

MANDATORY VACCINE POLICIES

November 10, 2021

Where do we go from here?

First Vaccine Rule Compliance Deadline Set for December 5, 2021

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CMS Interim Final Rule

- The CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (“CMS Rule”)
- Implements mandatory vaccine requirements announced by the Biden Administration in September

The Mandate

- All covered staff must receive the first dose of a two-dose FDA approved or a single-dose FDA approved vaccine by **December 5, 2021.**
- All covered staff must be fully vaccinated (14 days after last dose) by **January 4, 2022.***

**“CMS has relaxed this standard in a subsequent FAQ that Covered Staff who receive their final vaccination by January 4, 2022 are considered to have met these requirements.”*

The Exemptions

- Recognized medical conditions
- Strongly held religious beliefs, observances, or practices
- No other exceptions

CMS Rule > Conflicting State Law

- Many states have passed laws which prevent businesses / facilities in the state from requiring vaccination.
- Others have required additional exemptions, like a weekly testing option or exemption with proof of antibody presence.
- CMS Rule supersedes these state laws.

CMS Rule Applies to....

- Providers and suppliers regulated by the CMS Conditions of Participation.
- Generally, does not apply to physician offices, but may apply to clinics that:
 - Are Provider-Based (Outpatient Department of Hospital) or
 - Provide physical therapy or speech pathology services that are subject to the CMS Conditions of Participation

Full List of Covered Facilities

- Ambulatory Surgical Centers
- Hospitals
- Hospices
- Psychiatric Residential Treatment Facilities
- Long Term Care Facilities (but not facilities like Assisted Living)
- Intermediate Care Facilities for Individuals with Intellectual Disabilities
- Home Health Agencies
- Comprehensive Outpatient Rehabilitation Facilities
- Community Mental Health Centers
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services
- Home Infusion Therapy suppliers
- Rural Health Clinics / Federally Qualified Health Centers
- End-Stage Renal Disease Facilities

Who Must be Vaccinated?



- Any staff member on site at a covered health facility who provides patient care, or interacts with staff who provide patient care.
- Applies to staff who perform duties offsite, but not full telework staff.
- Applies to providers who provide patient care at health facility (for example, members of the Medical Staff).

Exemptions

MEDICAL EXEMPTION:

- Required to establish exemption process for Recognized Medical Conditions (Required by Americans with Disabilities Act of 1990 (ADA)).
- A valid request for accommodation must include specific documentation.

Exemptions – Medical Exemption

DOCUMENTATION MUST:

- Confirm recognized clinical contraindication to COVID-19 vaccine
- Support staff requests for medical exemption from vaccine
- Be signed and dated by licensed practitioner (may not be individual requesting exemption) who is acting within respective scope of practice
- Specify which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and
- Include statement by the authenticating practitioner recommending that the staff member should be exempted from the requirement based on the recognized clinical contraindications.

Approving a Medical Exemption

- If exemption request meets previous criteria, should be approved unless accommodation would be “undue hardship” for employer
- “Undue Hardship” – ADA defines as “an action requiring significant difficulty and expense.”
- Factors: cost + number of individuals in need of accommodation

Religious Exemption

- Required to grant exemption request for Strongly Held Religious Beliefs, Observances, or Practices by Title VII of the Civil Rights Act of 1964
- Employer must have enough information to make the employer aware that a conflict exists between the applicant's religious observance, practice, or belief and COVID-19 vaccination.

Religious Exemption - EEOC Guidance

- If the employer reasonably needs more information, the employer and applicant should discuss the request.
- Applicant may need to explain the religious nature of the belief, observance, or practice and the way it conflicts with the vaccination requirement.
- “In determining if a conflict exists, it is irrelevant that the employer does not view the work requirement as impacting a religious belief, or that most people of the applicant’s faith would not; it is the applicant's own religious belief that is relevant.”

Religious Exemption

1. Does the exemption request establish a sincere strongly held religious belief, observance, or practice? Develop a standardized process for documentation to be provided.
2. Is the requested accommodation a reasonable one?
3. If granted, does the requested accommodation impose an undue hardship on operations and the health and safety of coworkers?

Undue Hardship – the proposed accommodation poses more than a *de minimus* cost or burden (lower standard than ADA).

No Evading Vaccination

- No exemption request may be granted when the exemption request is solely to evade vaccination.

No Further Guidance

- CMS declined to give further guidance on considering religious exemption requests.
- Instead, the CMS Rule references the Equal Employment Opportunity Commission's Compliance Manual on Religious Discrimination.

Documentation for Compliance

Covered Facilities must have separate processes for:

1. Tracking and securely documenting vaccination status (including recommended booster doses)
2. Tracking and securely documenting exemption requests
3. Tracking and secure documentation of vaccination status of staff for whom vaccination must be temporarily delayed as recommended by CDC for clinical precautions and considerations

Contingency Plans for Unvaccinated

- 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 risk of transmission of COVID-19 to at-risk individuals

Enforcement

- CMS will work with State Survey Agencies – Accrediting Organizations will follow.
- State Survey Agencies will conduct onsite compliance reviews for the requirements of the CMS Rule during both Recertification Surveys and Complaint Surveys

Enforcement

Surveyors will check to determine if a facility has met 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 vaccinations

Enforcement for Non-Compliance

- Facilities that are out of compliance will be cited and provided an opportunity to return to compliance.
- If not, enforcement remedies include:
 - Civil Monetary Penalties
 - Denial of Payment
 - Termination from the Medicare and Medicaid program

OSHA ETS for Healthcare Providers

- The first OSHA ETS (issued June 10) is still in effect.
- Covered healthcare employers are required to develop a COVID-19 plan
- Most notably, the ETS may require employers to remove employees from the workplace and provide medical removal protection benefits.


Which Mandate Applies?

1. If the CMS Mandate applies to you, you don't need to comply with any other mandates.
2. If the CMS Mandate does not apply and you have more than 100 employees, you should comply with the OSHA Rule.
3. If the CMS Mandate and the OSHA Rule do not apply to you, check to see if you have any federal contracts which may require you to comply with the Federal Contractor mandate.

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