

PUBLICATION

Ten States Challenge CMS' COVID-19 Vaccine Mandate

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On November 10, 2021, the States of Missouri, Nebraska, Arkansas, Kansas, Iowa, Wyoming, Alaska, South Dakota, North Dakota, and New Hampshire (plaintiff states) filed an action in the U.S. District Court of the Eastern District of Missouri challenging the Centers for Medicare and Medicaid Services' (CMS) November 5, 2021 Interim Final Rule with Comment Period (IFC) entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination" (CMS Vaccine Mandate) 86 Fed. Reg. 61,555 (Nov. 5, 2021). Below, we address what the CMS Vaccine Mandate requires and how the legal challenge may impact these requirements.

What does the CMS Vaccine Mandate Require?

The CMS Vaccine Mandate requires a wide range of Medicare-certified health care facilities, providers, and suppliers to ensure their employees (part-time and full-time), licensed practitioners, volunteers, students, trainees, and contractors are all vaccinated. The Mandate applies to individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement. Additionally, the Mandate applies to facilities that are regulated under the CMS Conditions of Participation, Conditions for Coverage, or Requirements and therefore subject to CMS health and safety regulations. A few examples of such facilities include:

- Hospitals
- Ambulatory surgical centers
- Home Health
- Hospice
- Skilled Nursing Facilities

Other provider types, such as physician's offices, are not directly subject to the CMS Vaccine Mandate (but may be indirectly). If your facility is covered by the Mandate, all of your "eligible staff" must be vaccinated regardless of clinical responsibility or patient contact. Eligible staff must receive their first vaccine dose by December 5, 2021, and their second dose by January 4, 2022. There are very narrow exceptions to this requirement, which apply to staff with medical exemptions, religious exemptions, or those working 100 percent remotely.

Thus, all covered facilities must implement a plan for:

- Ensuring all eligible staff are vaccinated by the above deadlines;
- Receiving and evaluating exemption requests;
- Providing accommodations for those who are exempt (such as regular testing, physical distancing, source control);
- Adequately tracking and documenting staff vaccinations; and
- Ensuring vendors are in compliance.

Failure to comply with the mandate could result in any enforcement remedies available to CMS, such as civil monetary penalties, denial of payment, and termination from the Medicare and Medicaid program.

Why are the Plaintiff States Challenging the Mandate?

The plaintiffs challenge the CMS Vaccine Mandate on several grounds, claiming that the mandate is arbitrary and capricious, contrary to law, in excess of CMS' statutory authority, and issued in violation of procedural law. The specific allegations include that the mandate intrudes on states' police powers and that CMS lacked authority to issue a "good cause waiver" of the formal notice and comment period typically required for such a mandate.

A primary concern raised in the complaint is the prediction that many health care workers will chose to leave their jobs instead of getting vaccinated, leading to an even greater shortage of health care workers. With low vaccination rates in rural and underprivileged areas and among members of racial and ethnic minority communities, the complaint alleges that "minority workers in rural communities are among the most likely groups to lose their jobs under the mandate." The validity of this prediction and the merits of these legal challenges remain to be seen.

What should you do if you are covered by the CMS Vaccine Mandate?

If you are covered by the mandate, you should be working toward compliance, as the CMS Vaccine Mandate remains in effect. The plaintiff states request that the mandate be set aside, and that CMS be enjoined from enforcing it. However, no emergency motion for an order staying enforcement of the mandate has been filed, and no order staying enforcement has been issued.

Covered facilities should be working to implement a plan for vaccinating by the deadlines above, a plan for providing accommodations for those who are exempt, and a plan for tracking and documenting staff vaccinations. If you have questions about the CMS Vaccine Mandate, compliance, or the legal challenges, please contact [Bahati Mutisya](#), [Matt Wolfe](#) or any member of [Baker Donelson's Health Law](#) team.