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December 6, 2021

Lyle W. Cayce
Clerk of Court
U.S. Court of Appeals for the 5th Circuit
600 S. Maestri Place
New Orleans, LA 70130

RE: *State of Louisiana v. Becerra*, No. 21-30734

Dear Mr. Cayce:

We respectfully inform the Court that the Eleventh Circuit has denied Florida's motion to enjoin pending appeal the same HHS vaccination rule that is at issue in this case. Copies of the Eleventh Circuit's order and underlying district court rulings are attached.

Sincerely,

s/ Alisa B. Klein
Alisa B. Klein
U.S. Department of Justice
Appellate Staff, Civil Division

cc (via CM/ECF): Counsel of Record

CERTIFICATE OF COMPLIANCE

This letter complies with the type-volume limit of Federal Rule of Appellate Procedure 28(j) because the body of the letter contains 42 words.

s/ Alisa B. Klein

Alisa B. Klein

CERTIFICATE OF SERVICE

I hereby certify that on December 6, 2021, I electronically filed the foregoing letter 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

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

No. 21-14098-JJ

STATE OF FLORIDA,

Plaintiff - Appellant,

versus

DEPARTMENT OF HEALTH AND HUMAN SERVICES,
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES,
UNITED STATES OF AMERICA,
U.S. CENTERS FOR MEDICARE AND MEDICAID SERVICES,
ADMINISTRATOR OF THE CENTERS FOR MEDICARE AND MEDICAID,

Defendants - Appellees.

On Appeal from the United States
District Court for the Northern District of Florida

BEFORE: ROSENBAUM, JILL PRYOR, and LAGOA, Circuit Judges.

BY THE COURT:

Before the Court is Appellant's "Time-Sensitive Motion for Injunction Pending Appeal." The motion is DENIED, as Appellant failed to make the requisite showing for an injunction pending appeal. *See Nken v. Holder*, 445 U.S. 418, 434 (2009).

Judge Lagoa would grant the motion and dissents. Opinions will follow.

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION**

STATE OF FLORIDA,

Plaintiff,

v.

CASE NO. 3:21cv2722-MCR-HTC

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES, et al.,**

Defendants.

_____ /

ORDER

On November 20, 2021, the Court entered an order, ECF No. 6, denying the State of Florida’s request for a temporary restraining order (“TRO”) and preliminary injunction to prevent the implementation of an interim final rule issued by the Centers for Medicare and Medicaid Services (“CMS”), requiring all covered healthcare staff in state-run facilities that participate in Medicare and Medicaid programs to be vaccinated against COVID-19.¹ *See* Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555-01 (Nov. 5, 2021) (“IFC”). Florida appealed the Court’s denial of the motion and filed an Emergency Motion for Injunction Pending Appeal, arguing in part that this Court had not considered its

¹ The first dose must be administered by December 6, 2021, and a second dose by January 4, 2022.

asserted irreparable sovereign injury based on the IFC's preemption of Florida's recently enacted law prohibiting vaccine mandates by employers.² *See Fla. Stat. §§ 381.00317, 112.0441* (Nov. 18, 2021).

The Court denied the preliminary injunction pending appeal, ECF No. 13, but acknowledged that Florida's new law had not been addressed in the original order. At the time Florida filed its motion, the Florida Legislature was merely contemplating the legislation, which the Court found insufficient to show an irreparable sovereign injury.³ The State did not notify the Court of the law's passage before the Court's order was entered. Therefore, out of an abundance of caution and in an effort to ensure that the Eleventh Circuit had the benefit of the Court's full reasoning on appeal, the Court was willing to hear Florida's arguments and allow evidence regarding the impact of the new law at a hearing set for December 1. That

² In relevant part, Florida law now prohibits public employers from imposing any COVID-19 vaccine mandate on a public employee and subjects a public employer to a fine not to exceed \$5,000 per violation. Fla. Stat. § 112.0441. Florida's law also states that a private employer who terminates an employee for not complying with a vaccine mandate is subject to fines of up to \$50,000 per violation (for an employer with 100 or more employees). *See Fla. Stat. § 381.00317*. This law appears to provide for a wider range of exemptions than allowed under federal law (i.e., requiring exemptions for medical reasons, religious reasons, COVID-19 immunity, agreeing to undergo periodic testing, and use of employer-provided personal protective equipment).

³ The Court also found no showing of irreparable injury to the State to justify an immediate injunction because the agency heads' predictions of widespread resignations were speculative and conclusory, the threatened loss of federal funding would not occur on December 6, 2021, and this threatened harm could be remediated through this suit brought pursuant to the Administrative Procedure Act. The Court addressed all arguments that had been clearly presented.

portion of the Court's order requiring further briefing and a hearing has now been vacated and the hearing cancelled at the parties' joint request in light of the notice of appeal. Nonetheless, the Court finds it appropriate to address the new state law in aid of the appeal since the issue was not squarely addressed in the original order. *See United States v. Diveroli*, 729 F.3d 1339, 1341-44 (11th Cir. 2013) (“[A] timely notice of appeal normally divests the district court of authority to proceed further with respect to any matters involved in the appeal, except in aid of the appeal.”). On consideration of the state law, the undersigned would reach the same decision.

I. Legal Standard

A district court may grant a preliminary injunction only if there is (1) a substantial likelihood of success on the merits; (2) the plaintiff will suffer irreparable injury absent an injunction; (3) the threatened injury to the plaintiff outweighs whatever damage the proposed injunction may cause the opposing party; and (4) the injunction would not be adverse to the public interest. *Osmose, Inc. v. Viance, LLC*, 612 F.3d 1298, 1307 (11th Cir. 2010); *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000). A preliminary injunction is “an extraordinary and drastic remedy” granted only if the plaintiff has “clearly established” that each of the four requirements is satisfied. *Siegel*, 234 F.3d at 1176 (internal marks omitted). Thus,

the failure to establish any one of these four factors is fatal. *Am. C.L. Union of Fla., Inc. v. Miami-Dade Cty. Sch. Bd.*, 557 F.3d 1177, 1198 (11th Cir. 2009).

II. Discussion

A. Irreparable Harm

Florida argues that the IFC's preemption of its law prohibiting public employers from imposing a vaccine mandate (which was enacted *after* the IFC was issued) constitutes an irreparable sovereign injury. Florida argues that it suffers irreparable harm as *parens patriae* for Floridians “who work in healthcare and do not wish to receive a vaccine.”⁴ ECF No. 9 at 13. Florida also argues irreparable sovereign injury results from the IFC precluding Florida from enforcing its own law and forcing Florida's public health agencies and facility heads to make the untenable choice of deciding which law to follow and which to violate.

A state possesses an interest in “the exercise of sovereign power over individuals and entities within the relevant jurisdiction—this involves the power to create and enforce a legal code, both civil and criminal.” *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 601 (1982). It is also well-established that “a

⁴ Florida also claims a *parens patriae* interest for “patients who will lose access to access to adequate medical care because of CMS's mandate” if either widespread resignations or loss of federal funding occurs. ECF No. 9 at 13. The Court previously found the statements of widespread resignations to be conclusory and speculative.

State has a quasi-sovereign interest in the health and well-being—both physical and economic—of its residents in general.”⁵ *Id.* at 607. A State has a further interest in “ensuring that the State and its residents are not excluded from the benefits that are to flow from participation in the federal system.” *Id.* at 608. A *parens patriae* interest is sufficient to give standing to sue if the injury is one that the state “would likely attempt to address through its sovereign lawmaking powers,” if it could. *Id.* at 607. However, not everything a State does is “based on its sovereign character.” *Id.* at 601.

In this instance, Florida has exercised its sovereign lawmaking powers to broadly prohibit employers from imposing COVID-19 vaccination mandates on their employees. In passing the interim rule, the CMS expressly considered issues of federalism and determined that the IFC would pre-empt state laws such as Florida’s. 86 Fed. Reg. at 61,613 (finding that the agency’s authority allows it to require vaccinations of covered healthcare workers and staff as necessary to promote patient health and safety and efficient administration of the federal programs in state-

⁵ The Supreme Court in *Alfred L. Snapp & Son* discussed examples of instances in which a *parens patriae* interest was found, citing cases involving a need to abate public nuisances, to protect state citizens’ access to natural gas, and to prevent economic discrimination in the shipping industry. 458 U.S. at 601—607. The Court did not attempt to draw any definitive line as to the proportion of the state population that must be adversely impacted by the challenged behavior to give rise to a *parens patriae* interest, but made clear that “more must be alleged than injury to an identifiable group of individual residents.” *Id.* at 607.

run facilities that receive federal funding). Thus, by its terms, the IFC pre-empts Florida's law but only with regard to covered healthcare workers who are employees of a Medicare- or Medicaid-participating-facility—not an entire industry, as Florida contends. And, it is not a federal mandate that *all* Florida citizens must be vaccinated. While the mandate undoubtedly has far-reaching impacts given the many facilities that accept federal funding under the Medicare and Medicaid programs, vaccination mandates generally have not been found to be unlawful or unconstitutional.⁶ *See Jacobson v. Commonwealth of Mass.*, 197 U.S. 11, 37-39 (1905) (upholding a state compulsory vaccination law); *see also Does 1-3 v. Mills*, 2021 WL 5027177 (S. Ct. Oct. 29, 2021) (denying an application for injunctive relief pending appeal in a challenge to Maine's COVID-19 vaccination mandate for healthcare workers). Additionally, the IFC vaccination mandate provides

⁶ In any event, the state's police power has been discussed in the vaccine context only in circumstances where the state has in fact *imposed* a vaccination mandate to protect the health of its citizens. *See Jacobson*, 197 U.S. at 37-39 (upholding a state compulsory vaccination law); *see also Does 1-3 v. Mills*, 2021 WL 5027177 (S. Ct. Oct. 29, 2021) (denying an application for injunctive relief pending appeal in a challenge to Maine's COVID-19 vaccination mandate for healthcare workers). Florida, by contrast, asserts a police power to *prevent* the imposition of a measure that would be a health benefit to its citizens. In this case, at least at this very early stage, there is no evidence nor even any argument that healthcare workers face an undue health risk from the vaccine that would not be protected through the lawful exemptions allowed, and there is no case law cited to support a constitutional liberty interest in refusing an approved vaccine for those who choose to work in a federally funded healthcare facility. Also, as noted, the IFC does not impose a mandate on all Florida residents.

exemptions for employees based on medical and religious beliefs to safeguard individual rights. 86 Fed. Reg. at 61,572-73 (noting that certain allergies, recognized medical conditions, or religious beliefs, observances, or practices, may provide grounds for exemption). The Court cannot find a *parens patriae* interest in Florida's ability to shield employees who choose to work in a federally funded healthcare facility from the rules that govern administration of the federal program. *See Commonwealth of Mass. v. Mellon*, 262 U.S. 447, 485-86 (1923) ("It cannot be conceded that a state, as *parens patriae*, may institute judicial proceedings to protect citizens of the United States from the operation of the statutes thereof."); *see generally Virginia ex rel. Cuccinelli v. Sebelius*, 656 F.3d 253, 271 (4th Cir. 2011) ("To permit a state to litigate whenever it enacts a statute declaring its opposition to federal law . . . would convert the federal judiciary into a forum for the vindication of a state's generalized grievances about the conduct of government.").

Florida also argues that the conflict between federal and state law forces state-run agencies and facility heads to make a decision by December 6 as to which law to follow, which could give rise to an irreparable sovereign injury. This presents a more difficult question. While the timing of the state law's enactment only *after* the IFC was issued suggests an attempt to alter the status quo by creating a self-inflicted irreparable sovereign injury after the fact, the conflict now confronting agency heads

on December 6 is nonetheless real. If they comply with the CMS rule, they risk violating Florida law. However, if there is no likelihood that the IFC will be found unlawful on the merits, then the federal rule eliminates the conflict of choice faced by the agency heads by virtue of its express preemption determination. It is therefore necessary to consider the remaining preliminary injunction factors, the first of which is the likelihood of success on the merits.⁷

B. Likelihood of Success

Florida challenges the validity of the IFC under the Administrative Procedure Act (“APA”) and the Spending Clause. Pursuant to the APA, a court must “hold unlawful and set aside agency action” that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;” that is in excess of statutory authority; or that is “without observance of procedure required by law.” 5 U.S.C. § 706(2) (A), (C)–(D). The Eleventh Circuit has characterized the arbitrary and capricious standard as “exceedingly deferential.” *Miccosukee Tribe of Indians of Fla. v. United States*, 566 F.3d 1257, 1264 (11th Cir. 2009). This means a court is not authorized to substitute its judgment for the agency’s “as long as the agency conclusions are rational.” *Id.* A decision is arbitrary and capricious only if the

⁷ Statements in this Order about the merits should be understood only as statements about the likelihood of success as viewed at this early stage in the proceedings.

factors relied on are not what Congress would intend, if the agency “entirely failed to consider an important aspect of the problem,” if the agency offered an explanation counter to the evidence before the agency, or if the agency action “is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Id.* (quoting *Alabama–Tombigbee Rivers Coal. v. Kempthorne*, 477 F.3d 1250, 1254 (11th Cir. 2007)); *State v. Becerra*, No. 8:21-CV-839-SDM-AAS, 2021 WL 2514138, at *39 (M.D. Fla. June 18, 2021) (enjoining the Center for Disease Control’s conditional sailing order, which effectively shut down the cruise industry).

Florida argues that the CMS acted in excess of its statutory authority, contrary to law, and arbitrarily and capriciously by issuing the IFC without first consulting with the appropriate state agencies, without following notice and comment procedure, and without adequately considering less intrusive alternatives. These arguments are difficult to accept, given the law and the limited record before this Court, notwithstanding the wide implications of the interim rule. By law, the Secretary is broadly granted rulemaking authority over the Medicare and Medicaid programs to make such rules and regulations “as may be necessary to the efficient administration of the functions with which [it] is charged.” *See* 42 U.S.C. §1302(a);

see also 42 U.S.C. § 1395hh(a).⁸ The statutes require a notice of proposed rulemaking and comment procedure before a rule becomes final, 42 U.S.C. §§ 1302(b), 1395hh(b), and state generally that “the Secretary shall consult with appropriate State agencies” “[i]n carrying out its functions, relating to determination of conditions of participation by providers of services,” 42 U.S.C. § 1395z. This broad rulemaking authority is entitled to substantial deference, and “considerable weight” is given to the agency’s “construction of a statute it is entrusted to administer.” *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–44 (1984) (stating where Congress has not spoken directly on an issue but given an administrative agency the power to administer a program, this power necessarily includes the formation of policy and the making of rules to fill any gap left by Congress).

Regarding the consultation requirement, the CMS explained within the IFC’s comments that it interprets the statute as imposing no temporal requirement for the necessary consultation to occur *before* an interim rule is issued. *See* 86 Fed. Reg. 61,567. The Court finds that the agency’s interpretation of the statute as including no temporal requirement is likely to be given deference as reasonable because the

⁸ The IFC includes a table of statutory authorities for all providers and suppliers. 86 Fed. Reg. 61,567.

statute does not clearly express otherwise. *See generally Gonzales v. Oregon*, 546 U.S. 243, 255–56 (2006) (stating *Chevron* deference is warranted “when it appears that Congress delegated authority to the agency generally to make rules carrying the force of law and that the agency interpretation claiming deference was promulgated in the exercise of that authority”).⁹ The Court also finds that the CMS explained in detail its reasons for not consulting state agencies in advance, which also justified its reason for waiving the notice and comment procedure.

While notice and comment periods is ordinarily required, there is statutory authority indicating this requirement does not apply “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefore in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b). In waiving this process for the interim rule, the CMS provided a detailed explanation of its good cause determination based on the urgency presented by the ongoing pandemic, the 2021 outbreaks associated with the Delta variant, and the oncoming influenza season. The CMS determined that under these circumstances, it was impracticable

⁹ It should be noted that the CMS did not dismiss the requirement altogether but stated within the IFC that it intends to consult with state agencies and has invited them to submit comments through January 4, 2022.

and contrary to the public interest to follow the ordinary notice and comment procedure and still adequately safeguard the health and safety of staff and customers at state-run Medicare and Medicaid facilities. While acknowledging that the number of cases and deaths had been trending downward nationwide, the CMS noted that cases were rising in some areas causing some hospitals and health care systems to experience tremendous strain due to high case volumes coupled with persistent staff shortages, in part due to COVID-19 infection and quarantine measures. *See* 86 Fed. Reg. 61,583. The CMS explained that the current levels of vaccination coverage with no mandate in place have been inadequate to protect healthcare consumers and staff. Also, referencing data showing the importance of vaccination in curbing the spread of COVID-19 and lessening its serious consequences, the CMS determined that further delay in taking this action was impracticable and contrary to the public interest. *Id.* at 61,583–86. The CMS also expressly found as follows:

[T]he COVID-19 pandemic presents a serious and continuing threat to the health and to the lives of staff of health care facilities and of consumers of these providers' and suppliers' services. This threat has grown to be particularly severe since the emergence of the Delta variant. Any delay in the implementation of this rule would result in additional deaths and serious illnesses among health care staff and consumers, further exacerbating the newly-arising, and ongoing, strain on the capacity of health care facilities to serve the public.

86 Fed. Reg. at 61567. In addition, the CMS noted the need for a consistent federal policy to prevent healthcare workers from seeking employment with providers that do not have such patient protections, which in turn may cause facilities that implement such protections to see greater staff shortages. *Id.* at 61,584. This is but a brief summary of the explanation included within the IFC, which appears rationally related to the facts and scientific data recited. Florida contends—somewhat contrary to its asserted position that in fact CMS should have implemented the rule sooner—that the asserted good cause urgency no longer exists. The Court disagrees. Any delay experienced in publishing the mandate does little to diminish CMS’s good cause rationale, which is based on the nature of this ongoing pandemic and the emergence of the Delta variant. Given the CMS’s rational explanation and *no evidence to the contrary*, the Court cannot conclude at this juncture that Florida is likely to prevail on its claim that there was no good cause to waive the ordinary notice and comment period.

For the same reasons, the Court cannot find a likelihood of success on Florida’s argument that the CMS’s decision to mandate the vaccine is arbitrary and capricious due to a failure to consider less intrusive alternatives. The CMS explained its reasoning, discussed the alternatives it considered, and explained why it concluded they were unworkable. For instance, the CMS stated that it considered

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testing, waiving the mandate for those with immunity, graduated compliance expectations, reduced payments, and social distancing measures and concluded these were less effective and insufficient, “given the contagion rates of existing strains of coronavirus and their disproportionate impacts on Medicare and Medicaid beneficiaries.” *Id.* at 61,613. This policy choice between considered alternatives is likely to be accorded deference. Congress has given the agency authority to make rules necessary to the efficient administration of the program, and a court cannot substitute its own judgment for that of the agency on policy decisions regarding how best to efficiently administer the Medicare and Medicaid programs while keeping employees, staff and patients of federally participating facilities safe. *See Black Warrior Riverkeeper, Inc. v. U.S. Army Corps of Engineers*, 781 F.3d 1271, 1288 (11th Cir. 2015) (a court may not substitute its judgment for that of the agency). Again, at this early stage, Florida has presented no evidence to show that CMS’s decision runs counter to the evidence before the agency or that decision reached lacks a rational connection to the facts before the agency.¹⁰

¹⁰ The undersigned notes that a contrary decision was entered on November 29, 2021, in the Eastern District of Missouri, granting injunctive relief to several states. *See Missouri v. Biden*, Case No. 4:21cv1329-MTS, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021). Also, a nationwide injunction was entered in the Western District of Louisiana on November 30. *See Louisiana v. Becerra*, Case No. 3:21cv3970 (W.D. La. Nov. 30, 2021). In each instance, the record appears to be more extensive than the record in this case. Also, the undersigned respectfully disagrees and is not persuaded by the reasoning of those courts. The Louisiana case relies heavily on the Fifth
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Finally, Florida argues that CMS’s decision to require a vaccine mandate for all covered healthcare workers and staff is foreclosed by the statute prohibiting any federal officer from exercising supervision or control over the practice of medicine, the manner in which medical services are provided, or the operation of the institution. 42 U.S.C. § 1395. This argument misconstrues the nature of the vaccination mandate. The CMS is not regulating the practice of medicine, the health care that may be provided in facilities that accept federal funds, the manner in which medical services are provided, or the operation of the institution or its employees. Instead, the CMC is regulating a federal program by requiring facilities that receive federal funding to develop and implement policies and procedures to ensure the vaccination of covered healthcare workers and staff for the health and safety of patients within those facilities. The imposition of a vaccine mandate as a condition on the receipt of federal funds to ensure patient safety within those

Circuit’s decision to grant a stay of a vaccine mandate implemented by the Occupational Safety and Health Administration (“OSHA”). *See BST Holdings, LLC v. OSHA*, 17 4th 604 (5th Cir. 2021). The Court finds the *BST* case distinguishable, however, because contrary to the context of this case, OSHA is not charged with administering a program designed to provide healthcare to the most vulnerable and its rules implicate the Commerce Clause power, which the Fifth Circuit found does not extend to regulate “noneconomic inactivity traditionally within the States’ police power.” *Id.* Here, the CMS is not usurping the state’s police power to broadly regulate for the common good but instead has implemented a health precaution for the effective and efficient administration of the federal healthcare programs it is entrusted with administering.

facilities is not expressly foreclosed by this statute. There appears little likelihood of success on the APA claim.

Florida also argues that the vaccination mandate violates the Spending Clause. Specifically, Florida contends that any condition on the grant of federal money must be unambiguous, so the State can exercise its choice knowingly, citing *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). Florida argues that “any conditions must have been disclosed to Florida from the beginning.” However, it is inconceivable that every facet of the Medicare and Medicaid program would have been known and agreed to from the beginning of those programs, and more importantly, this condition now imposed is unambiguous and does not present an immediate all or nothing penalty. Under the IFC, if cited for noncompliance, providers may be subject to enforcement remedies including civil money penalties, denial of payment for new admissions, *or* termination of the Medicare/Medicaid provider agreement. 86 Fed. Reg. at 61,574. The IFC acknowledges that the CMS already uses discretion in its enforcement of regulations when its inspectors find rule violations, noting “[t]ermination of provider status is not normally an immediate consequence, as entities are typically given the opportunity to correct deficiencies.” *Id.* at 61,614. See *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 584 (2012) (plurality) (“Congress may use its spending power to create incentives for States to

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act in accordance with federal policies” as long as pressure does not turn into compulsion). Because the vaccine mandate is a condition related to the safe and efficient administration of the federal programs, does not alter or expand the existing federal programs, and provides an array of penalties for noncompliance, including penalties less than immediate termination, there is little likelihood of success on the claim.

C. Balancing of Equities

The last two requirements for a preliminary injunction involve a balancing of the equities between the parties and the public. Where the government is the party opposing the preliminary injunction, its interest and harm—the third and fourth elements—merge with the public interest. *Swain v. Junior*, 958 F.3d 1081, 1091 (11th Cir. 2020) (citing *Nken v. Holder*, 556 U.S. 418, 433-34 (2009)). In this instance, the safety of Medicare and Medicaid patients and staff administering the program throughout this pandemic, which has left hundreds of thousands of people dead, and the need to slow the spread of the virus, are greatly enhanced by virtue of the COVID-19 vaccine, according to the medical and public health science. This public safety interest is especially compelling within the context of healthcare facilities, which are charged with protecting vulnerable patients participating in the Medicare and Medicaid programs, and thus weighs heavily on the side of denying

injunctive relief. Florida has not denied the health benefits of the COVID-19 vaccine nor has it identified any public health benefit to its citizens from the enforcement of its statute prohibiting COVID-19 vaccine mandates by employers. It also has not shown any detriment to the health of its citizens from enforcing the CMS vaccine mandate or any constitutional right infringed that is not adequately protected through lawful exemptions. *See Norwegian Cruise Line Holdings, Ltd. v. Rivkees*, No. 21-22492-CIV, 2021 WL 3471585, at *25 (S.D. Fla. Aug. 8, 2021) (balance of equities weighed in favor of enjoining the state law prohibiting vaccine mandates on cruise lines because the cruise line demonstrated that public health will be jeopardized if it is required to suspend its vaccination requirement, but Florida identified no public benefit from the continued enforcement of the statute). Thus, on this record, the balance of equities weighs against granting the injunction.

Accordingly, Florida's enactment of a law prohibiting public employers from imposing vaccine mandates adds a sovereign interest to the analysis but does not alter the Court's previous decision that neither a TRO nor a preliminary injunction is warranted on this record in advance of December 6, 2021. The Clerk is directed to transmit a copy of this Order to the Eleventh Circuit as a supplement to this

Court's decision and to aid the appeal.

DONE AND ORDERED this 1st day of December 2021.

M. Casey Rodgers

M. CASEY RODGERS
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF FLORIDA
PENSACOLA DIVISION

STATE OF FLORIDA,

Plaintiff,

v.

CASE NO. 3:21cv2722-MCR-HTC

DEPARTMENT OF HEALTH AND
HUMAN SERVICES, et al.,

Defendants.

_____ /

ORDER

Pending is the State of Florida’s Motion for a Temporary Restraining Order (“TRO”) or Preliminary Injunction, ECF No. 2, seeking to enjoin an interim final rule of the Centers for Medicare and Medicaid Services (“CMS”) mandating COVID-19 vaccinations for all covered healthcare staff. Having fully reviewed the materials submitted, the Court finds no showing of irreparable injury to support entry of a TRO or preliminary injunction, and therefore the motion is due to be denied.¹

Background

On November 17, 2021, the State of Florida filed its Complaint, seeking preliminary and permanent injunctive and declaratory relief against the Department

¹ The motion does not request an evidentiary hearing, and the Court concludes that the motion can be decided on the basis of the affidavits submitted. Florida represents that the motion has been furnished to the Defendants by mail.

of Health and Human Services (“HHS”); Xavier Becerra, in his official capacity as Secretary of HHS; the United States of America; Chiquita Brooks-Lasure, in her official capacity as Administrator of the CMS; and the CMS.² The Complaint seeks a permanent injunction to prevent the implementation of the CMS’s interim final rule mandating COVID-19 vaccinations for covered healthcare staff, *see* Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555-01 (Nov. 5, 2021), and a declaration that the rule is unlawful. ECF No. 1. The Complaint asserts several causes of action, namely, that the agency action is in excess of the CMS’s statutory authority (Count 1), that the CMS failed to follow notice and comment rulemaking procedures (Count 2), and that the CMS’s action was arbitrary and capricious (Count 3), all in violation of the Administrative Procedure Act, 5 U.S.C. §§ 553, 706. Also, Florida claims the rule is an unconstitutional condition on Florida’s receipt of federal funds, in violation of the Spending Clause of the United States Constitution (Count 4), and seeks a “declaratory judgment that the Biden Administration’s policy is unlawful.” ECF No. 1 at 34.

In brief, the interim final rule, which was issued on November 5, 2021, “revises the requirements that most Medicare- and Medicaid-certified providers and

² According to the Complaint, the CMS is a component of HHS.

suppliers must meet to participate in the Medicare and Medicaid programs.” Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61555-01 (Nov. 5, 2021). More particularly, the rule requires covered healthcare staff to be vaccinated against COVID-19 and to have received at least a first dose by December 6, 2021. *See id.* at 61,573. The mandate is implemented in two phases. Phase 1 requires staff to have a first dose or a lawful exemption prior to December 6, 2021, and requires facilities to develop appropriate procedures by that date. *Id.* Phase 2 requires the second dose by January 4, 2022. Providers must document compliance and process requests for exemptions. *Id.* at 61,572. The rule provides that, as with all new or revised requirements, the CMS will issue interpretive guidelines and will advise and train State surveyors on how to assess compliance. *Id.* at 61,574. If cited for noncompliance, providers may be subject to enforcement remedies, listing as examples civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid provider agreement. *Id.* at 61,574.

In Section III of the interim final rule, the CMS explains that it found good cause to issue the rule without engaging in the ordinary notice and comment procedure prior to implementation, citing the urgency of the 2021 COVID-19 outbreaks associated with the Delta variant and the ongoing pandemic, declared by the President to be a national emergency, as well as the “vital importance of

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vaccination” in protecting healthcare consumers and staff alike. *Id.* at 61,583–61,586. Moreover, the CMS noted the pandemic’s strain on the United States’ healthcare system and that the onset of the 2021-2022 influenza season presents an additional threat. According to CMS, data on the health consequences of coinfection with influenza and COVID-19 is limited and complicated by the fact that COVID-19 has greater rates of mortality and hospitalization than influenza. Also, while the rule went into effect before notice and comment based on this finding of good cause, the CMS will receive comments through January 4, 2022. *Id.* at 61,601.

Simultaneously with its Complaint, Florida filed the pending motion for a TRO or preliminary injunction, seeking to enjoin the operation of the interim final rule prior to December 6, 2021. In support of the motion, Florida presents several affidavits of directors of State facilities, agencies or institutions, asserting ways in which their operations may be adversely impacted by the vaccine mandate.³ Florida’s agency for Health Quality Assurance (“HQA”) conducts surveys on behalf

³ Specifically, Florida includes the affidavits of Kimberly Smoak, Deputy Secretary for Health Quality Assurance, Florida Agency for Health Care Administration; Erica Floyd Thomas, Assistant Secretary for Substance Abuse and Mental Health, Florida Department of Children and Families; Mark S. Lander, Interim Deputy Secretary for County health Systems, Florida Department of Health; Carl Wesley Kirkland, Jr., Deputy Director of Institutional Operations, Florida Department of Corrections; Robert Asztalos, Deputy Executive Director of the Florida Department of Veterans’ Affairs; and Tom Rice, Deputy Executive Director for Programs at the Agency for Persons with Disabilities.

of CMS, reviewing facilities for compliance. HQA's Deputy Secretary Kimberly Smoak states that if it were to refuse to enforce the mandate, HQA would lose its substantial federal funding as a consequence or have its agreement with HHS terminated. ECF 2-1. Similarly, the Florida Department of Children and Families ("DCF") Substance Abuse and Mental Health Assistant Secretary, Erica Thomas, states that under the mandate, the failure of a psychiatric residential treatment facility to comply could subject the facility to enforcement remedies by CMS (such as civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid provider agreement). According to Thomas, DCF employs 3,013 employees in psychiatric residential treatment facilities; it already suffers from staffing shortages, especially in rural areas; and "some employees will refuse the vaccination," which will amplify the staffing shortage and may result in an inability to provide effective treatment or may result in clients spending longer periods in jail awaiting a residential placement. ECF 2-3. Also, in the event DCF were not to comply, it would lose substantial federal funding that is critical to supporting patient services.

The Interim Deputy for the Florida Department of Health ("DOH"), Mark Lander, expresses similar concerns, stating that DOH estimates it could lose "up to 12 employees" in three counties due to the vaccine mandate, which would adversely

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impact patient care by delaying services and requiring clients to travel long distances for primary care. ECF No. 2-3. As an example, Lander states that the Walton Community Health Center estimates “up to 57 employees may be lost” due to the vaccine mandate, causing a serious disruption in services, or, a failure to comply will result in a loss of significant federal funding that would have negative impacts on client care. *Id.*

Florida also presents affidavits from the directors of the Florida Department of Corrections, the Florida Department of Veterans’ Affairs, and the Agency for Persons with Disabilities, who likewise report existing staff shortages and the inability to provide necessary services to incarcerated individuals, veterans, or persons with disabilities if the vaccine mandate is imposed, either due to the anticipated loss of more employees or the negative impact that would result from the significant loss of federal funding if the agency is unable to comply. ECF Nos. 2-4, 2-5, 2-6. Carl Kirkland of the Florida Department of Corrections (DOC) states that in addition to an immediate staffing shortage, the DOC may have to engage in bargaining with the Florida Police Benevolent Association, which would object to a vaccine requirement for its members, but this negotiation could not be completed before December 6, 2021. ECF No. 2-4. Robert Asztalos of the Florida Department of Veterans’ Affairs, states that the vaccine mandate will exacerbate staffing

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shortages that already exist because “some employees may leave.” ECF No. 2-5. Deputy Executive Director for the Agency for Persons with Disabilities, Tom Rice, states that “if widespread resignations were to occur,” it would place the health and safety of residents at risk and consequently also result in Intermediate Care Facilities (“ICF”) losing their certification if unable to meet certain staffing ratios that exist to protect the health and welfare of residents. Rice further states that the agency already faces staffing challenges and that based on responses to a survey of employees and the indications of staff, he estimates the agency will lose about 10% of its total filled positions. He further states that at one ICF, 194 out of 559 employees are not vaccinated, and “based on [Rice’s] personal knowledge and indications from staff, close to 95% of the 194 could resign,” negatively impacting the ICF’s required staffing levels. ECF No. 2-6. Alternatively, Rice states that if an IFC fails to comply with the rule, it is subject to losing substantial federal funding that would likewise negatively impact the care and safety of residents in the facilities.

Discussion

A district court may grant a TRO or preliminary injunction only if there is (1) a substantial likelihood of success on the merits; (2) the plaintiff will suffer irreparable injury absent an injunction; (3) the threatened injury to the plaintiff outweighs whatever damage the proposed injunction may cause the opposing party;

and (4) the injunction would not be adverse to the public interest. *Osmose, Inc. v. Viance, LLC*, 612 F.3d 1298, 1307 (11th Cir. 2010); *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000). A restraining order or preliminary injunction is “an extraordinary and drastic remedy” granted only if the plaintiff has “clearly established” that each of the four requirements is satisfied. *Siegel*, 234 F.3d at 1176 (internal marks omitted). Thus, under Eleventh Circuit law, even if the plaintiff demonstrates a substantial likelihood of success on the merits, preliminary injunctive relief is improper “in the absence of a substantial likelihood of irreparable injury”—long considered “the *sine qua non* of injunctive relief.” *Id.*

On review of the record, the Court finds no adequate showing that irreparable injury will occur in the absence of a TRO or preliminary injunction prior to December 6, 2021. The affidavits in support of the motion include assertions of how the various agencies and institutions anticipate they may be adversely impacted by the mandate. In particular, the affidavits express opinions of agency heads who “estimate” that they “may” lose a certain percentage or a number of employees, or speculate as to the consequences they will suffer “if widespread resignations were to occur.” However, such opinions, absent supporting factual evidence, remain speculative and may be disregarded as conclusory. *See Rogers v. Evans*, 792 F.2d 1052, 1065 n.9 (11th Cir. 1986) (finding the district court properly struck an affidavit

that was “phrased in conclusory terms without citing facts”). The injury must be “neither remote nor speculative, but actual and imminent.” *Ne. Fla. Chapter of Ass’n of Gen. Contractors of Am. v. City of Jacksonville, Fla.*, 896 F.2d 1283, 1285 (11th Cir. 1990) (quoting *Tucker Anthony Realty Corp. v. Schlesinger*, 888 F.2d 969, 973 (2d Cir. 1989)). Additionally, statements regarding employees’ intent to resign are hearsay.

Also, it is represented that these agencies receive substantial federal funding, which may be cut off if they refuse to comply, resulting in a loss of services and patient care, or longer waits or longer drives for patients. However, economic loss such as the loss of funding is not irreparable. An injury is “irreparable” only if it cannot be undone through monetary remedies. *Id.* Florida argues that the economic harm its agencies will suffer from this loss of funding can establish irreparable harm in light of the sovereign immunity of the United States, against which it has no monetary recourse, citing *Odebrecht Const., Inc. v. Sec’y, Fla. Dep’t of Transp.*, 715 F.3d 1268, 1289 (11th Cir. 2013) (referencing a state’s Eleventh Amendment immunity from suit for damages in federal court). However, Florida has asserted claims under the APA and such violations, if found, can be remedied and restored in the ordinary course of litigation. “The possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of

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litigation, weighs heavily against a claim of irreparable harm.” *Ne. Fla. Chapter of Ass'n of Gen. Contractors*, 896 F.2d at 1285 (quoting *Sampson v. Murray*, 415 U.S. 61, 90 (1974)). Moreover, there is no evidence to suggest that the anticipated loss of federal funding from the State agencies’ noncompliance will occur immediately on December 6, 2021, because the asserted loss of staff is speculative, the affidavits fail take to into account any impact from the availability of the exemption process provided in the interim final rule, and even if noncompliance occurs, any potential termination of funding would not occur on December 6.

Florida also contends there is irreparable injury to its own sovereignty if state law is preempted or if there is interference with state policy. This argument lacks merit and even if this could state irreparable injury, Florida references no law or established policy in danger of preemption but argues only that the Florida Legislature is *contemplating* legislation that would prohibit vaccine mandates. This is insufficient to justify the kind of relief Florida seeks.

Accordingly, Florida’s Motion for a Temporary Restraining Order or Preliminary Injunction, ECF No. 2, is **DENIED**. Defendants are directed to respond

to the Complaint in due course.

DONE AND ORDERED this 20th day of November 2021.

M. Casey Rodgers

M. CASEY RODGERS
UNITED STATES DISTRICT JUDGE