IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

STATE OF MISSOURI, STATE OF NEBRASKA, STATE OF ARKANSAS, STATE OF KANSAS, STATE OF IOWA, STATE OF WYOMING, STATE OF ALASKA, STATE OF SOUTH DAKOTA, STATE OF NORTH DAKOTA, and STATE OF NEW HAMPSHIRE, *Plaintiffs*, v. JOSEPH R. BIDEN, Jr., in his official capacity as the President of the United States of America, *et al.*, *Defendants*.	No. 4:21-cv-01329-MTS

PLAINTIFF STATES' REPLY MEMORANDUM IN SUPPORT
OF MOTION FOR PRELIMINARY INJUNCTION

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INTRODUCTION

Dead set on their plan to impose multiple federal vaccine mandates, Defendants skipped notice and comment, failed to prepare a regulatory impact analysis, and ignored their obligation to consult with the States. Even now, Defendants dismiss as speculative and irrelevant 30 declarations detailing the coming catastrophe in the healthcare industry and its specific impact on rural Americans. It seems that nothing short of an immediate injunction from this Court will stop this impending disaster. This Court has jurisdiction to issue that remedy—which is warranted because all four equitable factors overwhelmingly favor Plaintiff States.

ARGUMENT

I. The Court has Jurisdiction.

This Court has jurisdiction. 28 U.S.C. § 1331. Defendants argue (at 2) that this Court "lacks jurisdiction" over Plaintiff States' claims because "Congress has withdrawn federal-question jurisdiction over claims like this one that arise under the Medicare statute," citing 42 U.S.C. § 405(h), as incorporated by 42 U.S.C. §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. This argument lacks merit.

As Defendants readily concede (at 19), "State governments" such as 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 themselves could not use that statute's vehicle for judicial review[.]" Thus, for this reason alone, Defendants' heavy reliance on *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), is deeply misplaced.

Despite their fatal concession, Defendants argue (at 19) that Plaintiff States are no different than the nursing home association in *Shalala*, but the Supreme Court concluded the association was effectively an "institution" under § 1395cc(h)(1) due to its theory of associational standing. 529 U.S. at 24. Here, by contrast, Plaintiff States' standing arises out of their procedural right

under the APA, 5 U.S.C. § 702, and their "stake in protecting [their] quasi-sovereign interests[.]" *Massachusetts v. E.P.A.*, 549 U.S. 497, 520 (2007); *accord California v. Azar*, 911 F.3d 558, 571 (9th Cir. 2018) (holding in a multi-state challenge over the validity of HHS's interim final rules seeking to enjoin enforcement of the IFRs "that the states have standing to sue on their procedural APA claim"); *Texas v. United States*, 809 F.3d 134, 152 (5th Cir. 2015) ("In enacting the APA, Congress intended for those 'suffering legal wrong because of agency action' to have judicial recourse, and the states fall well within that definition.") (citing 5 U.S.C. § 702) (footnote omitted).

Moreover, unlike Plaintiff States' challenge here, the Supreme Court's review in *Shalala* didn't even involve a claim under the APA—a statute where Congress has "reinforced" the presumption of judicial review over administrative action. 529 U.S. at 44 n.11 (Thomas, J., dissenting); *see also id.* at 51 n.14 (noting that the "Secretary did not seek review of the Court of Appeals' holding that [the] APA notice-and-comment challenge is ripe"); *Illinois Council on Long Term Care Inc. v. Shalala*, 143 F.3d 1072, 1078 (7th Cir. 1998) (Easterbrook, J.), *rev'd*, 529 U.S. 1 (2000) ("[T]he APA-based objection to adoption of the manual is within the district court's jurisdiction and should be addressed on the merits[.]"). Thus, *Shalala* has no application to this case, and no "statute[] preclude[s] judicial review[.]" 5 U.S.C. § 701(a)(1); *see also id.* §§ 702, 704.

In any event, Plaintiff States' claims that arise under the Medicaid Act—as opposed to the Medicare Act—are not subject to § 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 IFC that purport to change a Medicaid regulation are clearly not barred even under Defendants' arguments.

Accordingly, § 405(h), as incorporated by § 1395ii, does not divest this Court of federal-question jurisdiction under § 1331.

II. The Plaintiff States Are Likely To Succeed on the Merits of Their Claims.

A. CMS Lacked Statutory Authority to Issue the Vaccine Mandate.

CMS openly recognized that its action was unprecedented—never before had the agency mandated vaccination. *See, e.g.*, 86 Fed. Reg. at 61,567 ("We have not previously required any vaccinations"); *see also* Compl. ¶ 121 (collecting other cites). Yet, Defendants characterize this sweeping mandate as a routine exercise of the Secretary's regulatory authority. They're wrong.

To be sure, "[t]he Secretary's administrative authority is undoubtedly broad." *Merck & Co. v. United States Dep't of Health & Hum. Servs.*, 962 F.3d 531, 537 (D.C. Cir. 2020). "But it is not boundless." *Id.* The applicable statutes did not give CMS the power to impose a nationwide vaccine mandate. Section 1302(a) directs the Secretary to "make and publish such rules and regulations, not inconsistent with [the Social Security Act], as may be *necessary to the efficient administration of the functions* with which [the Secretary] is charged under" the Medicare and Medicaid programs. 42 U.S.C. § 1302(a) (emphasis added). Similarly, Section 1395hh(a)(1) directs the Secretary to "prescribe such regulations as may be *necessary to carry out the administration of the insurance programs* under" the Medicare Act. *Id.* § 1395hh(a)(1) (emphasis added).

The word "administration" is the "central focus" of these statutes, and its original meaning in 1935 was "the practical management and direction of its various programs (including eventually Medicare and Medicaid), as well as their management and conduct." *Merck*, 962 F.3d at 537. As the D.C. Circuit has aptly put it:

> [F]or a regulation to be "necessary" to the programs' "administration," 42 U.S.C. §§ 1302(a), 1395hh(a)(1), the Secretary must demonstrate an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs. The regulation's operational focus must also be on those two programs, and the rule's effect must be more than tangential. *For example, the Secretary would be hard pressed to defend as necessary to program administration a rule forbidding vending machines or smoking breaks at businesses that employ Medicare or Medicaid recipients just because those measures could promote healthier living and thereby reduce program costs*. In other words, the further a regulation strays from truly facilitating the "administration" of the Secretary's duties, the less likely it is to fall within the statutory grant of authority.

Id. at 537–38 (emphasis added).

Here, the IFC "strays far off the path of administration" for several reasons. *Id.* at 538. Chief among them is that under the logic of *Merck*, if the Secretary could not promulgate a regulation prohibiting vending machines at businesses that employ Medicare or Medicaid recipients to further healthier living and thus reduce program costs, he too would be "hard pressed" to defend a regulation that *mandates* similar recipients to adopt a plant-based diet. A sweeping vaccine mandate is no different; even if vaccination promotes health and safety and thus might reduce program costs, it still has nothing to do with the practical "management" of Medicaid or Medicare.

Defendants' invocation (at 21) of results-oriented purposivism—i.e., the Secretary has regulatory authority to promote the health and safety of Medicare and Medicaid recipients—is a poor substitute for any *text* in §§ 1302(a) and 1395hh(a)(1) that supports his authority. Indeed, neither statute even explicitly reference "health and safety." And even those specific statutes that do use that phrase still fail because they do not authorize the sweeping vaccine mandate the IFC purports to authorize here, as Plaintiff States have argued extensively in their opening brief. In any event, the mandate will actually result in patients *not* having access to essential healthcare

services, as the Plaintiff States' undisputed evidence shows; thus, it does not promote patients' "health and safety."

B. The CMS Mandate Is Arbitrary and Capricious.

The Court's review under the APA for arbitrary and capricious agency action "is not toothless. In fact, after *Regents*, it has serious bite." *Wages & White Lion Invs., L.L.C. v. United States Food & Drug Admin.*, 16 F.4th 1130 (5th Cir. 2021) (cleaned up). Applying that standard here, the IFC fails to pass muster under the APA.

Exacerbating Existing Healthcare Crisis. CMS arbitrarily concluded that its mandate will not exacerbate the existing healthcare crisis, and Defendants' feeble attempt to defend that conclusion shows just how unreasonable the agency's explanation is. Unable to deny that CMS's supporting data focused on the experiences of a few large healthcare providers in urban settings, Defendants pretend that CMS also considered data on rural providers by pointing to Novant Health. Opp. at 28. But Novant—a massive 35,000-employee healthcare system in North Carolina with locations clustered mostly in Charlotte, Winston-Salem, and their suburbs—is not remotely representative of the rural healthcare community, especially in Plaintiff States. *See id.* (citing websites). Defendants thus failed to consider the harsh impact of the mandate on rural healthcare. This failure was particularly unreasonable given CMS's recognition that "rural hospitals are having greater problems with employee vaccination . . . than urban hospitals." 86 Fed. Reg. at 61,613.

Defendants next cite a *New York Times* article that "reported a 92% compliance rate" with New York State's vaccine mandate for "650,000 hospital and nursing home workers." Opp. at 28. But a 92% compliance rate means that 8% of the healthcare workers in the State—a total of 52,000 people—were not compliant. This directly undercuts the sentence in the IFC that immediately

follows the *New York Times* article—CMS's unreasonable belief that its mandate "will result in *nearly all* health care workers being vaccinated." 86 Fed. Reg. at 61,569 (emphasis added).

Beyond this, the *Times* article raises alarming concerns that CMS failed to mention. The article noted that New York "hospitals and nursing homes continue[d] to brace for potential staffing shortages," that many "braced themselves by activating emergency staffing plans," and that "even minor staff losses because of [the vaccine mandate] could put some patients at risk." *Thousands of N.Y. Health Care Workers Get Vaccinated Ahead of Deadline*, N.Y. Times (Sept. 28, 2021). The article also discussed that the "governor declared a state of emergency" just days before the mandate's deadline "allow[ing] her to use the National Guard to fill staffing shortages," and that she "opened a crisis operations center for health care facilities to request help and . . . allow nurses and other health care workers from outside New York to assist." *Id.*[1] And the article reported that a hospital-affiliated nursing home in Buffalo placed 20% of its staff "on unpaid leave . . . for refusing to get vaccinated," causing the facility to "transfer[] staff in from other facilities, reduc[e] beds at the nursing home[,] and suspend[] some elective surgeries at the hospital." *Id.* Faced with these disturbing facts, it was unreasonable for CMS to fail to even mention them, let alone to rely on this article to *dismiss* the national healthcare workforce shortage concerns.[2]

[1] The governor has extended this state of emergency after recognizing that "severe understaffing in hospitals and other healthcare facilities is expected to continue." Executive Order 4.1 (Oct. 27, 2021), https://www.governor.ny.gov/sites/default/files/2021-10/EO%204.1.pdf.

[2] The facts on the ground continue to demonstrate the fallout from New York's vaccine mandate. *See Long Island hospital temporarily closing ER due to nursing staff shortages amid vaccine mandate*, ABC 7 New York (Nov. 22, 2021), https://www.msn.com/en-us/health/medical/long-island-hospital-temporarily-closing-er-due-to-nursing-staff-shortages-amid-vaccine-mandate/ar-AAR0C5t ("The emergency department at a Nassau County hospital has temporarily closed due to nursing staff shortages as a result of New York's vaccine mandate.").

Defendants again trot out their implausible claim that mandate-induced reductions in healthcare workers will be "offset" by "a return to work of employees who have stayed out of the workforce for fear of contracting SARS-CoV-2." Opp. at 29. But Defendants have not even attempted to refute Plaintiffs' argument that this offset argument is "pure speculation" because "CMS cited no evidence" that there is a significant pool of vaccinated workers who have stayed out of the workforce because they fear vaccinated workers but are willing to work with unvaccinated patients. Doc. 9, at 17. That New York continues to experience extreme healthcare worker shortages months after implementing its statewide healthcare vaccine mandate demonstrates that no such pool of workers exists. *See supra* nn. 1-2.

Defendants also insist that any workforce losses will "be dwarfed . . . by the ordinary degree of churn in the market of labor in the health care industry" because "there is no reason to believe that the need to find staffing will be noticeably more onerous" after the mandate. Opp. at 29. This is an irrational justification. CMS admits that the mandate covers "virtually all health care staff in the U.S" and that unvaccinated workers are now disqualified from those positions. 86 Fed. Reg. at 61,573. Excluding an entire category of workers from most healthcare jobs is not the ordinary "churn" of the labor market. It pours gasoline on an already volatile situation. The notion that "business as usual" measures can counteract the impending doom is unreasonable in the extreme.

Unreasonably Rejects Natural Immunity. Defendants' discussion of natural immunity misses Plaintiffs' point. Opp. at 31–33. Plaintiffs object to "CMS's inconsistencies" on that topic. Doc. 9, at 21. Specifically, CMS refuses to exempt from the mandate people who previously had COVID-19 while simultaneously acknowledging that each day 100,000 people are "recover[ing] from infection," that they "are *no longer sources of future infections*," and that their natural immunity "reduce[s] the risk to both health care staff and patients substantially." 86 Fed. Reg. at

61,604 (emphasis added); *see also United States v. Arencibia*, No. CR 18-294 ADM/DTS, 2021 WL 2530209, at *4 (D. Minn. June 21, 2021) (reciting the CDC's position that "[c]ases of reinfection with COVID-19 have been reported, but remain rare"). This unexplained inconsistency in CMS's position renders the mandate "arbitrary and capricious." *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126 (2016).

Defendants' attempt to paper over CMS's ignoring of key evidence on natural immunity also misses the mark. They claim that CMS "directly considered" Plaintiffs' "cited study" out of Israel, but what actually happened is that the IFC cited a CDC webpage, and on that webpage was a link to *another webpage* that cited the study. Opp. at 31–32. That is hardly the reasoned consideration that the APA demands.

Post Hoc/Pretextual Reasoning. Defendants want to ignore the Biden Administration's prior comments concerning vaccine mandates. Opp. at 33. But this Court should not—and indeed cannot—ignore the obvious pretextual and post-hoc reasoning. As Plaintiffs have explained, the Administration originally affirmed that mandating vaccines is "not the role of the federal government." Doc. 9, at 4. The President then announced that the CMS vaccine mandate is part of a broader program aimed at increasing vaccination rates. *Id.* And CMS now seeks to justify the mandate as necessary to protect patient health.

"In reviewing agency pronouncements, courts need not turn a blind eye to the statements of those issuing such pronouncements." *BST Holdings, L.L.C. v. Occupational Safety & Health Admin., United States Dep't of Lab.*, --- F.4th --- , No. 21-60845, 2021 WL 5279381, at *5 (5th Cir. Nov. 12, 2021) (citing *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). "In fact, courts have an affirmative duty *not* to do so." *Id.* CMS thus cannot ignore the Administration's original announcement and the President's later-stated rationale, preferring instead to

contrive a new justification under the Social Security Act. Such blatant pretext renders CMS's mandate arbitrary and capricious. *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2575–76 (2019); *see also BST Holdings*, 2021 WL 5279381, at *5 (identifying pretext as a "hallmark[] of unlawful agency actions"). Indeed, these kinds of "sudden[] revers[als]" of course "create[] the plausible inference that political pressure may have caused the agency to take action it was not otherwise planning to take." *Connecticut v. Dep't of Interior*, 363 F. Supp. 3d 45, 64–65 (D.D.C. 2019).

What's more, the Administration's shifting rationales across all vaccine mandates further demonstrate pretext. The OSHA mandate declares that vaccines are necessary to protect worker safety. *See* 86 Fed. Reg. 61,402 (Nov. 5, 2021). But that rationale would not suffice under the Social Security Act, so CMS contrived a new justification—patient safety—for its mandate. Accepting these conflicting agency justifications would require this Court to "exhibit a naiveté from which ordinary citizens are free." *New York*, 139 S. Ct. at 2575.

For all these reasons and those explained in Plaintiffs' initial memorandum, the CMS mandate is arbitrary and capricious.

C. The CMS Vaccine Mandate Violates Notice-and-Comment Requirements.

Defendants argue that good cause excuses notice-and-comment requirements because a delay would harm the health and safety of patients. Opp. at 35–36. This argument is unpersuasive because CMS's good-cause analysis did not even consider the mandate's harm to patients from exacerbating the healthcare workforce shortage and, as explained above, CMS elsewhere unreasonably dismissed that concern. Given these failures, Defendants cannot satisfy the close examination that good-cause analysis requires. *See Council of the S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 580 (D.C. Cir. 1981) ("[C]ircumstances justifying reliance on this exception are

'indeed rare' and will be accepted only after the court has 'examine[d] closely proffered rationales justifying the elimination of public procedures.'") (citation omitted).

Defendants' initial good-cause arguments focus on the health risks from COVID-19. Opp. at 36–37. But after almost two years, COVID-19 is a persistent feature of life and cannot itself constitute good cause. *See Florida v. Becerra*, 8:21-cv-839, 2021 WL 2514138, at *45 (M.D. Fla. June 18, 2021); *Regeneron Pharms., Inc. v. HHS*, 510 F. Supp. 3d 29, 48 (S.D.N.Y. 2020); *Ass'n of Cmty. Cancer Centers v. Azar*, 509 F. Supp. 3d 482, 496 (D. Md. 2020). To hold otherwise would effectively repeal notice-and-comment requirements indefinitely. *See also BST Holdings*, 2021 WL 5279381, at *3 & n.10 (OSHA vaccine mandate's "stated impetus—a purported 'emergency' that the entire globe has now endured for nearly two years . . . —is unavailing" because "society's interest in slowing the spread of COVID-19 cannot qualify as compelling forever") (cleaned up).

Professing good cause in an interim final rule published six months ago, CMS invoked many of the same reasons it offers now—the existence of a public health emergency, the need to protect vulnerable patient populations, and strain on the healthcare industry. *See* 86 Fed. Reg. 26,306, 26,320–21. But if the same conditions were present nearly six months ago, it strains credulity to assert them as an emergency justification now. *See Chamber of Commerce v. SEC*, 443 F.3d 890, 908 (D.C. Cir. 2006) ("The [good-cause] exception excuses notice and comment in *emergency* situations.") (emphasis added).

In their brief, Defendants next discuss recent events involving the Delta variant and speculation about "a renewed surge" of COVID-19 and "the coming flu season." Opp. at 37–39. But Defendants admit that "the 'intensity' of the coming flu season 'cannot be predicted.'" *Id.* at 39 (citing 86 Fed. Reg. 61,584). And the cited CDC website agrees that the "impact . . . of flu varies

from season to season." CDC, Flu Season, https://www.cdc.gov/flu/about/season/flu-season.htm. If such speculative divinations about surges and seasons suffice to establish good cause, CMS could easily conjure up some theory to justify eliminating notice and comment in countless circumstances. But that is inconsistent with the admonition that the good-cause exception be "reluctantly countenanced." *Nw. Airlines, Inc. v. Goldschmidt*, 645 F.2d 1309, 1321 (8th Cir. 1981).[3]

Finally, the "more expansive the regulatory reach of" a rule, "the greater the necessity for public comment" to allow those affected to be heard. *Am. Fed'n of Gov't Emp. v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981). There is no overlooking the magnitude of this rule, for CMS has "not previously required" mandatory vaccination for the healthcare industry. 86 Fed. Reg. at 61,567. And notice and comment process is even more vital in the Medicare and Medicaid context because those 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. Given this, good cause should be especially difficult to establish here.[4]

In sum, Defendants claim that this is an unparalleled "public health crisis." Opp. at 1. But it is equally true that this is an unparalleled mandate. Thus, notice and comment was required.

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[3] Defendants' reliance on *United States v. Gavrilovic*, 551 F.2d 1099, 1105 (8th Cir. 1977), *see* Opp. at 37, is unavailing because the Eighth Circuit there held that the agency's "finding of good cause was *not* based on an acute and immediate threat to public health and safety" and thus that the effective date could not be accelerated. (emphasis added).

[4] Case law refutes Defendants' argument (at 40) that CMS's two-month delay in promulgating its mandate shows that it "acted with appropriate dispatch. *See Regeneron*, 510 F. Supp. 3d at 48 (CMS's two-month delay "suggest[ed] a lack of urgency" that belied good cause). Moreover, Defendants themselves have previously suggested that a one-week delay is not acting fast enough. *See* ECF 15 at 3.

And because notice-and-comment was required, a regulatory impact analysis was also required under 42 U.S.C. § 1302(b)(1), which Defendants concede (at 41) the Secretary did not do.

D. The CMS Vaccine Mandate Violates the State-Consultation Requirement.

Defendants implausibly read a good-cause exception into 42 U.S.C. § 1395z's state-consultation requirement. Opp. at 40. The relevant statutory language says that "the Secretary shall consult with appropriate State agencies" and that he "may consult with appropriate local agencies." 42 U.S.C. § 1395z. Defendants argue that the word "appropriate" conveys "vast discretion" on CMS to skip state consultation before issuing an interim final rule. Opp. at 40. This, however, misunderstands the meaning of "appropriate" in this statute. The word merely expresses that certain state agencies—those connected with Medicare and Medicaid—are the appropriate agencies with which CMS must consult. It does not invite CMS to decide for itself whether consultation is "appropriate" in the first place. If consultation with state agencies were optional, or at CMS's discretion, Congress would not have used "shall" to describe consultation with state agencies and "may" to describe consultation with local agencies. *See Jennings v. Rodriguez*, 138 S. Ct. 830, 844 (2018) ("Unlike the word 'may,' which implies discretion, the word 'shall' usually connotes a requirement."). CMS thus violated its state-consultation obligation.

E. The CMS Vaccine Mandate is Unconstitutional.

Because Plaintiffs are likely to succeed on their statutory arguments, the Court need not reach these constitutional issues. *BST Holdings*, 2021 WL 5279381, at *3. But if the Court does reach them, it should conclude that Plaintiffs' are likely to prevail on their constitutional claims.

Defendants concede (at 41) that public health matters are within the province of the States. But choosing "how" to fund Medicare, Defendants argue, is not. That gives away the Government's case. Their justification for the CMS vaccine mandate is to promote patients' health

and safety. But it is indisputably the States' exclusive role to promote the health and safety of their citizenry (including Medicare and Medicaid recipients). *See Jacobson v. Massachusetts*, 197 U.S. 11, 24–25 (1905). The States are not challenging the Government's funding determinations over its own programs; rather, the States are challenging the Government's exercise of power not reserved to it. Indeed, for the reasons stated in Part II.A., *supra*, the CMS vaccine mandate is not a valid exercise of the agency's statutory authority. Thus, Plaintiff States are likely to succeed on the merits of their Tenth Amendment challenge.

Defendants argue (at 42) that they aren't commandeering anyone because "conditions on federal spending . . . are imposed on public or private entities that choose to participate in the Medicare and Medicaid programs, not on States in their capacity as States." That not only elevates form over substance, but also ignores the States' "stake in protecting [their] quasi-sovereign interests[.]" *Massachusetts*, 549 U.S. at 520. Moreover, Defendants seek to downplay (at 43–44) the commandeering that occurs when CMS charges state surveyors with enforcing the vaccine mandate. They argue that no commandeering occurs because the States voluntarily agreed to operate as surveyors. But the state surveyors never agreed to enforce a vaccination mandate. Because "[p]revious Medicaid [regulations] simply do not fall into the same category as the one at stake here," *NFIB v. Sebelius*, 567 U.S. 519, 585 (2012), any prior agreement by state surveyors does not encompass this demand.

Defendants further argue (at 42) that the CMS vaccine mandate "bear[s] some relationship" to federal spending on Medicaid and Medicare. But the relationship is so tenuous that this goes beyond *NFIB*, where the Supreme Court found a Spending Clause violation. 567 U.S. at 584. In *NFIB*, at least Medicaid expansion had something to do with the States' participation in the traditional Medicaid program. The CMS vaccine mandate simply does not. Defendants' argument

also assumes that the Secretary has a "statutory duty to protect the health and safety" of Medicare and Medicaid recipients, which he does not. *See* Part II.A., *supra*. Because he didn't have that statutory authority, the mandate comes out of left field, with no clear notice to the States.

All these constitutional problems, moreover, provide additional compelling reasons to reject CMS's claim that the statutes authorize this unprecedented mandate. *See, e.g., Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2490 (2021) (per curiam) (clear-statement rule for major questions and agency actions that disrupt the federal-state balance of authority); *Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Engineers*, 531 U.S. 159, 172–73 (2001) ("Congress does not casually authorize administrative agencies to interpret a statute to push the limit of congressional authority."); *Edward J. DeBartolo Corp. v. Florida Gulf Coast Building & Constr. Trades Council*, 485 U.S. 568, 575 (1988) (doctrine of constitutional avoidance).

III. The Remaining Injunction Factors Favor the Plaintiffs.

A. The Plaintiffs Face Irreparable Harm.

Sovereign Interests. Relying on out-of-circuit case law, Defendants contend that Plaintiffs do not have a cognizable Article III interest in the preemption of their laws. Opp. at 45. But just last year, the Eighth Circuit held that "State[s] . . . suffer irreparable harm" when they are "precluded from applying [their] duly enacted legislation." *Org. for Black Struggle v. Ashcroft*, 978 F.3d 603, 609 (8th Cir. 2020). And Defendants do not deny that Plaintiffs have many laws that CMS's mandate purports to preempt. *See* Doc. 9, at 38. This establishes irreparable harm and distinguishes the *Florida* case because, according to the court's order, the State there "reference[d] no law or established policy in danger of preemption." *Florida v. Dep't of Health & Human Servs.*, No. 3:21-cv-02722-MCR-HTC, Order at 10 (N.D. Fla. Nov. 20, 2021).

Quasi-Sovereign Interests. Invoking case law from the 1980s, Defendants argue that Plaintiffs cannot assert their quasi-sovereign interests against the federal government. Opp. at 45. This ignores the Supreme Court's 2007 landmark decision in *Massachusetts v. EPA*, 549 U.S. at 519–20 & n.17. The Court there held that Massachusetts had standing to assert quasi-sovereign interests against the federal government. Given Massachusetts's "procedural right" to "challenge the rejection of [a] rulemaking petition as arbitrary and capricious" and its "stake in protecting its quasi-sovereign interests, the Commonwealth [was] entitled to special solicitude in . . . standing analysis." *Id.* at 520. This special solicitude afforded Massachusetts the right "to litigate as *parens patriae* to protect quasi-sovereign interests—*i.e.*, public or governmental interests that concern the state as a whole." *Id.* at 520 n.17. Indeed, the Court rejected the suggestion that its cases cast "doubt on a State's standing to assert a quasi-sovereign interest . . . against the Federal Government." *Id.* *Massachusetts* thus establishes that Plaintiffs may assert their quasi-sovereign interest in ensuring, among other things, that widespread healthcare calamity does not befall their citizens.

Proprietary Interests. Plaintiffs also face irreparable harm as operators of healthcare facilities covered by the mandate. Defendants reduce these harms to mere economic harm. Opp. at 45. But this ignores the interests that Plaintiffs have asserted, which include, but are not limited to, "impos[ing] the CMS mandate on their own employees" and "disruptions in day-to-day operations" caring for patients. Doc. 9, at 40. This shows that the harm at stake is far more than money. Indeed, Plaintiffs' proprietary interests are like those of the businesses in the OSHA mandate case, which faced the "irreparabl[e] harm[]" of "the business and financial effects of a lost or suspended employee, compliance and monitoring costs associated with the Mandate, [and] the diversion of resources necessitated by the Mandate." *BST Holdings*, 2021 WL 5279381, at *8. To the extent that some of these harms are economic, they are nonetheless irreparable. *See id.* As Defendants'

own case law recognizes, "[t]he threat of unrecoverable economic loss does qualify as irreparable harm." *Iowa Utilities Bd. v. FCC*, 109 F.3d 418, 426 (8th Cir. 1996). Such unrecoverable losses include reduced tax revenues and money spent addressing the loss of state healthcare workers.

Likelihood of Harms. Defendants next argue that Plaintiffs' irreparable harms must be "certain." Opp. at 45–47. Even if that were the standard (which it's not), Plaintiffs would readily satisfy it. The sovereign harms involving preemption of Plaintiffs' laws are certain to occur. So are Plaintiffs' quasi-sovereign and proprietary harms of involuntarily forcing healthcare workers, including their own employees, to choose between their jobs and their private medical choices about vaccination.

In any event, Defendants are wrong to insist on a certainty standard because the Supreme Court's "frequently reiterated standard requires plaintiffs seeking preliminary relief to demonstrate that irreparable injury is *likely*"—not certain—to occur. *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008); *see also New York*, 139 S. Ct. at 2566 (allowing plaintiffs in an APA challenge to demonstrate harm by "showing that third parties will likely react in predictable ways"). Plaintiffs have shown that the irreparable harm relating to the mandate's catastrophic effects on the healthcare industry easily clear the likelihood standard. Plaintiffs' 30 declarations identify dozens of private and state-run facilities that, based on the information currently available to them, reasonably anticipate significant staff loses that will substantially disrupt—and in some cases even end—their operations. *See* Docs. 9-1–9-30. Despite what Defendants say (at 46), many of those declarations—from both private and state-run facilities—expressly consider the availability of exemptions. *See, e.g.*, Doc. 9-2, ¶ 9; Doc. 9-4, ¶ 8; Doc. 9-13, ¶ 13; Doc. 9-15, ¶ 14; Doc. 9-24, ¶ 14. In addition, the undisputed evidence shows that the CMS mandate has already compelled some healthcare works to resign. *See, e.g.*, Doc. 9-26, ¶ 8. Moreover, in six days, the

emergency amendment to Mo. Code Regs. Ann. tit. 19, § 30-82.010 will become effective, thus allowing healthcare facilities to close due to staffing shortages.

Amicus curiae Reliant Care Management Company—an operator of 21 skilled nursing facilities throughout Missouri, mostly in rural communities—further substantiates the irreparable harm. Doc. 26, at 1. Out of Reliant's 1,706 employees, 1,080 are not vaccinated. *Id.* at 3. Thus, "CMS's mandate places approximately 60% of Reliant's workforce in jeopardy, which will inevitably lead to facility closures in communities that simply cannot afford it." *Id.* "These daunting statistics, and the risks they pose to the continuity of healthcare in vulnerable communities, exemplify the situation playing out across Missouri right now and further justify the requested injunction." *Id.*

It's not just Plaintiffs and their amicus that establish the likelihood of irreparable harm. CMS's own materials help Plaintiffs make their case. As previously discussed, those materials indicate that 52,000 healthcare workers statewide did not comply with New York's vaccine mandate and that a Buffalo nursing home was forced to reduce services after placing 20% of its staff "on unpaid leave . . . for refusing to get vaccinated." *Thousands of N.Y. Health Care Workers Get Vaccinated Ahead of Deadline*, N.Y. Times (Sept. 28, 2021). If that weren't enough, a Long Island hospital just yesterday closed its "emergency department . . . due to nursing staff shortages as a result of New York's vaccine mandate." *Supra* n.2. There is thus more than enough evidence to establish the likelihood that CMS's mandate will devastate the nation's healthcare industry, especially in rural communities.

The robust record before this Court further distinguishes this case from the *Florida* decision on which Defendants rely. The court there found the asserted harms too "speculative." *Florida* Order at 8–10. But as detailed above, Plaintiff States' harms are anything but speculative. In

addition, the *Florida* court failed to cite (let alone apply) the special solicitude States are given under *Massachusetts*. *See Texas v. Biden*, 10 F.4th 538, 548 (5th Cir. 2021) (per curiam) (citing *Massachusetts*, 549 U.S. at 523, for the proposition that the Supreme Court found "traceability where the EPA's challenged action may have caused people to drive less fuel-efficient cars, which may in turn contribute to a prospective rise in sea levels, which may in turn cause the erosion of Massachusetts's shoreline").

B. The Balance of Harms and The Public Interest Favor an Injunction.

Enjoining CMS's mandate is in the public interest. "From economic uncertainty to workplace strife, the mere specter of the Mandate has contributed to untold economic upheaval in recent months." *BST Holdings*, 2021 WL 5279381, at *8. "The public interest is also served by maintaining our constitutional structure and . . . the liberty of individuals to make intensely personal decisions according to their own convictions." *Id.* 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). While Defendants argue (at 3) that injunctive relief would harm the public's interest in "protecting the health of Medicare and Medicaid patients," that argument actually cuts in favor of Plaintiff States: the 30 declarations submitted—none of which Defendants have disputed—assert concrete harms that will result in less access to healthcare services due to the CMS vaccine mandate. For this reason, Plaintiff States strongly disagree with Defendants' claim (at 22) that "a rule requiring the vaccination of health care facility employees protects the 'health and safety' of those facilities' patients[.]"

Defendants' public-interest arguments rest in large part on the assumption that the mandate will "slow[] the spread of COVID-19" by limiting transmission from unvaccinated healthcare workers to patients. Opp. at 48. Yet CMS itself undermines this assumption by recognizing that

"the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not currently known." 86 Fed. Reg. at 61,615. CMS thus weakens Defendants' public-interest argument.

In any event, there is no public interest in the perpetuation of unlawful agency action. As the Supreme Court said in *Alabama Ass'n of Realtors*, "[i]t is indisputable that the public has a strong interest in combating the spread of the COVID–19[;]" however, "our system does not permit agencies to act unlawfully even in pursuit of desirable ends." 141 S. Ct. at 2490.

IV. The Injunction Should Bar Defendants from Enforcing the Rule Anywhere.

Defendants seek to limit the scope of Plaintiffs' requested injunction. Opp. at 50–52. But the Court should not confine its reach. Because Defendants acted without statutory authority, violated multiple procedural requirements and engaged in arbitrary and capricious decision-making, no aspect of the IFC can stand, and it should be enjoined in its entirety. The APA provides that unlawful agency actions shall be vacated and "set aside" in their entirety, not in geographic piecemeal. *See BST Holdings*, 2021 WL 5279381, at *9 (ordering OSHA to "take no steps to implement or enforce the Mandate until further court order," thus effectively enjoining it nationwide).

In addition, affording full relief to Plaintiffs necessitates a nationwide injunction. Plaintiffs have explained how the healthcare industry is interconnected. *See* Doc. 9, at 41. Thus, allowing the mandate to take effect in Illinois, for example, will limit the healthcare services available in that State, and that, in turn, will further burden healthcare providers in Eastern Missouri as patients in Western Illinois cross the border to get the services they seek. Plaintiffs thus have a direct interest in this Court's issuing a broad injunction. At the very least, the injunction should apply to the First, Eighth, Ninth, and Tenth Circuits—where Plaintiff States reside.

CONCLUSION

The Court should grant Plaintiffs' motion for a preliminary injunction. And that injunction should apply to all aspects of the IFC because it is was promulgated without statutory authority, is arbitrary and capricious, failed to comply with procedural requirements, and violates the Constitution.

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CERTIFICATE OF SERVICE

I hereby certify that, on November 23, 2021, a true and correct copy of the foregoing and any attachments were filed electronically through the Court's CM/ECF system, to be served on counsel for all parties by operation of the Court's electronic filing system.

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