

## Compliance Today – May 2022

### Who gives a shot: An overview of the CMS vaccination mandate

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On November 5, 2021, the Centers for Medicare & Medicaid Services (CMS) issued an interim final rule with comment period (IFC) that amended Medicare and Medicaid conditions of participation related to COVID-19, staff vaccination, and infection prevention and control.<sup>[1]</sup> Specifically, providers and suppliers subject to the IFC must require applicable staff to be fully vaccinated for COVID-19 or receive an exemption. In addition, providers and suppliers must ensure that facilities are following nationally recognized infection prevention and control guidelines, including implementing additional precautions for staff who are not fully vaccinated against COVID-19.

#### Rulemaking process

Unlike most interim final rules, the IFC was not subject to notice of proposed rulemaking, making it effective as of the date of publication (i.e., November 5, 2021). This means that there was no opportunity for stakeholders to submit comments to CMS prior to the IFC's implementation. Instead, CMS accepted comments after the IFC was effective but before any of the deadlines imposed by the IFC had passed. The comment period closed on January 4. CMS chose to waive the notice period prior to implementing the IFC, citing a combination of factors, including the belief that any delay caused by the standard notice of proposed rulemaking would endanger the health and safety of patients and would be contrary to the public interest.<sup>[2]</sup>

Additionally, although the IFC was issued in response to the ongoing public health emergency, it is not tied specifically to the public health emergency declaration. As a result, the IFC does not automatically terminate when the public health emergency ends, and CMS retains the option to make the IFC permanent based on public comments, incidence, disease outcomes, and other factors.<sup>[3]</sup>

#### Litigation and implementation deadlines

In response to the IFC, two groups of states—24 in total—filed separate actions challenging the final rule in two U.S. district courts (the Western District of Louisiana and the Eastern District of Missouri).<sup>[4]</sup> In response to the actions, both district courts entered preliminary injunctions preventing CMS from enforcing the IFC in those 24 states. The federal government appealed the injunctions to the Eighth and Fifth Circuit Courts of Appeals, and those injunctions were upheld by both courts. Ultimately, the disputes ended up before the Supreme Court, and on January 13, the Supreme Court stayed the injunctions issued by the lower courts, permitting CMS to enforce

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the IFC in those 24 states while the actions challenging the IFC proceed.<sup>[5]</sup>

The Supreme Court noted that one of the functions of the Department of Health & Human Services is to ensure that healthcare providers serving Medicare or Medicaid patients “protect their patients’ health and safety,” and the IFC fell within that statutory authority. The Supreme Court concluded that the U.S. Department of Health & Human Services secretary “did not exceed his statutory authority” in requiring applicable providers and suppliers to ensure that their staff are vaccinated against COVID-19 in order to remain eligible to participate in Medicare and Medicaid.

Following the Supreme Court’s decision, one preliminary injunction applicable to the State of Texas remained in effect, but in response to the Court’s holding, the Texas case was dismissed without prejudice on January 19, 2022.<sup>[6]</sup>

The injunctions preventing CMS from enforcing the IFC have been removed, and the IFC is now being enforced in every state. However, actions challenging the IFC are still ongoing in the district courts, and any actions or decisions by those courts could apply to the following states: Alabama, Alaska, Arizona, Arkansas, 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 (collectively, Affected States). Providers in Affected States should remain aware of the status of those cases.

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