



Alerts

District Court in Missouri Blocks Implementation of CMS Emergency Regulation Mandating Workforce COVID-19 Vaccinations

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Health Care Alert

On Monday, November 29, 2021, a court in the Eastern District of Missouri issued an order granting a motion for a preliminary injunction of the Centers for Medicare and Medicaid Services' (CMS) interim final rule (the Rule), [issued earlier this month](#) on November 5, 2021. The Rule requires employees and contractors of certain healthcare facilities to be vaccinated fully by January 5, 2022. The challenge to the Rule was brought principally by the Attorneys General for ten states. Pending further court action, this order effectively blocks CMS from implementing and enforcing the Rule in Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming (collectively, the States).

The court found that CMS violated "traditional notions of federalism" by impeding upon what has been traditionally been state authority to regulate health and safety in general and vaccination requirements in particular. In deciding whether injunctive relief was appropriate the court made the following findings:

- the States are likely to succeed on the merits because CMS did not have authority to act in such a broad fashion without clear authorization from Congress;
- CMS improperly bypassed the notice and comment requirements for issuing a new rule. Specifically, the court mentioned CMS's delay in issuing the Rule without comment despite vaccination availability since December 2020;
- CMS likely could not establish that it had "good cause" to bypass notice and comment provisions;
- the States are threatened with irreparable harm if CMS enforces the mandate because facilities within their states would be exposed to staffing shortages and even facility closures in some areas. The irreparable harm finding was supported by affidavits from the plaintiffs, which included, for example, how one hospital could lose its only anesthesiologist which would compromise the ability of the facility to perform surgical procedures; and
- the States would suffer greater harm than CMS if the Rule went into effect because of the staffing shortages; whereas, the impact of the pandemic may be easing with increased vaccination rates and new therapeutics. In this regard, the court noted that CMS was unable to provide evidence of

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continued vaccine efficacy.

The court acknowledged CMS's concern regarding the upcoming influenza season and its impact on the pandemic. However, the court pointed out that such concern should weigh in favor of ensuring adequate health care worker staffing, as well as demonstrate that CMS has never required flu vaccines for health care workers despite the known risk of transmission.

We anticipate there will be an immediate appeal to the United States Court of Appeals for the Eighth Circuit. However, for now the enforcement of the Rule is stayed in Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming. Notably, there are other cases pending which also challenge the Rule, including one in the Western District of Louisiana. We urge you to consult your Hinshaw Health Care counsel with any questions about compliance with the Rule and its impact on your facility.

December 1 Update: Since publication of this alert, a federal district court in Louisiana in a separate proceeding now has blocked the implementation of the CMS rule on a nationwide basis. The decision relies heavily upon the rationale of the Fifth Circuit Court of Appeals in its decision to [stay enforcement](#) of OSHA's Emergency Temporary Standard. This order applies nationwide, except for the ten states that already succeeded in preliminarily enjoining the rule in the Missouri litigation reported on by Hinshaw yesterday. This case is also expected to proceed to the Fifth Circuit Court of Appeals.

December 2 Update: CMS issued a [memorandum](#) stating it will not enforce its vaccine mandate while it remains enjoined by the Missouri and Louisiana district courts. It further states that "while these preliminary injunctions are in effect, surveyors must not survey providers for compliance with the requirements of the" mandate. No information is provided on what CMS would do when and if the preliminary injunctions are stayed, such as setting new compliance dates.

December 15 Update: On December 15th, 2021, the Fifth Circuit Court of Appeals overturned the Louisiana district court's decision to block implementation of the CMS rule nationwide. The Fifth Circuit explained that the nationwide injunction was largely unexplained by the district court, and that litigants should have the option to have their cases heard around the country. Accordingly, the CMS rule is now only blocked in the states involved in the Louisiana and Missouri litigation: Alabama, Alaska, Arkansas, Arizona, Georgia, Idaho, Indiana, Iowa, Kansas, Kentucky, Louisiana, Mississippi, Missouri, Montana, Nebraska, New Hampshire, North Dakota, Ohio, Oklahoma, South Carolina, South Dakota, Utah, West Virginia, and Wyoming. The CMS rule is also blocked in Texas as a result of separate litigation.

December 30 Update: On December 28, 2021, CMS confirmed in a memorandum that it will enforce the vaccination mandate in the states not listed above, including: California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Nevada, New Jersey, New Mexico, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, Washington, and Wisconsin.

By January 27, 2022, subject facilities in those states must have policies and procedures in place to ensure that all facility staff have received at least one dose of the COVID-19 vaccine, or have requested/been granted an exemption. If the facility does not have 100% compliance by that date, the facility will receive a notice of non-compliance. As long as the facility is above 80% compliance and has a plan to achieve 100% compliance within 60 days, CMS will not institute additional enforcement action.

By February 28, 2022, all staff must have completed the vaccine series or been granted a qualifying exemption. If the facility does not have 100% compliance by that date, the facility will receive a notice of non-compliance. If the facility is above 90% compliance and has a plan to achieve 100% compliance within 30 days, CMS will not institute additional enforcement action.

By March 28, 2022 and thereafter, facilities must maintain 100% compliance or be subject to enforcement action.

Health care facilities should note that enforcement procedures will vary based on the level of deficiency cited. Providers should reference facility specific guidance [here](#) in developing policies and procedures.