UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

STATE OF MISSOURI, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	Case No. 4:21-cv-01329-MTS
	)	
JOSEPH R. BIDEN, JR., *in his official capacity as the President of the United States of America, et al.*,	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

I. INTRODUCTION

This case concerns the Centers for Medicare and Medicaid Services' ("CMS") federal vaccine mandate on a wide range of healthcare facilities. On November 5, 2021, CMS issued an Interim Final Rule with Comment Period ("IFC") entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination" (the "mandate"), 86 Fed. Reg. 61,555 (Nov. 5, 2021), revising the "requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs." 86 Fed. Reg. 61,555–601. Specifically, the mandate requires nearly every employee, volunteer, and third-party contractor working[1] at fifteen[2] categories of healthcare facilities to be vaccinated against SARS-

[1] The mandate applies to a wide-range of people working at the facilities, including, employees, trainees, students, volunteers, or *contractors*, who provide any care, treatment, or *other* services for the facility. 86 Fed. Reg. at 61,570 (emphasis added).

[2] The CMS vaccine mandate covers fifteen categories of Medicare- and Medicaid-certified providers and suppliers: (1) Ambulatory Surgical Centers (ASCs); (2) Hospices; (3) Psychiatric residential treatment facilities (PRTFs); (4) Programs of All-Inclusive Care for the Elderly (PACE); (5) Hospitals (acute care hospitals, psychiatric hospitals, long term care hospitals, children's hospitals, hospital swing beds, transplant centers, cancer hospitals, and rehabilitation hospitals); (6) Long Term Care (LTC) Facilities, generally referred to as nursing homes; (7) Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID); (8) Home Health Agencies (HHAs); (9) Comprehensive Outpatient Rehabilitation Facilities (CORFs); (10) Critical Access Hospitals (CAHs); (11) Clinics,

CoV-2 ("COVID") and to have received at least a first dose of the vaccine prior to December 6, 2021. *See id.* at 61,573. On November 10, 2021, Plaintiffs, the States of Missouri, Nebraska, Arkansas, Kansas, Iowa, Wyoming, Alaska, South Dakota, North Dakota, and New Hampshire (collectively, "Plaintiffs") filed a Complaint challenging the mandate. Doc. [1]. The Complaint seeks preliminary and permanent injunctive and declaratory relief. On November 12, 2021, Plaintiffs filed a motion for a preliminary injunction, Doc. [6], requesting that this Court issue a preliminary injunction enjoining Defendants from imposing the mandate.

Having fully reviewed the administrative record and submitted material, the Court finds that a preliminary injunction is warranted here.

II. DISCUSSION

A. **The Court has jurisdiction.**

Defendants argue that this Court "lacks jurisdiction" over Plaintiffs' claims because "Congress has withdrawn federal-question jurisdiction over claims like this one that arise under the Medicare statute," citing 42 U.S.C. § 405(h), as incorporated by 42 U.S.C. § 1395ii. Doc. [23] at 15–19. The Court does not agree. As Defendants readily concede, "State governments" such as the Plaintiff States are neither "institution[s]" nor "agenc[ies]" "dissatisfied" with the Secretary's determination regarding eligibility or receipt of benefits under 42 U.S.C. § 1395cc(h)(1) and, therefore, "the States[3] themselves could not use that statute's vehicle for judicial review." *Id.* at 19; *see Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 16 (2000) (explaining that § 405(h) does not apply if application "would mean no review at all"). In

rehabilitation agencies, and public health agencies as providers of outpatient physical therapy and speech-language pathology services; (12) Community Mental Health Centers (CMHCs); (13) Home Infusion Therapy (HIT) suppliers; (14) Rural Health Clinics (RHCs)/Federally Qualified Health Centers (FQHCs); and (15) End-Stage Renal Disease (ESRD) Facilities. 86 Fed. Reg. at 61,569–70.

[3] The Plaintiff States bring their claims in a number of capacities: sovereign, quasi-sovereign/*parens patriae*, and proprietary. *See, e.g.*, Doc. [1] ¶¶ 5, 7, 9.

addition, Plaintiffs' claims that arise under the Medicaid Act—as opposed to the Medicare Act—are not subject to the § 405(h)'s jurisdictional bar. *See Avon Nursing & Rehab. v. Becerra*, 995 F.3d 305, 311 (2d Cir. 2021) ("Unlike the Medicare Act, the Medicaid Act does not incorporate the Social Security Act's claim-channeling and jurisdiction-stripping provisions, 42 U.S.C. § 405(g) and (h). Federal courts thus have jurisdiction over claims arising under the Medicaid Act pursuant to 28 U.S.C. § 1331."). Thus, all aspects of the mandate that purport to change a Medicaid regulation are clearly not barred, even under Defendants' arguments. Nonetheless, the Court finds that it has jurisdiction over claims arising under both Medicare and Medicaid.

B. **A preliminary injunction is warranted here.**

Plaintiffs seek a preliminary injunction of the mandate's enforcement pending a full judicial review of the mandate's legality. The Court addresses their request today. Whether a court should issue a preliminary injunction involves consideration of (1) the threat of irreparable harm to the movant; (2) the state of the balance between this harm and the injury that granting the injunction will inflict on other parties litigant; (3) the probability that movant will succeed on the merits; and (4) the public interest. *Dataphase Sys., Inc. v. C L Sys., Inc.*, 640 F.2d 109, 113 (8th Cir. 1981). "While no single factor is determinative, the probability of success factor is the most significant." *Home Instead, Inc. v. Florance*, 721 F.3d 494, 497 (8th Cir. 2013) (internal quotations and citations omitted).

Each of these factors favors a preliminary injunction here.

a. Plaintiffs demonstrate a likelihood of success on the merits.

i. **Congress did not grant CMS authority to mandate the vaccine.**

Plaintiffs are likely to succeed in their argument that Congress has not provided CMS the authority to enact the regulation at issue here. "[A]n agency literally has no power to act, let alone

pre-empt[4] the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 357 (1986). While the Court agrees Congress has authorized the Secretary of Health and Human Services (the "Secretary") *general* authority to enact regulations for the "administration" of Medicare and Medicaid and the "health and safety" of recipients, the nature and breadth of the CMS mandate requires clear authorization from Congress—and Congressed has provided none.[5] *See Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2486 (2021) ("It would be one thing if Congress had specifically authorized the action that the CDC has taken. But that has not happened."). Courts have long required Congress to speak clearly when providing agency authorization if it (1) intends for an agency to exercise powers of vast economic and political significance; (2) if the authority would significantly alter the balance between federal and state power; or (3) if an administrative interpretation of a statute invokes the outer limits of Congress' power. Any one of those fundamental principles would require clear congressional authorization for this mandate, but here, all three are present. Even in exigency, the Secretary cannot "bring about an enormous and

[4] CMS intends for the mandate to preempt any arguably inconsistent state and local laws regarding vaccination. *See, e.g.*, 86 Fed. Reg. at 61,568 ("We intend . . . that this nationwide regulation preempts inconsistent State and local laws applied to Medicare- and Medicaid-certified providers and suppliers.").

[5] The Court notes that Congress has provided the Secretary of Health and Human Services (the "Secretary") authority to enact regulations "necessary to the efficient administration" of the Social Security Act and regulations "necessary to carry out the administration of" of Medicare. 42 U.S.C. §§ 1302(a), 1395hh(a)(1). Among the regulations the Secretary may promulgate under its power of "administration" is the setting of things like "standards," "criteria," or "requirements" for specific facilities. *See, e.g.*, *Id.* at § 1396d(h)(1)(B)(i) (governing Psychiatric Residential Treatment Facilities ("PRTFs") and mentioning "standards as may be prescribed in regulations by the Secretary"); *Id.* at § 1395i–4(e) (governing Critical Access Hospitals ("CAHs") and mentioning "criteria as the Secretary may require"); *Id.* at § 1395rr(b)(1)(A) (governing End-Stage Renal Disease ("ESRD") facilities and mentioning "requirements as the Secretary shall by regulation prescribe"). For some facilities, Congress has authorized the Secretary to set rules or conditions necessary to, or that will ensure, the "health and safety" of recipients of services. *See, e.g., Id.* at § 1395i–3(d)(4)(B) (addressing LTC facilities and mentioning "requirements relating to the health, safety, and well-being of residents . . . as the Secretary may find necessary"); *Id.* at § 1395x(e)(9) (addressing hospitals and mentioning "requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services"). However, the Court need not decide whether those regulations are properly interpreted by CMS to confer it authority to issue the vaccine mandate that it has. Instead, and irrespective of that determination, the Court's inquiry focuses on whether Congress specifically authorized such action, for reasons discussed above.

transformative expansion in [his] regulatory authority without clear congressional authorization." *See Util. Air Reg. Grp. v. EPA*, 573 U.S. 302, 324 (2014).

1. ***Given the vast economic and political significance of this vaccine mandate, only a clear authorization from Congress would empower CMS to act.***

First, Congress must "speak clearly when authorizing an agency to exercise powers of 'vast economic and political significance.'" *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489 (quoting *Util. Air Reg.*, 573 U.S. at 324). The mandate's economic cost is overwhelming. CMS estimates that compliance with the Mandate—just in the first year—is around 1.38 billion dollars. 86 Fed. Reg. at 61,613. Those costs, though, do not take into account the economic significance this mandate has from the effects on facilities closing or limiting services and a significant exodus of employees that choose not to receive a vaccination.[6] Likewise, the political significance of a mandatory coronavirus vaccine is hard to understate, especially when forced by the heavy hand of the federal government. Indeed, it would be difficult to identify many other issues that currently have more political significance at this time. Had Congress wished to assign this question fraught with deep economic and political significance to CMS, "it surely would have done so expressly." *See King v. Burwell*, 576 U.S. 473, 486 (2015). "It is especially unlikely that Congress would have delegated this decision to [CMS], which has no expertise in crafting" vaccine mandates. *Id.*

2. ***Because this mandate significantly alters the balance between federal and state power, only a clear authorization from Congress would empower CMS.***

Second, Congress must use "exceedingly clear language if it wishes to significantly alter the balance between federal and state power." *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489 (quoting

[6] Medicare and Medicaid programs "touch[] the lives of nearly all Americans" and are two of the "largest federal program[s]" in the country. *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). Even "minor changes" to the way those programs are administered "can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate." *Id.* at 1816.

United States Forest Service v. Cowpasture River Preservation Assn., 140 S. Ct. 1837, 1850 (2020)); *see also United States v. Bass*, 404 U.S. 336, 349 (1971). The regulation at issue alters that balance because it requires vaccination, which CMS has never attempted to do, for millions of individuals who would otherwise be outside the reach of the federal government. This concern is "heightened" since CMS's "administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power." *Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Engineers*, 531 U.S. 159, 173 (2001). It has long been the states' power to legislate health—including vaccination. *Gibbons v. Ogden*, 22 U.S. 1, 203 (1824) (noting "health laws of every description" belong to the states); *BST Holdings, L.L.C. v. Occupational Safety & Health Admin.*, 17 F.4th 604, ---, 2021 WL 5279381, at *7 (5th Cir. 2021) (citing *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")). Sometimes "the most telling indication of [a] severe constitutional problem . . . is the lack of historical precedent" for an agency's action. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 549 (2012). With such a history of exclusive state power, the Court is far from certain that Congress intended the *Center for Medicare and Medicaid Services* to require mandatory vaccinations for millions of Americans. *See Bond v. United States*, 572 U.S. 844, 858 (2014) (noting "it is incumbent upon the federal courts to be certain of Congress' intent before finding that federal law overrides the usual constitutional balance of federal and state powers" (internal quotations omitted)).

Truly, the impact of this mandate reaches far beyond COVID.[7] CMS seeks to overtake an area of traditional state authority by imposing an unprecedented demand to federally dictate the

[7] Of course, this situation is novel and messy in that COVID has created a "unique pandemic scenario," 86 Fed. Reg. at 61,568, but equally problematic is that it remains unclear that COVID-19—however tragic and devastating the pandemic has been—poses the kind of grave danger that justifies the federal government trampling on sovereign state

private medical decisions of millions of Americans. Such action challenges traditional notions of federalism, as discussed above. "The independent power of the States [] serves as a check on the power of the Federal Government: by denying any one government complete jurisdiction over all the concerns of public life, federalism protects the liberty of the individual from arbitrary power." *NFIB*, 567 U.S. at 536 (quoting *Bond v. United States*, 564 U.S. 211, 222 (2011)). This is especially true, since "a healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front." *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991).

3. ***In the absence of a clear indication that Congress intended for CMS to invoke such significant authority, the Court will not infer congressional intent.***

Third, "[w]here an administrative interpretation of a statute invokes the outer limits of Congress' power," Congress must provide "a clear indication that [it] intended that result." *Solid Waste*, 531 U.S. at 172. This "requirement" stems from the "prudential desire not to needlessly reach constitutional issues."[8] *Id.* And this requirement is "heightened" here since CMS's claim "alters the federal-state framework by permitting federal encroachment upon a traditional state power." *Id.* Whether Congress itself could impose the vaccination requirement is a tough question, cf. *BST Holdings*, 17 F.4th at ---, 2021 WL 5279381, at *7 (Duncan, J., concurring), one that CMS would force to its crisis. But even if Congress has the power to mandate the vaccine

rights. Regardless, disrupting this balance of power must have been expressly authorized by Congress, and as discussed, Congress has not.

[8] A court—especially a district court—should be reluctant to opine on an unsettled constitutional issue when the court can resolve a case on an alternative ground. *See Xiong v. Lynch*, 836 F.3d 948, 950 (8th Cir. 2016) (quoting *Lyng v. Nw. Indian Cemetery Protective Ass'n*, 485 U.S. 439, 445, 108 (1988)) ("A fundamental and longstanding principle of judicial restraint requires that courts avoid reaching constitutional questions in advance of the necessity of deciding them."). And, at the very least, the Court should "pause to consider the implications of the [State's] arguments" when confronted with such new conceptions of federal power. *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 550 (2012) (quoting *Lopez*,115 S. Ct. at 1624).

and the authority to delegate such a mandate to CMS—topics on which the Court does not opine today—the lack of congressional intent for this monumental policy decision speaks volumes.

In conclusion, even if Congress's statutory language was susceptible to CMS's exceedingly broad reading—which it is most likely not—Congress did not clearly authorize CMS to enact the this politically and economically vast, federalism-altering, and boundary-pushing mandate, which Supreme Court precedent requires.

ii. **CMS improperly bypassed notice and comment requirements.**

Even if CMS has the authority to implement the vaccine mandate—which the Court finds is unlikely, as discussed above—the mandate is likely an unlawful promulgation of regulations. Both the Administrative Procedure Act ("APA") and the Social Security Act ordinarily require notice and a comment period before a rule like this one takes effect.[9] 5 U.S.C. § 553; 42 U.S.C. § 1395hh(b)(1). Failure to allow notice and comment, where required, is grounds for invalidating the rule. *Iowa League of Cities v. EPA*, 711 F.3d 844, 876 (8th Cir. 2013) (vacating a rule based on an administrative agency's failure to abide by the APA's notice and comment procedure). The notice and comment requirements do not apply if "good cause" establishes that they "are impracticable, unnecessary, or contrary to the public interest" under the circumstances. 5 U.S.C. § 553(b)(B). The exception is read narrowly and only used in "rare" circumstances. *Nw. Airlines, Inc. v. Goldschmidt*, 645 F.2d 1309, 1321 (8th Cir. 1981) (noting that the good cause exception should be "narrowly construed and only reluctantly countenanced"); *Nat. Res. Def. Council, Inc. v. EPA*, 683 F.2d 752, 764 (3d Cir. 1982) (noting "circumstances justifying reliance on [the good cause] exception are indeed rare and will be accepted only after the court has examined closely proffered rationales justifying the elimination of public procedures" (internal quotations omitted)).

[9] The parties do not dispute that the notice and comment requirements applied to the mandate. 86 Fed. Reg. at 61,583.

CMS concedes it did not follow these requirements but attempts to justify its omission under the "good cause" exception. 86 Fed. Reg. at 61,583. Here, Plaintiffs are likely to succeed in their argument that CMS unlawfully bypassed the APA's notice and comment requirements.

1. ***CMS's own delay undermines its "emergency" justification for bypassing notice and comment requirements.***

Use of the "good cause" exception is "limited to emergency situations" and is "necessarily fact-or context-dependent." *Thrift Depositors of Am., Inc. v. Off. of Thrift Supervision*, 862 F. Supp. 586, 591 (D.D.C. 1994). Here, CMS's delay in requiring mandatory vaccination undermines its contention that COVID is an emergency such that it has the "good cause" necessary to dispense with notice and comment requirements. In justifying the good cause exception, CMS stated that "[t]he data showing the vital importance of vaccination" indicates that it "cannot delay taking this action" to protect peoples' health and safety. 86 Fed. Reg. at 61,583. Yet, CMS's good cause claim is undermined by its *own* delay in promulgating the mandate. *See United States v. Brewer*, 766 F.3d 884, 890 (8th Cir. 2014) ("[C]oncern for public safety further is undermined by [the Attorney General's] own seven-month delay in promulgating the Interim Rule."); *Chamber of Com. v. United States Dep't of Homeland Sec.*, 504 F. Supp. 3d 1077, 1089 (N.D. Cal. 2020) (finding an agency's six-month delay in promulgating rules relating to COVID precluded presumption of urgency); *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 115 (2nd Cir. 2018) ("Good cause cannot arise as a result of the agency's own delay, because otherwise, an agency unwilling to provide notice or an opportunity to comment could simply wait until the eve of a statutory, judicial, or administrative deadline, then raise up the 'good cause' banner and promulgate rules without following APA procedures." (internal quotations and

alterations omitted)). The CMS mandate was announced nearly two months[10] before the agency released it, and the mandate itself prominently features yet another one-month delay. Moreover, two vaccines were authorized under Emergency Use Authorization ("EUA")[11] more than ten months before the CMS mandate took effect, and one vaccine was fully licensed by the FDA well over two months before.[12] It is also worth mentioning that since the onset of COVID, CMS has issued five IFC mandates, such as the one here; the most recent on May 13, 2021. 86 Fed. Reg. at 61,561. One could query how an "emergency" could prompt such a slow response; such delay hardly suggests a situation so dire that CMS may dispense with notice and comment requirements[13] and the important purposes they serve.

The COVID pandemic is an event beyond CMS's control, yet it was completely within its control to act earlier than it did. *See* 86 Fed. Reg. at 61,583 ("CMS initially chose, among other actions, to encourage rather than mandate vaccination[.]"); *see id.* (explaining CMS had authority to impose vaccination requirements even when the only vaccines available were those authorized under EUAs in December 2020). The mere desire or need to have the mandate does not suffice for good cause. *Nat'l Ass'n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604, 621 (D.C. Cir. 1980) ("[G]ood cause to suspend notice and comment must be supported by more than the bare need to have regulations."); *United States v. Cain*, 583 F.3d 408, 421 (6th Cir. 2009) ("A desire to provide

[10] On September 9, 2021, the President announced his intention to promulgate federal vaccinate mandates, including the CMS vaccine mandate challenged here.

[11] The FDA issued vaccines under Emergency Use Authorization ("EUA") for two COVID vaccines on December 11, 2020 and December 18, 2020. According to CMS, the agency *could have* imposed a vaccine requirement, even when the only vaccines available are those authorized under EUAs. *See* 86 Fed. Reg. at 61,583.

[12] On August 23, 2021, the FDA licensed the first COVID vaccine.

[13] The Court also takes note that CMS reviewed several communications from stakeholders in *favor* of the mandate. Thus, CMS apparently found it quite possible to consult with the interested parties it selected. *See, e.g.*, 86 Fed. Reg. at 61,565.

immediate guidance, without more, does not suffice for good cause."). And good cause is not automatically created based on an agency's conclusion that bypassing the notice and comment requirements is necessary to protect public safety.[14] *See Brewer*, 766 F.3d at 889 (finding agency's stated reason of "protecting the public safety" was insufficient to waive notice and comment requirement); *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014) ("To accord deference to an agency's invocation of good cause would be to run afoul of congressional intent."). COVID cannot be a compelling justification forever, *Does 1-3 v. Mills*, --- S. Ct. ---, 2021 WL 5027177, at *3 (U.S. Oct. 29, 2021) (Gorsuch, J., dissenting), and CMS's evidence shows COVID no longer poses the dire emergency it once did. *See, e.g.*, 86 Fed. Reg. at 61,583 (noting "newly reported COVID-19 cases, hospitalizations, and deaths have begun to trend downward at a national level"). Notably, today, there are three widely distributed vaccines. Additionally, there are several therapeutics and treatments, and as CMS states, more are on the horizon. *See, e.g.*, *id.* at 61,609. Thus, CMS's purported "emergency"[15]—one that the entire globe has now endured for nearly two years, and to which CMS itself demonstrated ease in responding to—is unavailing. *United States v. Reynolds*, 710 F.3d 498, 512–13 (3rd Cir. 2013) ("Most, if not all, laws passed . . . are designed to eliminate some real or perceived harm. If the mere assertion that such harm will continue while

[14] Other circuits, like the Eighth, have held that protecting the public, without more, is insufficient to waive procedural requirements. *United States v. Reynolds*, 710 F.3d 498, 509 (3rd Cir. 2013); *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011); *United States v. Valverde*, 628 F.3d 1159, 1168 (9th Cir. 2010); *United States v. Cain*, 583 F.3d 408, 421–24 (6th Cir. 2009).

[15] CMS also asserted that there is an "emergency" *now* (such that CMS must immediately implement the mandate) because "the 2021–2022 influenza season" will soon begin. 86 Fed. Reg. at 61,584. CMS offered this justification while simultaneously admitting that "the intensity of the upcoming 2021-2022 influenza season cannot be predicted" and that "influenza activity during the 2020-2021 season was low throughout the U.S." *Id.* For a "risk of future harm" to "justify a finding of good cause," the "risk must be more substantial than a mere possibility." *Brewer*, 766 F.3d at 890. Thus, CMS did not find a concrete "threat" to remedy but rather speculated as to a mere possibility of harm, and there is a "difference between addressing present legal uncertainty and addressing the possibility of future legal uncertainty." *Id.* Notably, CMS did not mandate flu vaccines, despite mentioning that the flu has been daunting the healthcare system, that recent studies show approximately half of healthcare workers refuse the flu vaccine, *id.* at 61,568, and that CMS has evidence that influenza vaccination of health care staff is directly associated with declines in nosocomial influenza in hospitalized patients and nursing home residents. *Id.* at 61,557.

an agency gives notice and receives comments were enough to establish good cause, then notice and comment would always have to give way.").

2. ***CMS failed to meet its "good cause" burden, especially in light of the unprecedented, controversial, and health-related nature of the mandate.***

CMS also failed to meet its burden based on the unprecedented, controversial, and health-related nature of the mandate. *Alcaraz v. Block*, 746 F.2d 593, 612 (9th Cir. 1984) (holding that the inquiry into an agency invoking "good cause proceeds case-by-case, sensitive to the totality of the factors at play"). CMS had the burden "to establish that notice and comment need not be provided." *Nat. Res. Def. Council*, 894 F.3d at 113–14. In a situation like here, where there is significant and known opposition to the mandate, "good cause" is even more important than usual. *See, e.g.*, *Asbestos Information Ass'n of N. Am. v. Occupational Safety & Health Admin.*, 727 F.2d 415, 426 (5th Cir. 1984) (explaining that rules "may be more uncritically accepted after public scrutiny, through notice-and-comment rulemaking, especially when the conclusions it suggests are controversial"). The fact that this mandate effects issues relating to health[16] increases the importance even further. *See Nat'l Ass'n of Farmworkers*, 628 F.2d at 621 ("Especially in the context of health risks, notice and comment procedures assure the dialogue necessary to the creation of reasonable rules."); *Cmty. Nutrition Inst. v. Butz*, 420 F. Supp. 751, 754 (D.D.C. 1976) (noting that "when a health-related standard such as this is involved, the good cause exemption may not be used to circumvent the legal requirements designed to protect the public"). Accordingly, CMS's argument that undertaking normal notice and comment requirements would be "contrary to the public interest" based on delaying the mandate, *id.* at 61,586, is unavailing in light of the circumstances. *Alcaraz*, 746 F.2d at 612. Rather, these requirements "serve the public

[16] CMS acknowledges that "[s]erious adverse reactions [] have been reported following COVID-19 vaccines." 86 Fed. Reg. at 61,565.

interest by providing a forum for the robust debate of competing and frequently complicated policy considerations having far-reaching implications and, in so doing, foster reasoned decision making." *Id.* They are far from "mere formalities." *Id.*

Moreover, the failure to take and respond to comments feeds into the very vaccine hesitancy CMS acknowledges is so daunting. 86 Fed. Reg. at 61,559, 61,568. Besides fostering reasoned decision making, notice and comment "provide a 'surrogate political process' that takes some of the sting out of the inherently undemocratic and unaccountable rulemaking process." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1929 n.13 (Thomas, J., dissenting). Requiring already hesitant individuals to get the vaccine—without giving them an opportunity to be heard—undermines the democratic process that the APA's procedural safeguards are intended to protect and exacerbates the underlying hesitancy problem. *Batterton v. Marshall*, 648 F.2d 694, 703 (D.C. Cir. 1980) (according notice and comment great importance because it "reintroduce[s] public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies"). Far from being "good cause" for circumventing the normal rulemaking requirements, the unprecedented and controversial mandate affecting personal health constitutes a compelling reason to utilize those procedures, and CMS failed to provide the good cause necessary to overcome these factors.

In conclusion, because CMS's "emergency" does not justify use of the "good cause" exception, see *Thrift*, 862 F. Supp. at 591, and the unprecedented, controversial, and health-related mandate requires more good cause than CMS provided, *Alcaraz*, 746 F.2d at 612, Plaintiffs are likely to succeed in establishing that CMS improperly invoked the 5 U.S.C. § 553(b)(B) "good cause" exception.

iii. **The mandate is arbitrary and capricious.**

Finally, Plaintiffs are likely to succeed in establishing that the CMS vaccine mandate is arbitrary or capricious. Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary" or "capricious." 5 U.S.C. § 706(2)(A). The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained. *Fed. Commc'ns Comm'n v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021) ("A court simply ensures that the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision."). Under this "narrow" and deferential standard of review, a court may not substitute its own policy judgment for that of the agency. *Id.* Rather, the court must ensure there is a "rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

1. ***The mandate is arbitrary and capricious because the record is devoid of evidence regarding the covered healthcare facilities.***

CMS lacks evidence showing that vaccination status has a direct impact on spreading COVID in the mandate's covered healthcare facilities. CMS acknowledges its lack of "comprehensive data" on this matter but attempts to "extrapolate" the abundant data that it does have on Long Term Care Facilities ("LTCs"), generally referred to as nursing homes, to the other dozen-plus Medicare and Medicaid facilities covered by the mandate. 86 Fed. Reg. at 61,585. However, CMS's path of analysis appears misguided and the inferences it produced are questionable. *State Farm*, 463 U.S. at 43 (finding that in an arbitrary and capricious challenge, the court will "uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned"). As CMS's own record shows, COVID disproportionally devastates LTC facilities.

Residents of LTC facilities—who make up less than 1-percent of the U.S. population—accounted for more than 35-percent of all COVID deaths during the first twelve months of the pandemic. 86 Fed. Reg. at 61,566. Equally staggering is that "[o]f the approximately 656,000 Americans estimated to have died from COVID through September 10, 2021, 30-percent are estimated to have died during or after an LTC facility stay." *Id.* at 61,601. Thus, CMS's decision to extrapolate LTC data to justify its lack of data regarding the other fourteen facilities covered is likely not reasonable. *Michigan v. EPA*, 576 U.S. 743, 750 (2015) (requiring agencies to engage in "reasoned decision making"); *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 220 (2016) ("[A]n agency must give adequate reasons for its decisions."). While a wide-sweeping mandate might make sense in the context of LTCs, based on CMS's evidence, CMS presents no similar evidence for imposing a broad-sweeping mandate on the other fourteen covered facilities. *Camp v. Pitts*, 411 U.S. 138, 143 (1973) ("If [a] finding is not sustainable on the administrative record made, then the [agency's] decision must be vacated[.]"). Although the Court appreciates its deferential review, the Court's duty is not to "rubber-stamp" administrative decisions devoid of reasonableness. *Alaska Oil and Gas Ass'n v. Jewell*, 815 F.3d 544 (9th Cir. 2016) ("A court must not substitute its judgment for that of the agency, but also must not "rubber-stamp" administrative decisions.").

In general, the overwhelming lack of evidence likely shows CMS had insufficient evidence to mandate vaccination on the wide range of facilities that it did. Looking even beyond the evidence deficiencies relating to the specific facilities covered, the lack of data regarding vaccination status and transmissibility—in general—is concerning. Indeed, CMS states that "the effectiveness of the vaccine[s] to prevent disease transmission by those vaccinated [is] not

currently known."[17] 86 Fed. Reg. at 61,615.[18] CMS also admits that the continued efficacy of the vaccine is uncertain. *See, e.g., id.* at 61,612 ("[M]ajor uncertainties remain as to the future course of the pandemic, including but not limited to vaccine effectiveness in preventing 'breakthrough' disease transmission from those vaccinated, [and] the long-term effectiveness of vaccination[.]"). No one questions that protecting patients and healthcare workers from contracting COVID is a laudable objective. But the Court cannot, in good faith, allow CMS to enact an unprecedented mandate that lacks a "rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43; *see also Sierra Club v. Mainella*, 459 F. Supp. 2d 76, 90 (D.D.C. 2006) ("Under the APA . . . the function of the district court is to determine whether or not as a matter of law the evidence in the administrative record permitted the agency to make the decision it did."). The reasoned explanation and evidentiary requirement "of administrative law, after all, is meant to ensure that agencies offer genuine justifications for important decisions, reasons that can be scrutinized by courts and the interested public." *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2575 (2019). If judicial review is to be more than an "empty ritual," the Court here must demand something more than the explanation offered for the action taken by CMS here. *Id*.

2. ***The mandate is arbitrary and capricious because CMS improperly rejected alternatives to the mandate.***

CMS failed to consider or rejected obvious alternatives to a vaccine mandate without evidence. For example, CMS rejected daily or weekly testing—an option that even OSHA approved in its ETS—without citing any evidence for such a conclusion. 86 Fed. Reg. at 61,614.

[17] "As explained in various places within this RIA and the preamble as a whole, there are major uncertainties as to the effects of current variants of SARS-CoV-2 on future infection rates, medical costs, and prevention of major illness or mortality. For example, the duration of vaccine effectiveness in preventing COVID-19, reducing disease severity, reducing the risk of death, and the effectiveness of the vaccine to prevent disease transmission by those vaccinated are not currently known." 86 Fed. Reg. at 61,615.

[18] Also, CMS has no data showing forced vaccinations in the healthcare industry has stopped the spread of COVID in hospitals.

Rather, it assured that it "reviewed scientific evidence on testing" but "found that vaccination is a more effective infection control measure." *Id.* at 61,614. As discussed elsewhere, this conclusion comes despite its admission that it lacks solid evidence[19] regarding transmissibility of COVID by the vaccinated. *Id.* at 61,615, 61,612. Although it is not the Courts duty to ask whether CMS's decision was "the best one possible" or even whether there were "better [] alternatives," *Federal Energy Regulatory Commission v. Electric Power Supply Ass'n*, 136 S. Ct. 760, 782 (2016), the Court must ensure there exists a "rational connection between the facts found and the choice made." *State Farm*, 463 U.S. at 43.

As another example, CMS rejected[20] mandate alternatives in those with natural immunity by a previous coronavirus infection. 86 Fed. Reg. at 61,614 (noting "many uncertainties" about the immunity in those previously infected "compared to people who are vaccinated"). But, elsewhere, it plainly contradicts itself regarding the value of natural immunity. *Id.* at 61,604 ("[A]bout 100,000 a day have recovered from infection . . . . These changes reduce the risk to both health care staff and patients substantially, likely by about 20 million persons a month *who are no longer sources of future infections*.") (emphasis added). Such contradictions are tell-tale signs of unlawful agency actions. *See State Farm*, 463 U.S. at 43 (finding agency action arbitrary and capricious if the agency explained its decision in a way that "runs counter to the evidence before the agency"); *see also Bethesda Health, Inc. v. Azar*, 389 F. Supp. 3d 32, 41 (D.D.C. 2019) (setting aside as arbitrary and capricious agency action that contradicts its own regulations).

[19] Far from being reasonable to prohibit alternatives to vaccination, this constitutes a compelling reason to utilize, rather than reject, other alternatives before subjecting the public to a never-before CMS vaccine mandate.

[20] CMS also rejected natural immunity, despite an intense public debate and a trove of scientific data on the strength and durability of natural immunity from COVID-19—alone and compared to vaccine-induced immunity. *State Farm*, 463 U.S. at 43 (noting "the agency must examine the relevant data").

3. ***The mandate is arbitrary and capricious because of its broad scope.***

The broad scope of healthcare facilities covered by the mandate renders it arbitrary. The mandate applies equally to the varying healthcare facility types it covers, such as Psychiatric Residential Treatment Facilities ("PRTFs") for individuals under age twenty-one, *see* 86 Fed. Reg. at 61,576, and LTCs, *see id.* at 61,575. But, at the same time, CMS acknowledges that the risk of COVID to those in the former age group is markedly smaller. *See, e.g.*, *id.* at 61,610 n.247 (recognizing that "risk of death from infection from an unvaccinated 75-to 84-year-old person is 320 times more likely than the risk for an 18- to 29-years old person"); *id.* at 61,601 ("Among those infected, the death rate for older adults age 65 or higher was hundreds of time higher than for those in their 20s during 2020."); *id.* at 61,566 (noting those aged 65 years and older account for more than 80-percent of U.S. COVID-19 related deaths). What is more, besides applying to all facilities equally, the mandate applies to all facilities' staff equally, "*regardless of . . . patient contact*." *Id.* at 61,570 (emphasis added). The mandate goes so far as to cover a third-party vendor's "crew working on a construction project" whose members use the same bathrooms "during their breaks." *Id.* at 61,571. CMS provides no reasoned[21] explanation for this overbroad approach, and it further belies its asserted interest in protecting patients from COVID.[22] *Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1021 (D.C. Cir. 1999) ("Where the agency has failed to provide a reasoned explanation, or where the record belies the agency's conclusion, [the court] must undo its action.").

[21] As explained in *infra* note 24, upping vaccination nation-wide is not a "reasonable" reason for CMS to enact its mandate because the agency's powers are limited to Medicare and Medicare—not federalizing healthcare and reaching the general public. Rather, the overbroad approach indicates the pretextual nature of this mandate.

[22] The Court also notes that recently, on November 12, 2021, CMS itself revised its pandemic guidance for nursing home visitation, specifically opening facility visitation *"for all residents at all times" by family and friends who are not required to be vaccinated*. This also belies CMS's asserted interest in protecting patients from COVID, and instead, shows that the mandate's overbreadth is to increase the national vaccination rate by any means necessary.

4. ***The mandate is arbitrary and capricious due to CMS's sudden change in course.***

CMS failed to adequately explain its contradiction to its long-standing practice of encouraging rather than forcing—by governmental mandate—vaccination. For years, CMS has promulgated regulations setting the conditions for Medicare and Medicaid participation; *never* has it required any vaccine for covered facilities' employees—despite concerns over other illnesses and their corresponding low vaccination rates.[23] As recent as this May, CMS adopted an IFC requiring education on COVID vaccines but again decided against forced vaccination.

It is generally "arbitrary or capricious" to depart from a prior policy *sub silentio*; when agencies contradict a prior policy, they must show "good reasons for the new policy." *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *accord EPA v. EME Homer City Generation, L.P.*, 572 U.S. 489, 510 (2014) (holding that agency "retained discretion to alter its course [under a regulation] provided it gave a reasonable explanation for doing so"). Here, CMS's purported reason for changing its policy is to force those unwilling or hesitant to receive the vaccine into receiving it, all under the guise of protecting recipients of Medicare and Medicaid. *See* 86 Fed. Reg. at 61,583 (noting "CMS initially chose . . . to encourage rather than mandate vaccination" but "vaccine uptake among health care staff [was not] as robust as hoped for"); *id.* at 61,569 (noting that despite healthcare worker hesitation about the vaccine, "mandates have already been successfully initiated in a variety of health care settings, systems, and states"); *id.* at 61,560 (noting it was "compelled to require staff vaccinations for COVID-19" given its "responsibility to protect the health and safety of individuals . . . receiving care and services from for Medicare- and

[23] In the Mandate, CMS discusses how influenza is a major problem plaguing the healthcare industry. Nonetheless, CMS states that half of healthcare workers resist the seasonal influenza vaccine nationwide, 86 Fed. Reg. at 61,568, but that it continues to "recommend" influenza vaccination rather than mandate it. *Id.* Even though CMS has evidence that influenza vaccination of health care staff is associated with declines in nosocomial influenza in hospitalized patients and nursing home residents. *Id.* at 61,557.

Medicaid-certified providers and suppliers"). But even if forcing the administration of a specific vaccine, into the otherwise unwilling, in an effort to protect the recipients of these programs could be a reasonable explanation to justify the extraordinary action—action that long has been the province of the states, see *Zucht*, 260 U.S. at 176 (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)—CMS has not shown that it is reasonable in this instance.[24] Rather, it specifically notes that the vaccines' effectiveness to prevent disease transmission by those vaccinated is not currently known. 86 Fed. Reg. at 61,615 (noting "the duration of vaccine effectiveness in preventing COVID-19, reducing disease severity, reducing the risk of death, and the effectiveness of the vaccine to prevent disease transmission by those vaccinated are not currently known").

5. ***The mandate is arbitrary and capricious because CMS failed to consider or properly weigh necessary reliance interests.***

Because CMS changed course, it was required to "be cognizant that longstanding policies may have 'engendered serious reliance interests that must be taken into account.'" *Fox Television,*

[24] The inadequacy of the explanation for the reversal is especially true since Plaintiffs will likely succeed in demonstrating it is a pretextual rationale. *See Dep't of Com. v. New York*, 139 S. Ct. 2551, 2575–76 (2019); *id.* at 2583 (Thomas, J., concurring in part and dissenting in part) (noting Court "opened a Pandora's box of pretext-based challenges in administrative law"); *id.* at 2597 (Alito, J., concurring in part and dissenting in part). While a court may not set aside an agency's policymaking decision "solely because it might have been influenced by political considerations or prompted by an Administration's priorities," *Department of Commerce*, 139 S. Ct. at 2573, an agency's change in course "cannot be solely a matter of political winds and currents." *North Carolina Growers' Association, Inc. v. United Farm Workers*, 702 F.3d 755, 772 (4th Cir. 2012) (Wilkinson, J., concurring). Plaintiffs have demonstrated that they could likely show pretext. *See, e.g.*, Doc. [9] at 4 (citing Joseph Biden, Remarks at the White House (Sept. 9, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ (decrying "nearly 80 million Americans who have failed to get the shot" while announcing "a new plan to require more Americans to be vaccinated" and explaining that "[i]f you're seeking care at a health facility, you should be able to know that the people treating you are vaccinated. Simple. Straightforward. Period."); *see also* 86 Fed. Reg. at 61,601 ("the protective scope of this rule is far broader than the health care staff that it directly affects"); *see also id.* at 61,612 ("Staff vaccination will also provide significant community benefits when staff are not at work."). The Court "cannot ignore the disconnect between the decision made and the explanation given." *Dep't of Com.*, 139 S. Ct. at 2575.

556 U.S. at 515. Ignoring reliance interests is necessarily arbitrary and capricious. *Id.* Yet, it appears this is what CMS did. An agency is required to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns. *Regents*, 140 S. Ct. at 1915.

In concluding that the mandate's benefits outweigh the risks to the healthcare industry, CMS did not properly consider *all* necessary reliance interests of facilities, healthcare workers, and patients. 86 Fed. Reg. at 61,607–10. CMS looked only at evidence from interested parties in favor of the mandate, while completely ignoring evidence from interested parties in opposition. *Consumers Union of U. S., Inc. v. Consumer Prod. Safety Comm'n*, 491 F.2d 810, 812 (2d Cir. 1974) (noting agency "must not ignore evidence placed before it by interested parties"). In fact, CMS foreclosed these parties' ability to provide information regarding the mandate's effects on the healthcare industry, while simultaneously dismissing those concerns based on "insufficient evidence." 86 Fed. Reg. at 61,569. But facts do not cease to exist simply because they are ignored, and "[s]tating that a factor was considered[25] is not a substitute for considering it." *Texas v. Biden*, 10 F.4th 538, 556 (5th Cir. 2021) (internal quotations and alterations omitted); *Sierra Club*, 459 F. Supp. 2d at 100 ("Merely describing an impact and stating a conclusion of non-impairment is insufficient[.]"); *Gresham v. Azar*, 363 F. Supp. 3d 165, 177 (D.D.C. 2019) ("The bottom line: the Secretary did no more than acknowledge—in a conclusory manner, no less—that commenters forecast a loss in Medicaid coverage."). Had CMS followed the proper procedural requirements,

[25] Several times throughout the mandate, CMS acknowledges the countervailing effect it will have on the healthcare industry. *See, e.g.*, 86 Fed. Reg. at 61,607 ("currently there are endemic staff shortages for almost all categories of employees at almost all kinds of health care providers and supplier and these may be made worse if any substantial number of unvaccinated employees leave health care employment altogether"); *id.* at 61,567 ("and the urgent need to address COVID-related staffing shortages that are disrupting patient access to care, provides strong justification as to the need to issue this IFC requiring staff vaccination for most provider and supplier types over which we have authority."). Yet, despite these acknowledged concerns about intensifying an already-existing healthcare crisis, CMS decided to move forward anyway, without properly considering the totality of interests affected by the mandate, such as rural hospitals.

States, healthcare providers, and healthcare workers would have submitted critical information to CMS—instead of to the Courts[26]—showing that the mandate portends a disaster for the healthcare industry, particularly in rural communities. *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816, (2019) (requiring HHS to undertake notice-and-comment rulemaking, in part, because it "neglected to acknowledge the potential countervailing benefits"); *Time Warner Cable Inc. v. FCC*, 729 F.3d 137, 168 (2nd Cir. 2013) (explaining APA policies are "to ensure the agency has all pertinent information before it when making a decision"). By dispensing with those requirements, CMS ignored evidence showing that the mandate threatens devastating consequences to healthcare providers, staff, and patients throughout the nation.

Even if CMS did properly consider these reliance issues—which this Court finds it most likely did not—the scant evidence of record shows CMS was unable to adequately balance these reliance interests because it placed a rock on one side of the scale and a feather on the other. *Regents*, 140 S. Ct. at 1914 (failing to weigh reliance interests against competing policy concerns is arbitrary and capricious). And as already explained, these evidence deficiencies are solely a product of its own doing. So, either CMS entirely failed to consider an important aspect of the problem or failed to weigh the interests properly; regardless, either way the pendulum swings, CMS's actions, or rather, inaction, violates basic tenants of administrative law. *Id.*; *State Farm*, 463 U.S. at 43 (noting that "entirely fail[ing] to consider an important aspect of the problem" is

[26] It is not the job of this Court to collect evidence and opposition from affected parties; rather, this is the role, actually a duty, of CMS when promulgating a rule. *See District of Colombia v. United States Dep't of Agriculture*, 496 F. Supp. 3d 213, 228 (D.D.C. 2020) (emphasizing that one purpose of notice and comment rulemaking is to "give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review"); *Hoctor v. U.S. Dept. of Agriculture*, 82 F.3d 165, 167 (7th Cir. 1996) ("Notice and comment rulemaking . . . facilitates the marshaling of opposition to a proposed rule, and may result in the creation of a very long record that may in turn provide a basis for a judicial challenge to the rule if the agency decides to promulgate it.").

arbitrary and capricious); *Michigan*, 576 U.S. at 750–52 (noting "agency action is lawful only if it rests on a consideration of the relevant factors" and "important aspects of the problem").

In conclusion, Plaintiffs likely can show the CMS mandate is arbitrary and capricious because the evidence does not show a rational connection to support implementing the vaccine mandate, the mandate's broad scope, the unreasonable rejection of alternatives to vaccination, CMS's inadequate explanation for its change in course, and its failure to consider or properly weigh reliance interests.

Accordingly, Plaintiffs' challenges to the mandate show a great likelihood of success on the merits, and this fact weighs critically in favor of a preliminary injunction. *Home Instead*, 721 F.3d at 497 ("While no single factor is determinative, the probability of success factor is the most significant." (internal quotations and citations omitted)).

b. ***Plaintiffs demonstrate irreparable harm.***

The Court must next determine whether Plaintiffs have shown that they are "likely to suffer irreparable harm in the absence of preliminary relief." *Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)). Plaintiffs must show more than a mere "possibility," but they need not show a certainty; rather, they need to demonstrate "irreparable injury is *likely* in the absence of an injunction." *Winter*, 555 U.S. at 22. Plaintiffs have done so here.

The Plaintiff States bring their claims in a number of capacities: sovereign, quasi-sovereign/*parens patriae*, and proprietary. *See, e.g.*, Doc. [1] ¶¶ 5, 7, 9. Through their various interests, they have shown irreparable injury is more than likely in the absence of an injunction.

First, Plaintiffs sovereign interests[27] are likely to suffer irreparable harm without a preliminary injunction because they will be unable to enforce their duly enacted laws surrounding vaccination mandates and providing proof of vaccination. *See, e.g.*, Mo. Rev. Stat § 67.265; 2021 Alaska Sess. Laws ch. 2, § 17; Ark. Code § 20-7-143; *see also, e.g.*, Ark. Code § 11-5-118. The mandate notes that it "preempts inconsistent State and local laws as applied to Medicare- and Medicaid-certified providers and suppliers." 86 Fed. Reg. at 61,568. Generally, this preemption would be unremarkable. *See* U.S. Const. art. VI, § 2. But, as here, where CMS likely did not lawfully enact its mandate, Plaintiffs are harmed because they cannot enforce their duly enacted laws and no lawfully enacted regulation preempts them. The injury that results when a state cannot enforce "statutes enacted by representatives of its people" is irreparable. *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (quoting *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977) (Rehnquist, J., in chambers)); *accord Org. for Black Struggle v. Ashcroft*, 978 F.3d 603, 609 (8th Cir. 2020) ("Prohibiting the State from enforcing a statute properly passed . . . would irreparably harm the State.").

Second, Plaintiffs quasi-sovereign interests are likely to suffer irreparable harm without a preliminary injunction. Unlike the harm Plaintiffs likely would face to their sovereign interests—which though significant, is more abstract—the harm Plaintiffs likely would face to their quasi-sovereign interests would be observable and appreciable. Indeed, the likely harm would be *harm* in the colloquial sense—pain, suffering, distress. Plaintiffs have a quasi-sovereign interest "in the health and well-being—both physical and economic—of [their] residents, *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 607 (1982), and Plaintiffs have put forth evidence that this mandate would have a detrimental effect on the health and well-bring of their citizens.

[27] The States also have an interest in seeing their constitutionally reserved police power over public health policy defended from federal overreach, as discussed in depth in section II.B.a.i.2.

Review of the affidavits filed in support of Plaintiffs' motion for preliminary injunction shows the harm to the physical health and well-being of their states' citizens if the mandate is not enjoined. The Plaintiffs' affidavits came from varying healthcare entities and associations in their states impacted by the mandate. The affiants describe existing and significant staffing shortages as well as open and unfilled positions for an extended period of time, some for more than a year. *See, e.g.*, Doc. [9-7] at 3; Doc. [9-11] at 3; Doc. [9-25] at 3; Doc. [9-3] at 4. The affidavits also demonstrate that the mandate will more than likely exacerbate the already-existing staffing problem. Many of the affidavits generally describe the number of individuals employed by the entity and the number or percentage of employees either known or reasonably known to have not been vaccinated.[28] *See, e.g.*, Doc. [9-4] at 3, 4; Doc. [9-3] at 4. Through talks, surveys, and direct conversations with staff, the affiants know the individuals that will leave employment if CMS goes ahead with its mandate. *See, e.g.*, Doc. [9-4] at 3; Doc. [9-5] at 3; Doc. [9-13] at 4; Doc. [9-19] at 3; Doc. [9-20] at 3. Already, in some cases, the mere announcement of CMS's mandate has compelled some to resign. *See, e.g.*, Doc. [9-26] at 2.

Staff reductions due to implementing the mandate, especially in light of the already understaffed healthcare facilities, will cause a cascade of consequences. *See, e.g.*, Doc. [9-16] at 3–6. The mandate's effect of reducing staff will decrease the quality of care provided at facilities, compromise the safety of patients, and place even more stress on the remaining staff. *See, e.g.*, Doc. [9-11] at 4. The mandate "creates a risk in patient safety" and will create "ongoing ripple effects on . . . patients, remaining employees and [the] community for some time in the future." Doc. [9-18] at 5. An affiant noted that "even if we can technically staff services with extra shift and call, we are already doing that, have been doing that for more than a year, and our vaccinated

[28] CMS itself notes that rural hospitals are less vaccinated than urban. 86 Fed. Reg. at 61,613 (recognizing that "rural hospitals are having greater problems with employee vaccination . . . than urban hospitals").

staff will not be capable of doing it for much longer. At this point, considering it is nearly impossible to recruit clinical staff today, more will resign due to the stress and burnout that will inevitably exist." Doc. [9-23] at 5.

The loss of certain staffing categories will diminish entire areas of care within a facility that inevitably implicate others. *See, e.g.*, Doc. [9-19] at 3 (warning of the loss of the only remaining anesthesiologist); Doc. [9-21] at 3 (warning of the loss of 80% of imaging department); Doc. [9-14] at 3; Doc. [9-18] at 4; Doc. [9-25] at 4. Facilities in rural locations, already hard-pressed to find qualified applicants regardless of vaccination status, will have to evaluate what healthcare services they could still safely provide, if any at all, in the region they serve. *See, e.g.*, Doc. [9-4] at 4; Doc. [9-7] at 3–4; Doc. [9-9] at 2–5; Doc. [9-12] at 4; Doc. [9-13] at 4; Doc. [9-19] at 3; Doc. [9-23] at 4. As an example, for a general hospital located in North Platte, Nebraska, implementation of the mandate would result in the loss of the *only* remaining anesthesiologist. Doc. [9-19] at 3. Understandably, without an anesthesiologist, there could be no surgeries—at all. Thus, such a loss irreparably causes a cascading effect on the entire facility and a wide-range of patients. Other examples show the mandate's far-reaching implications not just on the administration of healthcare itself, but the functioning of the facilities in general. For example, the building manager of a nursing home in Memphis, Missouri states he will leave if the choice is between his job or the vaccine. Doc. [9-9] at 3–4. If the mandate takes effect, then, the nursing home would have "no one competent enough to run [the] building and [perform] all the complicated systems and required inspections." *Id.* Also, this type of position is not the kind that can be filled "quickly, especially with today's workforce and being in a rural setting." *Id.* Other affidavits also detail an especially hard impact to emergency services in rural areas. *See, e.g.*, Doc. [9-21] at 2–3 ("If we lose our imaging department we will have to divert many of our emergency

patients to other facilities; the closest one is 45 miles away."); Doc. [9-11] at 4 (explaining that in the event this hospital closes, the nearest one would be thirty miles away); Doc. [9-12] at 2–3 (similar); Doc. [9-16] at 6 (similar).

Further, the loss of staffing in many instances will result in *no care at all*, as some facilities will be forced to close altogether. For example, the Administrator of the Scotland County Care Center (SCCC), a nursing home located in Memphis, Missouri, notes that out of about sixty-five employees, twenty have indicated that they are opposed to taking the vaccine, and if the mandate is imposed, that they will quit.[29] Doc. [9-9] at 2. A loss of twenty staff members will cause SCCC to "close its doors" and displace residents that have lived in that community their entire lives. *Id.* at 5; *see also* Doc. [9-26] at 4. Thus, if the mandate goes into effect, it will irreparably harm patients[30] by impeding access to care for the elderly and for persons who cannot afford it—directly contrary to Medicare and Medicaid's core objective of providing proper care. In sum, Plaintiffs' evidence shows that facilities—rural facilities in particular—likely would face crisis standards of care or will have no choice but to close to new patients or close altogether, both of which would cause significant, and irreparable, harm to Plaintiffs' citizens. *Kai v. Ross*, 336 F.3d 650, 656 (8th Cir. 2003) (finding "danger to plaintiffs' health, and perhaps even their lives, gives them a strong argument of irreparable injury").[31]

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[29] This includes SCCC's billing and accounting staff members, which would create a "substantial disruption" in SCCC's business functions, as well as their building plant manager, "that would leave me with no one competent enough to run my building and all the complicated systems and required inspections." *Id.* at 4.

[30] Medicare and Medicaid programs "touch[] the lives of nearly all Americans" and are two of the "largest federal program[s]" in the country. *See Allina Health Servs.*, 139 S. Ct. at 1808.

[31] "No right is held more sacred, or is more carefully guarded . . . than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *Union Pacific R. Co. v. Botsford*, 141 U.S. 250, 251 (1891). As already explained, CMS most likely does not have the authority to promulgate the mandate, and clear congressional authorization is also lacking. "Irreparable harm occurs when a party has no adequate remedy at law, typically because its injuries cannot be fully compensated through an award of damages.'" *Rogers Group, Inc. v. City of Fayetteville, Ark.*, 629 F.3d 784, 789 (8th Cir. 2010) (quoting *Gen. Motors Corp. v. Harry Brown's, L.L.C.*, 563 F.3d 312, 319 (8th Cir. 2009)). It follows then,

Besides the harm to physical health that Plaintiffs have shown will likely occur absent a preliminary injunction, the mandate also would have a negative effect on the economies in Plaintiff states, especially, once again, in rural areas.[32] While economic injuries normally would be reparable at law, "federal agencies generally enjoy sovereign immunity for any monetary damages." *Wages & White Lion Invs., L.L.C. v. United States Food & Drug Admin.*, 16 F.4th 1130, 1142 (5th Cir. 2021); *see also* 5 U.S.C. § 702 (providing for an action seeking relief "other than money damages"). Therefore, the economic loses in Plaintiff states would be unrecoverable and thus irreparable. *Iowa Utls. Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996) ("The threat of unrecoverable economic loss, however, does qualify as irreparable harm."); *DISH Network Serv. L.L.C. v. Laducer*, 725 F.3d 877, 882 (8th Cir. 2013).

Fourth, and finally, Plaintiffs would likely face irreparable harm to their proprietary interests absent a preliminary injunction. Plaintiffs themselves operate healthcare facilities that CMS's mandate reaches. They therefore would face the same harms any private owner of a facility faces, like the "business and financial effects of a lost or suspended employee, compliance and monitoring costs associated with the Mandate, [or] the diversion of resources necessitated by the Mandate." *BST Holdings*, 17 F.4th at ---. As just noted, since these costs could not be recovered from the federal government, they are irreparable. *Iowa Utls. Bd.*, 109 F.3d at 426.

For all these reasons, the Court finds that Plaintiffs are likely to suffer significant irreparable harm absent a preliminary injunction.

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that forcing individuals to choose "between their job(s) and their jab(s)," *BST Holdings*, 17 F.4th at ---, substantially burdens the liberty interests of individuals, which cannot be fully compensated through an award of damages.

[32] For example, Callaway District Hospital and Medical Clinics is the largest employer in Callaway, Nebraska and is a "significant driver of the local business and agriculture economy." Doc. [9-12] at 4. The expected loss of staff would "almost certainly" lead to closure of the facility. *Id.* "Cherry County Hospital is a leader of employment" for its county. Doc. [9-16] at 6. "Kimball County Manor and Assisted Living employs 55 full time staff and as such is one of the largest employers in Kimball County, a rural county located in Nebraska's western panhandle." Doc. [9-22] at 3.

c. The balance of equities tip in favor of Plaintiffs, and the public has an interest in an injunction.

Finally, the Court must determine whether Plaintiffs have shown that the "balance of equities tips in [their] favor" and that "an injunction is in the public interest." *Winter*, 555 U.S. at 20. 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." *Id.* at 24. When the party opposing the injunction is the federal government, the balance-of-harms factor "merge[s]" with the public-interest factor. *Nken v. Holder*, 556 U.S. 418, 436 (2009).

The public has an interest in stopping the spread of COVID. No one disputes that. But the Court concludes that the public would suffer little, if any, harm from maintaining the "status quo" through the litigation of this case. Defendants argue that "enjoining the rule would harm the public interest by further exposing Medicare and Medicaid patients and staff—and the Medicare and Medicaid programs—to unvaccinated health care workers." Doc. [23] at 48. But CMS's own conclusions undercut this argument. *See id.* at 61,615 ("[T]he effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not currently known."); *id.* at 61,612. Regardless, the pandemic has continued more than twenty months now. Vaccine rates rise every day, and more therapeutics and treatments for the virus are available than ever before. The status quo today, without the CMS mandate, is still far better than the public faced even just a few months ago.

And while, according to CMS, the effectiveness of the vaccine to prevent disease transmission by those vaccinated is not currently known, what is known based on the evidence before the Court is that the mandate will have a crippling effect on a significant number of

healthcare facilities in Plaintiffs' states, especially in rural areas,[33] create a critical shortage of services (resulting in *no medical care at all* in some instances), and jeopardize the lives of numerous vulnerable citizens. The prevalent, tangible, and irremediable impact of the mandate tips the balance of equities in favor of a preliminary injunction.

To be sure, the Court looks at the principles underlying preliminary injunctions. *Dataphase*, 640 F.2d at 113 n.5 (quoting *Love v. Atchison, T. & S. F. Ry. Co.*, 185 F. 321, 331 (8th Cir. 1911) ("The controlling reason for the existence of the judicial power to issue a [preliminary] injunction is that the court may thereby prevent such a change in the relations and conditions of persons and property as may result in irremediable injury to some of the parties before their claims can be investigated and adjudicated."). Although the parties disagree on the magnitude of the mandate's disruption to the healthcare industry, both agree a disruption is certain and imminent. Thus, the importance of enjoining the mandate, and thus preserving the "status quo," is imperative. *Dataphase*, 640 F.2d at 113 (8th Cir. 1981) ("[T]he question is whether the balance of equities so favors the movant that justice requires the court to intervene to preserve the status quo until the merits are determined."). And "[t]here is clearly a robust public interest in safeguarding prompt access to health care." *Whitman-Walker Clinic, Inc. v. DHS*, 485 F. Supp. 3d 1, 61 (D.D.C. 2020).

The Court finds that in balancing the equities, the scale falls clearly in favor of healthcare facilities operating with some unvaccinated employees, staff, trainees, students, volunteers, and

[33] The disproportionate impact the mandate will have on rural communities is why CMA's "one-size-fits-all sledgehammer" approach does not work and in fact, undermines CMA's focus on providing proper care. *See BST Holdings*, 17 F.4th at ---. This is why healthcare matters are typically left to the States, because these policy decisions are matters dependent on local factors and conditions, and Federalism allows States to tailor such matters in the best interests of their communities. The Court agrees with Plaintiffs point that whatever might make sense in Chicago, St. Louis, or New York City, could be actually counterproductive and harmful in rural communities like Memphis (MO) or McCook (NE). Doc. [1] at 1–2.

contractors, rather than the swift, irremediable impact of requiring healthcare facilities to choose between two undesirable choices—providing substandard care or providing no healthcare at all.[34]

It is true that the Agency would face irreparable harm *if* it is unable to enforce a *properly authorized* and *enacted* regulation. But, as discussed above, the Court has concluded CMS likely did not enact the mandate at issue lawfully. Thus, any interest CMS may have in enforcing an unlawful rule is likely illegitimate. *See BST Holdings*, 17 F.4th at ---. By this same conclusion, the public would benefit from the preliminary injunction because it would ensure that federal agencies do not extend their power beyond the express delegation from Congress, as already discussed. And while "it is indisputable that the public has a strong interest in combating the spread of COVID-19," "our system does not permit agencies to act unlawfully even in pursuit of desirable ends." *Ala. Ass'n of Realtors*, 141 S. Ct. at 2490.

In conclusion, CMS mandate raises substantial questions of law and fact that must be determined, as discussed throughout this opinion. Because it is evident CMS significantly understates the burden that its mandate would impose on the ability of healthcare facilities to provide proper care, and thus, save lives, the public has an interest in maintaining the "status quo" while the merits of the case are determined. *Dataphase*, 640 F.2d at 113; *Love*, 185 F. at 331.

III. CONCLUSION

For the foregoing reasons, Plaintiffs' Motion for Preliminary Injunction, Doc. [6], is **GRANTED**.

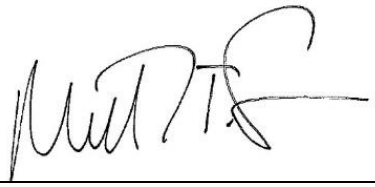
Accordingly,

[34] CMS also discusses that the upcoming influenza season will further exacerbate the strain on the healthcare system. However, one would assume that the onset of flu season coupled with COVID would be a reason to *avoid* critical staffing shortages at healthcare facilities—not to exacerbate them.

IT IS HEREBY ORDERED that Defendants are preliminarily enjoined from the implementation and enforcement of 86 Fed. Reg. 61,555 (Nov. 5, 2021), the Interim Final Rule with Comment Period entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination," against any and all Medicare- and Medicaid-certified providers and suppliers within the States of Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming pending a trial on the merits of this action or until further order of this Court. Defendants shall immediately cease all implementation or enforcement of the Interim Final Rule with Comment Period as to any Medicare- and Medicaid-certified providers and suppliers within the States of Alaska, Arkansas, Iowa, Kansas, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming.

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

Dated this 29th day of November, 2021.



MATTHEW T. SCHELP
UNITED STATES DISTRICT JUDGE