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STAYS IN LOUISIANA AND GEORGIA DISTRICT COURTS STIR UNCERTAINTY IN THE EVER-CHANGING LANDSCAPE OF COVID-19 VACCINE MANDATE LITIGATION

On November 30, 2021, the United States District Court, Western District of Louisiana ("WDL") issued a decision calling into question the legality of the Biden Administration's recent vaccine mandate regarding health care workers. Further casting doubt on the lawfulness of the Biden Administration's various vaccine mandates, on December 7, 2021, the United States District Court for the Southern District of Georgia ("SDG") issued a stay of the nationwide vaccine mandate that was imposed upon all companies that do business with the federal government.

As previously documented in earlier editions of In Focus, President Joseph R. Biden, Jr. issued mandates requiring employees, volunteers, and contractors at health care facilities that receive federal funding through the Medicare and Medicaid systems to be fully vaccinated. However, the WDL issued a nationwide stay of the enforcement of this mandate promulgated by the U.S. Center for Medicare and Medicaid Services ("CMS Mandate"). *State of Louisiana v. Becerra*, Case No.: 21-CV-3970 (TAD) (KDM) (W.D.La.; Nov. 30, 2021). According to the Court, the CMS lacked the executive authority to issue the CMS Mandate because the government "lacked . . . the superpowers they claim" to have. In a decision that closely tracked and supported the claims set forth in the plaintiffs' pleading, the WDL found that the plaintiffs, consisting of 14 states, demonstrated: i) sufficient standing to challenge the CMS Mandate, ii) a traceable, concrete, injury-in-fact, and iii) a likelihood of success on the merits. The Court also determined that the CMS exerted legislative authority by unlawfully promulgating the CMS Mandate, which they did not possess because this agency action fell short of the "major question doctrine," which requires the U.S. Congress to "speak clearly if it wishes to assign to an agency, decisions of vast economic and political significance." *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014). The bestowment of general rule making authority contained in the Social Security Act of 1935 ("SSA") did not contemplate the CMS Mandate.

Further, even if the SSA, or any other legislation, permitted the CMS to issue this mandate, such a promulgation would require the CMS to undergo the typical rulemaking process, set forth in the Administrative Procedures Act of 1946 ("APA") of notice and comment. Given that the CMS Mandate was promulgated and announced by the President on the same day it became effective, the CMS Mandate circumvented the notice and comment requirements of the APA. The WDL ignored the Biden Administration's attempt to justify the rushed issuance of the CMS Mandate on the ground that it possessed "good cause" in order to address a "grave danger." The Court found that the "good cause" exception to the typical rulemaking process "is read narrowly," is "indeed rare," and is not present in the instant matter. *State of Louisiana*, Case No.: 21-CV-3970, p. 16.

Additionally, in granting the nationwide stay to the CMS Mandate, the Court held that the plaintiffs demonstrated "irreparable harm." In a terse and cursory analysis that stands in contravention of the recent judicial decisions concerning various vaccine mandates, the WDL stated that the citizens in the plaintiff-states "will suffer irreparable injury by having a substantial burden placed on their liberty interests because they will have to choose between their jobs or taking a vaccine." *Id.*, p. 32. Moreover, the WDL determined that the balancing of equities and the public interest side in favor of the plaintiffs and the protection of their respective liberty interests over the requirement of taking a vaccine designed to end a pandemic that has already killed hundreds of thousands of Americans.

In *Georgia v. Biden*, Case No.: 21-CV-163 (RSB) (BKE) (S.D.Ga.; Dec. 7, 2021), the underlying mandate, which affects such multi-national companies as Lockheed Martin Corp, General Motors Co., and Microsoft Corp., is derived from the President's authority to "play a direct and active part in supervising the Government's management functions" and "to promote economy and efficiency in procurement," as codified in the Federal Property and Administrative Services Act of 1949 ("Procurement Act"). *Id.*, p. 18. However, in relying upon the standard set forth in *Utility Air Regulatory Group*, 573 U.S. 302, 324 (2014), U.S. District Judge R. Stan Baker found that, although the Procurement Act "bestows some authority upon the President, the Court is unconvinced, at this stage of the litigation, that it authorized him to direct the type of actions" contemplated in this mandate.

According to the SDG, the Procurement Act did not "speak clearly" to the restrictions, limitations, and requirements related to COVID-19 to empower the President to mandate that all employees of federal contractors to be fully vaccinated by January 18, 2022. Acknowledging that previous executive actions related to the pandemic, such as this mandate, have been lawful, the Court stated: "none have involved measures aimed at public health and none have involved the level of burdens implicated" by this mandate. Furthermore, the SDG determined that finding in favor of the defendants in this challenge could "give the President the right to impose virtually any kind of requirements on businesses that wish to contract with the Government." *Georgia*, Case No.: 21-CV-163, pp. 22-23. Additionally, the Court held that the administrative burdens and costs associated with complying with this mandate constituted an irreparable harm because it would involve, amongst other things, the loss of employees, compliance and monitoring costs, and diversion of resources. Based upon these factors, the SDG issued a nationwide injunction to this mandate.

OUTGOING MAYOR DE BLASIO CALLS FOR FIRST IN-THE-NATION COVID-19 VACCINE MANDATE FOR PRIVATE COMPANIES

On December 6, 2021, Mayor Bill de Blasio announced a COVID-19 vaccine mandate for all private companies without regard to number of employees or nature of business. Mayor de Blasio said that the mandate will go into effect on December 27, 2021 and will apply to in-person employees. Like other mandates, the City mandate will provide for medical and religious accommodations. However, unlike other mandates, the City mandate will not include testing as a general alternative to vaccination. New York City will publish much needed specific rules for the vaccine mandate on December 15, 2021. The City calculates that the new mandate will apply to 184,000 businesses. These businesses will have three weeks to comply with the mandates. The Mayor did not provide any information on the enforcement mechanism for the mandate.

Mayor de Blasio said the City's COVID-19 vaccine mandate will be the first-in-the-nation for private companies. Although Mayor de Blasio's term ends on December 31, 2021, he cited the dangers of the Omicron variant and holiday gatherings that could become super-spreader events as the reasons for taking "bold" action to issue the vaccine mandate in the final days of his term. Incoming Mayor Eric Adams has indicated that he "will evaluate this mandate and other COVID strategies when he is in office… based on science, efficacy and the advice of health professionals." Lawsuits challenging the mandate are widely expected.

HIPAA AND PRIVACY BARRIERS TO PERSONAL COVID-19 VACCINATION INFORMATION

With COVID-19 variants, including its most recent successor, Omicron, continuing to occupy the world's spotlight, the question of whether an employee's vaccination status is protected by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") continues to gain momentum. The U.S. Congress enacted HIPAA seeking to create national standards safeguarding sensitive, individual health information from being shared without the individual's consent. In turn, the U.S. Department of Health and Human Services ("HHS") promulgated the HIPAA Privacy Rule to accomplish the requirements of HIPAA.

The HIPAA Privacy Rule applies to Personal Health Information ("PHI") that is created, received, maintained, or transmitted by a covered entity or a business associate. Under HIPAA, a "covered entity" is any health plan, health care clearinghouse, and health care provider who electronically transmits any health information. Similarly, the term "business associate" is defined as any individual or entity that performs certain functions or activities that include the use or disclosure of PHI on behalf of, or provides services to, a covered entity.

Recently, HHS published guidance in the form of five questions and answers entitled, "HIPAA, COVID-19 Vaccination, and the Workplace." The guidance underscores that the Privacy Rule applies only to covered entities and, sometimes, their business

associates and does not prohibit businesses or individuals from asking whether their customers or clients have received a COVID-19 vaccine. Further, the Privacy Rule does not control whether covered entities and business associates can request information from patients or visitors; instead, it regulates "how and when covered entities and business associates are permitted to use and disclose" PHI (e.g., information about an individual's vaccination status). Additionally, the Privacy Rule does not prevent customers or clients of a business from disclosing whether they received a COVID-19 vaccine because, as stated above, the Privacy Rule applies only to covered entities and, to some extent, their business associates. Moreover, the Privacy Rule does not prohibit an employer from requiring an employee to disclose whether they have received a COVID-19 vaccine to the employer, clients, or other parties because the Privacy Rule does not apply to employment records including employment records held by covered entities or business associates in their role as employers.

While the Privacy Rule does not control what information can be requested from employees as part of the terms and conditions of employment, other federal or state laws govern the safeguarding of such information. For example, federal anti-discrimination laws do not prohibit an employer from making the choice to require that all employees physically entering the workplace be vaccinated against COVID-19 and produce documentation or other confirmation that they have satisfied the requirement. However, under Title I of the Americans with Disabilities Act, vaccination documentation once received must be protected as confidential and stored apart from the employee's personnel files. In addition, the Privacy Rule does not prohibit a covered entity or business associate from requiring its employees to disclose to their employers or other parties whether the employees have received a COVID-19 vaccine because, as stated above, the Privacy Rule does not apply to employment records held by covered entities or business associates in their role as employers.

In contrast to all the other questions answered by the HHS guidance, the Privacy Rule prohibits a doctor's office from disclosing an individual's PHI, including whether they have received a COVID-19 vaccine, to the individual's employer or other parties absent an individual's authorization or otherwise expressly permitted by the Privacy Rule. Under HIPAA, when a covered entity or business associate is allowed to disclose PHI, it is limited "to disclosing the PHI that is reasonably necessary to accomplish the stated purpose for the disclosure."

As the nation and the world continue to cope with the aftershocks of the pandemic, employers must continue to monitor federal and or state laws that may surface regarding the subject of employees' vaccination status and any protected or required disclosures.

REGULATORY NORMS FACE CHALLENGES NOW AND IN THE FUTURE DUE TO VACCINE MANDATE LITIGATION

Beginning on November 22, 2021, various plaintiffs in *In Re: OSHA COVID Rule*, Case No.: 21-07000, which consists of the consolidated actions currently pending in the United States Court of Appeals for the Sixth Circuit challenging the Emergency Temporary Standard Mandate ("ETS Mandate") issued by the Occupational Safety and Health Administration ("OSHA"), began asking for the extraordinary procedural relief of having *en banc* review of the nationwide stay issued by the United States Court of Appeals for the Fifth Circuit in *BTS Holding LLC, et al. v. OSHA*, Case No.: 21-60845 (5th Cir. Nov. 12, 2021). On November 29, 2021, in opposition to these applications by the various plaintiffs, the Biden Administration argued against this deviation in favor of the typical review by a three-judge panel.

Presumably to tip the scales of justices in their favor, the plaintiffs, led by several, Republican state attorneys general and the Republican National Committee, made this application for the full complement of 16 judges, 11 of which were nominated by Republican Presidents, to decide whether the stay should remain in effect. In favor of *en banc* review, the plaintiffs contend that the survival of the ETS Mandate is exceptionally significant and "present one of the most extraordinary important questions that the Court has ever faced." The defendants, meanwhile, argue that: "No sound reason exists to bypass the normal course of appellate proceedings here, especially given the need for expeditious resolution of these consolidated cases." Further, adherence to the established process is necessary given the importance of the instant matter, since full court review "is inefficient, unwieldy, and time-consuming." At the time of publication, the Court has not ruled on this issue.

Also last week, the United States District Court for the Eastern District of Missouri ("EDM") issued a preliminary injunction against the enforcement of a vaccine mandate promulgated by the U.S. Center for Medicare and Medicaid Services applying to employees, volunteers, and contractors at health care facilities that receive federal funding through the Medicare and Medicaid systems ("CMS Mandate"). This injunction was only applicable to the named-state plaintiffs and was rendered irrelevant by the nationwide stay arising out of *State of Louisiana v. Becerra*, Case No.: 21-CV-3970 (TAD) (KDM). However, the fallout from the EDM decision has potentially far-reaching ramifications due to the Court's analysis therein. U.S. District Judge Matthew Schlep undercut the federal government's ability to set safety standards and the use of Medicare and Medicaid funding to accomplish said goals.

It has long been established that the CMS sets the rules that recipients of federal funding must implement because CMS wants to pay for safe care. But by calling into question this arrangement, District Judge Schlep who determined that the CMS Mandate was not authorized by the U.S. Congress, has also injected unpredictability not only into this pandemic, but also other health crises in the future. For example, the CMS used similar guidance to control the spread of and treatment for Methicillin-resistant Staphylococcus Aureus ("MRSA"). The fear going forward is, if the CMS would not be

able to set such standards to address such diseases, federal funding will be going to facilities that are not providing safe and appropriate medical care with federal, tax dollars.

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