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 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