

COVID-19 Vaccinations Now Mandatory for Millions of Healthcare Workers

USA | November 8 2021

On November 5, 2021, the Centers for Medicare & Medicaid Services (CMS) issued an emergency regulation, the Omnibus COVID-19 Health Care Staff Vaccination Rule (the Rule). The Rule requires that eligible staff working at Medicare- or Medicaid-certified providers or suppliers be fully vaccinated against COVID-19. Eligible staff must receive a first dose of the vaccine by December 5, 2021 and any required second dose by January 4, 2022. Covered providers and suppliers must adopt policies and procedures that address a variety of topics to ensure that the vaccination requirement is met.

The Rule was issued as an Interim Final Rule with a comment period. While the requirements will go into effect immediately, stakeholders may submit formal comments on the Rule through January 4, 2022. Thereafter, CMS will consider and respond to comments through potential future rulemaking.

The Rule indicates that any provider or supplier covered by the Rule must comply with the Rule first, and then consider any other federal COVID-19 vaccine obligations that might apply (including federal contractor and OSHA requirements). This is an important distinction, as those other rules differ in important respects. Unlike the contemporaneously issued rule by the Occupational Safety and Health Administration (OSHA), this Rule does not allow covered providers or suppliers to offer eligible staff the choice between weekly testing and vaccination. And unlike the federal contractor obligations, the Rule does not contain requirements related to masking or remote workers. Furthermore, the Rule applies even in states that prohibit vaccine mandates.

Covered Providers and Suppliers

The Rule covers Medicare- and Medicaid-certified providers and suppliers that are regulated under CMS health and safety standards, such as Conditions of Participation, Conditions for Coverage, or Requirements for Participation. This includes hospitals, ambulatory surgery centers, long-term care facilities, home health agencies, hospices, end-stage renal disease facilities, and federally qualified health centers, among others.

The Rule recognizes only three types of providers and suppliers that are exempt from the vaccination requirement: religious nonmedical health care institutions, organ procurement organizations, and portable x-ray suppliers. Physician offices, assisted living facilities, group homes, and Medicaid home care services are not covered by the Rule because they are not subject to CMS health and safety regulations or are otherwise outside of CMS's regulatory authority. It is important to note, however, that these providers may still be subject to other federal or state COVID-19 vaccination requirements, such as those issued by OSHA.

Eligible Staff

The Rule applies broadly to staff who work for Medicare- and Medicaid-certified facilities ***regardless of clinical responsibility or patient contact***. This means that almost all employees must be vaccinated, as well as other staff who provide services for the facility, including students, volunteers, off-site workers, contractors, and providers with admitting privileges. Those employees who telework 100% of the time are not covered by this vaccination mandate. However, if a provider is also covered by the federal contractor COVID-19 obligations, the employee who teleworks may be subject to a vaccination requirement.

The Rule acknowledges that providers and suppliers must provide exemptions to the vaccine requirement to those who are entitled to an accommodation because of religious beliefs, a disability, or a recognized medical condition. CMS states that such exemptions "could be appropriate under limited circumstances," but emphasizes that "no exemption should be provided to any staff for whom it is not legally required . . . or who requests an exemption solely to evade vaccination."

If an unvaccinated staff member qualifies for an exemption, the provider or supplier must develop a process for implementing additional precautions to prevent the spread of COVID-19. While the Rule states that providers and suppliers should not provide exemptions from the vaccination requirement unless legally required to do so, it does not provide any guidance on what constitutes "legally required" in the view of CMS. Instead, the Rule directs providers and suppliers to the EEOC for guidance in evaluating requests for accommodation.

Specific Vaccine Requirements

CMS divides compliance with the Rule into two phases. For Phase 1, by December 5, eligible staff must have received, at a minimum, a first vaccine dose. For Phase 2, by January 4, eligible staff must have completed the CDC recommended vaccine series, meaning that if the first dose was part of a multi-dose vaccine, the staff member must receive the second shot. Therefore, as long as staff members have received all doses necessary by January 4, CMS will consider staff fully vaccinated for purposes of the Rule, despite the fact that the CDC does not consider an individual fully vaccinated until 14 days after the final dose of the vaccine regimen.

Currently, the Rule does not require booster shots or regular COVID-19 testing. However, CMS could require such measures in the future.

Conclusion

Covered providers and suppliers should immediately begin taking steps to comply with the Rule by implementing policies and procedures to require staff to become fully vaccinated by the applicable deadlines. Failure to do so could result in civil penalties, the denial of Medicare and Medicaid funds, or complete termination from the Medicare and Medicaid programs.

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