

CMS' COVID-19 Vaccine Mandate: What Health Care Providers and Suppliers Need to Know

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****Note that a federal court has issued a temporary injunction stopping the CMS COVID-19 vaccine mandate in certain states. Please read our blog post [here](#) for the latest information on this injunction.**

Last week, the Centers for Medicare and Medicaid Services (CMS) and the Occupational Safety and Health Administration (OSHA) published their much-anticipated rules mandating COVID-19 vaccinations. This article focuses on the new CMS rules, and you can read about Dorsey's analysis of the new OSHA Emergency Temporary Standard (ETS) [here](#). Please note that if the CMS COVID-19 vaccine mandate applies to your facility, you must comply with the CMS COVID-19 vaccine mandate instead of with the new OSHA ETS. However, the above link to our article on the new OSHA ETS provides useful guidance on topics which apply generally to employers such as how to handle vaccine exemption requests.

On November 4, 2021, the Centers for Medicare & Medicaid Services (CMS) issued its interim final rule (IFR) with comment period regarding staff vaccination requirements as a condition of receipt of Medicare or Medicaid funds. CMS estimates that there will be *more than 180 million* staff, patients, and residents employed or treated at facilities covered by the rule, making the impact colossal. The IFR is an emergency regulation, meaning that it takes effect on the date it is published in the federal register, November 5, 2021, and prior to the comment period. Stakeholders will have 60 days, until January 4, 2022, to submit formal comments. At that point, CMS will consider the comments in any future rulemaking it undertakes. CMS also issued a press release and published

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FAQs to assist health care facilities in the understanding of these new regulations.

The IFR applies to the following Medicare/Medicaid certified providers and suppliers:

- Ambulatory Surgical Centers (ASCs)
- Hospices
- Psychiatric residential treatment facilities (PRTFs)
- Programs of All-Inclusive Care for the Elderly (PACE)
- Hospitals (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 (ICFs-IID)
- Home Health Agencies (HHAs)
- Comprehensive Outpatient Rehabilitation Facilities (CORFs)
- Critical Access Hospitals (CAHs)
- Clinics, rehabilitation agencies, and public health agencies 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)
- End-Stage Renal Disease (ESRD) Facilities^[1]
- Indian Health Service (IHS) Facilities



A. What Must Covered Facilities Do?

Under the IFR, the above-described “covered facilities” must develop, by December 5, 2021, a plan and procedure for requiring the COVID-19 vaccine for covered staff (as defined below),^[2] collecting and storing vaccination data, considering medical and religious exemptions for covered staff, and contingency planning for unvaccinated staff. Individuals are on a deadline to be fully vaccinated against COVID-19, with accommodations considered as required by law (discussed below).

Unless exempted, staff must have their first dose of a two-dose COVID-19 vaccine or a one-dose COVID-19 vaccine by December 5, 2021.

Staff must complete the vaccination series, and be “fully vaccinated”, by January 4, 2022.

Fully vaccinated is defined as two or more weeks after the completion of a vaccination series; staff members will be considered compliant even if not fully vaccinated by

January 4 as long as they have completed the vaccination series by then.[3] A previous COVID-19 infection will not be considered a substitute for proof of vaccination. Staff hired after December 5, 2021 must receive their first vaccine dose prior to providing any care, treatment, or other services.

The IFR defines the term “staff” to include “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.”[4] The fact that care may not be provided in a formal clinical setting does not relieve staff from the mandate. How frequently a person physically enters a covered healthcare setting is also irrelevant.

Only those staff who perform 100% of their work remotely (i.e. telehealth or payroll) are fully exempt from the vaccine mandate. This means that even staff who “occasionally encounter fellow staff, such as in an administrative office or at an off-site staff meeting, who will themselves enter a health care facility or site of care for their job responsibilities,” also must be vaccinated under the IFR.

The IFR lists the following as acceptable proof of vaccination: CDC COVID-19 vaccination record card (or a legible photo of the card), documentation of vaccination from a health care provider or electronic health record, or a state immunization information system record. Covered facilities must keep the proof of vaccination confidential, i.e. with a facilities immunization record, health information files, or other relevant confidential documents. Facilities may choose how to collect and store this information.



B. Exemptions from COVID-19 Vaccination Requirements and Conflicts with State Laws

Title VII of the Civil Rights Act of 1964 (Title VII) and the Americans with Disabilities Act (ADA) allow for religious and medical exemptions, respectively, to the COVID-19 vaccine. The IFR specifically directs healthcare entities to provide exemptions from the COVID-19 vaccine consistent with federal

law, but medical exemptions appear narrow, including certain allergies and recognized medical conditions that make the COVID-19 vaccine contraindicated. The IFR specifically directs facilities to the CDC’s Summary Document for Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Authorized in the United States.

Medical exemption request must be supported by documentation that is:

Signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable State and local laws. Such documentation must contain

all information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and a statement by the authenticating practitioner recommending that the staff member be exempted from the facility's COVID-19 vaccination requirements based on the recognized clinical contraindications.

But, what happens when there are conflicts with state laws on exemptions? New state laws signed by the governors of Texas and Iowa, for example, provide employees with exemptions beyond those required by these federal laws. For example, employers in Texas must allow exemptions from the COVID-19 vaccine based on an employee's "reason of personal conscience." This Texas law expands the application of religious exemptions beyond a "sincerely held religious belief, practice or observance" which is the standard for a waiver under Federal law. In Iowa, employers must allow exemptions from the COVID-19 vaccine based on an employee's statement that receiving the vaccine "would be injurious to the health and well-being of the employee or an individual residing with the employee." The Iowa law not only expands the medical exemption beyond the ADA, but also removes the requirement that a medical exemption be supported by a licensed practitioner.

Anticipating such conflicts, the IFR explicitly states:

We understand that some states and localities have established laws that would seem to prevent Medicare- and Medicaid-certified providers and suppliers from complying with the requirements of this IFC. We intend, consistent with the Supremacy Clause of the United States Constitution, that this nationwide regulation preempts inconsistent State and local laws as applied to Medicare- and Medicaid-certified providers and suppliers.

...

As is relevant here, this IFC preempts the applicability of any State or local law providing for exemptions to the extent such law provides broader exemptions than provided for by Federal law and are inconsistent with this IFC. (Emphasis added)

The FAQs issued by CMS underscore this position, stating that no exemptions should be granted if not legally required under the ADA or Title VII, nor should an exemption be granted to someone "who requests an exemption solely to evade vaccination."^[5]

In response to the federal government's simultaneous release of the equally long-awaited Emergency Temporary Standard (ETS) from OSHA, Iowa Governor Kim Reynolds announced plans to challenge the ETS in court. She made no similar plans regarding the IFR. In addition, Arkansas, Alaska, Missouri, Iowa, Montana, Nebraska, New Hampshire, North Dakota, South Dakota and Wyoming joined in a federal lawsuit filed last week in Missouri challenging the government's vaccination requirements for federal contractors and subcontractors. The OSHA ETS was promptly stayed in court, and as of the publication of this article, we are awaiting a decision about whether the ETS will be permitted to proceed.

Healthcare employers are encouraged by CMS to follow the guidance released by the Equal Employment Opportunity Commission (EEOC) related to medical and religious exemptions for employees. Employers should develop a process for fairly reviewing medical and religious exemptions on an individualized basis that shows thoughtful consideration and analysis of each request. If employers grant exemptions, they must take steps to minimize the risk of COVID-19 transmission. Such steps could include additional or enhanced personal protective gear, separation barriers, elimination or substitution of less critical job duties, temporary modification of work schedules, or moving the location of where one performs work.

C. How the Federal Rules Interact: Conflicts Between Federal Laws

In addition to potential conflicts between state laws and the federal rules, healthcare facilities may also have questions about which of the *federal* rules reign supreme. The IFR's FAQs address this as well:

1. If a Medicare- or Medicaid-certified provider or supplier falls under the requirements of CMS's IFR, the IFR must be followed.

If facilities participate in and are certified under the Medicare and Medicaid programs and are regulated by the CMS health and safety standards known as the Conditions of Participation (CoPs), Conditions for Coverage (CfCs), and Requirements for Participation (RoPs), then they, too, are expected to abide by the requirements established in CMS's IFR.

Importantly, ***the IFR takes priority over other federal vaccination requirements*** (i.e. the Executive Order for federal contractors and subcontractors, and the OSHA ETS for employers with 100+ employees).

2. The Executive Order for federal contractors and subcontractors may apply to staff who are not subject to the vaccination requirements outlined in the IFR. If a facility is subject to both the Executive Order and the new OSHA ETS for large employers, the facility should follow the Executive Order for federal contractors and subcontractors.
3. The OSHA ETS for employers with 100+ employees applies to employers that are not subject to the CMS IFR or the Federal Contractor and Subcontractor Executive Order. Additionally, employers subject to the OSHA COVID-19 Healthcare ETS need not *also* comply with the new OSHA ETS for large employers.

The bottom line is that the federal government does not intend for an employer or covered facility to assure compliance with more than one federal rule. If there is some question about with rule applies to a particular entity, entities should comply with the strictest federal rule applicable to the entity.

Vaccine mandate laws, interpretations and challenges are rapidly developing across the U.S. If you have any questions about vaccine mandates, please contact your regular Dorsey attorney or any of the authors of this article.

[1] The IFR does not apply to other healthcare entities not regulated by CMS (i.e. physician offices, Assisted Living Facilities, Group Homes, home and community-based

services, or schools), but those entities could be subject to other federal vaccine requirements. In addition, Religious Nonmedical Health Care Institutions (RNHCIs), Organ Procurement Organizations (OPOs), and Portable X-Ray Suppliers are not covered by the IFR even though those entities are regulated by CMS. However, it is important to note that staff of these entities may be *indirectly* included in CMS' vaccine requirements through their service arrangements with hospitals, long term care facilities, and other providers and suppliers who are covered under the IFR. Further, it is possible that staff may be required by other federal or state laws to obtain a COVID-19 vaccination.

[2] Covered individuals will be referred to throughout this post as “staff,” because coverage of the rule extends beyond those individuals who are employed by covered facilities, but also includes medical staff, contractors and volunteers, as discussed herein.

[3] The IFR references booster vaccines but does not require them.

[4] CMS considered limiting vaccine requirements to full-time employees. Ultimately, CMS concluded that including a broader group of those required to be vaccinated would be manageable without creating major issues for compliance, enforcement, and record-keeping.

[5] The FAQs also add that the IFR preempts any contrary state laws pursuant to the Supremacy Clause of the United States Constitution.