

COVID-19



CMS RELEASES OMNIBUS COVID-19 HEALTHCARE STAFF VACCINATION INTERIM FINAL RULE

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On Nov. 4, 2021, the Centers for Medicare and Medicaid Services (“CMS”) released its long-awaited Interim Final Rule with Comment Period (the “Interim Final Rule”), requiring COVID-19 staff vaccination for Medicare- and Medicaid-certified providers and suppliers. The Interim Final Rule takes effect immediately and extends to more than 17 million healthcare staff and approximately 76,000 facilities. Healthcare staff covered by the Rule will need to be fully vaccinated by Jan. 4, 2022, unless the staff member receives a medical or religious exemption.

WHAT IS CMS’ VACCINATION REQUIREMENT?

The Interim Final Rule requires certain healthcare providers to establish a policy or procedure to ensure staff, except for those individuals who are granted an exception, are fully vaccinated. The Interim Final Rule sets forth minimum elements that must be included in a COVID-19 vaccination policy such as a process for tracking staff vaccination status, contingency plans for staff who are not fully vaccinated, and a process for staff to request an exemption from the vaccination requirement.

WHO MUST IMPLEMENT THE VACCINATION REQUIREMENTS?

The vaccination requirements apply to Medicare- and Medicaid-certified providers and suppliers (“Providers”) that are subject to the Medicare Conditions of Participation (“COPs”) or the Conditions for Coverage (“CfCs”). Specifically, the Interim Final Rule requires the following Providers meet vaccination requirements by the Jan. 4, 2022, deadline: ambulatory surgical centers (“ASCs”); hospices; psychiatric residential treatment facilities (“PRTFs”); programs of all-inclusive care for the elderly (“PACE”); hospitals; long-term care (“LTC”) facilities, including skilled nursing facilities (“SNFs”) and nursing facilities (“NFs”); intermediate care facilities for individuals with intellectual disabilities (“ICFs-IID”); home health agencies (“HHAs”); comprehensive outpatient rehabilitation facilities (“CORFs”); critical access hospitals (“CAHs”); clinics, rehabilitation agencies, and public health agencies

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as providers of outpatient physical therapy and speech-language pathology services; community mental health centers ("CMHCs"); home infusion therapy ("HIT") suppliers; rural health clinics ("RHCs")/federally qualified health centers ("FQHCs"); and end-stage renal disease ("ESRD") facilities.

WHO IS NOT REQUIRED TO IMPLEMENT THE VACCINATION REQUIREMENTS?

The Interim Final Rule **does not** apply to other healthcare entities that are not directly regulated by CMS (i.e., not certified by CMS through a survey process) such as physician offices. The vaccination requirements also **do not** apply to assisted living facilities (unless staff is shared with a Medicare-certified LTC facility), group homes, or Medicaid home care services such as home and community-based services ("HCBS") providers. However, these entities may be subject to other state or federal vaccination requirements such as the Occupational Safety and Health Administration ("OSHA") vaccination requirements for certain employees (hereinafter referred to as "OSHA Emergency Temporary Standard"). For more information on OSHA's Emergency Temporary Standard refer to Foulston's Issue Alert.

WHO MUST BE VACCINATED?

The vaccine requirement applies to new and current staff members, **regardless of the staff members' clinical responsibility or patient contact**. This includes: Provider employees; licensed practitioners; students; trainees; volunteers; administrative staff; Provider leadership; fiduciary board members; housekeeping and food services; and others. The vaccination requirements also apply to staff members that primarily provide services remotely via telework that occasionally encounter fellow staff such as in an administrative office or at an off-site staff meeting. The requirement applies to all individuals who provide care, treatment, or other services for the Provider and/or its patients, under contract or arrangement.

TO WHOM DO THE VACCINATION REQUIREMENTS NOT APPLY?

Individuals that provide remote services 100 percent of the time are not subject to the vaccination requirements. The vaccination requirements also do not apply to "one off" vendors, volunteers, or professionals that provide infrequent, ad hoc non-healthcare services and tasks performed in or for a healthcare facility such as annual elevator inspectors, delivery personnel, and repair personnel. However, these individuals may still be subject to other state or federal requirements for COVID-19 vaccination, i.e., OSHA Emergency Temporary Standard requirements.

DOES THE VACCINE REQUIREMENT ALLOW FOR EXEMPTIONS FROM VACCINATION?

Providers must implement a process by which staff may request an exemption based on certain allergies; recognized medical conditions; and religious beliefs, observances, or practices. Staff must also be able to request exemptions based on applicable federal law such as the Americans with Disabilities Act ("ADA") and Title VII of the Civil Rights Act of 1964, and Providers may be required by such applicable federal laws to grant accommodations. A Provider's COVID-19 vaccination policy must have a process for collecting and evaluating such requests for exemption.

DOES THE VACCINE REQUIREMENT ALLOW FOR TESTING OF UNVACCINATED STAFF?

No. The Interim Final Rule does not permit testing of unvaccinated staff in lieu of full vaccination. Entities not covered by the Interim Final Rule should refer to the OSHA Emergency Temporary Standard for separate vaccination and testing requirements.

HOW DOES THE INTERIM FINAL RULE INTERACT WITH STATE LAW?

CMS has taken the position that under the Supremacy Clause of the U.S. Constitution the Interim Final Rule preempts any state law to the contrary.

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HOW DOES THE INTERIM FINAL RULE INTERACT WITH OSHA'S EMERGENCY TEMPORARY STANDARD?

CMS instructs Providers covered by the Interim Final Rule to look to and comply with the Interim Final Rule requirements first. The Interim Final Rule supersedes other federal requirements.

HOW WILL CMS ENFORCE THE VACCINATION REQUIREMENT?

CMS will use state survey agencies to conduct onsite compliance reviews. The surveyor will review the Provider's COVID-19 vaccination policy, the number of resident and staff COVID-19 cases over the previous four weeks, and a list of all staff and their vaccination status. If a Provider is deemed to be noncompliant, CMS has several enforcement tools in its arsenal ranging from civil monetary penalties to termination of the Provider's Medicare agreement.

WHAT IS THE IMPLEMENTATION TIMELINE?

CMS adopted a phased approach for implementation of the vaccination requirement. In Phase 1, staff must have received their first dose of a two-shot vaccine (Moderna or Pfizer) or a single dose of a one-shot vaccine (Johnson & Johnson) by Dec. 5, 2021. Staff must complete Phase 1 before they can provide any care, treatment, or other services for the Provider and/or its patients. In Phase 2, staff must complete the primary vaccination series by Jan. 4, 2022.

While the Interim Final Rule provides important details regarding this vaccination requirement, we expect CMS will supplement this rule with interpretive guidance aimed at providing more information on how it will assess compliance, i.e., updates to the COPs and CfCs should follow. For those Providers who want to comment on the Interim Final Rule, the Comment Date is set for no later than 5 p.m., on Jan. 4, 2022.

WHAT SHOULD PROVIDERS DO NOW?

Providers should start working on their policies and procedures in order to comply with the Interim Final Rule, including, but not limited to, implementing a process for tracking staff vaccination status, implementing a contingency plan for staff who are not fully vaccinated, and adopting a process for staff to request an exemption from the vaccination requirement based on an applicable federal law. Providers should consider embarking on an education campaign with **all** staff members to inform them of the requirements of the Interim Final Rule and the timeline for compliance.

CMS released Frequently Asked Questions ("FAQs") that further address the Interim Final Rule. Providers can access the FAQs [here](#). Providers can access a full copy of the Interim Final Rule.

FOR MORE INFORMATION

If you have questions or want more information regarding the requirements of CMS' Interim Final Rule, contact your legal counsel. If you do not have regular counsel for such matters, Foulston Siefkin LLP would welcome the opportunity to work with you to meet your specific business needs. Foulston's healthcare lawyers maintain a high level of knowledge regarding federal and state regulations affecting the healthcare and long-term care industries. At the same time, our healthcare practice group's relationship with Foulston's other practice groups, including the taxation, general business, labor and employment, and commercial litigation groups, enhances our ability to consider all of the legal ramifications of any situation or strategy. For more information, contact **Brooke Bennett Aziere** at 316.291.9768 or baziere@foulston.com, **Amanda Wilwert** at 913.253.2181 or awilwert@foulston.com, or **Gabriella Grause** at 316.291.9750 or ggrause@foulston.com. For more information on the firm, please visit our website at www.foulston.com.

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