

CMS and OSHA Issue Vaccine Mandates

The CMS and OSHA vaccine mandate rules were just posted this morning. That's the CMS Interim Final Rule and the OSHA Emergency Temporary Standard. CMS is also planning to issue new visitation guidance today. Here are some high level points and answers from the CMS FAQ that we feel are most relevant to members. CMS leaders will present and discuss the interim final on the nursing home call scheduled for 1:00 PM today.

[CMS Interim Final Rule with Comment](#)

TIMING: The CMS policy requires providers to ensure all eligible staff get at least one dose prior to providing care or any other services by December 5. All staff must be fully vaccinated by January 4, 2022. The rule asks providers to have a plan in place within 30 days; the plan must include policies and procedures the organization will follow.

WHO IS COVERED: The CMS rule covers all 16 Medicare and Medicaid provider types. It does not cover physician offices.

EXEMPTIONS: The CMS rule includes both medical and religious exemptions. Individuals who receive these exemptions will have to test regularly. The CMS rule also spells out accommodations intended to protect residents from unvaccinated exempt employees.

CMS or OSHA? If a provider both accepts Medicare and or Medicaid AND has over 100 employees, the provider should comply with the CMS rule.

COMPLIANCE: The CMS rule will be enforced through established survey mechanisms – reaccreditation or complaint.

CMS CALL TODAY: As a reminder, here is the call in information for today's 1:00 PM call: [Participants wishing to join the call must RSVP here.](#)

[CMS Press Release.](#)

[OSHA Emergency Temporary Standard](#)

Deadline is January 4: The Occupational Safety and Health Administration (OSHA) issued an Emergency Temporary Standard (ETS) today that covers companies with 100 or more employees (applying to an estimated 84 million workers). Employers must ensure their workers are either fully vaccinated against COVID-19 by January 4, 2022, or that they produce a negative COVID-19 test at least once a week. The ETS will take effect as soon as it's published in the Federal Register.

Workers must get paid time off to get vaccinated: Employers must pay workers for the time it takes to get vaccinated and provide sick leave for workers to recover from any side effects.

Employers don't need to pay for testing: The rule does not require employers to pay for or provide testing to workers who decline the vaccine. However, collective bargaining agreements or other scenarios may dictate otherwise in some cases – especially any state law specific to this issue.

Unvaccinated must wear masks: Unvaccinated workers must also wear face coverings while on the job.

Exemptions: The OSHA ETS includes both medical and religious exemptions. The OSHA ETS addresses scenarios of the exemptions relative to the vaccinations and testing.

Court Challenge: We anticipate that the ETS will be challenged in federal court by a group of governors and state attorneys general.

Below are CMS FAQ's from: <https://www.cms.gov/files/document/cms-omnibus-staff-vax-requirements-2021.docx>

Q. What about Assisted Living Facilities, Group Homes, or other similar settings?

A: This regulation 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. This regulation will also not apply to physician's offices because they are not subject to CMS health and safety regulations.

Q. Does this requirement apply to Medicaid home care services, such as Home and Community-based Services (HCBS), since these providers receive Medicaid funding but are not regulated as certified facilities?

A. No, this regulation 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.

Q: Why didn't CMS include all health care settings?

A: CMS is using the authority established by Congress under the Social Security Act to regulate Medicare and Medicaid-certified health facilities. Sections 1102 and 1871 of the Social Security Act (the Act) grant the Secretary of Health and Human Services authority to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary to the efficient administration of the functions with which the Secretary is charged under this Act. Citations to the relevant statutory authorities for each specific type of provider and supplier is set out in the discussion of each provider- and supplier-specific provision of the regulation. This authority does not extend to certain facilities nor independent physicians/clinicians.

Q: Does "fully vaccinated" include additional doses or booster shots? For example, a third dose of mRNA vaccines is now recommended for individuals

who are immunocompromised, and boosters are recommended or available for individuals who are 65 or older? Does a completed vaccine series include additional doses or boosters?

A: 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 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). 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, we refer individuals to CDC's Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States for additional details.

Furthermore, to improve immune response for those individuals with moderately or severely compromised immune systems who received either the Pfizer-BioNTech COVID-19 Vaccine or Moderna COVID-19 Vaccine, CDC advises an additional (third) dose after completing the primary vaccination series. Additionally, and for the purposes of this rule, documented receipt of additional or booster doses is not needed for staff who have completed a COVID-19 primary vaccination series authorized or licensed by the FDA, or listed by the WHO for emergency use. Staff who have not received all manufacturer recommended doses of a vaccine listed for emergency use by the WHO may receive an FDA licensed or authorized COVID-19 vaccination series.

Q. Will there be different requirements for existing staff versus new staff?

A. No. Staff at all health care facilities included within the regulation must have received, at a minimum, the first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine by the regulatory deadline, or prior to providing any care, treatment, or other services for the facility and/or its patients.

Q: Are exemptions allowed?

A: 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.

Q: Is there provision for certain individuals for whom a vaccination should be delayed, for example, because of a recent COVID-19 diagnosis?

A: Yes. The regulation addresses staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations,

Q: Does the regulation include exemptions for staff that show they have COVID-19 antibodies?

A: No. Staff who have previously had COVID-19 are not exempt from these vaccination requirements. Available evidence indicates that COVID-19 vaccines offer better protection than natural immunity alone and that vaccines, even after prior infection, help prevent reinfections. CDC recommends that all people be vaccinated, regardless of their history of symptomatic or asymptomatic SARS-CoV-2 infection.

Q: How will facilities determine if an individual's request for a religious exemption is valid?

A: CMS encourages facilities to review the Equal Employment Opportunity Commission's Compliance Manual on Religious Discrimination for more information on religious exemptions.

Q: What is the process for staff to seek a religious exemption?

A: 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.

Q: What is the process for staff to seek a medical exemption?

A: Similar to religious 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.

Q. How do accommodations work for staff members who meet the requirements for an exemption and are not vaccinated?

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

Q: How will this new requirement be enforced on facilities?

A: CMS works directly with the State Survey Agencies to regularly review compliance with Medicare/Medicaid regulations across multiple health care settings.

CMS expects state survey agencies to conduct onsite compliance reviews of these requirements in two ways:

- State survey agencies would assess all facilities for these requirements during the standard recertification survey.
- State survey agencies would assess vaccination status of staff on all complaint surveys.

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 4 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.

Q: How do the penalties work/are providers immediately denied payment?

A: 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, home health agencies, and hospice (beginning in 2022), this includes civil monetary penalties, denial of payment, and even termination from the Medicare and Medicaid program as a final measure. 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.

Questions that still remain.

For those with acceptable exemptions, what will the expectations be from state survey agencies on additional precautions?

For new staff that are hired after the two-dose deadline, will those staff be able to provide care during the time between their shots if the Moderna or Pfizer vaccine is utilized?

If you have additional questions, please email them to Robin Wolzenburg (rwolzenburg@leadingagewi.org) or Brent Rapos (brapos@leadingagewi.org).

In the coming days and weeks LeadingAge Wisconsin will work to get questions answered and advocate for special circumstances or exemptions from enforcement where needed. Please keep us informed about the impacts this is having in your communities so we can

help to tell your story to policy makers.



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