHA COVID-19 ETS provides the following guidance:

Develop a COVID-19 Plan: Develop and implement a COVID-19 plan (in writing, if more than ten employees) that includes a designated safety coordinator with authority to ensure compliance, a workplace-specific hazard assessment, involvement of non-managerial employees in hazard assessment and plan development and implementation, and policies and procedures to minimize the risk of transmission of COVID-19 to employees.

Health Screening and Medical Management

- Screen employees before each workday and shift.
- Require each employee to promptly notify the employer when the employee is COVID-19 positive, suspected of having COVID-19, or experiencing certain symptoms.
- Notify certain employees within 24 hours when a person who has been in the workplace is COVID-19 positive.
- Follow requirements for removing employees from the workplace.
- Employers with more than ten employees, provide medical removal protection benefits in accordance with the standard to workers who must isolate or quarantine.

Record keeping: Establish a COVID-19 log of all employee instances of COVID-19 without regard to occupational exposure and follow requirements for making records available to employees and representatives.⁸

PHYSICIAN PRACTICES WITH 100 OR MORE EMPLOYEES SHOULD FOLLOW THE OSHA COVID-19 ETS

On November 4, 2021, OSHA issued the [Emergency Temporary Standard on Vaccination and Testing](#) (OSHA Vaccination ETS) requiring worker vaccinations for any employers with 100 or more employees or weekly testing for those who remain unvaccinated without an eligible exemption. The OSHA Vaccination ETS for employers with greater than 100 employees applies to employers who are not subject to the preceding two regulations (i.e., CMS Vaccination Rule or OSHA COVID-19 ETS). Facilities should review the inclusion criteria for these regulations and comply with all applicable requirements.

The OSHA Vaccination ETS provides the following guidance:

Which employers are **NOT** Covered by the OSHA Vaccination ETS: Those in settings where any employee provides health care services or health care support services when subject to the requirements of the OSHA COVID-19 ETS.⁹

8 <https://www.osha.gov/sites/default/files/publications/OSHA4122.pdf>

9 <https://www.osha.gov/sites/default/files/publications/OSHA4161.pdf>

VIII. KAMMCO Risk Management Recommendations:

KAMMCO has the following risk management recommendations:

1. Determine which regulation for COVID-19 vaccination requirements applies to your facility or practice.
2. Review the full set of requirements for your work setting, as provided in each section above.
3. Establish your written COVID-19 vaccination policy.
 - Your policy should be consistent with the mission, vision, and values of your facility or practice.
 - Outline the requirements of the appropriate regulation for your facility or practice.
 - Identify and include expectations for those in your facility or practice outside your employment (e.g., vendors and contract or agency staff).
 - Outline the documentation process for vaccination and exemption status.
4. Provide a robust educational campaign for all staff in the facility or practice.
5. Ensure each employee receives the policy, reviews the policy, and has the opportunity to ask questions regarding the policy.
6. Combat misinformation regarding the vaccine, policy, and mission of the facility or practice.
7. Ensure the facility or practice can meet the accommodation requirements of those receiving exemptions.
8. Be cautious when implementing new incentive programs; consider those employees who already completed their vaccinations and how a new program will affect the morale of the facility or practice.

You can find additional risk management resources at www.kammco.com. For more information, contact the KAMMCO Risk Management Team at 1.800.232.2259, or you can write our risk advisors at their emails below.

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Addendum A — Online Resource List

The White House Vaccination Policy Fact Sheet (November 4, 2021)

<https://www.whitehouse.gov/briefing-room/statements-releases/2021/11/04/fact-sheet-biden-administration-announces-details-of-two-major-vaccination-policies/>

CMS Press Release on Biden-Harris Administration Emergency Regulations (November 4, 2021)

<https://www.cms.gov/newsroom/press-releases/biden-harris-administration-issues-emergency-regulation-requiring-covid-19-vaccination-health-care>

CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (November 5, 2021)

<https://www.federalregister.gov/documents/2021/11/05/2021-23831/medicare-and-medicaid-programs-omnibus-covid-19-health-care-staff-vaccination>

CMS Staff Vaccination Requirements — FAQ

<https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.pdf>

EEOC Religious Accommodation Request Form Template

<https://www.eeoc.gov/sites/default/files/2021-10/EEOC%20Religious%20Accommodation%20Request%20Form%20-%20for%20web.pdf>

EEOC What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws

<https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>

OSHA COVID-19 Healthcare Emergency Temporary Standard (June 17, 2021)

<https://www.osha.gov/coronavirus/ets>

OSHA Emergency Temporary Standard — Fact Sheet (Subpart U—COVID-19 Healthcare ETS)

<https://www.osha.gov/sites/default/files/publications/OSHA4122.pdf>

OSHA Emergency Temporary Standard on Vaccination and Testing (November 4, 2021)

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

OSHA Emergency Temporary Standard on Vaccination and Testing - Fact Sheet

<https://www.osha.gov/sites/default/files/publications/OSHA4161.pdf>

OSHA Emergency Temporary Standard on Vaccination and Testing - FAQ

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

Addendum B — Acronyms and Terms Defined

ADA: Americans with Disabilities Act

CDC: Centers for Disease Control and Prevention

CMS: Centers for Medicare & Medicaid Services

CMS Vaccination Rule or Vaccination Rule: *Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (November 5, 2021)*

EEOC: U.S. Equal Employment Opportunity Commission

OSHA: U.S. Occupational Safety and Health Administration

OSHA COVID-19 ETS: *OSHA COVID-19 Healthcare Emergency Temporary Standard (June 21, 2021)*

OSHA Vaccination ETS: *OSHA Vaccination and Testing Emergency Temporary Standard (November 4, 2021)*

Title VII: Civil Rights Act of 1964