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CMS Issues Emergency Regulation Requiring COVID-19 Vaccination for Health Care Facility Workers

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On November 4, 2021, the Centers for Medicare & Medicaid Services (CMS) issued heavily anticipated <u>emergency regulations</u> requiring COVID-19 vaccination of eligible staff at health care facilities that participate in the Medicare and Medicaid programs. CMS issued an Interim Final Rule (IFR) in response to the COVID-19 "Path out of the Pandemic" Action Plan announced by President Biden on September 9, 2021, that per CMS is intended to protect the health and safety of residents, patients and staff at health care facilities. See our previous analysis of the Plan <u>here</u>.

Below please find key takeaways regarding the new COVID-19 vaccination requirements for health care facilities and staff:

TO WHOM DOES IT APPLY?

The IFR <u>Heading 3</u>applies to the following Medicare- and Medicaid-certified providers and suppliers: Ambulatory Surgical Centers, Hospices, Program of All-Inclusive Care for the Elderly facilities, Hospitals, Long Term Care facilities, Psychiatric Residential Treatment Facilities, 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 Facilities.

Notably, the IFR by its terms does not apply to physician offices not directly regulated by CMS, but, it does apply to "facility staff" in regulated facilities (not limited to employees), including the following: "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."

VACCINATION DEADLINE – DOSE #1

The IFR requires Medicare- and Medicaid-certified providers and suppliers to establish a policy ensuring that all eligible staff have received the first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine prior to providing any care, treatment, or other services by **December 5**, **2021**.

VACCINATION DEADLINE – DOSE #2

All eligible staff must be fully vaccinated, defined as having received either two doses of Pfizer or Moderna or one dose of Johnson & Johnson, by **January 4, 2022**.

RECORDKEEPING

Facilities must track and document the vaccination status of each staff member, including temporary delays in vaccination, requests for exemption, and results of exemption requests.

EXEMPTIONS

The IFR requires facilities to allow for exemptions based on recognized medical conditions for which vaccines are contraindicated, as a reasonable accommodation under the Americans with Disabilities Act (ADA), or due to sincerely held religious beliefs, observances, or practices, as established under Title VII of the Civil Rights Act of 1964 (Title VII).

Entities subject to the IFR will need to establish a process by which staff may request exemptions as a part of its policies and procedures, and a process by which such requests are evaluated in alignment with federal law. CMS indicates that no exemption should be given any staff for whom it is not legally required under the ADA or Title VII or who requests an exemption only to evade vaccination. In granting any exemptions or accommodations, providers and suppliers must ensure they continue to minimize the risk of transmission of COVID-19 to at-risk individuals.

• ENFORCEMENT OF THE VACCINATION REQUIREMENTS

CMS will assess compliance with the new COVID-19 vaccination requirements through established survey and enforcement processes. If a provider or supplier does not meet the requirements, a surveyor will cite it as being non-compliant, and the provider or supplier will have an opportunity to become compliant before CMS takes additional action. CMS has indicated that its goal is to bring health care providers into compliance and that it will not hesitate to use its full enforcement authority to protect patients' health and safety.

NO TESTING ALTERNATIVE TO VACCINATION

Notably, the IFR does not allow for regular COVID-19 testing as an alternative to complying with the vaccine mandate.

COMMENTS AND EFFECTIVE DATE

CMS is accepting comments on the IFR for a period of 60 days starting November 5, 2021. However, as an emergency regulation, the IRF's requirements go into effect immediately upon formal publication on November 5, 2021.

OSHA EMERGENCY TEMPORARY STANDARD

Pursuant to the Plan, the Occupational Safety and Health Administration is also publishing its COVID-19 Emergency Temporary Standard on November 5, 2021.

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