

Vaccine Mandates are Here...Will They Impact Your Practice?

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On November 5, 2021, the Secretary of Health and Human Services issued an Interim Final Rule that amended the conditions of participation in Medicare and Medicaid to require certain providers and suppliers to ensure their covered staff are vaccinated against COVID-19 ("Rule"). Enforcement of this vaccine mandate was delayed due to pending legal challenges by several states. On January 13, 2022, the Supreme Court weighed in on these challenges, ultimately upholding the Rule. As such, the vaccine mandate for eligible staff at Medicare and Medicaid-certified facilities is in effect.

To What Providers and Suppliers Does the Rule Apply?

The vaccination requirements apply to Medicare and Medicaid-certified provider and supplier types that are regulated under Medicare and Medicaid health and safety standards (collectively, the Facilities). These Facilities include: Ambulatory Surgery Centers, 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, Clinics, Rehabilitation Agencies, and Public Health Agencies as Providers of Outpatient Physical Therapy and Speech-Language Pathology Services, Psychiatric Residential Treatment Facilities (PRTFs), Programs for All-Inclusive Care for the Elderly (PACE) Organizations, Rural Health Clinics/ Federally Qualified Health Centers (Medicare only), and Long Term Care facilities.

The Rule applies to eligible staff at almost all of these Facilities regardless of patient contact or clinical responsibility. This includes current staff and any new staff who will provide care, treatment or other services to the Facilities and/or their patients. For example, employees, licensed practitioners, students, trainees and volunteers, and any individuals who provide care, treatment, or other services for Facilities and/or their patients under contract or other arrangements. The Rule does not apply to individuals who provide services 100% remotely and do not have any direct contact with patients and/or other staff members.

The vaccine requirements do not apply to independent physician or dental practices, as they are not subject to CMS health and safety regulations. Individual physicians working for practices that have admitting or staff privileges at any of the Facilities, however, will be subject to vaccine requirements in order for the Facilities to comply with the Rule. In practice, this means that while a physician group itself does not have to comply with the Rule, physicians practicing within the group may be required

to comply as a condition of hospital staff or other privileges.

What are the Requirements of the Rule?

The Rule requires health care providers to establish a process or policy to fulfill the staff vaccination requirements over two phases:

Phase 1: Requires staff at all health care facilities covered by the regulation to have received, at a minimum, the first dose of a primary series or a single dose COVID-19 vaccine prior to staff providing care, treatment or other services for the facility and/or its patients.

Phase 2: Requires staff at all health care facilities included in the regulation to have completed the primary vaccination series.

Due to prior legal challenges, the actual Phase 1 and Phase 2 deadlines vary from state-to-state.

Facilities must have a process or plan in place for documenting and tracking staff vaccinations. Acceptable proof of vaccinations includes:

- CDC COVID-19 vaccination record card, or legible photo of the card;
- documentation of vaccination from a health care provider or electronic health record; or
- state immunization information system record.

Exemptions are allowed for staff as a reasonable accommodation for a disability or a sincerely held religious belief, observance or practice, and for medical reasons. Facilities should establish policies and procedures for evaluating and documenting exemptions. The Rule does not include testing requirements for unvaccinated staff members, nor does it establish new data reporting requirements.

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