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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
MISSOULA DIVISION

<p>MONTANA MEDICAL ASSOCIATION, et al., Plaintiffs, v. AUSTIN KNUDSEN, et al., Defendants.</p>	<p>Cause No. CV-21-108-M-DWM</p> <p>NOTICE OF SUPPLEMENTAL AUTHORITY</p>
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Pursuant to D. Mont. L.R. 7.4, Defendants Austin Knudsen and Laurie Esau (hereafter “the State”) submit this notice of supplemental authority in the above captioned matter.

Plaintiffs referenced the pending CMS vaccine mandate in their response to the State’s Second Motion to Dismiss. Doc. 23 at 34 n.4 citing 86 Fed. Reg. 61555 (Nov. 5, 2021).

After the State’s Second Motion to Dismiss was fully briefed, a preliminary injunction was issued in *Louisiana and Montana, et al. v. Becerra et al.*, No. 3:21-CV-03970, Doc. 28 (W.D. La. Nov. 30, 2021). The Court enjoined enforcement of the CMS vaccine mandate for Medicare and Medicaid healthcare providers, including providers in Montana.

The Louisiana Court’s order addresses issues raised in briefing in this case. “Congress does not normally intrude upon the police power of States.” *Id.* at 29 citing *Bond v. United States*, 572 U.S. 844, 857–58 (2014). Further;

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.

Id. The State raised similar arguments in its briefing. *See e.g.* Doc. 21 at 24, 34–35.

Additionally, the Court entered findings such as "even if you are fully vaccinated, you still may become infected with the COVID-19 virus" and "that mandatory COVID-19 vaccines for hospitals do not increase safety for employees or hospital patients." *Louisiana and Montana, et al.*, Doc. 28 at 26. The State raised similar points in its briefing. *See e.g.* Doc. 21 at 17.

The Court concluded, "[i]f human nature and history teach anything, it is that civil liberties face grave risks when governments proclaim indefinite states of emergency." *Louisiana and Montana, et al.*, Doc. 28 at 33. The State raised similar arguments in its briefings. *See e.g.* Doc. 21 at 8–10.

DATED this 30th day of November, 2021.

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**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 States¹ are entitled to a preliminary injunction against the Government Defendants² 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 concluded⁹ 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 mandatory¹¹. On September 9, 2021, President Biden changed his mind announcing his intention to impose a national mandate¹².

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 Solitude

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 solitude. 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 solitude.

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 interests¹⁹ 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 statute.

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 Gruber²⁸ 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. McCullough³¹ 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 virus³².

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.

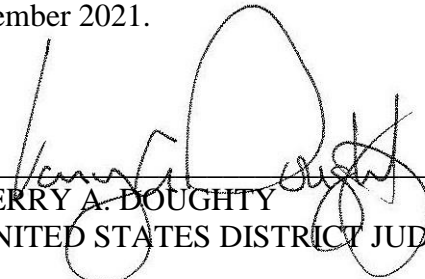
This Court will additionally address security under Fed. R. Civ. P. 65. The requirement of security is discretionary. *Kaepa, Inc. v. Achilles Corp.*, 76 F.3d 624, 628 (5th Cir. 1996). Plaintiff States are fourteen sovereign states. This Court will not require Plaintiff States to post security for this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