IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

THE STATE OF LOUISIANA, By and through its Attorney General, JEFF LANDRY, et al., PLAINTIFFS, v. XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, et al., DEFENDANTS.	Civil Action No. 3:21-cv-03970 District Judge Terry A. Doughty Magistrate Judge Kayla D. McClusky

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

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SUMMARY OF REPLY

The common thread connecting the myriad legal defects arising from Defendants' implementation of the President's vaccine decree is CMS's remarkable admission that it sought no input from States or providers, particularly those in rural communities, and performed no analytical assessment of the negative impact of the Vaccine Mandate on access to care for millions who rely on Medicare and Medicaid. CMS's failure to abide by fundamental rule-making procedures both constitutes actionable illegality itself and provides context for substantive errors that riddle the Mandate. To be sure, this was no mere oversight. Rather, it was purposely designed to fast-track an unprecedented, unauthorized, far-reaching social experiment, which could be accomplished only by steamrolling States and stakeholders while avoiding judicial review. Legal safeguards for democratic participation such as the APA were readily discarded in service of the President's diktat to vaccinate as many people as quickly as possible.[1] So too were concerns for reduced care for Medicare and Medicaid beneficiaries, whose provider access is the price for advancing the President's autocratic agenda. Indeed, at least one federal court has already found that the Vaccine Mandate contains multiple constitutional and procedural defects, any of which are fatal. *See* Memorandum and Order, ECF No. 28, *Missouri v. Biden*, No. 4:21-cv-01329-MTS (E.D. Mo. Nov. 29, 2021).

All of this is unlawful, as found by Judge Schelp. Defendants exceeded their authority, disregarded constitutional limits, skipped notice and comment, failed to prepare a regulatory impact analysis, and ignored their obligation to consult with the States. An immediate injunction from this Court is proper because all four equitable factors overwhelmingly favor Plaintiff States.

[1] *See* The White House, Path Out of the Pandemic: President Biden's Covid-19 Action Plan, https://bit.ly/3adkMXx (last visited Nov. 29, 2021); The White House, Vaccination Requirements Are Helping Vaccinate More People, Protect Americans from COVID-19, and Strengthen the Economy (Oct. 7, 2021), https://bit.ly/3lorbp0.

ARGUMENT

I. The Court Has Jurisdiction under 28 U.S.C. § 1331.

Defendants argue (Opp. at 8-11) that this Court "lacks jurisdiction" over Plaintiff States' claims based on the Medicare Act's "channeling" requirement, 42 U.S.C. § 405(h), as incorporated by 42 U.S.C. § 1395ii. This argument lacks merit for three reasons.

First, Defendants' assertion that "[a]ll of Plaintiffs claims plainly arise under the Medicare statute," Opp. at 10, is wrong. Plaintiff States' claims arise under both the Medicare statute and the Medicaid statute, as well as the Constitution, Administrative Procedure Act, and Congressional Review Act. *See* Complaint (Doc. 1) at ¶¶ 27, 53, 57, 65, 126, 181, 182, 184 (citing implicated Medicaid provisions). Defendants themselves rely on both statutory schemes as authority. *See e.g.*, Opp. at 11 (citing 42 U.S.C. § 1302(a) (Medicaid) and § 1395hh(a)(1) (Medicare)). Accordingly, Plaintiffs' claims are not subject to Section 405's jurisdictional bar. *See Ass'n of Cmty. Cancer Centers v. Azar*, 509 F. Supp. 3d 482, 490-91 (D. Md. 2020) (explaining that the channeling requirement applies to claims under subchapter XVIII (Medicare), not to other subchapters (covering Medicaid)).[2] *See also 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.").

Second, the Medicare channeling requirement does not apply in cases such as this "where judicial review would be unavailable through the prescribed administrative procedures." *See Sw. Pharmacy Sols., Inc. v. Centers for Medicare and Medicaid Services*, 718 F.3d 436, 439 (5th Cir. 2013). As Defendants concede, Medicare's administrative review procedures do not apply to "State governments" such as Plaintiff States. Opp. at 11. Thus, "the States themselves could not

[2] 42 U.S.C. § 1395ii ("section 405 of this title[] shall also apply *with respect to this subchapter* to the same extent as [it is applicable with respect to subchapter II…") (emphasis added).

use that statute's vehicle for judicial review." *Id.* The Eastern District of Missouri rejected Defendants' § 405(h) jurisdictional argument for this very reason. *See Missouri*, No. 4:21-cv-01329, ECF No. 28 at 2-3.

Third, Defendants' reliance on *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), is deeply misplaced. In that case, the Court treated a nursing home association as an "institution" under § 1395cc(h)(1) when asserting the rights of its members, *see id*. at 24 ("The Council speaks only on behalf of its members institutions… It is essentially their rights to review that are at stake"), and thus subject to the Medicare channeling requirement. By clear contrast, Plaintiff States have independent standing arising out of the various ways in which the Mandate undermines their sovereign and pecuniary interests, independent of the rights of the States' institutions, as well as a "stake in protecting [their] quasi-sovereign interests[.]" *Massachusetts v. E.P.A.*, 549 U.S. 497, 520 (2007).

The States' Medicare-related claims, in other words, have no connection to the claims-related lawsuits Congress sought to channel via § 1395hh(a)(1). The Court in *Illinois Council* expressly addressed only the situation where "one who *might* later seek money or some other benefit from (or contest the imposition of a penalty by) the agency challenges in advance (in a § 1331 action) the lawfulness of a policy, regulation, or statute that *might* later bar recovery of that benefit (or authorize the imposition of the penalty)." *Illinois Council*, 529 U.S. at 10. But the States in their roles as sovereigns or quasi-sovereigns present no prospect of "later seek[ing] money of some other benefit" from CMS. Their claims therefore do not "arise under" the Social Security Act in the way contemplated by § 405(h) and *Illinois Council*.

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

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 recognizes its action is unprecedented—never before had the agency mandated vaccination. *See, e.g.*, 86 Fed. Reg. 61,567 ("We have not previously required any vaccinations"). Yet, Defendants characterize this sweeping mandate as a routine exercise of the Secretary's regulatory authority. They are wrong.

The applicable statutes do 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 & Co. v. United States Dep't of Health & Hum. Servs.*, 962 F.3d 531, 537 (D.C. Cir. 2020). As the D.C. Circuit has aptly put it, "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. Here, the Vaccine Mandate strays far off the path of administration, into the realm of federalized healthcare policy. 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 (Opp. at 12) 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. This especially falls short of the Supreme Court's admonition that such authority must be "clearly" stated in this context. *See Alabama Ass'n of Relators v. HHS*, 141 S. Ct. 2485, 2489 (2021) (requiring Congress to speak clearly when it wishes to "authoriz[e] an agency to exercise powers of vast economic and political significance" or "significantly alter the balance between federal and state power"). Indeed, neither provision even explicitly references "health and safety." And even those specific provisions that do use that phrase still fail because they do not authorize the sweeping vaccine mandate the interim final rule purports to authorize here. In any event, the Mandate's unquestionable reduction in patient access to essential healthcare services—as Plaintiff States' undisputed evidence shows—demonstrates that it does not promote patients' "health and safety."

B. The Vaccine Mandate Is Arbitrary and Capricious.

APA review for arbitrary and capricious agency action "has serious bite." *Wages & White Lion Invs., L.L.C. v. F.D.A.*, 16 F.4th 1130 (5th Cir. 2021) (cleaned up). Here that bite devours the Vaccine Mandate.

Diminished Access to Care Caused by Staffing Shortages. Defendants attempt to whitewash the Secretary's avoidance of the access-to-care issue by pointing to reliance on "real world experience with vaccination requirements" from a few urban hospital systems, Opp. at 11, 17, none of which are located in the Plaintiff States.[3] But Defendants' reliance on the "empirical

[3] For example, the labor market for Houston Methodist (Opp. at 17) is hardly representative of the labor market in all but a few uber-populated urban areas in the country. And Novant Health is a massive 35,000-employee healthcare system in North Carolina with locations clustered mostly in Charlotte, Winston-Salem,

data" (Opp. at 17) fails under the actual regulatory record, which reflects obvious insecurity by the drafters about the Secretary's broad predictions. *See* 86 Fed. Reg. at 61,612 ("A major caution about these estimates…"; "Another unknown is what currently unvaccinated employees would do …"; "Again, we have no way to estimate …"; "As indicated by the preceding analysis, predicting the full range of benefits and costs in either the short run or the next full year with any degree of estimating precision is all but impossible."); *id*. at 61,603 ("This rule presents additional difficulties in estimating both costs and benefits due to the high degree to which current provider and supplier staff have already received information about the benefits and safety of COVID–19 vaccination, and the rare serious risks associated with it.").[4]

To recap, CMS admits knowing "endemic staff shortages" throughout the healthcare industry "will be made worse if any substantial number of unvaccinated employees" leave the workforce because of the Mandate. *Id*. at 61,607; *see id.* at 61,559 (recognizing that staff shortages "have ramifications for patient access to recommended and medically appropriate services"). Yet, CMS, which astonishingly declared it could not identify a "single entity" worth consulting about the impact of its actions, claims it does not know how many "recalcitrant unvaccinated employees" will exit the workforce under the Mandate because it has "no way to estimate such behavioral changes," *id*. at 61,612, and "there is insufficient evidence to quantify and compare adverse

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and their suburbs. CMS's reliance on New York's 92% vaccination compliance rate is particularly remarkable given reports that New York hospitals are closing doors. *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.").

[4] The assertion that it is impossible to analytically assess the potential labor market impact is disingenuous. *See, e.g.*, Liz Hamel, *et al.*, *KFA COVID-19 Vaccine Monitor: October 2021*, KFF (Oct. 28, 2021), https://www.kff.org/coronavirus-covid-19/poll-finding/kff-covid-19-vaccine-monitor-october-2021/ ("More than a third (37%) of unvaccinated workers (5% of adults overall) say they would leave their job if their employer required them to get a vaccine or get tested weekly").

impacts on patient and resident care associated with temporary staffing losses." *Id*. at 61,569. By CMS's own admission, these difficult questions "remain" unanswered. *Id*. at 61,612. (Had it asked, it would have received a different answer, as demonstrated by the Declarations submitted here.)

How, then, can CMS propose such an unprecedented, far-reaching, and disruptive rule without understanding the impact of the rule on the access to care of the statutory beneficiaries? The answer, according to CMS, is both philosophical, *see id.* at 61,612 ("*we believe* it is clear" that the "larger benefits" will prevail) (emphasis added), and absurd. *See id*. at 61,609 ("there is *no reason* to think this will be a net minus even in the short term, given the magnitude of normal turnover and the relatively small fraction of that turnover that will be due to vaccination mandates") (emphasis added). Again, CMS *sought no input*, therefore it conveniently finds nothing to contradict its misinformed conclusions. But deliberately unsubstantiated predictions cannot suffice under the APA.

First, the Secretary's *belief* in the efficacy of the program and the resiliency of the healthcare labor market is no substitute for reasoned analysis, particularly in the face of explicit warnings in the agency record about the paucity and limitations of the evidence it considered. The APA requires an agency to "examine the relevant data and articulate a satisfactory explanation for its actions including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). "[U]nsupported supposition" is neither reasoned nor rational. *United Techs. Corp. v. Dep't of Def.*, 601 F.3d 557, 562 (D.D. Cir. 2010).

Second, Defendants' claim, Opp. at 18, that any workforce losses will "be dwarfed by the ordinary degree of churn in the market of labor in the health care industry" and that "there is no reason to believe that the need to find staffing will be noticeably more onerous" after the Mandate likewise

lacks evidence, or even intuitional support. Because the Mandate covers most of the healthcare industry, unvaccinated workers are now essentially removed from the labor force in that industry. Excluding an entire category of workers from most healthcare jobs across the Nation is hardly comparable to ordinary "churn" of the labor market. To the contrary, it pours gasoline on an already volatile situation. The foundationless notion that "business as usual" measures can counteract the impending doom is unreasonable in the extreme.

The Secretary's dismissive treatment of such an "important aspect of the problem" is fatal to the rule. *See Humane Soc'y of United States v. Zinke*, 865 F.3d 585, 606 (D.C. Cir. 2017) ("failure to address 'an important aspect of the problem' that is factually substantiated in the record is unreasoned, arbitrary, and capricious decisionmaking") (quoting *Motor Vehicle Mfrs. Ass'n.*, 463 U.S. at 43 (1983); *Stewart v. Azar*, 313 F. Supp. 3d 237, 261 (D.D.C. 2019) ("The fundamental failure here [] is that he (the Secretary) ignored" the Medicaid Act's core objective of providing care to the needy) (underscore in original); *Gresham v. Azar*, 363 F. Supp. 3d 165, 177 (D.D.C. 2019) ("The Secretary's approval letter did not consider whether [Arkansas Work Amendments] would reduce Medicaid coverage) (underscore in original); *Philbrick v. Azar*, 397 F. Supp. 3d 11, 24 (D.D.C. 2019) ("it can hardly be disputed that the agency needs to address the magnitude" of the number of beneficiaries who will lose coverage) (underscore in original).

Unreasonably Rejects Natural Immunity. CMS further renders its actions invalid by its refusal 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," and "are *no longer sources of future infections*," and 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).

Post Hoc/Pretextual Reasoning. Defendants want to ignore the Biden Administration's prior comments concerning vaccine mandates. Opp. at 19-20. But this Court should not—and indeed cannot—ignore the obvious pretextual and post-hoc reasoning. As Plaintiff States have explained, the Administration originally affirmed that mandating vaccines is "not the role of the federal government." Doc. 2-1, at 3. The President then unabashedly announced that the CMS Vaccine Mandate is part of a broader program aimed at generally increasing vaccination rates. *Id.* Yet 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. OSHA*, __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).

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. (It is also worth noting that CMS has not adopted a mandate for actual patients.) 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 Plaintiff States' initial memorandum, the Vaccine Mandate is arbitrary and capricious.

C. The 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 22-24. But 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 United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011) ("[I]t is well established that the 'good cause' exception to notice-and-comment should be read narrowly in order to avoid providing agencies with an 'escape clause' from the requirements Congress prescribed.").

Defendants' good-cause arguments focus on the health risks from COVID-19. But after almost two years, COVID-19 is a persistent feature of life and cannot itself constitute good cause; similarly, COVID-19 vaccinations have been approved under emergency authorizations for nearly a year. *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). After so much time has passed, to deem the desire for universal vaccination against COVID-19 "good cause" for ignoring notice-and-comment requirements would effectively repeal those 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 (May 13, 2021). 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).[5]

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 the 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

[5] For the same reasons, it makes little sense that the Secretary could not have consulted with appropriate State and local agencies in advance of the rule. The post-rule consultations that Defendants allegedly intend to undertake, see Op. at 23-24, do not comply with the plain text of 42 U.S.C. § 1395z and that statute's clear purpose to ensure that States are stakeholders and participants in Medicare—not mere subjects.

(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. Defendants' neglect of notice and comment lacks any good cause justification.

III. The Remaining Injunction Factors Favor the Plaintiffs.

A. The Plaintiffs Face Irreparable Harm.

Sovereign Interests. Defendants' argument (Opp. at 26-27) that Plaintiff States have "suffered no cognizable harm" to their sovereign interest blinks reality *and* defies clear Fifth Circuit precedent. *See, e.g.*, *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 734 F.3d 406, 419 (5th Cir. 2013). A State's interest in "in not being pressured to change its law" is sufficiently "related to its sovereignty" for these purposes. *Texas v. United States*, 787 F.3d 733, 752 n.38 (5th Cir. 2015); *see also Veasey v. Abbott*, 870 F.3d 387, 391 (5th Cir. 2017) ("[T]he State necessarily suffers the irreparable harm of denying the public interest in the enforcement of its laws.").

Likewise, Defendants' reliance (Opp. at 26) on *Massachusetts v. EPA*, 549 U.S. 497 (2007) for the proposition that Plaintiff States lack standing is misplaced. *Massachusetts* expressly noted that, given the state'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 had standing "to litigate in *parens patiae* to protect quasi-sovereign interests—i.e., public or governmental interests that concern the state as a whole." *Id.* at 520, n.17.

Proprietary Interests. Plaintiff States also face irreparable harm as arising out of their relationships with healthcare facilities covered by the Mandate. Defendants reduce these harms to "mere" economic harm. Opp. at 26-27. But "[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); *accord East Bay*

Sanctuary Covenant v. Biden, 993 F.3d 640, 677 (9th Cir. 2021); *Kansas Health Care Ass'n, Inc. v. Kansas Dep't of Soc. & Rehab. Servs.*, 31 F.3d 1536, 1543 (10th Cir. 1994); *Temple Univ. v. White*, 941 F.2d 201, 214-15 (3d Cir. 1991). As the Fifth Circuit has stated, "complying with a regulation later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs." *Texas v. E.P.A.*, 829 F.3d 405, 433 (5th Cir. 2016) (cleaned up). And the Vaccine Mandate will impose enormous non-economic costs on the States' institutions' own employees and will cause real disruptions in day-to-day operations caring for patients. This shows that the harm at stake is far more than money.

The recent decision from Florida on which Defendants primarily rely, *Florida v. Dep't of Health & Hum. Servs.*, _F. Supp. 3d._, 2021 WL 5416122 (N.D. Fla. Nov. 20, 2021) (denying injunction for lack of irreparable harm), is in clear conflict with controlling Fifth Circuit precedent. *See Texas*, 787 F.3d at 752 n.38, and *Veasey*, 870 F.3d 387, 391; *see also Texas v. E.P.A.*, 829 F.3d at 433; *Wages & White Lion Invs., L.L.C. v. F.D.A.*, 16 F.4th 1130, 1142 (5th Cir. 2021) ("because federal agencies generally enjoy sovereign immunity for any monetary damages," so an injured party has no redress"). By comparison, the decision from Missouri provides a more thorough analysis of the irreparable harm element consistent with precedent applicable here. *See Missouri*, No. 4:21-cv-01329, ECF No. 28 at 23-28.

Likelihood of Harms. Defendants next argue that Plaintiffs States' irreparable harms must be "imminent." Opp. at 28. Even if that were the standard (which it is not), Plaintiff States would readily satisfy it. The sovereign harms involving preemption of Plaintiff States' laws are certain to occur. So are Plaintiff States' 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"). Plaintiff States have shown that the irreparable harm relating to the Mandate's catastrophic effects on the healthcare industry easily clear the likelihood standard. Plaintiffs' 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. 2-2—2-17.

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).

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 States' requested injunction. Opp. at 29-30. 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 CMS Vaccination Mandate 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). Affording full relief to Plaintiff States necessitates a nationwide injunction. *See Louisiana v. Biden*, 2021 WL 2446010, at *22 (W.D. La. June 15, 2021).

CONCLUSION

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

Dated: November 29, 2021

Respectfully Submitted,

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**Pro Hac Vice admission application forthcoming*

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that I presented the above and foregoing for filing and uploading to the CM/ECF system which will send electronic notification of such filing to all counsel of record.

Alexandria, Louisiana, this 29th day of November, 2021.

/s/ Jimmy R. Faircloth, Jr.
OF COUNSEL