

Health Care Worker Vaccine Mandates: New Strings Attached for Federal Funds

November 05, 2021

On November 4, the Centers for Medicare & Medicaid Services (CMS) [announced the publication](#) of an interim final rule with comment period (IFC) requiring that workers in most Medicare and Medicaid participating health care facilities be vaccinated against COVID-19. This IFC follows on the heels of President Biden's September 9, 2021, issuance of a [COVID-19 Action Plan](#) that includes several actions to combat the COVID-19 pandemic, including a strategy to "vaccinate the unvaccinated." This strategy encompasses several federal vaccination mandates, which require vaccination for federal workers, federal contractors, employees of large employers, guests of large entertainment venues, and notably, most health care workers and providers.

Vaccine mandates for nursing home workers have been on the radar since mid-August when the White House announced an impending regulation mandating COVID-19 vaccination for workers in Medicare and Medicaid-certified nursing homes. However, as a result of the virulent delta variant's impact on COVID-19 numbers and hospitalizations, CMS elected to expand the mandate through the IFC to most Medicare and Medicaid-certified facilities.

Conditions of participation (CoPs) are federal regulations with which health care facilities must comply to participate in and receive payment from the Medicare and Medicaid programs, the largest health care payors in the United States. CMS is using the IFC to create conditions of participation that will require COVID-19 vaccination for approximately 17 million health care workers in the United States.

Centrally, the IFC requires covered health care facilities to establish policies and procedures ensuring covered staff members have received either the initial dose of a multi-dose COVID-19 vaccine or a single-dose vaccine by December 5, 2021. The IFC also requires these health care facilities' policies and procedures to ensure applicable staff members are "fully vaccinated" by

January 4, 2022, as defined below. Notably, the IFC's preamble provides that natural immunity is not equivalent to receiving the COVID-19 vaccine.

The IFC requires covered facilities to maintain policies and procedures that provide for:

- A process to ensure covered persons have received an initial shot of a two-dose vaccine, or a single-dose vaccine, by December 5, 2021.
- A process to ensure covered persons are fully vaccinated by January 4, 2022. Staff members are considered fully vaccinated if it has been two weeks or more since they have received a single-dose COVID-19 vaccine or all doses of a multi-dose vaccine.

**On January 4, 2022, facilities will be considered compliant with the fully vaccinated requirement absent the 14-day waiting period, so long as the precautions noted directly below are used. After this compliance grace period, facilities must ensure all covered staff are fully vaccinated.

- A process for implementing additional precautions for all staff who are not fully vaccinated intended to mitigate the transmission and spread of COVID-19.
- A process for tracking and securely documenting the vaccination status of all covered staff.
- A process for tracking and securely documenting the status of covered staff who have received vaccine booster doses as recommended by the Centers for Disease Control and Prevention (CDC).
- A process by which staff can request exemptions provided under federal law.
- A process for documenting and tracking information provided by staff requesting exemptions and staff for whom exemptions have been granted.
- A process to ensure all required documentation for medical exemptions is signed by a licensed provider acting within their scope of practice, as defined by, and in accordance with, all applicable state and local laws.
- A process to track and document COVID-19 vaccination status of covered staff for whom vaccinations must be temporarily delayed, as recommended by the CDC.
- Contingency plans for covered staff who are not fully vaccinated.

CMS casts a wide net with the IFC. The health care facility policies and procedures must ensure the vaccination policy applies to any individual that provides "care, treatment or other services *for the facility* and/or its patients/residents, under contract or other arrangement." The IFC covers

employees, contractors, and licensed practitioners as well as students, trainees, and volunteers. However, the IFC's vaccination requirement does not apply with regard to:

- Exemptions based on federal law (including religious beliefs).
- CDC-recognized exemptions based on medical conditions.
- Staff exclusively providing telehealth or telemedicine services outside of the care setting *and* who do not have any contact with patients, patient families or representatives, or any staff covered by the vaccination policy.
- Staff performing services exclusively outside of the care setting who do not have direct contact with patients, patient families or representatives, or other staff covered by the vaccination policy.

Further, the IFC includes essentially any health care facility providing services that are paid for by the Medicare and/or Medicaid program, including:

- Hospitals
- Ambulatory surgery centers (ASCs)
- Hospices
- Psychiatric residential treatment facilities for individuals under 21 years old
- Programs of all-inclusive care for the elderly
- Long-term care facilities (i.e., Medicaid nursing facilities and Medicare skilled nursing facilities)
- Intermediate care facilities for individuals with intellectual disabilities or related conditions
- Home health agencies
- Comprehensive outpatient rehabilitation facilities
- Clinics, rehabilitation agencies, or public health agencies that provide outpatient physical therapy or speech-language pathology services
- Community mental health centers
- Home infusion therapy suppliers
- Rural health clinics
- Federally qualified health centers
- End-stage renal disease facilities

Although the penalties for noncompliance could be severe, the IFC’s preamble indicates that CMS will use discretion in enforcement. Facilities cited for noncompliance may be subject to enforcement remedies available under federal law, including civil money penalties, denial of payment for new admissions, or termination of the facility’s Medicare/Medicaid provider agreement. Termination of participation is rarely an immediate consequence, as facilities are typically given notice of and the opportunity to correct deficiencies.

The IFC’s preamble provides guidance to facilities regarding how they should handle religious and medical exemptions, and a November 4, 2021, [White House press release](#) clarified that the Occupational Safety and Health Administration’s COVID-19 Vaccination and Testing Emergency Temporary Standard would not apply to facilities covered by the IFC. The preamble also noted that federal employment discrimination laws continue to apply and that accommodations may be required. To note, CMS chose to establish minimal compliance burdens for exemptions based on medical contraindications and religious objections but reserved the right to revisit the evidentiary standards should significant abuse issues arise.

We expect legal challenges to the IFC from states and industry groups, and the IFC’s preamble anticipates this by stating that through the supremacy clause of the U.S. Constitution, the IFC “preempts inconsistent State and local laws as applied to Medicare- and Medicaid-certified providers.” The IFC allows for the submission of public comments through January 4, 2022.

Should you or your organization need more information about CMS’ IFC, or how the IFC could affect your organization’s reimbursement, accreditation, operations, or compliance obligations, please contact your Carlton Fields attorney.

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