

November 4, 2021

## CMS Issues Interim Final Rule Requiring Mandatory COVID-19 Vaccinations for Workers in Hospitals and Most Health Care Settings

*See details on applicability, enforcement, exemptions and other key policies*

The Centers for Medicare & Medicaid Services (CMS) today issued an [interim final rule](#) requiring COVID-19 vaccinations for workers in most health care settings, including hospitals and health systems, that participate in the Medicare and Medicaid programs. The rule is effective as of Nov. 5. Under the regulation, all eligible workers must be fully vaccinated by Jan. 4, 2022.

Also this morning, the Occupational Safety and Health Administration (OSHA) issued an [emergency temporary standard](#) requiring all employees at private businesses with 100 or more workers to be vaccinated by Jan. 4 or get tested for COVID-19 weekly.

In addition to preempting state and local law, CMS asserts that its rule takes priority above other federal vaccination requirements.

**AHA Take:** In a [statement shared with the media](#) today, AHA President and CEO Rick Pollack said, “Today’s vaccine mandate regulations set clear expectations, and streamline and simplify compliance requirements for health care providers. Importantly, they clarify that hospitals will need to comply with only the CMS rule, eliminating unnecessary complexity in implementing vaccine mandates. Additionally, we welcome that the CMS regulation provides time to come into compliance, offers guidance on medical and religious exemptions, clarifies interactions with state and local laws, and provides a level playing field across healthcare facilities. AHA has been supportive of hospitals that call for mandated vaccination of health care workers in order to better protect patients and

### Key Takeaways

In the interim final rule, CMS establishes a Condition of Participation that:

- Requires workers in health care settings to be fully vaccinated by Jan. 4.
- Applies to all employees, including volunteers and students, in health care settings regardless of whether their positions are clinical or non-clinical.
- Requires processes to be established for medical and religious exemptions.
- Takes priority over other federal vaccine requirements in an effort to eliminate the unnecessary confusion and contradiction of multiple standards.
- Preempts state law that would otherwise prevent a facility from complying with this rule.

the communities we serve. We will further review today's regulations and assist our members in coming into compliance.”

While CMS' interim final rule provides many important details about this new requirement, the AHA expects the agency soon will supplement this rule with interpretive guidance aimed at providing more information on how it will assess compliance. In addition, CMS provided a number of [frequently asked questions](#) on the rule.

Highlights of CMS' interim final rule follow. The AHA will provide additional details in a future communication on the OSHA ETS for organizations that may be subject to those regulations.

## HIGHLIGHTS OF CMS' INTERIM FINAL RULE

**Applicability:** The interim final rule establishes a Condition of Participation that applies to most health care settings, including hospitals, critical access hospitals, ambulatory surgery centers, comprehensive outpatient rehabilitation facilities, home health agencies, rural health clinics, federally qualified health centers and long term care facilities. The vaccination requirement applies to all eligible staff working at a facility that participates in the Medicare and Medicaid programs, regardless of clinical responsibility or patient care, including staff who work in offsite locations, such as homes, clinics or administrative offices. The requirement does not apply to individuals who provide services 100% remotely and have no direct contact with patients and other staff.

**Vaccination Process and Requirements:** The regulation requires health care providers to establish a process or policy to ensure staff, except for those individuals who are granted an exemption, are fully vaccinated over two phases:

- Phase 1: Within 30 days of the rule's publication, **or by Dec 6**, staff at all health care facilities where the regulation applies must have received their first dose of a 2-shot series (Moderna or Pfizer, currently) or a single dose of a 1-shot vaccine (Johnson and Johnson, currently). **Staff must complete this step before they can provide any care, treatment or other services for the facility and/or its patients.**
- Phase 2: Within 60 days of the rule's publication, **or by Jan 4**, all staff must complete the primary vaccination series.

Under the vaccination requirement, staff at health care facilities **must be fully vaccinated**. Fully vaccinated is defined by CMS as two weeks or more since the individual completed a primary vaccination series for COVID-19. Staff who complete their primary vaccination series by the Phase 2 implementation date will be considered fully vaccinated even if they have yet to complete the two-week post-series waiting period. In addition to the three vaccines currently approved in the U.S. (Pfizer, Moderna and Johnson and Johnson), the agency will recognize as fully vaccinated those staff who received vaccines listed by the World Health Organization for emergency use, but

not yet approved by the Food and Drug Administration. The vaccination requirement **applies only to the primary series. It does NOT include booster shots.**

In a situation where state law prohibits the implementation of a vaccine mandate, CMS clearly states **the federal vaccination requirement pre-empts any state law that is contrary to the federal requirement.**

**Vaccination Exemptions:** The rule requires health care facilities to allow for exemptions to staff with recognized medical conditions or religious beliefs, observances or practices. Facilities must establish a process for staff to request either exemption and ensure that the requests are appropriately documented and evaluated. In instances of medical exemption requests, providers must ensure that all documentation confirming recognized clinical contraindications are signed and dated by a licensed practitioner other than the individual requesting the exemption. **Staff who previously had COVID-19 are NOT exempt from the vaccination requirements.**

In instances where a staff member meets the requirements for an exemption and is therefore unvaccinated, the facility must develop a process for implementing additional precautions to mitigate transmission and spread of COVID-19. This could include reassigning the non-vaccinated staff to non-patient care settings. Further, when granting an exemption or accommodation, providers must take steps to minimize the risk of COVID-19 transmission to at-risk individuals.

While the regulation does not require testing for unvaccinated staff, the agency indicates it is considering such a requirement in the future. For now, providers may voluntarily institute testing alongside other infection prevention measures to mitigate any risk of COVID-19 transmission.

**Enforcement:** CMS will expect state survey agencies to conduct onsite compliance reviews of the vaccination requirements in two ways:

- Standard recertification surveys
- Assessment of vaccination status of staff on all complaint surveys

In instances where a surveyor is onsite at a facility, they will review:

- The provider's COVID-19 vaccination policies and procedures;
- The number of resident and staff COVID-19 cases over the previous four weeks; and
- A list of all staff and their vaccination status.

In addition to the state survey agencies, CMS will require all Accrediting Organizations to update their survey processes to assess compliance with the new vaccination requirements.

If a provider is deemed to be noncompliant with the requirement, CMS has a number of enforcement tools at its disposal. For nursing homes, home health agencies and hospice, the agency can enforce civil monetary penalties, denial of payment and termination from the Medicare and Medicaid program as a last resort. For hospitals and health systems, noncompliance with the requirement can lead to termination; **however, the agency expresses its intent to work with noncompliant health care facilities to bring them into compliance.**

**CMS Vaccination Requirement’s Interaction with OSHA Requirements:** CMS asserts its rule takes priority above other federal vaccination requirements. In instances where a facility is not regulated by the Conditions of Participation because of nonparticipation in the Medicare and Medicaid programs, then the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors or the OSHA COVID-19 Vaccination and Testing Emergency Temporary Standard (ETS), also issued today, apply. It should be noted that OSHA differently asserts that its new ETS does not apply in settings where employees provide health care services or health care support services subject to the requirements of the [OSHA Healthcare ETS](#) (29 CFR 1910.502), or in workplaces covered under the “Safer Federal Workforce Task Force COVID-19 Workplace Safety: Guidance for Federal Contractors and Subcontractors.” This could leave some organizations worried about whether they are subject to more than one rule, so AHA is seeking clarification from the agencies.

## **NEXT STEPS**

- Please share this document with your organization’s leadership, quality and patient safety team, and compliance team.
- Ensure that your organization has a process in place to implement this requirement, including a process by which to grant medical and religious exemptions.
- Even though it is effective immediately, formal comments on the emergency regulation can be submitted by Jan. 4.

If you have further questions, please contact Akin Demehin, director of policy, at [ademehin@aha.org](mailto:ademehin@aha.org), or Mark Howell, senior associate director of policy, at [mhowell@aha.org](mailto:mhowell@aha.org).