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 6, 2021)

• Additionally, your process or plan for vaccinating staff must ensure that all eligible staff receive:
  • 1st Dose or One-Dose Vaccine by December 6, 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 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 6, 2021
  • 60-days → January 4, 2022