UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

STATE OF TEXAS; TEXAS HEALTH AND HUMAN SERVICES COMMISSION,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	
	§	
XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare & Medicaid Services; MEENA SESHAMANI, in her official capacity as Deputy Administrator and Director of Center for Medicare; DANIEL TSAI, in his official capacity as Deputy Administrator and Director of Medicaid and CHIP Services; THE CENTERS FOR MEDICARE & MEDICAID SERVICES; JOSEPH R. BIDEN, in his official capacity as President of the United States; UNITED STATES OF AMERICA;	§	Case No. 2:21-CV-00229-Z
	§	
Defendants.	§	

PLAINTIFFS' NOTICE TO THE COURT OF FIFTH CIRCUIT STAY PROCEEDINGS

As it is relevant to the Court's forthcoming decision on Defendants' motion to stay proceedings, Texas advises the Court that the federal defendants in *Louisiana v. Becerra*, in which a federal district court in Louisiana issued a nationwide injunction of the CMS Vaccine Mandate, have appealed that decision and filed an emergency motion for stay pending appeal with the Fifth Circuit. *Louisiana v. Becerra*, No. 21-30734. According to their notice of filing, the federal

defendants have requested that the Fifth Circuit rule on their emergency motion for stay by Monday, December 6. A copy of the stay motion is attached. Should the Fifth Circuit grant any relief that would allow the CMS Vaccine Mandate to take effect in Texas, Texas will immediately inform the Court. Texas continues to request that the Court deny Defendants' motion to stay proceedings.

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I hereby certify that the foregoing document and all attachments were filed via CM/ECF, causing electronic service on all counsel of record.

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United States Court of Appeals for the Fifth Circuit

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Case Name: State of Louisiana v. Becerra
Case Number: 21-30734
Document(s): Document(s)

Docket Text:
OPPOSED MOTION filed by Appellants Mr. Xavier Becerra, Secretary, U.S. Department of Health and Human Services, Ms. Chiquita Brooks-Lasure, Centers for Medicare and Medicaid Services and HHS for stay pending appeal [9725101-2] Ruling is requested by: 12/06/2021. Date of service: 12/02/2021 via email - Attorney for Appellees: Faircloth, Murrill, St. John; Attorney for Appellants: Klein, McElvain [21-30734] (Alisa Beth Klein)

Notice will be electronically mailed to:

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No. 21-30734

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

STATE OF LOUISIANA, et al.,

Plaintiffs-Appellees,

v.

XAVIER BECERRA, et al.,

Defendants-Appellants.

DEFENDANTS-APPELLANTS' EMERGENCY MOTION FOR STAY PENDING APPEAL

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases: **Page(s)**

Statutes:

Regulations:

Other Authorities:

INTRODUCTION AND SUMMARY OF ARGUMENT

Congress spends hundreds of billions of dollars each year under the Medicare and Medicaid programs to protect the health of Americans. Congress specified that hospitals and other participating facilities must meet requirements set by the Secretary of Health and Human Services (HHS) to ensure the health and safety of patients. In the rule at issue here, the Secretary established a condition of participation requiring covered staff at such participating facilities to be vaccinated against COVID-19, to prevent transmission of the virus to patients. Because cases and deaths are expected to spike in the coming winter months, unvaccinated staff at participating facilities must receive their first vaccine dose by December 6, or request an exemption by that date. The Secretary projected that the rule will save hundreds and potentially thousands of lives every month.

More than 50 leading professional organizations representing health care workers—including the American Medical Association and the American Nurses Association—support COVID-19 vaccination requirements for health care workers. *Joint Statement in Support of COVID-19 Vaccine Mandates for All Workers in Health and Long-Term Care (Joint*

Statement).[1] These organizations emphasized that this step "is the logical fulfillment of the ethical commitment of all health care workers to put patients as well as residents of long-term care facilities first and take all steps necessary to ensure their health and well-being." *Id*. As the Secretary explained, health care workers have long been required by employers to be vaccinated against diseases such as influenza, hepatitis B, and other infectious diseases.

Nonetheless, the district court enjoined the vaccination rule's enforcement against Medicare- and Medicaid-participating facilities. The court declared that the rule exceeds the Secretary's statutory and constitutional authority, that it is arbitrary and capricious, and that the Secretary did not have good cause to make the rule effective without delay. Moreover, the court made its preliminary injunction effective in dozens of States that declined to join this lawsuit, and also overrode a sister court's denial of Florida's request for the same relief. *See* Op., *State of Florida v. Department of Health and Human Services*, No. 3:21-cv-02722 (N.D. Fla. Dec.

[1] https://perma.cc/ECD8-ARE2.

1, 2021) (*Florida* Op.) (providing additional reasoning for its earlier denial of a preliminary injunction), *appeal pending*, No. 21-14098 (11th Cir.).

The preliminary injunction rests on a series of errors and should be immediately stayed pending appeal or, at a minimum, stayed except as to state-run facilities within the plaintiff States. The Secretary has explicit statutory authority to require facilities voluntarily participating in Medicare and Medicaid to meet health and safety standards for the protection of patients. Longstanding regulations require these facilities to have infection-control programs that prevent the transmission of communicable disease. And ample evidence supports the Secretary's determination that the staff-vaccination requirement will provide crucial protections for patients in the coming months, when COVID-19 cases are expected to spike.

The Secretary comprehensively addressed the only practical concern that plaintiffs identified: the risk that the vaccination requirement will prompt unvaccinated workers to quit in large numbers and exacerbate labor shortages. The Secretary found on the basis of recent empirical evidence that this concern is overstated and outweighed by other effects. The Secretary explained, for example, that after a large hospital system in

Texas imposed a COVID-19 vaccine mandate, 99.5% of its 26,000 workers received the vaccine. Likewise, 98% of 33,000 workers complied with a Detroit-based system's vaccine mandate. More than 97% complied with vaccine mandates imposed by a Delaware-based health system with more than 14,000 employees and a North Carolina-based system with more than 35,000 employees. Furthermore, the Secretary found that the potential adverse effect of the vaccination rule in the labor market would be offset by reduced staff absenteeism and dwarfed by the regular churn of employees in the health care workforce, where about a quarter of a health care facility's staff on average are new hires each year.

In short, plaintiffs' claims are meritless, and the remaining stay factors overwhelmingly favor the federal government. The preliminary injunction should be immediately stayed pending appeal.

STATEMENT

A. The Medicare And Medicaid Programs

Under the Medicare and Medicaid programs, Congress spends hundreds of billions of dollars each year to pay for health care. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019) (noting that Medicare alone spends about $700 billion annually). Medicare, which is funded entirely by

the federal government, covers individuals who are over age 65 or who have specified disabilities. *See id*. Medicaid, which is funded by the federal government and States, covers eligible low-income individuals including those who are elderly, pregnant, or disabled. *See National Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 583, 585 (2012).

The facilities that provide health care to Medicare and Medicaid beneficiaries are entities such as hospitals, skilled nursing facilities (also known as nursing homes or long-term care facilities), home-health agencies, and hospices. If a facility wishes to participate in these programs, it enters into a provider agreement for the applicable program after demonstrating that it meets the conditions for participation. 42 U.S.C. §§ 1395cc, 1396a(a)(27).

Congress charged the Secretary with responsibility to ensure that facilities participating in these programs protect the health and safety of their patients. For example, the Medicare statute authorizes payments for "hospital services," 42 U.S.C. § 1395d(a), and defines a "hospital" as an institution that meets such "requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution," *id.* § 1395x(e)(9); *see also, e.g.*, *id.* § 1395i-

3(d)(4)(B) (providing that a "skilled nursing facility must meet" such "requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary"). The Medicaid statute also imposes health and safety requirements, *see, e.g., id.* § 1396r(d)(4)(B)), or incorporates by cross reference analogous Medicare standards for psychiatric hospitals, *see id.* § 1396d(h); rural health clinics, *id.* § 1396d(*l*)(1), and hospices, *id.* § 1396d(o).

Longstanding regulations establish detailed "Conditions of Participation" for participating facilities that address (among other things), the qualifications of employees, the condition of the facilities, and other requirements that the Secretary deems necessary to protect patient health and safety. These regulations include the requirement that the facility maintain an effective "infection prevention and control program" to "provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections." *See, e.g.*, 42 C.F.R. § 483.80 (long-term care facilities); *id.* § 482.42(a) (hospitals); *id.* § 416.51(b) (ambulatory surgical centers).

B. The Vaccination Rule For Facilities That Participate In Medicare Or Medicaid

The rule at issue here amended the infection-control regulations for facilities that participate in Medicare or Medicaid. To prevent health care workers from infecting patients with the virus that causes COVID-19, the rule requires facilities certified to participate in Medicare or Medicaid to ensure that their staff are fully vaccinated against COVID-19, unless exempt for medical or religious reasons. 86 Fed. Reg. 61,555, 61,561, 61,572 (Nov. 5, 2021).[2] Covered staff must receive the first dose of a two-dose vaccine or a single-dose vaccine by December 6, 2021, or otherwise request an exemption by that date. *Id.* at 61,573. Non-exempt covered staff must be fully vaccinated by January 4, 2022. *Id.*

The rule rests on the Secretary's comprehensive analysis and finding that "vaccination of staff is necessary for the health and safety of individuals to whom care and services are furnished." *Id.* at 61,561. While many health care workers are vaccinated against COVID-19, vaccination rates remain too low in many health care facilities. *Id.* at 61,559. For

[2] The rule exempts staff who telework full-time, and vendors and other professionals who perform infrequent, non-healthcare services. 86 Fed. Reg. at 61,571.

example, as of mid-September 2021, COVID-19 vaccination rates for hospital staff and long-term care facility staff averaged 64% and 67%, respectively. *Id.*

Unvaccinated staff pose a threat to patients because the virus that causes COVID-19 is highly transmissible and dangerous. *Id.* at 61,556-57. Given the virulence of this virus, it is readily spread among health care workers and from health care workers to patients. *Id.* at 61,557 n.16. In particular, unvaccinated health care workers are highly susceptible to transmitting the virus to their colleagues and patients. *Id.* at 61,558 n.42. And due to many of the factors that qualify them for enrollment (such as age, disability, and/or poverty), Medicare and Medicaid patients are more likely to face a high risk of developing severe disease and of experiencing severe outcomes from COVID-19 if infected. *Id.* at 61,566, 61,609.

Unvaccinated staff also jeopardize patients' access to needed medical care and services. *Id.* at 61,558. Out of a fear of exposure to the virus, patients are refusing care from unvaccinated staff, thereby limiting the ability of providers to meet the health care needs of their patients. *Id.* Patients also are forgoing medically necessary care altogether to avoid contracting the virus that causes COVID-19 from health care workers. *Id.*

Absenteeism among health care staff as a result of infection with the virus has also created staffing shortages that have disrupted patient access to care. *Id.* at 61,559.

The Secretary explained that, in July 2021, more than 50 health care associations—including the American Medical Association and the American Nurses Association—jointly advocated for vaccine mandates for health care workers. 86 Fed. Reg. at 61,565 & n.122. The signatories represent millions of workers throughout the U.S. health care industry, including groups representing doctors, nurses, long-term care workers, home care workers, pharmacists, physician assistants, public health workers, hospice workers, and epidemiologists. *Id.* Due to "the recent COVID-19 surge and the availability of safe and effective vaccines," these organizations urged that "all health care and long-term care employers require their workers to receive the COVID-19 vaccine." *Joint Statement*. The signatories explained that this step "is the logical fulfillment of the ethical commitment of all health care workers to put patients as well as residents of long-term care facilities first and take all steps necessary to ensure their health and well-being." *Id.*

In issuing the rule, the Secretary acknowledged the concern that the vaccination requirement could prompt some health care workers to leave their jobs rather than be vaccinated, but concluded on the basis of recent empirical evidence that this concern was overstated and outweighed by other effects and countervailing considerations. 86 Fed. Reg. at 61,608. The Secretary explained, for example, that after a large hospital system in Texas imposed a vaccine mandate, 99.5% of its staff received the vaccine. *Id*. at 61,569. Only 153 of its 26,000 workers—that is, only 0.6%—resigned rather than receive the vaccine. *Id*. at 61,566, 61,569.[3] Similarly, a Detroit-based health system that imposed a vaccine mandate reported that 98% of its 33,000 workers were fully or partially vaccinated or in the process of obtaining a religious or medical exemption when the requirement went into effect, with exemptions comprising less than 1% of staff members. *Id*. at 61,569. A long-term care parent corporation established a vaccine mandate for its more than 250 facilities, leading to more than 95% of its workers being vaccinated; again, very few workers quit their jobs rather

[3] *See also More than 150 Employees Resign or Are Fired from Houston Hospital System After Refusing to Get Vaccinated*, Tex. Trib. (June 23, 2021), https://perma.cc/F2SA-53D6.

than be vaccinated. *Id*. A health care system that is the largest private employer in Delaware with more than 14,000 employees, and an integrated health system in North Carolina with more than 35,000 employees, instituted vaccination requirements and achieved vaccination rates of at least 97% among their staffs. *Id*. at 61,566. And when New York enacted a state-wide vaccine mandate for health care workers, it recorded a jump in vaccine compliance in the final days before the requirements took effect on October 1, 2021. *Id*. at 61,569.

Furthermore, the Secretary concluded that the potential adverse effect in the health care labor market would be offset by reduced staff absenteeism from lowered rates of infection, quarantine, and illness among staff, as well as a return to work of employees who have stayed out of the workforce for fear of contracting the virus that causes COVID-19. *Id*. at 61,608. More generally, the Secretary explained that about a quarter of a health care facility's staff on average are new hires each year, and that this regular churn in the health care workforce would dwarf the effect of workers leaving for other employment as a result of the vaccination requirement. *Id*.

Based on his comprehensive analysis, the Secretary determined that "the available evidence for ongoing healthcare-associated COVID-19 transmission risk is sufficiently alarming in and of itself to compel [the agency] to take action," i*d*. at 61,558, and that the rule should be made effective without delay, *id*. at 61,583-85. The Secretary explained that patients in facilities funded by the Medicare and Medicaid programs are more likely than the general population to suffer severe illness or death from COVID-19, *id*. at 61,609; that there have already been more than half a million COVID-19 cases among health care staff, *id*. at 61,585; that COVID-19 case rates among staff have grown since the Delta variant's emergence, *id*.; that COVID-19 cases are expected to spike during the coming winter months, *id*. at 61,584; and that this spike will coincide with flu season, raising the additional danger of combined infections, *id*. The Secretary predicted that the rule will save hundreds and potentially thousands of lives every month, and that "a further delay in imposing a vaccine mandate would endanger the health and safety of additional patients and be contrary to the public interest." *Id*. at 61,584.

ARGUMENT

In considering a stay motion, a court considers: (1) whether the applicant has made a strong showing that it is likely to succeed on the merits; (2) whether the applicant will be irreparably injured absent a stay; (3) whether issuance of the stay will substantially injure the other parties interested in the proceeding; and (4) where the public interest lies. *Nken v. Holder*, 556 U.S. 418, 425–26 (2009). Every factor supports the federal government here.

A. The Injunction Exceeds The District Court's Jurisdiction.

As a threshold matter, the injunction—which purports to bar HHS from enforcing the vaccination rule against facilities participating in Medicare or Medicaid, App. 34—exceeds the district court's jurisdiction in multiple ways.

First, although the district court purported to show "special solicitude" for States, App. 8, it made its injunction effective in 24 States that did not challenge the rule and two States that challenged it elsewhere.

Second, even within their States, plaintiffs lack standing to seek relief on behalf of *privately-run* facilities or health care workers. As the *Florida*

court explained, a State cannot sue *parens patriae* "to shield employees who choose to work in a federally funded healthcare facility from the rules that govern administration of the federal program." *Florida* Op. 7.

Third, plaintiffs' *state-run* facilities must follow the jurisdictional requirements of the Medicare statute which, as the Supreme Court explained in *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), preclude pre-enforcement challenges to conditions of Medicare participation. Such challenges may proceed only through the special review system that the Medicare statute provides.[4] Just as the trade association in *Illinois Council* could not circumvent that bar by bringing a pre-enforcement action on behalf of its members, neither can plaintiffs do so on behalf of their state-run facilities.

B. Plaintiffs' Challenges To The Vaccination Rule Are Meritless.

Assuming there is jurisdiction to consider the issues, plaintiffs' challenges to the vaccination rule are meritless.

[4] Likewise, if a facility violates a rule that applies to both Medicare and Medicaid, the facility must seek review of the determination through the Medicare administrative appeals procedure. *In re Bayou Shores SNF, LLC*, 828 F.3d 1297, 1309 (11th Cir. 2016).

1. The vaccination rule is within the Secretary's statutory authority and presents no constitutional issue.

The Secretary has express statutory authority to require facilities participating in Medicare or Medicaid to adhere to standards that protect the health and safety of their patients. For example, the Medicare statute authorizes payments for "hospital services," 42 U.S.C. § 1395d(a), and defines a "hospital" as an institution that meets such "requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution," *id.* § 1395x(e)(9); *see also supra*, pp. 5-6 (similar provisions for other types of facilities). Requiring health care workers to become vaccinated against a highly transmissible and deadly disease is a straightforward example of a "requirement[]" that is "necessary in the interest of the health and safety" of the patients that medical facilities exist to serve.

Moreover, Congress vested the Secretary with authority to issue such regulations "as may be necessary to the efficient administration of the functions with which" he is charged under the Social Security Act, which include the Medicare and Medicaid programs. 42 U.S.C. § 1302(a). The Supreme Court has emphasized that § 1302(a) and similarly worded

delegations confer "broad rule-making powers." *Thorpe v. Housing Auth. of City of Durham*, 393 U.S. 268, 277 n.28 (1969). "Where the empowering provision of a statute states simply that the agency may 'make . . . such rules and regulations as may be necessary to carry out the provisions of this Act,'" "the validity of a regulation promulgated thereunder will be sustained so long as it is 'reasonably related to the purposes of the enabling legislation.'" *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356, 369 (1973) (quoting *Thorpe*, 393 U.S. at 280-81).

Contrary to the district court's premise, the CMS vaccination rule does not present an issue of "vast economic and political significance," App. 20, or "radically readjust the balance of state and national authority," App. 29. Congress spends hundreds of billions of dollars annually to pay for health care at facilities that participate in Medicare and Medicaid. "Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare" and "to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare." *Sabri v. United States*, 541 U.S. 600, 605 (2004). This power applies regardless of whether Congress legislates "in an area historically of state concern." *Id.* at 608 n.*.

The vaccination rule is a condition on federal funding for health care facilities. It does not intrude on state police powers or control the practice of medicine, 42 U.S.C. § 1395, any more than do the longstanding, unchallenged regulations requiring such providers to prevent the spread of infection within their facilities. *See, e.g.*, 42 C.F.R. §§ 416.51(b), 482.42(a), 483.80. The district court's analysis "misconstrues the nature of the vaccination mandate" at issue here. *Florida* Op. 15.

For the same reason, the district court's reliance on this Court's order in *BST Holdings, L.L.C. v. OSHA*, ---F.4th---, 2021 WL 5279381 (5th Cir. Nov. 12, 2021), and the Supreme Court's order in *Alabama Association of Realtors v. Dept. of Health and Human Resources*, 141 S. Ct. 2485 (2021), was misplaced. Those orders addressed the scope of agency authorities under different statutes, enacted pursuant to Congress's Commerce Clause power. Nothing in those orders called into question the Secretary's ability to require facilities voluntarily participating in Medicare and Medicaid to meet health and safety standards for the protection of patients.

Nor does the vaccination rule violate the "liberty interests" of health care workers. App. 32. As the *Florida* court explained (Op. 6), the Supreme Court has rejected the contention that there is an individual right to refuse

vaccination for communicable disease, *see Jacobson v. Massachusetts*, 197 U.S. 11 (1905), and the Supreme Court recently refused to enjoin pending appeal Maine's COVID-19 vaccination mandate for health care workers, *see Does 1-3 v. Mills*, -- S. Ct. --, 2021 WL 5027177 (U.S. Oct. 29, 2021); *see also Klaassen v. Trustees of Indiana Univ.*, 7 F.4th 592, 593 (7th Cir. 2021) (Easterbrook, J.) (noting that vaccination requirements that are conditions of participation pose even less of a concern). Health care workers have no right to endanger their patients. As the leading organizations representing health care workers have explained, the requirement to be vaccinated for COVID-19 "is the logical fulfillment of the ethical commitment of all health care workers to put patients as well as residents of long-term care facilities first and take all steps necessary to ensure their health and well-being." *Joint Statement*. The "ethical duty of receiving vaccinations is not new, as staff have long been required by employers to be vaccinated against certain diseases, such as influenza, hepatitis B, and other infectious diseases." 86 Fed. Reg. at 61,569.

2. Ample evidence supports the Secretary's determination that the vaccination rule will provide crucial protections for patients.

There is likewise no merit to plaintiffs' contention that the vaccination rule is arbitrary and capricious. As the *Florida* court explained (Op. 11-14), ample evidence supports the Secretary's determination that staff vaccination at facilities participating in Medicare and Medicaid will provide important protections for patients.

More than 50 health care associations—including the American Medical Association and the American Nurses Association—jointly urged that "all health care and long-term care employers require their workers to receive the COVID-19 vaccine." *Joint Statement*. The signatories represent millions of workers throughout the U.S. health care industry, including groups representing doctors, nurses, long-term care workers, home care workers, pharmacists, physician assistants, public health workers, hospice workers, and epidemiologists. 86 Fed. Reg. at 61,565 & n.122. For example, the American Nurses Association—which "represent[s] the interests of the nation's 4.2 million registered nurses"—"supports health care employers mandating nurses and all health care personnel to get vaccinated against COVID-19 in alignment with current recommendations for immunization

by public health officials." *ANA Supports Mandated COVID-19 Vaccinations for Nurses and All Health Care Professionals* (July 26, 2021).[5]

The district court erred by substituting its views on epidemiology for the judgment of public health experts. Its discussion of "natural immunity" is illustrative. The court opined that health care workers previously infected with the virus that causes COVID-19 should be allowed to rely on "natural immunity," instead of vaccination, to prevent transmission of the virus to patients. App. 25-26. But as the Secretary explained, infection-induced immunity is not equivalent to receiving vaccination for COVID-19, 86 Fed. Reg. at 61,559, and even among those persons with prior infections, vaccination provides strong protection against reinfection, *id*. at 61,585 n.205. The Secretary accordingly followed the recommendations of the Centers for Disease Control & Prevention (CDC), which has found that the best academic evidence supports vaccination regardless of infection history. *Id*. at 61,560 & n.70.

[5] https://perma.cc/MS5A-4WTU.

3. Ample evidence supports the Secretary's determination that the rule's benefits for patients exceed the risks of causing labor shortages.

The Secretary specifically addressed the practical concern that the district court emphasized: the risk that the vaccination requirement will prompt significant numbers of health care workers to quit rather than receive the vaccine and will exacerbate labor shortages. The Secretary found based on recent empirical data that any adverse impact on the labor market is likely to be small, offset by countervailing effects, and dwarfed by the regular churn in the health care workforce.

For example, after the Houston Methodist Hospital system imposed a COVID-19 vaccine mandate, only 153 of its more than 26,000 workers—that is, only 0.6%—resigned rather than receive the vaccine. *See supra*, pp. 10-11. Widespread compliance with vaccine mandates likewise occurred at a North Carolina-based health system with more than 35,000 employees, a Detroit-based health system with more than 33,000 employees, a Delaware-based health system with more than 14,000 employees, and a long-term care corporation with more than 250 facilities. 86 Fed. Reg. at 61,566, 61,569. For example, at the North Carolina-based Novant Health system, only 375 of 35,000 employees across 15 hospitals, 800 clinics, and hundreds

of outpatient facilities—that is, only 1% of the workforce—failed to comply.[6] Moreover, as the American Hospital Association emphasized, the vaccination rule at issue here "provides a level playing field across healthcare facilities," which further reduces the likelihood that health care workers will leave their jobs for other employment. *AHA Statement on CMS and OSHA Vaccine Mandate Rules* (explaining that the American Hospital Association "has been supportive of hospitals that call for mandated vaccination of health care workers in order to better protect patients and the communities we serve").[7]

Furthermore, the Secretary found that any adverse effect on the labor market caused by the rule would be offset by a reduction in COVID-19-induced staff absenteeism. 86 Fed. Reg. at 61,608. And more generally, such effects are dwarfed by the ordinary churn in the market for labor in the health care industry. In any given year, it is typical for about 2.66 million employees in health care settings to be new hires, out of a total workforce of 10.4 million employees. *Id*. Plaintiffs provided no basis to reject these findings.

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[6] *See* Novant Health, *About Us*, https://perma.cc/K4PH-EE66.
[7] https://perma.cc/H6D9-XEQK.

4. Ample evidence supports the Secretary's determination that the vaccination rule should be established without delay.

There is likewise no basis to reject the Secretary's determination that there was good cause to make the vaccination rule effective immediately. *See* 86 Fed. Reg. at 61,583-85. The procedural statute on which plaintiffs relied, 42 U.S.C. § 1395z, generally instructs the Secretary to consult with "appropriate State agencies" but does not require that such consultations occur in advance—particularly not in advance of an urgent, interim action like the rule here. *See Florida* Op. 10 (citing 86 Fed. Reg. at 61,567). And the Secretary detailed why the rule's protections should be put in place before an anticipated surge in COVID-19 cases in the coming winter months. The Secretary explained that patients in facilities funded by the Medicare and Medicaid programs are more likely than the general population to suffer severe illness or death from COVID-19, *id*. at 61,609; that there have already been more than half a million COVID-19 cases among health care staff, *id*. at 61,585; that rates among staff have grown since the Delta variant's emergence, *id*.; that COVID-19 cases are expected to spike during the coming winter months, *id*. at 61,584, and that this spike will coincide with flu season, raising the additional danger of combined infections, *id*.

The Secretary determined that "a further delay in imposing a vaccine mandate would endanger the health and safety of additional patients and be contrary to the public interest." *Id*. The Secretary predicted that the rule will save hundreds and potentially thousands of lives every month, *id*. at 61,612, which is ample cause to proceed without advance notice and comment. *See Sorenson Communications Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014) ("[W]e have approved an agency's decision to bypass notice and comment where delay would imminently threaten life."). Plaintiffs' suggestion that the Secretary should have acted sooner, App. 18, would not, even if true, be reason to block a rule that will prevent many patient deaths in the coming months, *see Florida* Op. 13.

C. The Remaining Factors Overwhelmingly Favor A Stay Pending Appeal.

The remaining factors all support a stay pending appeal. The district court's balancing of the equities rested on an incorrect legal premise: that a preliminary injunction is necessary to maintain "the liberty of individuals who do not want to take the COVID-19 vaccine." App. 32. As explained above, that premise is contrary to the Supreme Court's longstanding

decision in *Jacobson* and its recent refusal to enjoin a State's COVID-19 vaccination mandate for health care workers in *Does 1-3 v. Mills*.

By contrast, if the rule is not implemented in advance of the anticipated COVID-19 surge, hundreds and potentially thousands of patients at hospitals, nursing homes, and other facilities participating in Medicare and Medicaid may die as the result of COVID-19 infections transmitted to them by staff. That threat to human life and health far exceeds the potential indirect harms to patients resulting from workers who may quit rather than receive the vaccine. There is no sound reason to reject the consensus of leading health care organizations and the judgment of the Secretary that the benefits of requiring health care workers to be vaccinated far outweigh any countervailing concerns. Moreover, any sanctions that might be imposed against facilities that fail to comply with the rule are neither imminent nor irreparable, because they are reviewable in court.

The balance of equities and public interest are unaltered by state laws purporting to restrict vaccine mandates. Even assuming that a sovereign's abstract interest in enforcing its law is a cognizable Article III interest, the federal government has a sovereign interest in enforcing the vaccination

rule at issue here. Thus, the balance of equities and public interest do not depend on abstract notions of sovereignty, but on the real world impact of the CMS vaccination rule. And as already explained, the protections that the rule provides for the health and safety of patients vastly outweigh any countervailing concerns.

D. Any Relief Must Be Limited To Those State-Run Facilities That Established Irreparable Injury.

Assuming *arguendo* that any relief is appropriate, it must be limited to the facilities that the plaintiff States operate and that demonstrated irreparable injury. "[S]tanding is not dispensed in gross," and the plaintiff must establish standing "separately for each form of relief sought." *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650 (2017). The Supreme Court has emphasized that a "remedy must be tailored to redress the plaintiff's particular injury," *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018), and that "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs," *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994) (quotation marks omitted).

Here, as already explained, plaintiff States could not seek relief on behalf of the 24 States that declined to challenge the rule or the two States that opted to challenge it separately. The district court's view that "there are unvaccinated healthcare workers in other states who also need protection," App. 34, did not give it license to exceed the bounds of its jurisdiction.

Nor could the plaintiff States speak for privately-run facilities or their workers, whose leading professional associations strongly support vaccination requirements for staff. Thus, the Court should at a minimum stay the injunction except as to those state-run facilities that demonstrated irreparable harm.

CONCLUSION

The preliminary injunction should be stayed pending appeal or, at a minimum, stayed except as to those state-run facilities that demonstrated irreparable harm from the vaccination rule.

Respectfully submitted,

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December 2021

CERTIFICATE OF COMPLIANCE

This motion complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 5,091 words. This opposition also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Book Antiqua 14-point font, a proportionally spaced typeface.

s/ Alisa B. Klein
Alisa B. Klein

CERTIFICATE OF SERVICE

I hereby certify that on December 2, 2021, I electronically filed the foregoing motion with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Alisa B. Klein
Alisa B. Klein

No. 21-30734

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

STATE OF LOUISIANA, et al.,

Plaintiffs-Appellees,

v.

XAVIER BECERRA, et al.,

Defendants-Appellants.

ADDENDUM TO EMERGENCY MOTION FOR STAY PENDING APPEAL

TABLE OF CONTENTS

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

STATE OF LOUISIANA ET AL	**CASE NO. 3:21-CV-03970**
VERSUS	**JUDGE TERRY A. DOUGHTY**
XAVIER BECERRA ET AL	**MAG. JUDGE KAYLA D. MCCLUSKY**

MEMORANDUM RULING

The issue before this Court is whether the Plaintiff States[1] are entitled to a preliminary injunction against the Government Defendants[2] as a result of a COVID-19 CMS vaccine mandate ("CMS Mandate") implemented by the Government Defendants on November 5, 2021. 86 Fed. Reg. 61555-01. The CMS Mandate requires the staff of twenty-one types of Medicare and Medicaid healthcare providers to receive one vaccine by December 6, 2021, and to receive the second vaccine by January 4, 2022. Failure to comply with the CMS Mandate may result in penalties up to and including "termination of the Medicare/Medicaid Provider Agreement." 86 Fed. Reg. at 61574.

According to the CMS, the CMS Mandate regulates over 10.3 million health care workers in the United States. *Id.* at 61603. Of those 10.3 million, 2.4 million healthcare workers are currently unvaccinated. *Id.* at 61607.

Implicit in determining whether a preliminary injunction should be granted is determining whether the Government Defendants have the statutory and/or constitutional authority to implement the CMS Mandate. Finding that the Government Defendants do not have

[1] Plaintiff States consist of Louisiana, Montana, Arizona, Alabama, Georgia, Idaho, Indiana, Mississippi, Oklahoma, South Carolina, Utah, West Virginia, Kentucky, and Ohio.
[2] The Government Defendants consist of Xavier Becerra, in his official capacity as Secretary of Health and Human Services, The U.S. Department of Health and Human Services ("DHH"), Chiquita Brooks–Lasure, in her official capacity as Administrator of the Center for Medicare and Medicaid Services ("CMS").

the authority to implement the CMS Mandate, this Court GRANTS Plaintiff States' Motion for Preliminary Injunction [Doc. No. 2] and IMMEDIATELY ENJOINS and RESTRAINS the Government Defendants from implementing the CMS Mandate.

I. BACKGROUND

This case is about COVID-19 vaccine mandates. The CMS Mandate requires over 10.3 million healthcare workers to be fully vaccinated with one of the COVID-19 vaccines in two months. The first of two COVID-19 vaccines is required by December 6, 2021, and the second by January 4, 2022. The factual statements made herein should be considered as findings of fact and legal conclusions should be considered conclusions of law. This Court's job is to examine the appropriate statutes and/or constitutional authority for the Government Defendants to issue the specific CMS Mandate discussed herein. The opinion expressed hereto is legal, not political or personal.

On March 13, 2020, President Trump declared the COVID-19 pandemic a national emergency. On March 11, 2020, the World Health Organization ("WHO") declared COVID-19 a global pandemic.

On December 11, 2020, the U.S. Food and Drug Administration ("FDA") issued an Emergency Use Authorization ("EUA") for the Pfizer-BioNTech vaccine. The FDA issued an EUA for the Moderna COVID-19 vaccine on December 18, 2020, and issued an EUA for the Janssen COVID-19 vaccine on February 27, 2021.[3] The Pfizer-BioNTech COVID-19 vaccine received FDA approval on August 23, 2021 for individuals sixteen years of age and older.[4] On

[3] https://www.fda.gov>COVID19-fre.
[4] https://www.cdc.gov>vaccines.

November 19, 2021, the FDA authorized Pfizer-BioNTech and Moderna COVID-19 boosters for all adults ages eighteen and older.[5]

The first cases of COVID-19 in the United States were recorded in January 2020.[6] Cases began surging thereafter with the highest surge from October 2020 to February 2021. The seven-day average for cases in the United States recorded a high on January 12, 2021, at 250,512 cases. For the last ninety days, the seven-day average has declined from 164,374 on September 2, 2021, to 94,335 on November 23, 2021.[7]

In response to the pandemic, CMS issued six previous rules with regard to COVID-19. These rules were issued on April 6, 2020, May 8, 2020, September 2, 2020, November 6, 2020, May 13, 2021, and June 21, 2021. 86 Fed. Reg. at 61561. These previous actions dealt with revision of regulations, data reporting, and infection control requirements to protect healthcare workers from exposure to COVID-19. The June 21, 2021, Healthcare Emergency Temporary Standard ("ETS") required healthcare workers to develop a plan for each workplace, which included patient screening, protective equipment, aerosol procedures, physical distancing, physical barriers, cleaning and disinfecting, ventilation, health screening, training, recordkeeping, and reporting. *Id.*

A. November 5, 2021 CMS Mandate

On November 5, 2021, CMS issued the disputed Interim Final Rule ("IFR"), which contained the requirements for mandating COVID-19 vaccines. The IFR was described by CMS as "revises the requirements that Medicare and Medicaid certified providers and suppliers must meet to participate in the Medicare and Medicaid Programs."

[5] https://www.nbcnews.com>health.
[6] https://www.history.com>first-conf.
[7] https://www.nytimes.com>us>cov.

The Mandate was effective on November 5, 2021, and established COVID-19 vaccination requirements for staff, and this included Medicare and Medicaid – certified providers and suppliers. The Mandate implemented the COVID-19 vaccinations in two phases. The first vaccine is to be required by December 6, 2021, and the second vaccine is to be required by January 4, 2022. The CMS Mandate went into effect immediately; there was no notice and comment under the Administrative Procedures Act 5 U.S.C. 553.

The mandate applies to the employees of Medicare and Medicaid providers and suppliers listed. 86 Fed. Reg. at 61556. CMS claimed authority to issue the mandate pursuant to §§ 1102, 1863, and 1871 of the Social Security Act. 86 Fed. Reg. at 61560, 61567. The reasoning for the mandate was: "In light of our responsibility to protect the health and safety of individuals providing and receiving care and services from the Medicare and Medicaid certified providers and suppliers, and CMS's broad authority to establish health and safety regulations, we are compelled to require staff vaccinations for COVID-19 in these settings." 86 Fed. Reg. 61560.

CMS indicated its mandate was "complementary to the OSHA ETS",[8] which also requires mandatory vaccinations. (Occupational Safety and Health Administration ("OSHA")). CMS admittedly has not previously required any vaccinations. 86 Fed. Reg. 61567. The mandate discussed the potential effect of health care workers choosing to leave their jobs rather than be vaccinated but concluded[9] there was insufficient evidence to quantify and compare adverse impacts on patient and residential care associated with temporary staffing losses. 86 Fed. Reg. at 61569.

[8] The United States Court of Appeals for the Fifth Circuit has stayed the implementation of the OSHA ETS pending adequate judicial review of the motions for preliminary injunction. *BST Holding's LLC v. Occupational Safety and Health Administration* 21-60845 (November 12, 2021).
[9] Despite approximately 2.4 million unvaccinated healthcare workers.

Like the OSHA mandate,[10] the CMS mandate is described as a "common set of provisions for each applicable provider and supplier as there are no substantive regulatory differences across settings." 86 Fed. Reg. at 61570.

The CMS mandate also requires that the medical providers and suppliers "track and securely document" the vaccination status of each staff member, including storing staff members' medical records showing proof of vaccination. 86 Fed. Reg. 61572. The CMS mandate allows exemptions that are based upon existing Federal law. The mandate specifically states that it "preempts" the applicability of any state or local law providing for exemptions. 86 Fed. Reg. 61572.

In not inviting notice and comment pursuant to the Administrative Procedures Act, 5 U.S.C. 553, CMS found "good cause" that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest based upon the reasons set out at 86 Fed. Reg. 61583 to 61585.

B. The Executive Branch's Vaccine Policy

President-Elect Biden initially did not think vaccines should be mandatory[11]. On September 9, 2021, President Biden changed his mind announcing his intention to impose a national mandate[12].

Both the OSHA Mandate and the CMS Mandate were imposed approximately two months later on November 5, 2021.

[10] Described by the Fifth Circuit as a "one size-fits-all sledgehammer." *BTS Holdings, LLC* 21-60145@8.
[11] Jacob Jarvis Fact Check: Did Joe Biden Reject Idea of Mandatory Vaccines in December 2020, Newsweek (Sept. 10, 2021), https://bit.ly/3ndyTn.5
[12] Kevin Liptak & Kaitlan Collins, Biden Announces New CMS Mandates that could cover 100 Million Americans, CNN (Sept. 9, 2021).

C. Medicare and Medicaid

Medicare is a federal program that pays for healthcare for the elderly. Medicaid is a cooperative state-funded program that helps States finance medical care for their poor and disabled citizens. The Secretary of Health and Human Resources is charged through the Social Security Act with administrative responsibilities related to maintaining the Medicare and Medicaid Programs. 42 U.S.C. 301, et al.

The Social Security Act also delegates to the Secretary certain rule-making authority. As relevant here, 42 U.S.C. 1302(a) gives the Secretary the authority to make and publish rules and regulations that may be necessary to the efficient administration of the functions with which the Secretary is charged.

II. JURISDICTION

The Government Defendants maintain this Court does not have jurisdiction to hear the Plaintiff States' claims based upon the Medicare Act's channeling requirement, 42 U.S.C. 405(g) as incorporated by 42 U.S.C. 1395ii. The Government Defendants argue that Medicare and Medicaid's exclusive review scheme bars pre-enforcement challenges. The Government Defendants further claim the Plaintiff States are required to go through the statute's administrative review scheme and have an administrative hearing before filing suit in district court. Plaintiff States' claims arise under both the Medicare and Medicaid statutes, the United States Constitution, the Administrative Procedure Act, and the Congressional Review Act.

The Government Defendants cite *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000) for the proposition that any "arising under" jurisdictional claims must undergo the SSA's administrative process and that Congress made the review exclusive.

However, both 42 U.S.C. 405(g) and 42 U.S.C. 1395ii do not apply in this case. 42 U.S.C. 405(h) states that the SSA administrative process only applies to actions "to recover on any claim arising under this subchapter." The "subchapter" refers to claims for benefits under the SSA. It does not apply to a claim for declaratory and injunctive relief as to the authority of CMS to make regulations. Plaintiff States are neither "institutions" nor "agencies" who are "dissatisfied" with the Secretary's determination regarding eligibility or receipt of benefits. The channeling requirement does not apply to "state governments." Since Plaintiff States would be unable to use this statutory scheme (even if they wanted to) it would mean "no review at all" under *Shalala*, which would allow Plaintiff States to have jurisdiction in this Court.

Additionally, the Medicare Act's channeling requirement only applies to Medicare and not to Medicaid claims. *Avon Nursing & Rehab. V. Becerra*, 995 F.3d 305, 311 (2d. Cir. 2021).

Therefore, this Court has jurisdiction to hear these claims.

III. STANDING

Although the Plaintiff States' standing has not been challenged by the Government Defendants, this Court must next determine whether it has judicial power to hear the case. The United States Constitution limits exercise of judicial power to certain "cases" and "controversies." U.S. Constitution Article III Section 2.

Under the doctrine of "standing," a federal court can exercise judicial power only where a plaintiff has demonstrated that it (1) suffered an injury in fact, (2) fairly traceable to the challenged conduct of the defendant, and (3) likely to be redressed by a favorable decision. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61, 112 S. Ct. 2130, 119 L. Ed. 2d 351 (1992). The party invoking federal jurisdiction bears the burden of establishing these elements. *Id*. at 561.

The Plaintiffs in this case are fourteen (14) states. States are not normal litigants for purposes of invoking federal jurisdiction. *Massachusetts v. E.P.A.*, 549 U.S. 497, 518, 127 S. Ct. 1438, 167 L. Ed. 2d 248 (2007). Rather, a state is afforded "special solicitude" in satisfying its burden to demonstrate the traceability and redressability elements of the traditional standing inquiry whenever its claims and injury meet certain criteria. *Id*. at 520; *Texas v. United States*, 809 F.3d 134, 151–55 (5th Cir. 2015), *as revised* (Nov. 25, 2015). Specifically, a state seeking special solicitude standing must allege that a defendant violated a congressionally accorded procedural right that affected the state's "quasi-sovereign" interests in, for instance, its physical territory or lawmaking function. *Massachusetts*, 549 U.S. at 520–21; *Texas*, 809 F.3d at 151–55.

Plaintiff States have standing under the normal inquiry because they are entitled to special solicitude. Plaintiff States have standing to challenge the CMS Mandate because the Government Defendants' actions harm Plaintiff States' sovereign, proprietary, and *parens patriae* interests.

In *State of Florida v. Becerra*, __ F. Supp. 3d _, 2021 WL 2514138 (M.D. Fla. June 18, 2021) the State of Florida attacked a Centers for Disease Control and Prevention ("CDC") "conditional order," which required a series of steps before cruise ships were allowed to sail. The Court found Florida had standing to protect its proprietary interests and its sovereign interests.

The State of Texas was found to have standing in a suit against the U.S. Dept. of Homeland Security's 100 day pause of the removal of illegal aliens in *Texas v. U.S.*, 524 F. Supp. 3d 598 (S.D. Tex., February 23, 2021). In *State v. Biden*, 10 F. 4th 538 (5th Cir. 2021), the State of Texas was also found to have standing based on "special solicitude." (Injunction request against the U.S. Dept. of Homeland Security to suspend its Migrant Protection Protocols.)

Texas was again found to have standing under "special solicitude" in *Texas v. U.S.*, 809 F. 3d 134 (5th Cir. 2015). Texas sued to prevent implementation of a DAPA Program by the Department of Homeland Security. The Fifth Circuit further noted that, pursuant to their sovereign interest, states may have standing based on federal assertions of authority to regulate matters they believe they control, federal preemption of state law, and interference with the enforcement of state law. *Id.* at 153.

In *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592 (1982), the U.S. Supreme Court held Puerto Rico, like a state, had "*parens patriae*" standing to bring an action against east coast apple growers for allegedly violating federal law in preferring domestic laborers over foreign temporary workers. Puerto Rico was found to have a "quasi-sovereign" interest on behalf of its residents.

In *Texas v. Equal Employment Opportunity Commission*, 933 F.3d 433 (5th Cir. 2019), the Fifth Circuit found standing for Texas after there was an increased regulatory burden, pressure to change state law, and deprivation of a procedural right to protect its concrete interests.

A. Injury in Fact

A plaintiff seeking to establish injury in fact must show that it suffered "an invasion of a legally protected interest" that is "concrete," "particularized," and "actual or imminent, not conjectural or hypothetical." *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548, 194 L. Ed. 2d 635 (2016), *as revised* (May 24, 2016). For an injury to be "particularized," it "must affect the plaintiff in a personal and individual way." *Id.* at 1548. A "concrete" injury must be "de facto," that is, it must "actually exist." "Concrete" is not, however necessarily synonymous with "tangible." Intangible injuries can nevertheless be "concrete." *Id.*, at 1548-49.

This Court finds the Plaintiff States' alleged injuries are both particularized and concrete. Plaintiff States have a "*parens patriae*" standing and/or a quasi-sovereign interest in protecting its citizens from being required to submit to vaccinations. Additionally, the Plaintiff States have standing to regulate matters they believe they control, to attack preemption of state law by a federal agency, and to protect the enforcement of state law. The CMS Mandate specifically preempts state laws with regard to COVID-19 Vaccine requirements and/or exemptions.

The Plaintiff States also have standing and injury, based upon the alleged loss of jobs, loss of businesses, loss of tax revenue, and other damages allegedly resulting from employees being fired for refusing the vaccine and/or providers being terminated by CMS from the Medicare/Medicaid provider agreement.

B. Traceability

Plaintiff States must show a "fairly traceable" link between their alleged injuries and the CMS Mandate. As a general matter, the causation required for standing purposes can be established with "no more than de facto causality." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2556, 204 L. Ed. 2d 978 (2019). The plaintiff need not demonstrate that the defendant's actions are "the very last step in the chain of causation." *Bennett v. Spear*, 520 U.S. 154, 169–70, 117 S. Ct. 1154, 137 L. Ed. 2d 281 (1997).

Here, there is an obvious link between the CMS Mandate and the Plaintiff States' alleged injuries. All of the above alleged injuries are "fairly traceable" to CMS's Mandate.

C. Redressability

The redressability element of standing to sue requires a plaintiff to demonstrate "a substantial likelihood that the requested relief will remedy the alleged injury in fact." *El Paso Cty., Texas v. Trump*, 982 F.3d 332, 341 (5th Cir. 2020).

The Plaintiff States have demonstrated a substantial likelihood that the requested relief would remedy the alleged injury in fact. If Plaintiff States are successful in having the CMS Mandate declared invalid, this would redress their alleged injuries.

4. Special Solicitude

Although this Court has found that Plaintiff States have proven standing through the normal inquiry, they also can establish standing as a result of special solicitude. Plaintiff States assert a congressionally bestowed procedural right, the Administrative Procedures Act ("the APA"), and the government action at issue affects the Plaintiff States' quasi-sovereign interests (damage to citizens, loss of jobs, businesses, loss of tax funding and/or protection of State laws). *Massachusetts*, 549 U.S. at 519–20.

Therefore, any infirmity in Plaintiff States' demonstration of traceability or redressability are remedied by the Plaintiff States' special solicitude.

IV. PRELIMINARY INJUNCTION

A preliminary injunction is an extraordinary remedy never awarded of right. *Benisek v. Lamone*, 138 S. Ct. 1942, 1943, 201 L. Ed. 2d 398 (2018). In each case, the courts must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24, 129 S. Ct. 365, 172 L. Ed. 2d 249 (2008).

The standard for a preliminary injunction requires a movant to show (1) the substantial likelihood of success on the merits, (2) that he is likely to suffer irreparable harm in the absence of a preliminary injunction, (3) that the balance of equities tips in his favor, and (4) that an injunction is in the public interest. *Benisek*, 138 S. Ct. at 1944. The party seeking relief must satisfy a cumulative burden of proving each of the four elements enumerated before a temporary

restraining order or preliminary injunction can be granted. *Clark v. Prichard*, 812 F.2d 991, 993 (5th Cir. 1987). None of the four prerequisites has a quantitative value. *State of Tex. v. Seatrain Int'l, S. A.*, 518 F.2d 175, 180 (5th Cir. 1975).

A. Likelihood of Success on the Merits

Plaintiff States argue that (1) the Government Defendants issued the CMS Mandate without following statutorily required processes (5 U.S.C. 553), (2) the CMS Mandate is beyond the authority of the Government Defendants, (3) the CMS Mandate is contrary to law, (4) the CMS Mandate is arbitrary and capricious in violation of 5 U.S.C. 706(2)(A), and (5) the CMS Mandate violates the Spending Clause, Tenth Amendment and Anti-Commandeering Doctrine.

BST Holdings, LLC v. OSHA

It is not often a Court has such a recent Circuit Court case addressing an almost identical issue. We do here. In *BST Holdings, LLC v. Occupational Safety and Health Administration*, No. 21-60845 17 F.4th 604 (5th Cir. November 12, 2021), the Fifth Circuit addressed a request for a stay as to the OSHA vaccine mandate which was put into place by way of an EST on November 5, 2021. The OSHA vaccine mandate required employees of covered employers to undergo a COVID-19 vaccination or to take weekly COVID-19 tests and wear a mask.[13]

The Court initially stayed the OSHA Mandate because of perceived grave statutory and Constitutional issues pending briefing and an expedited judicial review.[14] The Court, after conducting the expedited judicial review, reaffirmed the initial stay. Many of the issues are similar to the issues here included in the CMS Mandate. The factors the Court evaluate for a stay are similar to factors that are evaluated for a preliminary injunction, including a strong

[13] 86 Fed. Reg. 61402 (Nov. 5, 2021).
[14] 2021 WL 5166656.

likelihood of success on the merits, irreparable injury to the applicant, and where the public interest lies .[15]

In finding the applicants were likely to succeed on the merits, the Court made the following findings:

1) the OSHA Mandate was both overinclusive ("one-size-fits-all sledgehammer") and underinclusive (did not apply to employers with 98 or fewer workers;[16]

2) the OSHA Mandate was not an "emergency" response under 29 U.S.C. 655, since OSHA spent nearly two months (September 9, 2021 to November 5, 2021) responding to it;

3) the OSHA Mandate grossly exceeded OSHA's statutory authority, No. 21-60845 at 7.

The Court stated the Applicants had made a compelling argument that, although 29 U.S.C. 655 gave broad authority to OSHA, to avoid "giving unintended breadth to Acts of Congress" the Court should use the principle of "*noscitur a sociis*" – meaning, a word is known by the company it keeps – to limit OSHA's authority.[17]

The Court also found the COVID-19 pandemic was not the type of grave danger 29 U.S.C. 655 contemplates, noting that the OSHA Mandate made no attempt to explain why OSHA and the President were against CMS Mandates previously. The Court noted it is generally "arbitrary and capricious" to depart from a prior policy without providing a detailed explanation.

The Court further noted the OSHA Mandate raised serious constitutional concerns that either make it more likely that the petitioners will succeed on the merits, or at least counsel

[15] No. 21-60845 of 5.
[16] "The underinclusive nature of the Mandate implies that the Mandate's true purpose is not to ensure workplace safety, but instead to ramp up vaccine uptake by any means necessary. No. 21-60845 at 15.
[17] Neighboring phrase of "toxicity" and "poisonousness" in the statute did not give OSHA authority to mandate vaccines.

against adopting OSHA's broad reading of Section 655(c) as a matter of statutory interpretation. The "serious Constitutional concerns" found by the Court in *BST Holdings* are some of the same ones at issue in the case at bar.

The "serious Constitutional concerns" noted by the Court in *BST Holdings* were:

(a) that the OSHA Mandate exceeded the federal government's authority under the Commerce Clause because it regulated noneconomic inactivity (person's choice to remain unvaccinated) that falls squarely within the State's police power;

(b) that separation of powers principles ("the major questions doctrine")[18] casts doubt over the OSHA Mandate's assertion of virtually unlimited power to control individual conduct under the guise of a workplace regulation.

Additionally, the Court found "irreparable harm" to the petitioners' liberty interests[19] of having to choose between their jobs and the vaccine. The Court noted that the loss of constitutional freedoms for even minimal periods of time constitutes irreparable injury.[20]

The Court also found a stay of the OSHA Mandate to be in the public interest in maintaining the country's constitutional structure and maintaining the liberty of individuals and to make intensely personal decisions, even when those decisions frustrate government officials.

1. Statutorily Required Processes – 5 U.S.C. 553

The Court will now address Plaintiff States' five arguments. Title 5 U.S.C. 553 of the Administrative Procedures Act requires federal agency rules to undergo notice and comment unless they are exempt. The federal agency is required to give general notice of proposed rulemaking to be published in the Federal Register not more than thirty days before the proposed rules' effective date and to give interested persons an opportunity to participate in the rule

[18] The "major questions doctrine" holds that Congress must speak clearly if it wishes to assign to an agency, decisions of vast economic and political significance. *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014).
[19] In addition to the free religious exercise of certain employees.
[20] *Elrod v. Burns* 427 U.S. 347, 373 (1976).

making through submission of written data, views, or arguments. Failure to give required notice and comment requires the rule to be vacated.

This "notice and comment" procedure does not apply to interpretive rules, general statements of policy, rules of agency organization, procedure, or practice, or when the agency finds "good cause" for not requiring notice and comment. The Government Defendants did not go through the notice and comment process with regard to the CMS Mandate. The CMS Mandate became effective on November 5, 2021, which is the same day it was published in the Federal Register.

The vaccine mandate is not alleged to be an interpretive rule, a general statement or policy, or a rule of agency organization, procedure, or practice. The failure to perform the required notice and comment is entirely based upon the "good cause" exception.

Title 5 U.S.C. 553(b)(3)(B) states**:**

(B) this section does not apply -- when the agency for good cause finds (and incorporates the finding and a brief statement of reasons thereafter in the rules issued) that notice and public procedure therein are impracticable, unnecessary, or contrary to the public interest.

In failing to perform the notice and comment procedure, CMS found good cause. 86 Fed. Reg. 61583-86. The reasons given by CMS for failing to perform the notice and comment procedure were:

1. 2021 outbreaks associated with the SARS-Cov-2 Delta variant have shown that current levels of vaccination coverage have been inadequate, requiring no delay;

2. Encouraging vaccinations through public education campaigns and through State and employer-based efforts among healthcare staff to has been inadequate;

3. The COVID-19 pandemic continues to strain the U.S. healthcare systems, most of which patients are unvaccinated;

4. Although hospitalizations and deaths have begun to trend downward, there are emerging indications of potential increases during the upcoming colder months;

5. The upcoming 2021-2022 influenza season could be more severe than normal, and vaccinations would decrease stress on the U.S. health care system;

6. The upcoming 2021-2022 influenza season could result in infections of both influenza and COVID-19, which would result in more severe medical outcomes;

7. Since health care workers were among the first groups provided access to the vaccinations, many did not get vaccinations due to the initial emergency use authorization. Now that one of the vaccines (Pfizer-BioNTech) has been fully approved by the FDA, more healthcare workers will want to get the vaccine;

8. The estimates of healthcare workers deaths and/or positive tests for COVID-19 have likely been underestimated since healthcare workers status has only been reported in approximately 18% of cases;

9. Healthcare workers who are unvaccinated may pose a direct threat to patients;

10. The COVID-19 vaccines have been shown to be highly effective in preventing COVID-19 cases and severe outcomes;

11. The COVID-19 vaccines have been shown to be highly effective in preventing infections; and

12. It would be impracticable and contrary to the public interest to delay imposing the CMS Mandate due to a combination of all factors.

The "good cause" exception in 5 U.S.C. 553 is read narrowly in order to avoid providing agencies with an escape clause from the ADA notice and comment requirements. *United States v. Johnson,* 632 F.3d 912 (5th Cir. 2011). Circumstances justifying reliance on this exception are "indeed rare." *Council of Southern Mountains, Inc. v. Donovan,* 653 F.2d 573 (D.C.C. 1981). The good cause exception was described in *Sorenson Communications, Inc. v. F.C.C.,* 755 F.3d 702 (D.C.C. 2014) as "meticulous and demanding," "narrowly construed," "reluctantly countenanced," and evoked only in "emergency situations."

Due to this stringent standard, the good cause exception to notice and comment is rarely upheld. See *U.S. v. Johnson* 632 F.3d 912, 928 (5th Cir. 2011) (need for immediate guidance under the Sex Offender Registration and Notification Act and in prior attempts to protect the public were not good cause); *Mack Trucks, Inc. v. E.P.A.* 682 F.3d 87, 94-95 (D.C. Cir. 2012)

(EPA interim final rule requiring penalties for sellers of non-compliant diesel engines not good cause when one manufacturer would be unable to sell the engines without the interim rule); *Sorenson Communications, Inc. v. F.C.C.*, 755 F.3d 702, 706-07 (D.C. N.Y. Cir. 2014) (FCC did not have good cause to issue interim and final rules for reimbursement for telecommunication services due to potential depletion of the fund used to pay for reimbursement); *State v. Becerra*, _ F.Supp. 3d _, 2021 WL 2514138 at 35-36 (M.D. Florida, June 18, 2021) (CDC did not have good cause for a rule issuing a conditional sailing order for cruise ships due to COVID-19); *Regeneron Pharmaceuticals, Inc. v. United States Dept. of Health and Human Resources*, 510 F.Supp. 3d, 29, 48 (S.D. NY. December 30, 2020) (CMS's rule regulating drug prices based on the Most Favored Nation Rule was not good cause where reasons were general risks of high drug prices and the COVID-19 pandemic); *Regeneron Pharmaceuticals, Inc. v. United States Dept. of Health and Human Resources*, 510 F.Supp. 3d, 29, 48 (S.D. NY. December 30, 2020) (not good cause where reasons by DHS for an interim final rule regarding prevailing wages with regard to the VISA program were based on the COVID-19 pandemic and economic consequences of it); *Chamber of Commerce of the United States v. United States Dept. of Homeland Security*, 504 F. Supp. 3d 1077, 1094 (N.D. Cal., December 1, 2020); *Association of Community Cancer Centers v. Azar*, 509 F. Supp. 3d 482, 496 (D. Maryland, December 23, 2020) (not good cause where CMS claimed reduced costs would help alleviate financial instability caused by the COVID-19 pandemic).

There are fewer cases where the good cause exception was upheld. In *Council of Southern Mountains, Inc. v. Donovan*, 653 F.2d 573 (D.C. Cir. 1981), calling it an "extremely close case," the Court upheld the Secretary of Labor postponing the implementation of Mine Safety and Health Adm. Regulations dealing with self-contained self-rescuers which provided

oxygen to miners after a cave-in. The deadline was extended for six months due to only a small number of the devices being available, the agency acted with diligence, it was deferred for a very short period of time, and circumstances were beyond the agency's control.

It should be noted that this issue was discussed in *BST Holdings* at 8, but OSHA had authority for a six-month "emergency temporary standard" ("ETS") pursuant to 29 U.S.C., 655(a)(1). Although the notice and comment requirements of 5 U.S.C. 553 did not apply, the Court did not believe COVID-19 posed the kind of grave danger required for an ETS. The Court stated:

> The Mandate's stated impetus – a purported "emergency" that the entire globe has now endured for nearly two years, and which OSHA itself spent nearly two months responding to-is unavailing as well.

No. 21-60845 at 7.

Government Defendants maintain they had "good cause" for the reasons set forth by CMS in the CMS Mandate. The Government Defendants argue that the Secretary is entitled to deference as to his predictive judgment that COVID-19 cases would increase during the winter months and put a burden on the healthcare system.

After reviewing the reasons listed by CMS for bypassing the notice and comment requirement, the Court finds Plaintiff States are likely to succeed on the merits on this claim. It took CMS almost two months, from September 9, 2021 to November 5, 2021, to prepare the interim final rule at issue. Evidently, the situation was not so urgent that notice and comment were not required. It took CMS longer to prepare the interim final rule without notice than it would have taken to comply with the notice and comment requirement. Notice and comment would have allowed others to comment upon the need for such drastic action before its implementation.

It does not appear to this Court that the Government Defendants will be able to meet the stringent requirements for the good cause exception in 5 U.S.C. 553 to apply.

2. Authority of The Government Defendants

Plaintiff States maintain that the CMS Mandate must also be enjoined because it exceeds the Government Defendants' authority. The U.S. DHH and the CMS are a part of the Executive Branch of the government.

Only Congress, as the Legislative branch, has the authority to make laws.[21] The Executive branch must take care that the laws be faithfully executed.[22] Because the Executive branch cannot make laws, it is given its powers through Acts of Congress.

The CMS claims authority to issue the CMS Mandate through Sections 1102 and 1871 of the Social Security Act. 86 Fed. Reg. at 61560. Sections 1102 and 1871 are set out in 42 U.S.C. 1302 and 42 U.S.C. 1395hh. Title 42 U.S.C. 1395hh gives the Secretary authority to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under this subchapter." The remaining portions of 1395hh deal with procedure for the regulations.

> 42 U.S.C. 1302 states:
>
> (a) The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services, respectively, shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which each is charged under this chapter.

Additionally, the Government Defendants reference "Table 1: Authorities for All Providers and Suppliers," 86 Fed. Reg. at 61567, which sets out statutory authority for each specific category of Provider/Supplier.

[21] Article I, Section 8, United States Constitution.
[22] Article II, Section 3, United States Constitution.

Sections 1102 and Section 1871 are general authorizations to prescribe rules and regulations that may be necessary to carry out the Medicaid and Medicare programs. The Statutes listed in Table 1 are also general authority to specify "standards" for the various types of providers and suppliers. None of these statutes give the Government Defendants the "superpowers" they claim. Not only do the statutes not specify such superpowers, but principles of separation of powers weigh heavily against such powerful authority being transferred to a government agency by general authority.

Major Questions Doctrine

The "major questions doctrine" requires that Congress must "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). In *Utility Air*, the U.S. Supreme Court found that EPA exceeded its authority when the EPA adjusted levels set forth in the Clean Air Act regarding greenhouse-gas emissions.

Like the present case, EPA used general authority to expand its power. Justice Scalia wrote:

> EPA's interpretation is also unreasonable because it would bring about an enormous and transformative expansion in EPA's regulatory authority without clear congressional authorization. When an agency claims to discover in a long-extant statute an unheralded power to regulate "a significant portion of the American economy," *Brown & Williamson*, 529 U.S. at 159, 120 S. Ct. 1291, we typically greet its announcement with a measure of skepticism. We expect Congress to speak clearly if it wishes to assign an agency decision of vast "economic and political significance." 573 U.S. at 324.

This is exactly what has occurred in this case. Government Defendants have used general authority statutes to mandate COVID-19 vaccines for over 10.3 million healthcare workers. Certainly, this is a decision of vast economic and political significance.

The Fifth Circuit Court of Appeals found the same with the similar OSHA Vaccine Mandate in *BST Holdings.* Judge Engelhardt wrote:

> There is no clear expression of Congressional intent in Section 655(c) to convey OSHA such broad authority, and this Court will not infer one. Nor can the Article II executive breathe new power into OSHA's authority – no matter how thin patience wears. No. 21-60845, at 18.

See also *Food and Drug Admin. v. Brown & Williamson Tobacco Corp.* 529 U.S. 120, 159 (2000); *Alabama Association of Realtors v. Dept. of Health and Human Resources*, 141 S.Ct. 2485, 2489 (2021); *Tiger Lily, LLC v. United States Department of Housing and Urban Development*, 5 F.4th 666, (6th Cir. 2021); *Paul v. United States*, 140 S.Ct. 342 (2019); *State of Florida v. Becerra*, 2021 WL 2514138 at 20 (M.D. Fla. June 18, 2021); and *King v. Burwell*, 576 U.S. 473, 486 (2015).

The Government Defendants maintain this general authorization gives them authority to mandate vaccines to 10.3 million healthcare workers arguing CMS can do almost anything the Secretary feels is necessary to ensure the health and safety of patients. The "major questions doctrine" is not addressed.

Alabama Association of Realtors supra warrants discussion. In finding the nationwide eviction moratorium enacted by the CDC beyond the CDC's authority, the CDC had a statute that was more broadly worded than the ones the CMS uses in this case. The Supreme Court called the expansive authority of CDC "unprecedented," and stated "Section 361(a)[23] is a wafer-thin reed on which to rest such sweeping power." 141 S.Ct. at 2489.

There is no question that mandating a vaccine to 10.3 million healthcare workers is something that should be done by Congress, not a government agency. It is not clear that even

[23] The statute used for CDC's authority.

an Act of Congress mandating a vaccine would be constitutional. Certainly, CMS does not have this authority by a general authorization statue.

Plaintiff States are likely to succeed on their claim that the Government Defendants exceeded their authority in enacting the CMS Mandate.

3. Contrary to Law

The Plaintiff States additionally claim that the CMS Mandate is contrary to law, arguing that it violates additional provisions in the Social Security Act. The first provision Plaintiff States claim the mandate violates is 42 U.S.C. 1395z, which requires the Secretary to consult with appropriate state agencies relating to conditions of participation by providers of services. The Government Defendants concede that the CMS Mandate was issued without complying with this directive, but state they will meet with the State agencies FOLLOWING the issuance of this rule.[24]

The second provision Plaintiff States claim the mandate violates is 42 U.S.C. 1395, which provides that nothing in the Social Security Act shall be construed to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the situation, tenure or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person. Plaintiff States argue these provisions prohibit the dictation of the hiring and firing policies of these institutions for unvaccinated workers. The statute also prohibits supervision and control over both the "selection" and "tenure" of unvaccinated employees.

[24] 86 Fed. Reg. at 61567.

The third provision Plaintiff States claim the mandate violates is 42 U.S.C. 1302(b)(1), which requires that whenever the Secretary publishes a general notice of proposed rulemaking for any rule or regulation proposed that "may" have a significant impact on the operations of a substantial number of small rural hospitals, an initial regulatory impact analysis is to be conducted. Plaintiff States argue the CMS Mandate "may" have a significant impact on a substantial number of small rural hospitals due to loss of workers and/or income due to the CMS Mandate. No regulatory impact analysis for rural hospitals was conducted in this case.

Because the Government Defendants did not comply with any of the above provisions, the Plaintiff States are likely to succeed on the merits that the CMS Mandate is contrary to law.

4. Arbitrary and Capricious

Federal administrative agencies are required to engage in reasoned decision-making. *Allentown Mack Sales & Serv., Inc. v. N.L.R.B.*, 522 U.S. 359, 374, 118 S. Ct. 818, 139 L. Ed. 2d 797 (1998). The Plaintiff States allege the CMS Mandate is arbitrary and capricious under Title 5 U.S.C. 706(2)(A).

If an administrative agency does not engage in reasoned decision making, a court, under the APA, shall hold unlawful and set aside agency action, findings and conclusions found to be arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. 706(2)(A).

The grounds upon which an administrative order must be judged are those upon which the record discloses that its action was based. *Sec. & Exch. Comm'n v. Chenery Corp.*, 318 U.S. 80, 87, 63 S. Ct. 454, 87 L. Ed. 626 (1943).

Plaintiff States argue Government Defendants' CMS Mandate ignores the Social Security Act's focus on patient wellbeing and instead focuses on the health of healthcare providers. The Plaintiff States further maintain the goal of the CMS Mandate is to increase individual vaccine rates, which will actually have the effect of harming patient well-being due to staff shortages of providers and suppliers.

This is backed up by a number of declarations of various individuals that verify healthcare worker shortages, a significant number of healthcare workers that remain unvaccinated, and the harm that will be caused to these facilities in the event that even a few of the unvaccinated healthcare workers quit or are fired as a result of the CMS Mandate.[25] Some of the declarations also verify the huge percentage of money paid to these facilities through the Medicare and Medicaid Programs, showing these facilities would have to shut down or severely cut back on healthcare services if funding is cut off by the Government Defendants to these facilities.[26] The Plaintiff States also provided a declaration which shows the increased enforcement costs that would result if required to survey and enforce the CMS Mandate.[27]

In other words, the Plaintiff States maintain that although the purpose of the Social Security Act is to help healthcare patients, the CMS Mandate would have the opposite effect due to the loss of healthcare workers and funding to healthcare facilities. This is not the "reasoned decision-making" required by the APA. Requiring COVID-19 vaccinations to healthcare workers covered by the mandate would hurt the patients the Social Security Act was meant to help.

[25] Doc. No. 2-2, 2-3, 2-6, 2-7, 2-8, 2-9, 2-10, 2-11, 2-12 and 2-16.
[26] Doc. No. 2-4, 2-5, 2-15.
[27] Doc. No. 2-14.

Additionally, the Plaintiff States argue the Government Defendants failed to consider or arbitrarily rejected obvious alternatives to the CMS Mandate. These alternatives include daily or weekly COVID-19 testing, wearing masks or shields, natural immunity and/or social distancing. The Plaintiff States maintain the apparent rejection of these alternatives to COVID-19 vaccines is unsupported by evidence. The Declaration of Tracy Gruber[28] declares that since July 2021, employees at the Utah State Hospital and Utah State Development Center have been required to be vaccinated or take a weekly COVID-19 test. That alternative has caused no apparent harm to patients or staff.

The rejection of natural immunity as an alternative is puzzling. Natural immunity is the immunity of people who have been infected with the COVID-19 virus. In rejecting this alternative, the CMS Mandate stated:

> While a significant number of healthcare staff have been infected with SARS-Co-V2, evidence indicates their infection-induced immunity, also called "natural immunity" is not equivalent to receiving the COVID-19 vaccine.

86 Fed. Reg. at 61559.

The "evidence" CMS relied upon in rejecting that alternative is not provided. The Declaration of Dr. Jay Bhattachary,[29] Director of Stanford University's Center for Demography and Economics of Health and Aging disputes CMS's assertion that natural immunity is not equivalent to receiving a COVID-19 vaccine. Citing studies from *Qatar* (which tracked 927,321 individuals for six months after COVID-19 vaccinations), California (which tracked the infection rates from over 5 million patients vaccinated with two Pfizer doses), and U.S. Veterans (which tracked 620,000 vaccinated U.S. Veterans), Plaintiff States assert these studies overwhelmingly

[28] Doc. No. 2-8.
[29] Doc. No. 2-13.

conclude that natural immunity provides equivalent or greater protection against severe infection than immunity generated by COVID-19 vaccines.

The CMS Mandate does not yet require boosters to the COVID-19 vaccines. However, the CDC recently recommended boosters.[30] If boosters are needed six months after being "fully vaccinated," then how good are the COVID-19 vaccines, and why is it necessary to mandate them?

Additionally, the Plaintiff States provided evidence in the Declaration of Dr. Peter A. McCullough[31] that the COVID-19 vaccines do not prevent transmission of the disease among the vaccinated or mixed vaccinated/unvaccinated populations, and that mandatory COVID-19 vaccines for hospitals do not increase safety for employees or hospital patients. McCullough declared that additional treatment with other drugs and supplements has resulted in an 85% reduction in hospitalizations and death of high-risk individuals presenting with COVID-19.

Of note, Dr. McCullough declared the Delta variant of SARS-Cov-2 accounts for 98.9% of the present cases in the United States, United Kingdom, and Israel. Dr. McCullough further declared that because of the progressive mutation of the spike protein, the virus has achieved an immune escape from COVID-19 vaccines. He stated the Delta variant is not adequately covered by the vaccines. In other words, even if you are fully vaccinated, you still may become infected with the COVID-19 virus[32].

The Plaintiff States further argue that CMS failed to adequately explain its departure from its prior position of not requiring mandatory vaccines. An agency must provide a more detailed justification when a new policy rests upon factual findings that contradict those which

[30] cdc.gov (November 19, 2021).
[31] Doc. No. 2-17.
[32] CDC also noted the WHO (World Health Organization) has classified a new variant named Omicron, cdc.gov (November 29, 2021).

underlay its prior policy. *State v. Biden*, 10 F.4th 538, 554 (5th Cir. 2021); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009).

Although CMS spent pages and pages attempting to explain the need for mandatory COVID-19 vaccines, when infection and hospitalizations rates are dropping, millions of people have already been infected, developing some form of natural immunity, and when people who have been fully vaccinated still become infected, mandatory vaccines as the only method of prevention make no sense.

The Plaintiff States also argue that CMS's rationale is flagrantly pretextual. The Government Defendants say it is not pretextual, but it is obvious that the mandate was enacted as a result of President Biden's September 9, 2021, declaration of his intention to impose a national CMS Mandate.[33] Both the CMS and OSHA vaccine mandates were published on the same day, November 5, 2021. However, the 46-page CMS Mandate does not even mention President Biden's declaration of a national vaccine mandate. The presence of pretext is enough to render a rule arbitrary and capricious.[34]

The Plaintiff States also argue the CMS Mandate ignores the Plaintiff States' overwhelming reliance interests in their Medicare and Medicaid programs. The CMS Mandate is arbitrary and capricious if CMS ignores those reliance interests. *DHS v. Regents of the University of California*, 140 S.Ct. 1891, 1913-14 (2020). The Plaintiff States have substantial reliance interests in those programs.[35] The threatened cutoff of federal funding would be devastating to the Plaintiff States' healthcare facilities. CMS's plan to meet with the appropriate state agency after the rule is issued (86 Fed. Reg. at 61567) would be too late. By that time,

[33] See FN 11.
[34] *Department of Commerce v. New York*, 139 S.Ct. at 2575-76.
[35] No. 2-4.

unwilling healthcare employees would have had to decide whether to take the vaccine or quit their jobs.

Lastly, the Plaintiff States allege the "scope" of the CMS Mandate is arbitrary and capricious. The Plaintiff States argue that the CMS Mandate applies to all ages, even to psychiatric residential treatment facilities for individuals under twenty-one years of age,[36] which is not related to CMS's asserted interest in protecting elderly and infirm patients from COVID-19 transmissions.[37] As noted by the Court in *BST Holdings* in regard to the OSHA Mandate:

> The Mandate is a one-size-fits-all sledgehammer that makes hardly any attempt to account for differences in workplaces (and workers) that have more than a little bearing on workers' varying degrees of susceptibility to the supposedly "grave danger" the Mandate purports to address.

No. 21-60845 at 8.

The Plaintiff States have made a substantial showing that they are likely to succeed on the merits of their arbitrary and capricious claim.

5. Other Constitutional Issues

Other arguments made by the Plaintiff States are based upon a violation of the States' police power, violation of the Spending Clause, violation of the Tenth Amendment and violation of the Anti-Commandeering Doctrine.

(a) Police Power/Tenth Amendment

In the federal system, the federal government has limited powers. The States and the people retain the remainder.[38] The States have broad authority to enact legislation for the public good ("police power"), but the federal government has no such authority, and can only exercise the powers granted to it, including the power to make all laws which may be necessary and

[36] 86 Fed. Reg. at 61576.
[37] 86 Fed. Reg. at 61610.
[38] 10th Amendment to the United States Constitution.

proper for carrying into execution the enumerated powers. If the federal government would radically readjust the balance of state and national authority, those charged with the duty of legislating must be reasonably explicit about it. The Supreme Court will not be quick to assume Congress has meant to effect a significant change into the sensitive state and federal relations. Congress does not normally intrude upon the police power of States. *Bond v. United States*, 572 U.S. 844, 857-58 (2014).

Absent a clear statement of intention from Congress, there is a presumption against statutory construction that would significantly affect the federal-state balance. *Boelens v. Redman Homes, Inc.* 748 F.2d 1058, 1067 (5th Cir. 1984).

The CMS Mandate specifically preempts state and local law. 86 Fed. Reg. at 61572. As noted by the Fifth Circuit in *BST Holdings:*

> First, the Mandate likely exceeds the federal government's authority under the Commerce Clause because it regulates noneconomic inactivity that falls squarely within the States' police power. A person's choice to remain unvaccinated and forego regular testing is noneconomic inactivity. *Cf. NFIB v. Sebelius*, 567 U.S. 519, 522 (2012) (Roberts, C.J. concurring); see also *Id.* at 652-53 (Scalia, J., dissenting). And to mandate that a person receive a vaccine or undergo testing falls squarely within the States' police power. *Zucht v. King*, 260 U.S. 174, 176 (1922) (noting that precedent had long "settled that it is within the police power of a state to provide for compulsory vaccination"); *Jacobson v. Massachusetts*, 197 U.S. 11, 25-26 (1905) (Similar). No. 21-60845 at 16-17.

The Plaintiff States make a strong case that the CMS Mandate violates the States' police power.

(b) Anti-Commandeering Doctrine

The Anti-Commandeering Doctrine is simply the expression of a fundamental structural decision incorporated into the Constitution, i.e., the decision to withhold from Congress the power to issue orders directly to the States. Congress cannot command a state government to

enact state legislation. The Tenth Amendment confirms that all other power is reserved to the States. *Murphy v. National Collegiate Athletics Ass'n.*, 138 S.Ct. 1461, 1476 (2018).

In *Printz v. U.S.*, 521 U.S. 898, 928 (1997), the Court held invalid a federal law that commanded state and local enforcement officers to conduct background checks on prospective handgun purchasers and to perform certain related tasks.

Although many of the health care facilities required to track and regulate the CMS Mandate are private, many are likely run by some or all of the Plaintiff States, which could result in violation of the Anti-Commandeering Doctrine. As this Court is unable to tell (at this point) whether and/or how many of the providers and suppliers are run by states, there is no evidence to prove the violation.

(c) Non-Delegation Doctrine

Under the Non-Delegation Doctrine, Congress lacks the authority to delegate "unfiltered power" over the American economy to an executive agency. *Solid Waste Agency of Northern Cook County v. U.S. Army Corps of Engineers*, 121 S.Ct. 675 (2001).[39]

This is a similar doctrine to the Major Questions Doctrine, but if the Government Defendants have the power and authority they claim (to mandate vaccines for 10.3 million workers), these government agencies would have almost "unfiltered power" over any healthcare provider, supplier, and employees that are covered by the CMS Mandate. If CMS has the authority by a general authorization statute to mandate vaccines, they have authority to do almost anything they believe necessary, holding the hammer of termination of the Medicare/Medicaid Provider Agreement over healthcare facilities and suppliers.

The Plaintiff States are likely to succeed on the merits of this claim.

[39] There is a serious constitutional question of whether Congress could even transfer "unfettered power" to a government agency. *Paul v. United States* 140 S.Ct. 342 (2019) (Kavanaugh, J. Statement).

(d) Spending Clause

The Spending Clause protects the status of States as independent sovereigns in our federal system. Under the Spending Clause,[40] Congress may use its spending power to create incentives for states to act in accordance with federal policies, but when the pressure turns into compulsion, the legislation runs contrary to our system of federalism. The Constitution simply does not give Congress the authority to require the States to regulate. *NFIB v. Sebelius*, 567 U.S. 519, 577 (2012).

In *NFIB*, a provision in the Affordable Care Act which required States that participated in Medicaid to expand their Medicaid programs with the threatened loss of all Medicaid funds to states that refused to expand was held to be unconstitutionally coercive. Since it is unclear at this time whether there is state involvement with the providers, suppliers or employers, the Plaintiff States are at this time not likely to succeed on the merits of this issue.

B. Irreparable Injury

The second requirement for a preliminary injunction is irreparable injury. The Plaintiff States must demonstrate "a substantial threat of irreparable injury" if the injunction is not issued. *Texas v. U.S.*, 809 F.3d 134, 150 (5th Cir. 2015). For injury to be "irreparable," plaintiffs need only show it cannot be undone through monetary remedies. *Burgess v. Fed. Deposit Inc., Corp.*, 871 F.3d 297, 304 (5th Cir. 2017).

Being deprived of a procedural right to protect its concrete interests (by violation of the ADA's notice and comment requirements) is irreparable injury. *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019).

[40] Article I, Section 8, United States Constitution

The Plaintiff States will suffer irreparable injury by not being able to enforce their laws which have been preempted by the CMS Mandate, by incurring the increased cost of training and of enforcing the CMS Mandate, and by having their police power encroached. The Plaintiff States' citizens will suffer irreparable injury by having a substantial burden placed on their liberty interests because they will have to choose between losing their jobs or taking the vaccine. Additionally, the health care facilities and suppliers will be burdened with the task of tracking and enforcing the mandate or else face the loss of Medicare and Medicaid funding

The Plaintiff States have shown irreparable injury.

C. The Balance of Equities and The Public's Interest

The Plaintiff States have satisfied the first two elements to obtain a preliminary injunction. The final two elements they must satisfy are that the threatened harm outweighs any harm that may result to the Government Defendants and that the injunction will not undermine the public interest. *Valley v. Rapides Par. Sch. Bd.*, 118 F.3d 1047, 1051 (5th Cir. 1997). These two factors overlap considerably. *Texas*, 809 F.3d at 187. In weighing equities, a court must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief. *Winter*, 555 U.S. at 24. The public interest factor requires the court to consider what public interests may be served by granting or denying a preliminary injunction. *Sierra Club v. U.S. Army Corps of Engineers*, 645 F.3d 978, 997–98 (8th Cir. 2011).

This Court believes the balance of equities and the public interest favors the issuance of a preliminary injunction. The public interest is served by maintaining the constitutional structure and maintaining the liberty of individuals who do not want to take the COVID-19 vaccine. This interest outweighs Government Defendants' interests. It is very important that the public's

interest be taken into account by the Court before allowing the Government Defendants to mandate the vaccines.

V. CONCLUSION

If the separation of powers meant anything to the Constitutional framers, it meant that the three necessary ingredients to deprive a person of liberty or property – the power to make rules, to enforce them, and to judge their violations – could never fall into the same hands. *Tiger Lily, LLC v. United States Housing and Urban Development*, 5 F.4th 666 (6th Cir. 2021). (Thapar, J. Concurrence). If the Executive branch is allowed to usurp the power of the Legislative branch to make laws, two of the three powers conferred by the Constitution would be in the same hands.

If human nature and history teach anything, it is that civil liberties face grave risks when governments proclaim indefinite states of emergency. *Does 1-3 v. Mills*, _ S.Ct. _, 2021 WL 5027177 at 3 (October 29, 2021) (Gorsuch, J. dissenting).

During a pandemic such as this one, it is even more important to safeguard the separation of powers set forth in our Constitution to avoid erosion of our liberties. Because the Plaintiff States have satisfied all four elements required for a preliminary injunction to issue, this Court has determined that a preliminary injunction should issue against the Government Defendants.

This matter will ultimately be decided by a higher court than this one. However, it is important to preserve the status quo in this case. The liberty interests of the unvaccinated requires nothing less.

In addressing the geographic scope of the preliminary injunction, due to the nationwide scope of the CMS Mandate, a nationwide injunction is necessary due to the need for uniformity. *Texas*, 809 F.3d at 187-88. Although this Court considered limiting the injunction to the fourteen Plaintiff States, there are unvaccinated healthcare workers in other states who also need

protection. Therefore, the scope of this injunction will be nationwide, except for the states of Alaska, Arkansas, Iowa, Kansas, Missouri, New Hampshire, Nebraska, Wyoming, North Dakota, South Dakota, since these ten states are already under a preliminary injunction order dated November 29, 2021, out of the Eastern District of Missouri.

This Court will additionally address security under Fed. R. Civ. P. 65. The requirement of security is discretionary. *Kaepa, Inc. v. Achilles Corp.*, 76 F.3d 624, 628 (5th Cir. 1996). Plaintiff States are fourteen sovereign states. This Court will not require Plaintiff States to post security for this Preliminary Injunction.

For the reasons set forth in this Court's ruling, Plaintiff States' Motion for Preliminary Injunction [Doc. No. 2] is **GRANTED**. Therefore, the U.S. Department of Health and Human Services and the Center for Medicare and Medicaid Services, along with their directors, employees, Administrators and Secretaries are hereby **ENJOINED** and **RESTRAINED from implementing the CMS Mandate** set forth in 86 Fed. Reg. 61555-01 (November 5, 2021) as to all healthcare providers, suppliers, owners, employees, and all others covered by said CMS Mandate.

This preliminary injunction shall remain in effect pending the final resolution of this case, or until further orders from this Court, the United States Court of Appeals for the Fifth Circuit, or the United States Supreme Court.

No security bond shall be required under Federal Rule of Civil Procedure 65.

MONROE, LOUISIANA, this 30th day of November 2021.

TERRY A. DOUGHTY
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

STATE OF LOUISIANA ET AL	**CASE NO. 3:21-CV-03970**
VERSUS	**JUDGE TERRY A. DOUGHTY**
XAVIER BECERRA ET AL	**MAG. JUDGE KAYLA D. MCCLUSKY**

ORDER

For the reasons set forth in the Court's Memorandum Ruling,

IT IS ORDERED that the Plaintiff States' Motion for Preliminary Injunction [Doc. No. 2] is **GRANTED**.

IT IS THEREFORE ORDERED that the U.S. Department of Health and Human Services and the Center for Medicare and Medicaid Services, along with their directors, employees, Administrators and Secretaries are hereby **ENJOINED** and **RESTRAINED** from implementing the CMS Mandate set forth in 86 Fed. Reg. 61555-01 (November 5, 2021), as to all healthcare providers, suppliers, owners, employees, and all others covered by said CMS Mandate.

IT IS FURTHER ORDERED that the scope of this injunction shall be nationwide, except for the states of Alaska, Arkansas, Iowa, Kansas, Missouri, New Hampshire, Nebraska, Wyoming, North Dakota, South Dakota, since these ten states are already under a preliminary injunction order dated November 29, 2021, issued by the Eastern District of Missouri. *Missouri v. Biden*, No. 4:21-CV-01329-MTS (E.D. Mo. Nov. 29, 2021).

IT IS FURTHER ORDERED that this preliminary injunction shall remain in effect pending the final resolution of this case, or until further orders from this Court, the United States Court of Appeals for the Fifth Circuit, or the United States Supreme Court.

IT IS FURTHER ORDERED that no security bond shall be required under Federal Rule of Civil Procedure 65.

MONROE, LOUISIANA, this 30th day of November 2021.

Terry A. Doughty
United States District Judge