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### **CMS ISSUES VACCINE MANDATE FOR HEALTHCARE EMPLOYERS**

On November 4, 2021, the Centers for Medicare and Medicaid Services (CMS) issued an [Interim Final Rule](#) (the Rule) requiring healthcare employers to mandate COVID-19 vaccinations for staff. The Rule was issued at the same time as the Occupational Safety and Health Administration's (OSHA) COVID-19 Vaccination and Testing Emergency Temporary Standard (ETS) for employers with 100 or more employees. Unlike the OSHA ETS, the CMS Rule does not allow for testing instead of vaccination.

Under the CMS Rule, healthcare workers will need to be fully vaccinated by January 4, 2022. Although legal challenges are expected, below is a summary of the Rule's primary requirements as currently set forth by CMS.

#### **Which facilities are covered?**

The Rule applies to all Medicare- and Medicaid-certified facilities regulated under Conditions of Participation, Conditions of Coverage, or Requirements. Specifically, the Rule applies to the following Medicare- and Medicaid-certified provider and supplier types:

- Ambulatory surgical centers,
- Hospices,
- Psychiatric residential treatment facilities,
- Programs of all-inclusive care for the elderly (PACE),
- Hospitals (including acute care hospitals, psychiatric hospitals, hospital swing beds, long-term care hospitals, children's hospitals, transplant centers, cancer hospitals, and rehabilitation hospitals/inpatient rehabilitation facilities),
- Long-term care (LTC) facilities, including skilled nursing facilities (SNFs) and nursing facilities (NFs), generally referred to as nursing homes,
- Intermediate care facilities for individuals with intellectual disabilities,
- Home health agencies,
- Comprehensive outpatient rehabilitation facilities,
- Critical access hospitals,
- Clinics, rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services,
- Community mental health centers,

- Home infusion therapy suppliers,
- Rural health clinics/federally qualified health centers, and
- End-stage renal disease (ESRD) facilities.

The Rule does **NOT** cover physician offices and health care entities that CMS does not regulate. However, these employers may be covered by other regulations, such as the OSHA ETS, depending on other criteria. Additionally, although religious nonmedical healthcare institutions, organ procurement organizations, or portable X-ray suppliers are not included in the Rule, CMS noted that the Rule would indirectly regulate the latter two entities through service contracts with providers and suppliers.

### **Which individuals are covered?**

The Rule requires that all staff working at a covered facility, regardless of clinical responsibility or patient contact, must be fully vaccinated. This covers all staff who provide any care, treatment, or other services for the facility and/or its patients, including:

- Facility employees,
- Licensed practitioners,
- Students, trainees, and volunteers, and
- Individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement.

This is a broad Rule that encompasses any individual who is present in the facility. As such, the Rule applies to administrative staff because they may occasionally encounter fellow staff who will enter the facility to provide patient care.

The Rule sweeps as broadly to include “administrative staff, facility leadership, volunteer or other fiduciary board members, housekeeping and food services, and others.”

- The Rule does provide exceptions for individuals who are not present in the facility and allows facilities’ policies to exclude:
- Fully remote telehealth providers or individuals furnishing payroll services, if they do not have direct contact with patients, residents, or other staff members, and
- Vendors, volunteers, and professionals who perform infrequent “one off” services and tasks for the facility and who do not have direct contact with patients or staff in the facility.

### **What does the Rule require?**

The Rule requires covered facilities to develop and implement:

- A process ensuring that all covered staff have received, at least, the first dose of a primary series or a single dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the facility and/or its patients,

- A process for ensuring that all staff are fully vaccinated,
- A process for tracking and securely documenting COVID-19 employee vaccination status, including those who have received boosters,
- A process to consider exemption requests based on applicable federal law (i.e., Title VII of the Civil Rights Act of 1964 (Title VII) and the Americans with Disabilities Act (ADA)), including a process for tracking and securely documenting: (1) information provided by requesting staff and (2) all granted exemptions, and
- A contingency plan for staff who are not fully vaccinated from COVID-19.

These requirements are uniform across different settings of care, and all healthcare facilities should prepare to implement vaccine policies and exemption forms. CMS has referred to resources in the Rule that facilities may use to implement policies and exemption forms, such as the [CDC Summary Document for Interim Clinical Considerations](#), and attorneys can help draft policies and forms as required.

It is important for healthcare facilities to note that, unlike the OSHA, there is no opt-out of the vaccine mandate for individuals who instead wish to undergo weekly COVID-19 testing. CMS expressly addressed this in its answers to frequently asked questions as follows:

Q: Does the regulation include testing requirements for unvaccinated staff?

A: No, this regulation requires staff vaccination only. While CMS considered requiring daily or weekly testing of unvaccinated individuals, scientific evidence on testing found that vaccination is a more effective infection control measure. CMS will continue to review the evidence and stakeholder feedback on this issue, however facilities may voluntarily institute testing alongside other infection prevention measures such as physical distancing and source control. Of note, CMS published an emergency regulation in September 2020 that established new requirements for Long Term Care facilities (nursing homes) to test facility residents and staff for COVID-19. CMS expects continued compliance with this requirement. Additionally, CMS encourages facilities not covered under this regulation to review the OSHA Emergency Temporary Standard for separate vaccination and testing requirements.

### **Are there exceptions to the Rule?**

CMS has provided for limited exceptions to the Rule. In addition to fully remote staff who do not have direct contact with patients, residents, or other staff members and the “one off” service vendors identified above, the Rule includes limited exemptions based on applicable federal law. Specifically, individuals who are legally entitled to a reasonable accommodation under federal civil rights laws due to a disability or a sincerely held religious belief, practice, or observance that conflicts with the vaccination requirement may be exempt.

Facilities are required to develop a process or plan for permitting disability and religious exemptions according to federal law. The process must include tracking and documenting information provided by staff who request exemption, the facility’s decision, and any accommodations provided. [Guidance from the Equal Employment Opportunity Commission](#) may be helpful in developing and executing this process.

### **When does the rule become effective?**

The Rule took effect immediately upon its publication in the Federal Register on November 5, 2021. It will be implemented in two phases.

First, covered employees must receive, at a minimum, the first dose of a primary, multi-dose series or a single dose COVID-19 vaccine within 30 days of the Rule's publication (i.e., December 5, 2021). Providers and suppliers must establish a policy ensuring that eligible staff have received the vaccine accordingly prior to providing any care, treatment, or other services by December 5, 2021.

Second, covered employees must be fully vaccinated for COVID-19 within 60 days of the publication date (i.e., January 4, 2022), except for staff who are exempt from the vaccination requirement or for whom vaccination must be temporarily delayed due to clinical precautions and considerations as recommended by the CDC. Although individuals are not considered fully vaccinated until 14 days after the final dose of a vaccine, CMS has noted that, for purposes of compliance with the Rule, staff who have received a final dose by January 4, 2022 will meet the vaccination requirement.

### **How will the Rule be enforced?**

CMS notes that it will use its established survey and enforcement process and will cite facilities as being non-compliant before taking further action. Specifically, CMS will work with state survey agencies to conduct on-site compliance reviews. The survey procedures will include provider and supplier records of staff vaccination statuses and qualifying exceptions, interviews to verify vaccination status, and reviews of policies and procedures.

Facilities that violate the Rule will be subject to penalties depending on the facility's classification. For nursing homes, home health agencies, and hospices, these penalties include civil monetary penalties, denial of payment, and termination from Medicare and Medicaid as a final measure. For hospitals and certain other acute and continuing care providers, penalties include termination from the Medicare and Medicaid program.

### **How does the Rule interact with the OSHA ETS?**

Healthcare facilities and providers that are not covered by the CMS Rule may still be subject to vaccination rules set forth by the November 4, 2021 OSHA ETS. The Rule is meant to be complementary to the ETS, which requires employees of employers with at least 100 employees to either be fully vaccinated or undergo weekly COVID-19 testing and wear a face covering in the workplace. More information on the ETS requirements is included in [Cline Williams' November 8, 2021 E-Alert](#).

Additionally, the Rule states that it preempts all conflicting state or local laws as applied to Medicare- and Medicaid-certified providers and suppliers, including laws that ban or limit an employer's authority to require vaccinations, masks, or testing for COVID-19.

### **How does CMS respond to healthcare employers' fear that staff will leave?**

CMS has expressly acknowledged the staffing challenges that healthcare employers currently face, including challenges that may be a result of state, local, and organizational vaccine mandates and pandemic-related burnout. In response, CMS states:

We are aware of concerns about health care workers choosing to leave their jobs rather than be vaccinated. While we understand that there might be a certain number of health care workers who choose to do so, there is insufficient evidence to quantify and compare adverse impacts on patient and resident care associated with temporary staffing losses due to mandates and absences due to

quarantine for known COVID-19 exposures and illness. We encourage providers and suppliers, where possible, to consider on-site vaccination programs, which can significantly reduce barriers that health care staff may face in getting vaccinated, including transportation barriers, need to take time off of work, and scheduling. However, vaccine declination may continue to occur, albeit at lower rates, due to hesitancy among particular communities, and the Assistant Secretary for Planning and Evaluation (ASPE) indicates that vaccination promotion and outreach efforts focused on groups and communities who experience social risk factors could help address inequities.

The Rule is intended to create a consistent standard across the country to prevent employees from leaving facilities with certain vaccination policies to work at other facilities with policies the employee may prefer.

### **What happens next?**

Many healthcare employers are curious about the potential for future litigation to stop implementation of the Rule. Typically, CMS regulations undergo a notice and comment period wherein stakeholder may respond to a proposed rule before CMS issues a final rule. Here, CMS will accept comments about the Rule until 5:00 p.m. on January 4, 2022.

Although litigation over the Rule is anticipated, healthcare providers must comply with its requirements. Cline Williams continues to monitor this developing area of the law and may provide additional updates and analyses.

For more information on these issues, please reach out to a member of Cline Williams' [Health Care](#) or [Labor and Employment Law Section](#).