

Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule with Comment

Centers for Medicare & Medicaid Services (CMS)

Agenda

- Opening Remarks
- Overview of the Interim Final Rule and Guidance
 - Eligibility
 - Basic Requirements
 - Enforcement
 - Interactions with other Regulations and Requirements
 - Action to Take
- Questions and Answers (Time Permitting)

Eligibility – Who is included?

Requirements apply to facilities regulated under the Medicare Conditions of Participation (CoPs)

This Includes:

- Ambulatory Surgery Centers
- Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services
- 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
- Long Term Care Facilities
- Programs for All-Inclusive Care for the Elderly Organizations (PACE)
- Psychiatric Residential Treatment Facilities
- Rural Health Clinics/Federally Qualified Health Centers

So What? – If you are one of the above providers or suppliers, this regulation applies to you and you must abide by the requirements

Eligibility – Who is excluded?

The following provider and supplier types are not included in this requirement:

- Religious Nonmedical Health Care Institutions (RNHCIs)
- Organ Procurement Organizations
- Portably X-Ray Suppliers

Additionally, the requirements do not apply to the following:

- Assisted Living Facilities
- Group Homes
- Home and Community-based Services
- Physician's Offices

Key Fact to Remember: This regulation and the requirements within only apply to providers and suppliers regulated under the CMS Conditions of Participation (CoPs)

Requirements – What must my facility do?

There are three basic requirements that facilities must complete:

1. You must have a process or plan for vaccinating all eligible staff
2. You must have a process or plan for providing exemptions and accommodations for those who are exempt
3. You must have a process or plan for tracking and documenting staff vaccinations

Requirements – When must my facility do it?

- You must have your process or plan in place for vaccinating staff, providing exemptions and accommodations, and tracking and documenting staff vaccinations within 30-days (by December 5, 2021)
- Additionally, your process or plan for vaccinating staff must ensure that all eligible staff receive:
 - 1st Dose or One-Dose Vaccine by December 5, 2021
 - Received all shots for full vaccination by January 4, 2022

The infographic consists of two side-by-side white boxes with dark blue headers and footers, set against a light blue background. The left box features a syringe icon on a yellow circle. The right box features a checkmark icon on a teal circle.

Requirement	Deadline
1st Dose or One-Dose Vaccine	by December 5, 2021
Received all shots for full vaccination	by January 4, 2022

Requirements – Who in my facility must be vaccinated?

- The vaccination requirements **apply to all eligible staff**, both current and new, working at a facility regardless of clinical responsibility or patient contact, including:
 - Facility Employees
 - Licensed Practitioners
 - Students
 - Trainees
 - Volunteers
 - Contracted Staff
- The vaccination requirements also apply to staff who perform duties offsite (e.g. home health, home infusion therapy, etc.) and to individuals who enter into a CMS regulated facility
 - Example: A physician with privileges in a hospital who is admitting and/or treating patients onsite
- This requirement does not apply to full time telework staff

Requirements – How does CMS define fully vaccinated?

- CMS considers staff fully vaccinated if it has been two weeks or more since they completed a primary vaccination series for COVID-19
 - **Important Note:** 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
- Completion of a primary vaccination series for COVID-19 means:
 - Staff received a single-dose vaccine
 - Janssen (Johnson & Johnson) COVID-19 Vaccine
 - Staff received all required doses of a multi-dose vaccine
 - Pfizer-BioNTech COVID-19 Vaccine (interchangeable with the licensed Comirnaty Vaccine)
 - Moderna COVID-19 Vaccine
 - Staff received vaccines listed by the World Health Organization (WHO) for emergency use (in accordance with CDC guidelines)
- *Are boosters included?* – No, however CMS strongly encourages facilities and staff to review the CDC's *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States* for additional detail on additional doses

Requirements – How do exemptions work?

CMS requires facilities to allow for the following exemptions to staff in accordance with federal law:

- Recognized medical conditions for which vaccines are contraindicated
- Religious beliefs, observances, or practices

Basics for Medical Exemptions:

- Facilities must develop a process for permitting staff to request a medical exemption
- Facilities must ensure all documentation is signed and dated by a licensed practitioner
- Documentation must contain all information specifying why the COVID-19 vaccines are clinically contraindicated for the staff member
- Documentation must include a statement by the authenticating practitioner recommending the staff member be exempted

Basics for Religious Exemptions:

- Facilities must develop a process for permitting staff to request a religious exemption
- Facilities must ensure all requests for religious exemptions are documented and evaluated in accordance with applicable federal law and as a part of the facility's policies and procedures

Requirements – How do accommodations work?

- CMS requires facilities to develop a process for implementing additional precautions for any staff who are not vaccinated
- Potential accommodations for exempted staff could include, but are not limited to:
 - Testing
 - Physical Distancing
 - Source Control
- *In all cases – facilities must ensure that they minimize the risk of transmission of COVID-19 to at-risk individuals*

Requirements – Anything else my facility should know?

- Vaccination is the only option – this regulation **does not include a testing option** for unvaccinated staff
 - Facilities are encouraged to voluntarily institute testing alongside other infection prevention measures such as physical distance and source control
- There are **no new data reporting requirements** within this regulation
 - Facilities, specifically hospitals and nursing homes, are still expected to continue complying with the facility-specific data reporting requirements set forth in emergency regulations issued by CMS in May 2020, August 2020, and May 2021, respectively

Enforcement – How will CMS check for compliance?

- 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 for the requirements in two ways:
 - Recertification Surveys
 - Complaint Surveys
- Surveyors will check to determine if a facility has met the three basic requirements:
 1. Having a process or plan for vaccinating all eligible staff
 2. Having a process or plan for providing exemptions and accommodations for those who are exempt
 3. Having a process or plan for tracking and documenting staff vaccinations
- Accrediting Organizations will also assess for compliance

Enforcement – What if my facility is out of compliance?

Surveyors will cite facilities based on the level or severity of the noncompliance

So what? – Facilities that are out of compliance will be cited and provided an opportunity to return to compliance

If not? – CMS may use enforcement remedies, such as civil monetary penalties, denial of payment, and even termination from the Medicare and Medicaid program as a final measure

Interactions with Other Regulations and Requirements

Bottom Line Up Front: *If* your facility participates in the Medicare and Medicaid programs and is regulated under the CMS Conditions of Participation, Conditions for Coverage, or Requirements, *then* the CMS Omnibus COVID-19 Health Care Staff Vaccination Regulation takes priority and your facility is expected to abide by the requirements

Other Considerations:

- *If* facilities are not certified under the Medicare and Medicaid programs and therefore not regulated by the CoPs, *then* the Executive Order on Ensuring Adequate COVID Safety Protocols for Federal Contractors or OSHA COVID-19 Healthcare Emergency Temporary Standard apply
- *If* none of the above regulations apply, *then* employers are subject to the OSHA Employer Emergency Temporary Standard (for facilities with greater than 100 employees)
- Lastly, this regulation pre-empts any state law under the Supremacy Clause of the United States Constitution

Actions to Take

- DO review the Omnibus COVID-19 Health Care Staff Vaccination Regulation and the specific sections applicable to your facility
- DO review the Frequently Asked Questions document specific to this regulation on the CMS Emergencies Page
- DO begin developing your process or plan for vaccinating staff, providing exemptions and accommodations, and documenting and tracking staff vaccinations
- DO note the two milestone dates by which compliance is expected
 - 30-days → December 5, 2021
 - 60-days → January 4, 2022