

U.S. Supreme Court Lifts Injunction Against CMS' Health Care Facility Vaccine Mandate: What Does This Mean for Your Health Care Facility?

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Health care employers are not alone in feeling overwhelmed by the constantly changing legal status of the various federal vaccine mandates. On Thursday afternoon, the Supreme Court made its rulings on two preliminary challenges to workplace mandates related to the COVID-19 pandemic: the Occupational Safety and Health Administration (OSHA)'s Emergency Temporary Standard (ETS) for large employers (100+ employees), and the Centers for Medicare and Medicaid Services (CMS) vaccine mandate for health care employers. This article focuses on the current status of CMS's Interim Final Rule (IFR), issued on November 4, 2021. The IFR detailed staff vaccination requirements as a condition of receipt of Medicare or Medicaid funds. CMS estimated that there would be more than 180 million staff, patients, and residents employed or treated at facilities covered by the rule.

Legal Challenges to CMS's Vaccine Mandate

On November 29, 2021, a federal court in Missouri stayed the CMS vaccine mandate in Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming. On December 15, 2021, a federal court in Louisiana stayed the CMS rule for fourteen additional states: Louisiana, Montana, Arizona, Alabama, Georgia, Idaho, Indiana, Mississippi, Oklahoma, South Carolina, Utah, West Virginia, Kentucky and Ohio. Therefore, at that time, the CMS rule was on hold in the 25 (referred to in this article as the "injunction states") and enforceable in the rest of the country (referred to in this article as the "non-injunction states"). A few days later, though, CMS indicated that it would temporarily halt enforcement nationwide.

The next day, the federal government filed a Petition asking the Supreme Court to lift the CMS IFR stay in the 25 injunction states. The Supreme Court heard oral arguments on that Petition, as well as whether the OSHA ETS nationwide stay, on January 7, 2022.

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The Supreme Court's Ruling

On January 13, 2021, the Supreme Court overturned the stay of the CMS vaccine mandate in the injunction states in a 5-4 decision.

In the ruling, a majority of Supreme Court justices held that CMS's IFR "fits neatly within the language of the statute" that authorizes the Secretary of Health and Human Services to impose conditions on

the receipt of Medicare and Medicaid funding that are "necessary in the interest of the health and safety of individuals who are furnished services." This includes other vaccination requirements, such as hepatitis B, influenza, and measles, mumps, and rubella.



The court focused on the fact that those seeking health care services at this time are likely more susceptible to contracting the COVID-19 virus, and stated:

[E]nsuring that providers take steps to avoid transmitting a dangerous virus to their patients is consistent with the fundamental principle of the medical profession: first, do no harm. It would be the "very opposite of efficient and effective administration for a facility that is supposed to make people well to make them sick with COVID-19."

For their part, the dissenting justices were concerned with a federal agency forcing health care workers to choose between getting a vaccine that they have thus far failed to receive and remaining employed. In addition, the dissent disapproved of CMS's decision to issue the vaccine mandate prior to receiving and addressing public comments.

Finally, the dissent took issue with the federal government getting involved in an issue (vaccine mandates) typically reserved for states. According to the dissent, "[i]f Congress had wanted to grant CMS authority to impose a nationwide vaccine mandate, and consequently alter the state-federal balance, it would have said so clearly. It did not." Somewhat in response to that argument, the majority cautioned that while federal agencies' ability to exercise their powers is not limitless, "such unprecedented circumstances provide no grounds for limiting the exercise of authorities that the agency has long been recognized to have."

With the majority of the Supreme Court voting to lift the stay, the CMS IFR is back on.

CMS Guidance Regarding its Vaccine Mandate

Prior to the ruling (on December 28, 2021), CMS issued QSO-22-07-ALL, Guidance for the Interim Final Rule. That guidance essentially rescinded CMS's temporary halt on nationwide enforcement of the IFR and established compliance deadlines and additional

guidance for covered facilities operating in the non-injunction states. The Guidance included provide-specific instructions for each type of facility covered by the CMS IFR (for example, Long Term Care and Skilled Nursing Facilities, Ambulatory Surgical Centers, Hospitals, Community Mental Health Centers, and Outpatient Physical Therapy).



The Supreme Court's ruling did not change the requirements of the CMS IFR. In essence, covered facilities must:

1. Implement a process or plan to vaccinate all eligible staff by the compliance deadline (which is different for the injunction and non-injunction states). The CMS IFR is not a "vaccinate-or-test"

mandate like the OSHA ETS. Rather, under the IFR, vaccination is the only option unless staff qualify for a medical or religious exemption.

2. Implement a process or plan to consider requests medical and religious exemptions.
3. Implement a process or plan to track and document staff vaccines and exemptions so each facility can produce the documentation during a survey. Our prior blog post, available [here](#), provides additional detail on the IFR's requirements as well as practical recommendations for compliance and next steps.

In response to the Supreme Court's ruling, on January 14, 2022 CMS issued additional guidance, QSO-22-09-ALL for the IFR, applying to all but one of the injunction states (Texas was exempted from the new guidance due to ongoing separate challenges, and CMS instructed state surveyors in the guidance to not undertake any efforts to enforce the IFR at this time). That new CMS guidance contains the same provider-specific instructions as the previous guidance, except that there are new compliance deadlines for the injunction states.

Under QSO-22-07-ALL and QSO-22-09-ALL:

- Penalties for non-compliance in nursing homes, home health agencies, and hospice include civil monetary penalties, denial of payments, and *as a final measure*, termination of participation in Medicare and Medicaid programs.
- Penalties for non-compliance for hospitals and other acute and continuing care providers is termination of participation in Medicare and Medicaid programs. However, "CMS's primary goal is to bring health care facilities into compliance."
- Termination from the Medicare and Medicaid programs will generally only occur after CMS gives a facility an opportunity to come into compliance.
- Absent approved medical or religious exemptions, CMS will consider facilities non-compliant if facility staff (as defined by the IFR) vaccination rates are under 100%. To provide covered facilities an opportunity to reach that 100% vaccination rate, CMS has adopted a phase-in period:
- Facilities are considered **compliant** with CMS's IFR if, **30 days** after the applicable QSO: 1) the facility has policies and procedures developed to ensure all facility staff are vaccinated for COVID-19, and 2) 100% of staff have at least dose of a COVID-19 vaccine (unless exempted) **or** 80% of staff have at least one dose of a COVID-19

vaccine and the facility has a plan to achieve 100% vaccination within 60 days. For the non-injunction states, the 30-day deadline is January 27, 2022. For the injunction states, the 30-day deadline is February 13, 2022.

- Facilities are considered **non-compliant** with CMS's IFR if, **60 days** after the applicable QSO, less than 100% of all non-exempted staff have at least one dose of a one-dose COVID-19 vaccine or two doses of a two-dose series. In that case, the facility will receive a notice of non-compliance, **except that** facilities with a vaccination rate (less exemptions) above 90% with a plan to reach 100% (less exemptions) within 30 days will not be subject to additional enforcement action. For the non-injunction states, the 60-day deadline is February 28, 2022. For the injunction states, the 60-day deadline is March 15, 2022.
- Facilities are considered **non-compliant** with CMS's IFR if, **90 days** after the applicable QSO (and anytime thereafter), less than 100% of all non-exempted staff have received at least one dose of a one-dose COVID-19 vaccine or two doses of a two-dose series. These facilities may be subject to enforcement action. For the non-injunction states, the 90-day deadline is March 28, 2022. For the injunction states, the 90-day deadline is April 14, 2022.

It is important to note that the Supreme Court did not rule on the merits (legality) of the CMS IFR. Last week's ruling is limited to whether the CMS IFR should be enjoined prior to a ruling on the merits. The merits question is still yet to be resolved and when federal courts make those decisions, they will almost certainly make their way back to the Supreme Court for a final decision. Given the language and reasoning of the Supreme Court's injunction decision, it appears there is a high likelihood that a majority of Supreme Court justices would uphold CMS's vaccine mandate on the merits.

The bottom line is that the CMS IFR is now in effect throughout the country, except in Texas, and despite CMS's message that it will provide entities with some leeway as described above, covered entities should immediately take steps to become compliant. Dorsey's health care and labor & employment attorneys are available to assist any health care provider with questions about implementation of CMS' vaccine mandate.