

Understanding the CMS and OSHA Vaccine Mandates

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Status of Legal Challenges

- ▶ OSHA Vaccine/Testing Mandate
 - On November 12, 2021 the United States Court of Appeals for the Fifth Circuit granted a STAY of the OSHA ETS pending adequate judicial review of a Motion for Permanent Injunction. The Court ordered OSHA to take no further steps to implement or enforce the ETS.
 - The Sixth Circuit won the “lottery” and will hear the merits of challenges to the OSHA ETS.
 - On 11/17/21, OSHA has released a statement on its website stating that it has suspended activities related to the implementation and enforcement of the ETS pending future developments in the litigation.
 - *Note* the June OSHA Healthcare ETS has not been challenged and remains in effect.

Status of Legal Challenges cont...

▶ CMS Vaccine Mandate

- On November 10, 2021, ten states filed a lawsuit in the United States District Court for the Eastern District of Missouri seeking a declaratory ruling as well as preliminary and permanent injunctions preventing CMS from imposing its mandate. On November 15, 2021 twelve more states filed suit in the United States District Court of Louisiana Monroe Division.
- There have been no court ruling based on these legal challenges as of today.
- Absent further rulings from the courts, providers should plan to comply with the CMS Vaccine Mandate regulation.

CMS Vaccine Mandate

▶ Topics:

- Who is Covered (provider types)?
- Who is Not Covered (provider types)?
- What employees, volunteers, ancillary providers, etc. are subject to the vaccine mandate?
- What policies and processes must the LTC provider develop?
- What are the effective dates?
- What is the enforcement mechanism?

CMS Vaccine Mandate

▶ Key Dates To Keep In Mind

- Providers' process or plan for vaccinating required staff must ensure that all covered staff receive:
 - 1st Dose or One-Dose Vaccine by **December 6, 2021**
 - Received all shots for full vaccination by **January 4, 2021**
- Basic Rule: Under the CMS Mandate, a covered staff member must be vaccinated by the above deadlines prior to providing any care, treatment or other services to the covered facility or its residents/patients.
 - CMS regulation does not provide a testing option for unvaccinated staff who have not been approved for an exemption.

CMS Vaccine Mandate

▶ Who is covered (provider types)?

- 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

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- ▶ **Who is not covered (provider types)?**
 - Religious Nonmedical Health Care Institutions (RNHCIs)
 - Organ Procurement Organizations
 - Portable X-Ray Suppliers
 - Assisted Living Facilities/Personal Care Homes
 - Group Homes
 - Home and Community-Based Services
 - Physician's Offices
 - Though not specifically addressed in the regulation, Senior Housing/Independent Living also would not be covered, as it is not a Medicare/Medicaid certified operation

Applicability of Mandate Rules to CCRC, Senior Housing and PCH/AL

- ▶ On its face the CMS Vaccine Mandate does not apply to CCRCs, Senior Housing and Personal Care Homes and Assisted Living providers, however these providers must keep in mind:
 - The June OSHA ETS would apply to these providers, and if the providers have more than 100 employees, the November OSHA ETS would apply to them as well should that ETS ultimately go into effect
 - Pennsylvania DHS could introduce guidance or orders that would involve staff vaccination that providers may need to comply with as well.
 - As discussed further below, if any staff of CCRCs, Senior Housing, PCH, or AL providers cross over and work in other facilities or work directly with staff who work in facilities that are covered by the CMS mandate then they must also be compliant with the CMS vaccine mandate.

CMS Vaccine Mandate

- ▶ **What individuals/positions are subject to the mandate?**
 - The vaccine 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 (e.g. physicians, nurses, etc.)
 - Students
 - Trainees
 - Volunteers
 - Contracted Staff
 - Board Members (potentially)

CMS Vaccine Mandate

- ▶ **What individuals/positions are subject to the mandate? (cont...)**
 - The mandate also applies to staff who perform duties offsite (examples would be home health, and home infusion therapy) and to individuals who enter into a CMS regulated facility (example a physician with privileges in a hospital who is admitting and treating patients onsite)
 - Individuals who provide care, treatment, services under contract or arrangement; i.e. Ancillary Providers who come into facility to provide services to residents (e.g. therapists)
 - Individuals who have direct contact with either facility residents or any of the facility staff who are subject to the mandate
 - This catch-all category is important for determining which individuals are subject to the mandate in a CCRC/campus type of setting;
 - Requires facility to determine and analyze the “cross-over” of administration and other employees not necessarily assigned to the nursing facility setting
 - Do ALR/PCH staff interact with nursing staff? Do they ever go into the nursing facility?
 - Does non-nursing staff (e.g. independent living, PCH) interact with management team members who do go into the nursing facility, and who are subject to the mandate?
 - As a practical matter, in a CCRC setting, it can be challenging to try to “parse out” those individuals who may not be subject to the mandate, and it may be administratively challenging to apply a policy that segregates employees by “level of care”
 - This analysis would also govern the applicability of the mandate to Board Members

CMS Vaccine Mandate

- ▶ The mandate does not apply to:
 - Staff who exclusively provide telehealth/telemedicine services outside of the facility and who do not have any direct contact with residents and other staff who are subject to the mandate;
 - Staff who provide support services for the facility that are performed exclusively outside of the facility setting and who do not have any direct contact with residents and other staff who are subject to the mandate; and
 - Individuals who provide non-healthcare services on an “ad hoc” basis.

CMS Vaccine Mandate

- ▶ CMS is requiring providers to allow for the following exemptions to staff in accordance with federal law:
 - Recognized medical conditions for which vaccines are contraindicated; and
 - Sincerely held religious beliefs, observances, or practices.

CMS Vaccine Mandate-- Exemptions

- ▶ Medical Exemption
 - Available for recognized clinical contraindications to COVID-19 vaccines.
 - Temporary delay in vaccination may also be available for individuals due to “clinical precautions and considerations,” which may include acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment.
- ▶ Medical Exemption Form should include:
 - Information specifying which of the available vaccines are contraindicated and the recognized clinical reasons for the contraindication;
 - A statement that the employee be exempted from vaccination due to recognized contraindications;
 - Licensed practitioner’s signature and date;
 - Information indicating the practitioner is acting within the scope of her/his practice; and
 - Information indicating that the licensed practitioner is not the employee seeking exemption.

CMS Vaccine Mandate-- Exemptions

▶ Religious Exemption

- Available to employees whose sincerely held religious belief, observance, or practice prevents them from being vaccinated against COVID-19.
- EEOC guidance states: “an employer should assume that a request for religious accommodation is based on sincerely held religious beliefs. However, if an employer has an objective basis for questioning either the religious nature or the sincerity of a particular belief, the employer would be justified in making a limited factual inquiry and seeking additional supporting information.”

▶ Religious Exemption Forms and Options

- Simple Form
 - Explains the basis and sincerity of the religious belief, observance or practice AND why it prevents employee from being vaccinated; and,
 - OPTIONAL for employee to submit religious texts, statements from clergy, etc.
- Complex Form
 - Asks a longer, more detailed series of questions that elicit more detailed information about the employee’s religious belief, observance, or practice, when they came to believe that way, how it compares to their other beliefs, information about the religion itself, etc.

Exemption Considerations / Analysis

▶ Medical Exemption

- Exemption is complete, signed, and dated by licensed practitioner.
- LP is practicing within the scope of practice.
- LP is not the employee requesting exemptions.
- Clearly indicates employee's contraindications.
- Contraindications are recognized and clinically appropriate.

Exemption Considerations/Analysis cont...

▶ Religious Exemption

- Employee clearly identifies religious belief and it does not appear to be merely philosophical, moral, or political.
- Employee demonstrates the sincerity of the belief by explaining WHY the religious belief prevents vaccination.
- There is no objective information that casts doubt on sincerity of belief or its religious nature. (e.g. first requested a medical exemption, but submitted a religious exemption upon denial)

CMS Vaccine Mandate

- ▶ To be compliant with the regulation providers must ensure that staff who work in the provider's facility are fully vaccinated or have been granted an exemption by January 4th.
- ▶ For staff who are not fully vaccinated or who have not been granted an exemption by January 4th, a provider must:
 - Ensure the staff member is not on-site by suspending, terminating, granting leave or characterizing as a voluntary resignation.
 - or
 - Redefine the staff member's work responsibilities to ensure that they perform their work duties 100% offsite, and do not interact directly at all with any staff who do work on site.

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- ▶ CMS is requiring providers to develop a process for implementing additional precautions for any staff who are not vaccinated due to an exemption.
- ▶ Is an accommodation possible?
- ▶ Potential accommodations for exempted staff could include but are not limited to the following:
 - Testing
 - Physical Distancing
 - Source control

CMS Vaccine Mandate

▶ What policies and plans must providers develop?

- The regulations (42 CFR § 483.80 and §483.430) require the following at a minimum:
 - Documentation that staff were provided education regarding the benefits and risks and potential side effects associated with the COVID-19 vaccine
 - Documentation that staff were offered the COVID-19 vaccine or information on obtaining the COVID-19 vaccine.

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- Documentation that vaccines were offered, and whether accepted or declined.
- A process for ensuring all staff (unless exempted) have received the first vaccine prior to providing care.
- A process for ensuring all staff (unless exempted) are fully vaccinated by the deadline.
- A process for ensuring implementing precautions to mitigate transmission by all staff not vaccinated.
- A process for tracking and securely documenting staff vaccination status.
- A process for tracking which staff have received booster(s).
- A process by which staff may request an exemption.
- A process for tracking and documenting information from staff regarding exemption requests.

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- A process for tracking and documenting information from staff regarding exemption requests.
- A process for ensuring all appropriate documentation respecting a medical exemption is collected.
- A process for ensuring and tracking the vaccination status of all staff for whom the vaccination must be delayed.
- Contingency plans for staff who are not fully vaccinated.

CMS Vaccine Mandate

- ▶ **Enforcement– What happens if a provider is not in compliance?**
 - CMS is expecting the State Survey Agencies to conduct onsite compliance reviews for the requirements of the vaccine mandate during either, recertification surveys or complaint surveys
 - For providers that are not in compliance with the requirements of the vaccine mandate, CMS may use enforcement remedies such as civil monetary penalties, denial of payment, and even termination from the Medicare and Medicaid programs
 - We await further guidance from CMS and DOH on their specific inspection and sanction plans for providers.
 - Question: Will CMS/DOH account for care and staffing issues that may result from the mandate, and the status of “outbreaks” and COVID within the local area?

CMS Vaccine Mandate

- ▶ To help provide guidance in interpreting this regulation, CMS has issued an FAQ that answers some questions that it has received thus far from providers. CMS has advised that this FAQ is going to be updated by the agency.
- ▶ CMS has also advised that it will be updating the State Operations Manual, Appendix PP to provide further guidance and clarity related to its expectations for long term care providers.

Recommendations

- ▶ Ensure that written policies and forms are in place, including at a minimum:
 - Vaccination Policy
 - Medical Exemption Form
 - Religious Exemption Form
- Other forms could include materials to help with exemption decisions, information for vendors, and correspondence communicating exemption decisions.

Questions?

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