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CMS Issues Guidance After Supreme Court Greenlights CMS Health Care Facility Vaccine Mandate, Blocks OSHA Vaccine-or-Test Mandate

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On January 13, 2022, the U.S. Supreme Court ruled on two related appeals seeking emergency relief from COVID-19 vaccination mandates. In one ruling, the Supreme Court stayed enforcement of a rule that would have required workplaces with 100 or more employees to adopt "vaccine-or-test" requirements. In the other, the Supreme Court permitted the Centers for Medicare & Medicaid Services (CMS) to impose COVID-19 vaccination requirements in virtually all health care facilities—with no testing option.

Following the Supreme Court's ruling, CMS issued additional guidance with new compliance deadlines for its rule. Through its guidance documents issued December 28, 2021, January 14, 2022, and January 20, 2022, CMS establishes three separate compliance timelines: one for states that were already subject to the vaccination mandate, one for states that were subject to the vaccination mandate pursuant to the Supreme Court's decision, and one for Texas, which was subject to an injunction that was lifted a week later following the Supreme Court's decision.

CMS Rule: Health Care Staff Vaccine Mandate

In <u>Biden v. Missouri</u>, the government petitioned the Supreme Court to overturn a patchwork of appellate court injunctions that partially blocked a rule issued by CMS requiring vaccination of staff at health care facilities. At issue was <u>CMS's COVID-19 Health Care Staff Vaccination</u> interim final rule with comment period, issued November 5, 2021, which requires virtually all staff of Medicare- and Medicaid-certified providers and suppliers to be vaccinated against COVID-19. The CMS Rule does not have a weekly testing option; the only permitted exemptions are those necessary to comply with the law (e.g., reasonable accommodations under the Americans with Disabilities Act) and narrow exemptions for certain fully remote employees. The CMS Rule was immediately challenged in dozens of states. In a 5–4 ruling, the Supreme Court held that the CMS Rule "fits neatly within the language of the statute" authorizing the Secretary of Health and Human Services to impose conditions on the receipt of Medicare and Medicaid funds.

Procedurally, the Supreme Court's ruling on the CMS Rule is a temporary stay of the lower court injunctions pending resolution of the merits of the case. Practically speaking, however, the Supreme Court's reasoning will likely be followed by the lower courts as the case continues on the merits, and health care facilities will need to come into compliance before the case is resolved to avoid potential enforcement action.

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ETS: Vaccine-or-Test Mandate

In *National Federation of Independent Businesses v. Department of Labor*, the petitioners sought an emergency stay of the Occupational Safety and Health Administration's (OSHA) November 5, 2021 emergency temporary standard (ETS), which required employers with 100 or more employees to compel those employees to be vaccinated against COVID-19 or to be tested weekly. The ETS had only narrow exceptions to this policy for employees who work 100% remotely or who work exclusively outdoors.

Just one day after the ETS was issued, the U.S. Court of Appeals for the Fifth Circuit issued a stay of the ETS. Dozens of cases challenging the ETS were consolidated before the Sixth Circuit, which <u>vacated</u> the Fifth Circuit's stay on December 17, ruling that the ETS was likely consistent with the agency's statutory and constitutional authority. The plaintiffs challenging the rule filed petitions with the Supreme Court within hours of the Sixth Circuit's decision. The Justices took up the case on an expedited basis on December 22, 2021 and heard oral arguments on January 7, 2022. Within a week of oral arguments, a divided Supreme Court ruled 6–3 that OSHA had exceeded its authority in issuing the mandate, explaining that "[a]Ithough Congress has indisputably given OSHA the power to regulate occupational dangers, it has not given that agency the power to regulate public health more broadly. Requiring the vaccination of 84 million Americans, selected simply because they work for employers with more than 100 employees, certainly falls in the latter category."

The Supreme Court's opinion stays enforcement of the ETS pending the final disposition by the Supreme Court of the challenges to the rule on the merits. This means that even if the Sixth Circuit ultimately finds that the rule is valid and can go into effect, the Supreme Court's stay will still remain in place until the Supreme Court either takes the case back up or declines to do so following the Sixth Circuit's ruling. While the Supreme Court's ruling is not the procedural end of the case, the Supreme Court's opinion is likely to have a material impact on the Sixth Circuit's review. The substance of the majority's opinion made very clear that the majority thinks that the ETS goes well beyond OSHA's statutory authority, which will make it very difficult for the government to now convince the Sixth Circuit to uphold the rule on the merits.

As a practical matter, employers are not required to comply with the ETS at the moment, and it appears unlikely that the rule will ever go into effect. But the litigation will likely continue in the Sixth Circuit, unless the government decides to withdraw the ETS and obviate the need for further litigation.

CMS Implements the CMS Rule – Different Compliance Timelines for Different States

When the Supreme Court agreed to hear the case on December 22, 2021, the CMS Rule had been blocked in 25 states by three federal appellate courts. CMS issued <u>guidance</u> (including <u>facility-type-specific guidance</u>) on December 28, 2021 setting forth CMS's plan to proceed with implementation and enforcement of the vaccination requirements in states where the CMS Rule had not been enjoined by court order—25 states, the District of Columbia, and the U.S. Territories. On January 14, 2022, one day after the Supreme Court lifted the lower court injunctions, CMS issued <u>additional guidance</u> setting forth a modified timeline for providers and suppliers in states where injunctions were lifted by the Supreme Court's ruling. Except for compliance deadlines, the guidance documents are substantively the same. Notably, when the Supreme Court issued its ruling, one state—Texas—was still subject to an injunction against the CMS Rule pursuant to a December 15, 2021 <u>order</u> from the U.S. District Court for the Northern District of Texas. Pursuant to the Supreme Court's precedent, the Texas district court lifted the injunction and dismissed the case on January 19. Shortly thereafter, CMS issued a <u>third guidance document</u> outlining a compliance timeline specific to Texas.

What does the guidance say?

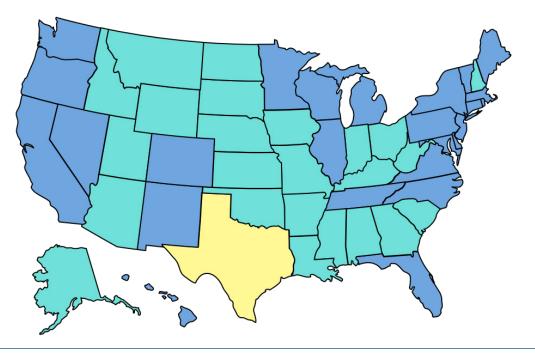
CMS's guidance interpreting many fundamental requirements of the CMS Rule has been consistent since the Rule was first issued. The scope of "staff" the requirements of the Rule apply to is broadly construed, reaching all who interact with other staff or patients, and essentially only carving out those who telework 100% of the time. CMS's definition of "vaccinated" continues to not require booster shots. CMS last updated its <u>FAQs</u> guidance on December 28, 2021. For further details on the CMS Rule's requirements, see our November 5 advisory <u>here</u>.

Which CMS guidance document applies to which states?

The December 28, 2021 guidance from CMS remains in effect for the states listed below. The January 14, 2022 guidance from CMS sets forth a modified compliance and enforcement timeline for providers and suppliers in jurisdictions that were, until January 13, 2022, subject to a court injunction blocking enforcement of the CMS Rule. Finally, the January 20, 2022 guidance from CMS sets forth a modified compliance and enforcement timeline only applicable to Texas.

Specifically:

- The **December 28, 2021 guidance** continues to apply to the following 25 states, as well as the District of Columbia and the U.S. Territories ("Group 1," colored blue in the map and chart below):
 - California, Colorado, Connecticut, Delaware, Florida, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, North Carolina, Nevada, New Jersey, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Tennessee, Vermont, Virginia, Washington, and Wisconsin
- The January 14, 2022 guidance applies to the following 24 states ("Group 2," colored green in the map and chart below):
 - 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
- The January 20, 2022 guidance applies only to Texas (colored yellow in the map and chart below).



What are my compliance timeframes?

Each group of states has a compliance timeframe with deadlines occurring 30, 60, and 90 days after issuance of the applicable guidance. The table below outlines the phases of compliance for each group of states. Federal, state, accrediting organization, and CMS-contracted surveyors will begin surveying for compliance with these requirements as part of initial certification, standard recertification or reaccreditation, and complaint surveys **30 days** following issuance of the applicable guidance.

	Phase 1	Phase 2	Full Enforcement
GROUP 1 Deadline	January 27, 2022 (30 days after Dec. 28 guidance)	February 28, 2022 (60 days after Dec. 28 guidance, +2 days because 60 days falls on Saturday, Feb. 26)	March 28, 2022 (90 days after Dec. 28 guidance)
GROUP 2 Deadline	February 14, 2022 (30 days after Jan. 14 guidance, +1 day because 30 days falls on Sunday, Feb. 13)	March 15, 2022 (60 days after Jan. 14 guidance)	April 14, 2022 (90 days after Jan. 14 guidance)
Texas Deadline	February 22, 2022 (30 days after Jan. 20 guidance, +3 days because 30 days falls on Saturday, Feb. 19)	March 21, 2022 (60 days after Jan. 20 guidance)	April 20, 2022 (90 days after Jan. 20 guidance)
Compliance	 Facility has requisite policies & procedures.¹ 100% of staff have either: At least one vaccine dose; Qualifying exemption (pending or granted); or CDC-recommended delay. 	 Facility has requisite policies & procedures.¹ 100% of staff have either: All vaccine doses;² Qualifying exemption (granted); or CDC-recommended delay. 	
Enforcement Thresholds	A facility that is above 80% and has a plan to achieve 100% staff vaccination rate within 60 days would not be subject to additional enforcement action. ³	A facility that is above 90% and has a plan to achieve 100% staff vaccination rate within 30 days would not be subject to additional enforcement action. ³	Within 90 days of issuance of the applicable guidance, facilities failing to maintain compliance with the 100% standard for compliance may be subject to enforcement action.
Enforcement Action	Failure to meet the 100% compliance or applicable 80% / 90% partial compliance thresholds may result in additional enforcement actions depending on the severity of the deficiency and the type of facility (e.g., plans of correction, civil monetary penalties, denial of payment, termination). ⁴		

¹ Facilities must have policies and procedures developed and implemented for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact, are vaccinated for COVID-19.

- ² This means one dose of a single-dose vaccine or all doses of a multiple-dose vaccine series. *The CMS Rule does not require individuals to have received booster doses*. The requirements are considered to be satisfied once the individual has received the doses; compliance by the deadline does not require completion of the 14-day waiting period after vaccination.
- ³ CMS noted that states should work with their CMS location for cases that exceed these partial compliance thresholds yet pose a threat to patient health and safety.
- 4 Noncompliant facilities (including those that meet the partial compliance thresholds described above) will receive notice of noncompliance with the 100% standard through CMS Form-2567, using the applicable Automated Survey Processing Environment (ASPEN) federal tag.

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