SCOTUS BLOCKS OSHA'S ETS AND ALLOWS CMS MANDATE TO GO INTO EFFECT

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SCOTUS RULES ON VACCINE MANDATES: (1) BLOCKS OSHA'S ETS AND (2) ALLOWS CMS MANDATE TO GO INTO EFFECT

On 13 January 2022, the United States Supreme Court issued two rulings on the challenges to the Occupational Safety and Health Administration's (OSHA) Emergency Temporary Standard (ETS) (OSHA Ruling)¹ and the Centers for Medicare and Medicaid Services (CMS) Interim Final Rule with Comment (CMS IFR) (CMS Ruling)² (discussed here). In a 6–3 decision, the Supreme Court blocked the OSHA ETS from going into effect, while in a 5–4 decision it allowed the CMS mandate to go into effect in 24 states where a stay had been imposed. Pursuant to these rulings, large private employers are no longer required to comply with the vaccination and testing provisions of the OSHA ETS, while covered CMS facilities in those 24 states must develop and implement a mandatory vaccination program in light of a rapidly approaching initial compliance deadline. Although large private employers are not subject to the OSHA ETS, they may have to navigate a patchwork of state and local mandates that address vaccination in the workplace as well as additional guidance and increased enforcement of general workplace standards by OSHA. Likewise, the Supreme Court's ruling does not prohibit employers from voluntarily electing to implement a vaccine mandate, provided they comply with local and state law requirements and limitations. This Alert discusses the respective Supreme Court rulings, compliance requirements for CMS covered facilities, and best practices for covered employers in the face of the ongoing COVID-19 pandemic.

BREAKING DOWN THE RULINGS

OSHA ETS: The OSHA Ruling

As expected, the Supreme Court's decision was based predominantly on the major questions doctrine. The Court determined that Congress needed to delegate more clearly and specifically before OSHA could issue such a broad mandate on a matter of public health that was not specific to the workplace (e.g., impacting the general public not just the workplaces it sought to regulate). The majority in the OSHA Ruling determined that OSHA was regulating with too broad a brush (the general public health risk of COVID-19), that Congress would need to specifically authorize such action (major questions doctrine), but that OSHA does have authority to regulate more specific occupational-related risks as to COVID-19 (which may come into play down the line when OSHA's permanent standard is issued). Even though it could not issue the ETS, OSHA continues to retain its general duty clause authority, which allows it to ensure general occupational safety and health and protect employees from workplace risks. While it remains open as a possibility, it is very likely that OSHA will take provisions of the ETS and seek to issue them as subregulatory guidance under the general duty clause. Indeed, Secretary of Labor,

Marty Walsh, has already issued a <u>statement</u> in response to the Supreme Court's ruling indicating that OSHA will be vigorously enforcing the general duty clause in this area. At the same time, OSHA continues to proceed with notice and comment rulemaking for a permanent COVID-19 vaccination/testing standard. If OSHA heeds the Supreme Court's guidance, and seeks to focus the permanent standard on specific industries or specific workplace risks caused by COVID-19, it is possible OSHA may ultimately come forward with a defensible regulation.

CMS IFR: The CMS Ruling

Unlike the OSHA ETS, in the CMS Ruling, the Supreme Court determined, by a 5–4 majority, that HHS regulated within the statutory authority delegated by Congress when it issued the CMS IFR. This decision was impacted by the fact that the Secretary of the Department of Health and Human Services (HHS) has long issued regulations protecting the health and safety of patients and governing the qualifications and duties of healthcare workers in facilities that participate in Medicare and Medicaid. The Supreme Court held that Congress has authorized the Secretary of HHS to impose conditions on the receipt of Medicaid and Medicare funds that "the Secretary finds necessary in the interest of the health and safety of individuals who are furnished Services." Acknowledging that COVID–19 is a highly contagious, dangerous, and—especially for Medicare and Medicaid patients—deadly disease, the Court relied upon the responsibility and expertise of the Secretary of HHS in determining that a COVID–19 vaccine mandate will substantially reduce the likelihood that healthcare workers will contract the virus and transmit it to their patients, and that the Secretary of HHS appropriately concluded that a vaccine mandate is "necessary to promote and protect patient health and safety" in the face of the ongoing pandemic. Therefore the Court held that the CMS IFR fits neatly within the language of the statute.

Additionally, the Court acknowledged that "ensuring 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." The Court explained that the "very opposite of efficient and effective administration for a facility that is supposed to make people well [would be] to make them sick with COVID19." While the majority of the decision focused on the analysis of the Secretary's statutory authority to promulgate the CMS IFR, the Court also held that (1) the CMS IFR is not arbitrary and capricious; (2) there was good cause for the Secretary to waive typical notice-and-comment rulemaking procedures; and (3) the CMS IFR does not violate the "directive in §1395 that federal officials may not 'exercise any supervision or control over the . . . manner in which medical services are provided, or over the selection [or] tenure . . . of any officer or employee of any facility. That reading of section 1395 would mean that nearly every condition of participation the Secretary has long insisted upon is unlawful."

In short, the Supreme Court upheld the CMS IFR, removing the impediments of the preliminary injunctions issued by the Missouri and Louisiana District Courts that prohibited implementation of the CMS IFR in 24 states. Also pertinent, and of interest for those potentially subject to the currently enjoined federal contractor vaccine mandate, the Court made a point of emphasizing that health care providers accepted these regulations as a condition of receiving Medicare and Medicaid funds. Health care providers need to continue implementing and complying with the CMS IFR, as the President has already stated that the Biden Administration plans to enforce the CMS IFR in response to the Supreme Court's ruling.⁷

LARGE EMPLOYERS: WHAT DOES THE FUTURE HOLD?

Although large private employers are no longer required to implement mandatory vaccination or testing policies under the ETS, there may be additional action or enforcement on the part of OSHA. Further, OSHA may still proceed with more formal notice-and-comment rulemaking to establish a workplace standard on COVID-19. As per the Secretary of Labor's announcement released the evening of the ruling (13 January) on the ETS employers were reminded that they "are responsible for the safety of their workers on the job" and "OSHA has comprehensive COVID-19 guidance" to assist employers in maintaining a safe workplace. The Secretary of Labor's statement also noted that "OSHA will do everything in its existing authority to hold businesses accountable for protecting workers, including under the Covid-19 National Emphasis Program and General Duty Clause." In light of this statement, and in the absence of a formal standard, OSHA may increase its enforcement efforts under the general duty clause, and employers, regardless of size, should incorporate OSHA's guidance on COVID-19, especially as it applies to masking, social distancing, and management of employees with COVID-19. Therefore, employers should ensure their COVID-19 policies address current OSHA guidelines for a safe workplace⁸ as well as applicable state and local guidance.

Additionally, for employers located in the 22 states with OSHA-approved State Plans for private employers, the state occupational safety and health agency is not prevented from implementing its own standard, which may be similar to or more stringent that the OSHA ETS. Since the OSHA Ruling did not preclude states from imposing such mandates, employers may see additional regulations as to COVID-19 vaccination and testing for unvaccinated workers. As evidenced by the recently adopted vaccination mandate in New York City, private employers may see increasing state and municipal regulations both across certain industries as seen in the various public sector mandates or as applied more generally to private workplaces. Employers should also be aware that state and local regulations may also include requirements related to booster doses of the vaccine, which were not incorporated into the OSHA ETS. Thus, employers must continue to monitor developments at the federal, state, and local level to ensure compliance.

It is important to note that the OSHA Ruling does not affect private employers' ability to voluntarily implement mandatory vaccination or testing policies so long as employees are permitted to seek accommodations under both federal and state law. Although the OSHA ETS may have provided employers with an argument as to preemption of state or local restrictions on employers' abilities to impose vaccination mandates (discussed here and here), employers must navigate state regulations providing for more broad exemptions and those that protect a worker from discrimination based on vaccination status. These may require modifications of how a policy is applied across a workforce, especially for employers operating across state lines. Finally, though vaccine-related leave is no longer required at a federal level, employers in multiple jurisdictions may still be required to provide paid leave for vaccination, including recovery from side effects, and in some cases booster doses.

IMMEDIATE IMPACT ON MEDICARE- AND MEDICAID-CERTIFIED HEALTHCARE PROVIDERS AND SUPPLIERS

Pursuant to the CMS Ruling, the CMS IFR is now in effect in the 24 states where it had been enjoined. Immediately following the release of the CMS Ruling, CMS <u>announced</u> that health care providers subject to the CMS IFR in the 24 states¹⁰ (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) where it had been enjoined, now need to establish plans and procedures for compliance with the vaccine mandate requirements as applicable to the providers' staff. As background, the CMS IFR establishes COVID-19 vaccination requirements for staff, which includes both employees and non-employees at different types of Medicare- and Medicaid-certified providers and suppliers, including but not limited to hospitals, critical access hospitals, ambulatory surgical centers, hospices, and skilled nursing facilities/nursing facilities. The requirements will be enforced through the existing survey process that applies to certified providers and suppliers, including the potential for imposition of penalties through that existing process. Per guidance issued by CMS to State Survey Agency Directors on 14 January 2022 (CMS Guidance), healthcare facilities in the 24 states that are now covered by the CMS IFR following the CMS Ruling will have to implement a mandatory vaccination policy for all covered staff in accordance with the three phases for compliance dates. Specifically, by 14 February 2022, covered facilities must implement Phase 1 of the CMS IFR:

- Develop and implement policies and procedures for ensuring all facility staff, regardless of clinical responsibility or patient or resident contact are vaccinated for COVID-19; and
- 100% of staff have received at least one dose of COVID-19 vaccine, or have a pending request for, have been granted a qualifying exemption, or be eligible for a temporary delay in vaccination as recommended by the CDC.

Facilities that do not meet this requirement will receive notice of non-compliance, but if vaccination rates are above 80% and the facility has a plan to achieve a 100% staff vaccination rate within 60 days, CMS states that the facility would not be subject to additional enforcement action.

By 14 March 2022, covered facilities must implement Phase 2. To be compliant, 100% of staff at a covered facility must have received the necessary doses to complete the primary vaccination series (i.e., one dose of a single-dose vaccine or all doses of a multiple-dose vaccine series), have been granted a qualifying exemption, or be eligible for a temporary delay in vaccination as recommended by the CDC. Facilities that do not meet this requirement will receive notice of non-compliance, but if vaccination rates are above 90% and the facility has a plan to achieve a 100% staff vaccination rate within 30 days, CMS states that they would not be subject to addition enforcement action.

By 15 April 2022, CMS states that facilities covered by the CMS IFC that fail to maintain compliance with the 100% standard may be subject to enforcement action. The CMS Guidance addresses the enforcement process for covered facilities and outlines the possible sanctions for noncompliance, including civil monetary penalties, denial of payment, and termination from the Medicare/Medicaid program.

Finally, the CMS Ruling does not alter the compliance timelines included in the 28 December 2021 CMS guidance¹³ already in place and being implemented in jurisdictions where the preliminary injunction was previously lifted by the Sixth Circuit. Further, covered facilities with 100 or more employees will no longer be required to comply with the OSHA ETS, including the testing mandate for any accommodated workers who remained unvaccinated at the worksite.

STAYED, BUT NOT FORGOTTEN: STATUS OF THE FEDERAL CONTRACTOR MANDATE

Notably, the federal contractor vaccine mandate under Executive Order 14042 (EO 14042) was not at issue in any of the stay-related litigation before the Supreme Court. EO 14042 remains subject to several injunctions, and is presently enjoined nationwide. Nevertheless, it is likely that the OSHA Ruling and CMS Ruling will have a significant impact in how EO 14042 is litigated, as well as its ultimate fate. The federal contractor vaccine mandate under EO 14042 is a general public health measure more similar to the OSHA ETS than the CMS IFR; in that respect, it may be more likely to be blocked by the Supreme Court if they were to rule on the mandate. At the same time, EO 14042 involves federal contractors agreeing to the vaccination mandate as a condition of their federal contracts and in order to receive federal funds through those contracts, which renders the mandate more similar to the CMS IFR than the OSHA ETS. The question of whether EO 14042 is more akin to the OSHA ETS or the CMS IFR is likely to determine the eventual outcome. Accordingly, federal contractors and subcontractors need to continue to be vigilant in preparing to comply with the vaccination mandate if the current injunctions are lifted and EO 14042 becomes applicable again.

WHAT ABOUT PREEMPTION?

With various state and local laws purporting to limits employers' ability to impose a vaccination mandate, many employers have questions about the issue of preemption. The Supreme Court's decisions to stay the OSHA ETS and to allow the CMS IFR to be enforced both simplify and complicate the situation. First, the OSHA ETS included a broad preemption clause that could be relied on to establish a national testing/vaccine standard. Under that clause, the national standard would have taken precedence over state and local regulations (with only State OSHA Plans being able to adopt more stringent rules). With the Supreme Court's decision to stay the OSHA ETS, employers will need to carefully consider state and local regulations in the jurisdictions where they operate. At the same time, the decision to allow the CMS IFR to proceed may simplify the issue of preemption for covered health care providers, as CMS takes the position that the CMS IFR preempts any state laws that conflict with its provisions. However, providers should evaluate state and local laws and consult counsel as they navigate potentially conflicting requirements as to exemptions from the vaccination requirement. Finally, the situation remains complicated for federal contractors and subcontractors, who need to continue preparing for the possible resumption of enforcement of the contractor vaccine mandate, while also recognizing that the preemptive status of EO 14042 remains unclear in light of the nationwide injunction. At the very least, the guestion of whether federal contractors with 100 or more employees need to comply with the OSHA ETS while the contractor mandate remains enjoined has been answered. As the OSHA ETS is now stayed by order of the Supreme Court, federal contractors can now focus solely on preparing to potentially comply with EO 14042 if it becomes effective again.

PRACTICAL GUIDANCE

As the legal landscape surrounding vaccination mandates is constantly evolving, private employers must regularly monitor developments at the federal, state, and local level that may impact a workplace vaccination or testing policy. For healthcare employers subject to the CMS mandate, compliance deadlines are fast approaching, and employers across the nation should prepare for implementation. Finally, in light of OSHA's announcements as to increased enforcement, all employers should incorporate OSHA's general workplace guidance as well as any industry-specific guidance to avoid the risk of citations and penalties. Our lawyers regularly advise clients on

COVID-19 matters and we are well prepared to assist businesses as they navigate operations or seek clarifying quidance regarding reopening. Visit the K&L Gates HUB for information about our available COVID-19 resources.

Our Labor, Employment, and Workplace Safety lawyers assist with all aspects of a mandatory vaccination program, including determining coverage under the various directives and proposed regulatory actions, addressing compliance with federal and state laws, developing COVID-19 safety policies and procedures, and crafting communications to employees and contractors.

Our Healthcare and FDA lawyers and professionals can help clients navigate the various mandate requirements and applicable issues, both state and federal, and work closely with our Labor, Employment, and Workplace Safety practice to address the multi-pronged needs that arise assessing regulatory requirements and implementation.

Our Government Contracts and Procurement Policy lawyers and professionals can help federal contractors understand the new obligations and risks that will emerge as a result of this latest action by the White House related to COVID-19.

FOOTNOTES

- ¹ Nat'l Fed'n of Indep. Bus. v. Dep't of Labor, 595 U. S. (2022).
- ² Biden v. Missouri, 595 U.S. ____ (2022).
- ³ 42 U. S. C. §1395x(e)(9).
- ⁴ Citing to 86 Fed. Reg. 61,557–61,558.
- ⁵ Citing to 86 Fed. Reg. 61,613.
- ⁶ Florida v. Department of Health and Human Servs., 19 F. 4th 1271, 1288 (CA11 2021).
- ⁷ See <u>Statement by President Joe Biden on the U.S. Supreme Court's Decision on Vaccine Requirements</u> (last visited January 14, 2022).
- ⁸ See OSHA, <u>Protecting Workers: Guidance on Mitigating and Preventing the Spread of COVID-19 in the Workplace</u> (last visited January 13, 2022)
- ⁹ As of the date of publication, 11 states had imposed some form of restrictions on an employer's ability to mandate the COVID-19 vaccination for private employees.
- ¹⁰ As the stay issued by the Northern District of Texas was not before the Supreme Court, it remains in place as of the date of publication. State of Texas et al v. Becerra et al, No. 2:2021cv00229 (N.D. Tex. 2021).
- ¹² This term is used generally to refer to the Medicare providers and suppliers that are subject to the CMS IFR.
- ¹³ Memo to State Survey Agency Directors, Guidance for the Interim Final Rule Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination (QSO-22-07-ALL) (Dec. 28, 2021), available at

here (last visited Jan. 14, 2022).

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