UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
AMARILLO DIVISION

STATE OF TEXAS; TEXAS HEALTH AND HUMAN SERVICES COMMISSION,	§	
	§	
Plaintiffs,	§	
	§	
v.	§	
	§	
XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE, in her official capacity as Administrator of the Centers for Medicare & Medicaid Services; MEENA SESHAMANI, in her official capacity as Deputy Administrator and Director of Center for Medicare; DANIEL TSAI, in his official capacity as Deputy Administrator and Director of Medicaid and CHIP Services; THE CENTERS FOR MEDICARE & MEDICAID SERVICES; JOSEPH R. BIDEN, in his official capacity as President of the United States; UNITED STATES OF AMERICA;	§	Case No. 2:21-CV-00229-Z
	§	
Defendants.	§	

PLAINTIFFS' REPLY IN SUPPORT OF MOTION FOR TEMPORARY RESTRAINING ORDER AND PRELIMINARY INJUNCTION

Table of Contents

Table of Authorities

Page(s)

Cases:

Statutes and Rules:

Other Authorities:

CMS apparently saw no reason to require a vaccine mandate until President Biden announced there would be one. It then spent two months attempting to justify its now-declared emergency requiring the vaccination of millions of healthcare workers. But it never had the statutory authority to issue such an extraordinary rule, its claim of an emergency is undercut by its own delay, and the mandate itself is arbitrary and capricious. The CMS Vaccine Mandate has already been enjoined in ten States. *Missouri v. Biden*, No. 4:21-CV-1329-MTS, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021). The Court should similarly enjoin it here.

I. THE COURT HAS SUBJECT-MATTER JURISDICTION.

Defendants first assert that the Court lacks subject-matter jurisdiction because statutory channeling provisions require Texas to go through an administrative-review process. Resp. 11-15; *see* 42 U.S.C. §§ 1395cc(h)(1), 1395ii (incorporating 42 U.S.C. § 405). As the district court in Missouri just held, Defendants are wrong. *Missouri*, 2021 WL 5564501, at *1. This Court has jurisdiction.

First, the channeling provisions do not apply to Texas because it is not an "institution or agency" that is dissatisfied with a determination of the Secretary, as required by section 1395cc(h)(1)(A). Defendants admit as much but argue that the channeling provisions still apply because Texas is standing in the shoes of healthcare facilities whose claims would be channeled. Resp. 15. But Texas is bringing suit to, *inter alia*, vindicate its quasi-sovereign interest "in the health and well-being—both physical and economic—of its residents." *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607 (1982); *see also Massachusetts v. E.P.A.*, 549 U.S. 497, 520 n.17 (2007) (permitting suits against the federal government). And the CMS Vaccine Mandate poses physical and economic harm to Texas residents: unvaccinated healthcare workers face job loss, unvaccinated medical students face an inability to complete their education, and patients face harm from an inability to access healthcare services due to staffing shortages caused by the mandate. Compl. ¶¶ 143-45; App.206-48. Thus, Texas's interests in this case go far beyond those of healthcare facilities.

Second, the channeling provisions do not apply when judicial review is unavailable as a legal or practical matter. *UnitedHealthcare Ins. Co. v. Price*, 248 F. Supp. 3d 192, 202 (D.D.C. 2017); *Am. Lithotripsy Soc. v. Thompson*, 215 F. Supp. 2d 23, 28-29 (D.D.C. 2002); *Frontier Health Inc. v. Shalala*, 113 F. Supp. 2d 1192, 1193 (E.D. Tenn. 2000). Administrative review is available to beneficiaries and providers. *Nat'l Athletic Trainers' Ass'n, Inc. v. U.S. Dep't of Health & Human Servs.*, 455 F.3d 500, 504 (5th Cir. 2006). But as described in Texas's briefing, other individuals will be harmed: healthcare workers, volunteers, contractors, medical students, and patients at facilities subject to the mandate. These individuals do not have claims for benefits and are not contesting a sanction imposed on them such that they could obtain review through the channeling provisions. *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 14 (2000). Asserting quasi-sovereign interests based on the harm caused by loss of jobs and access to healthcare, Texas has no recourse but to proceed directly to federal court to obtain judicial review of the CMS Vaccine Mandate.

As a practical matter, the "hardship likely found in many cases turns what appears to be simply a channeling requirement into *complete* preclusion of judicial review." *Id.* at 22-23; *see also Sw. Pharmacy Sols., Inc. v. CMS*, 718 F.3d 436, 441 (5th Cir. 2013) (looking for hardship that was "sufficiently widespread"). The CMS FAQ page makes clear that, while nursing homes, home health agencies, and hospices may face monetary penalties before termination, "[t]he remedy for non-compliance among hospitals and certain other acute and continuing care providers is termination." CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (External FAQ) at 10 (last visited Nov. 30, 2021), https://perma.cc/7W7B-CNPR.

Thus, those healthcare facilities face the choice of (1) compliance with no grounds for judicial review, or (2) noncompliance and termination of Medicare and Medicaid contracts. For many, that is no choice at all. *See, e.g.*, App.207, 245. That makes this case different from *Physician Hospitals of America v. Sebelius*, 691 F.3d 649, 655 (5th Cir. 2012), which concerned only whether a hospital

would be reimbursed—not whether its Medicare and Medicaid contracts would be terminated. Because judicial review is practically unavailable to many facilities, the channeling provisions are not applicable.

And *third*, the channeling provisions do not apply to claims regarding Medicaid. *Avon Nursing & Rehab. v. Becerra*, 995 F.3d 305, 309 (2d Cir. 2021) (noting that "the Medicaid Act does not incorporate sections 405(g) or (h)"); *Missouri*, 2021 WL 5564501, at *1. Thus, there is subject-matter jurisdiction over Texas's claims as they pertain to Medicaid regardless of any channeling of Medicare claims.

II. TEXAS IS LIKELY TO SUCCEED ON THE MERITS.

A. CMS lacked statutory authority to issue its vaccine mandate.

Defendants' answer to Texas's challenge to its authority to mandate the vaccination of millions of healthcare workers is to generally assert that the Secretary has broad authority. Resp. 15-20. But that authority "is not boundless." *Merck & Co., Inc. v. U.S. Dep't of Health & Human Servs.*, 962 F.3d 531, 537 (D.C. Cir. 2020). Congress has given the Secretary the authority to make rules regarding the "administration" of Medicare and Medicaid. 42 U.S.C. §§ 1302(a), 1395hh(a)(1). And as Defendants admit, the administration of Medicare and Medicaid has never before included mandating vaccines. Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,568 (2021); *see also Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 549 (2012) ("[S]ometimes the most telling indication of [a] severe constitutional problem . . . is the lack of historical precedent for Congress's action." (internal quotation marks omitted)).

Defendants fail to recognize the fundamental difference between health-and-safety measures such as infection control (sterilization of instruments, handwashing, etc.) versus a vaccine mandate. The former concerns the external such as cleanliness of facilities or the outer body; the latter concerns an invasive, unreversible medical treatment that infringes on deeply personal health choices of individuals.

And the mandate applies not just to individuals who interact with patients, but to individuals who interact with individuals who interact with patients. 86 Fed. Reg. at 61,570. Such a drastic expansion of authority, and one that shifts responsibility for the health of individuals from the States to the federal government, cannot have come without a clear indication from Congress. *See Ala. Ass'n of Realtors v. Dep't of Health & Human Servs.*, 141 S. Ct. 2485, 2489 (2021); *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014); *Missouri*, 2021 WL 5564501, at *2 (noting that "the nature and breadth of the CMS mandate requires clear authorization from Congress"). And as the Missouri district court recognized, "'[i]t is especially unlikely that Congress would have delegated this decision to [CMS], which has no expertise in crafting' vaccine mandates." *Missouri*, 2021 WL 5564501, at *3 (quoting *King v. Burwell*, 576 U.S. 473, 486 (2015)).

Congress has spoken in one respect: Defendants may not "control" the selection and tenure of employees at covered facilities. 42 U.S.C. § 1395. Defendants assert that demanding that covered facilities terminate all unvaccinated employees upon pain of losing their Medicare and Medicaid contracts is not exercising "control" because participation in Medicare and Medicaid is voluntary. Resp. 20. But that interpretation robs the statute of any effect. Congress does not want the federal government interfering in employment decisions.

As the D.C. Circuit has explained, the Secretary's statutory authority would likely not permit him to adopt 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." *Merck*, 962 F.3d at 538. The same holds here. The Secretary has attempted to transform his administrative duties regarding the provision of federal assistance to ensure healthcare for vulnerable individuals into the power to mandate the Secretary's view of best practices in healthcare. *See* Resp. 21 (claiming that "[t]he Secretary's primary responsibility is to protect the health and safety of patients"). Congress has not given him that power, and the CMS Vaccine Mandate should be enjoined and set aside.

B. CMS failed to follow proper rule-making procedures.

1. Failure to follow notice-and-comment procedures: Defendants assert they had good cause to ignore the required notice-and-comment procedures because (1) the mandate will save lives, and (2) flu season is coming. Resp. 31-35. Neither reason suffices.

The good cause exception "should be read narrowly" and "should not be used . . . to circumvent the notice and comment requirements whenever an agency finds it inconvenient to follow them." *U.S. Steel Corp. v. U.S. E.P.A.*, 595 F.2d 207, 214 (5th Cir. 1979). "The burden is on [CMS] to establish that notice and comment need not be provided." *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 113-14 (2d Cir. 2018). Defendants' claim that the mandate will save "several hundred" or "several thousand" lives per month is entirely speculative and contrary to the evidence. Resp. 31 (citing 86 Fed. Reg. at 61,612). Since April 2021, an average of 34 healthcare workers have died of COVID each month. 86 Fed. Reg. at 61,612. And Defendants cite no evidence of how many patients at healthcare facilities have died after contracting COVID from an unvaccinated healthcare worker in recent months. COVID does not create a perpetual emergency for CMS to take whatever actions it deems necessary.

Further, despite the professed emergency, CMS found time to review input from "stakeholders" who supported its decision, 86 Fed. Reg. at 61,565-66, but could not find time to permit comments from those who do not. But the over 1400 comments it has received since announcing the mandate are overwhelmingly opposed to the rule, demonstrate the severe burdens it will place on healthcare systems, and show that the matter is one of deep public interest.[1]

Moreover, given CMS's admission that the impact of the upcoming flu season "cannot be predicted," *id.* at 61,584, there is also no reason for CMS to have waited until November to issue its mandate. It could have made its speculative predictions at any point this year and gone through notice and comment. Regardless, the mere possibility that flu season will place a greater strain on

[1] https://www.regulations.gov/document/CMS-2021-0168-0001/comment. Specific examples of concerns regarding staffing shortages can be found in the comments with the following tracking numbers: kvn-lkqs-nxas, kvt-rlrg-fcoo, and kw6-tzic-yb46, to list only a few.

healthcare facilities is insufficient to bypass notice and comment. *See Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 707 (D.C. Cir. 2014) (finding unsupported speculation of harm insufficient to bypass notice and comment).

Defendants' claim of a present emergency is incompatible with (1) CMS's actions in waiting eleven months after the vaccines became available to conclude that healthcare facilities needed a nearly 100% vaccination rate to be considered "safe"; (2) CMS's decision not to issue a vaccine mandate during the summer months, when it admits the delta variant created a surge in COVID cases, 86 Fed. Reg. at 61,559; and (3) CMS's implicit admission that it had no intention of issuing such a mandate—despite all the evidence it now relies on—until President Biden announced it in September, Resp. 32 (explaining it completed the 73-page rule within two months of President Biden's announcement). *See, e.g.*, *Chamber of Com. of United States v. U.S. Dep't of Homeland Sec.*, 504 F. Supp. 3d 1077, 1089 (N.D. Cal. 2020) (rejecting good-cause exception).

CMS saw no emergency until it needed to find one. *Nat. Res. Def. Council*, 894 F.3d at 114-15 (noting that "[g]ood cause cannot arise as a result of the agency's own delay"); *BST Holdings, LLC v. Occupational Health & Safety Admin.*, No. 21-60845, 2021 WL 5279381, at *3 n.11. (5th Cir. Nov. 12, 2021) (regarding the two-month delay of the OHSA vaccine mandate: "One could query how an 'emergency' could prompt such a 'deliberate' response."). Notice and comment was required before imposing such a drastic measure on millions of healthcare workers.

2. Failure to consult state agencies: Defendants argue that they did not have to "consult with appropriate State agencies" as required by 42 U.S.C. § 1395z because the alleged emergency meant it was not "appropriate" to consult with any agency. Resp. 33-34. The text of section 1395z does not permit that conclusion. The question is not whether *consultation* is appropriate—the statute says "shall consult"—but which *agency* is appropriate. Allowing the Secretary to decide when consultation is appropriate would create an exception that swallows the rule.

3. Failure to prepare a rural-impact analysis: Defendants also claim they were not required to prepare a rural-impact analysis because the vaccine mandate was published as an interim final rule, rather than a proposed rule. Resp. 34; 42 U.S.C. § 1302(b)(1). But the Supreme Court has previously treated an interim final rule as a notice of proposed rulemaking. *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 140 S. Ct. 2367, 2384 (2020). And Defendants' assertion that a rural-impact analysis is not warranted is contradicted by its admission that rural hospitals were having problems with vaccine refusals. 86 Fed. Reg. at 61,613.

C. The CMS Vaccine Mandate is arbitrary and capricious.

Defendants have failed to demonstrate that the CMS Vaccine Mandate is not arbitrary and capricious for the reasons identified in Texas's motion. Consequently, it must be set aside. 5 U.S.C. § 706(2).

1. Reliance on inadequate data: Defendants lack data showing significant rates of transmission of COVID from unvaccinated healthcare workers to patients (who may or may not be vaccinated). The first study Defendants cite (at 3, 21) was based on pre-vaccination data from 2020. AR03696. And the second study did not discuss transmission of COVID between healthcare workers and patients. AR01080. Defendants also assert (at 3, 21) that unvaccinated healthcare workers are "highly susceptible" to transmitting COVID to colleagues and patients but cite a study finding a "relatively low frequency" of COVID cases. AR00672.

Defendants continue to rely on unspecified anecdotes and a "concern" that individuals are reluctant to seek healthcare for fear of unvaccinated staff. Resp. 22-23 (citing 86 Fed. Reg. at 61,558). But a "concern" is not a substitute for evidence. And Defendants do not dispute that, while complaining of a 64% staff vaccination rate at long-term care (LTC) facilities, that percentage had increased to 76% at the time the vaccine mandate was issued. Mot. 25-26. In short, Defendants' decision to require a nearly 100% vaccination rate is not based on evidence that evidence that a 100% vaccination rate is necessary to prevent significant transmission of COVID from healthcare workers to patients.

2. **Overbroad application:** Defendants admit that they focused on and extrapolated from data from LTC facilities to create a rule that applied to very different types of facilities. Resp. 24-25. Yet residents of LTC facilities, although less than 1% of the population, accounted for more than 35% of all COVID deaths in the first year of the pandemic. 86 Fed. Reg. at 61,566; *see also id.* at 61,601 (finding that 30% of Americans who died from COVID through September 2021 did so during or after an LTC facility stay). Extrapolating from the most extreme set of data is not reasonable. Defendants also fail to justify extending the mandate to all employees, volunteers, and contractors who do not have patient contact, but might interact or use the same spaces as those who do. Resp. 25. Citing evidence that COVID is transmissible does not justify CMS's sweeping mandate that covers everyone from doctors, to accountants, to construction workers. Defendants cannot justify the arbitrary line they have drawn.

3. **Failure to consider the full impact of the mandate:** Defendants agree that there are staff shortages around the country, but appear to attribute them, without evidence, to healthcare workers missing time due to COVID infections. Resp. 26 (citing 86 Fed. Reg. at 61,559). And Defendants' belief that forcing more healthcare workers to leave due to the vaccine mandate will not exacerbate the problem is contradicted by their admission that "we have no way to estimate" what unvaccinated employees will do. 86 Fed. Reg. at 61,612. Defendants point to some healthcare providers in urban areas that have achieved high vaccination rates. Resp. 27. But not all healthcare providers can do so—a fact Defendants would have learned through notice and comment. *See, e.g.*, App.208, 248. Regardless, applying New York's 92% vaccination rate (Resp. 27) just to the 2.4 million healthcare workers who have yet to be vaccinated (86 Fed. Reg. at 61,607) would still result in 192,000 unvaccinated healthcare employees forced to leave their jobs. Defendants' additional belief that individuals will come back to work once they knew their coworkers are vaccinated—even though they still will have to treat unvaccinated patients—is entirely unsupported. Resp. 28; 86 Fed. Reg. at 61,607. And the claim (at 28) that healthcare providers routinely replace employees

does not account for (1) rural areas in which replacement employees are frequently unavailable, and (2) new employees who also do not wish to be vaccinated. Defendants' rosy predictions are inconsistent with reality. *Humane Soc'y of United States v. Zinke*, 865 F.3d 585, 606 (D.C. Cir. 2017) (noting the "failure to address an important aspect of the problem that is factually substantiated in the record is unreasoned, arbitrary, and capricious decisionmaking").

4. **Lack of flexibility:** Defendants assert that the alternative of regular COVID testing was rejected because testing is less effective than vaccination, but Defendants cite only (1) a study finding that outbreak testing was an effective approach when combined with infection-control measures, and (2) a study that showed some COVID tests were only 80% accurate. Resp. 29 (citing AR02949-50 & AR03307). Given Defendants' admission that the effectiveness of vaccines at reducing transmissibility is unknown, 86 Fed. Reg. at 61,615, this is an insufficient reason to reject testing as an alternative. Similarly, Defendants refused to treat natural immunity resulting from a previous COVID infection as an alternative to vaccination, *id.* at 61,614, despite admitting that individuals who have recovered from COVID are "no longer sources of future infections," *id.* at 61,604. Such inconsistencies demonstrate that the CMS Vaccine Mandate is arbitrary and capricious. *See Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 222 (2016).

III. TEXAS HAS MET THE OTHER ELEMENTS OF A PRELIMINARY INJUNCTION.

A. Texas has demonstrated irreparable harm.[2] Mot. 33-35. Texas's sovereign interests will be irreparably harmed as Defendants seek to prevent Texas from enforcing its own law banning vaccine mandates. *See Missouri*, 2021 WL 5564501, at *11; App.250-52. Texas's quasi-sovereign interest in the health and well-being of its residents will be irreparably harmed: CMS itself admits that 2.4 million healthcare workers require vaccination—many of whom hold two jobs, 86 Fed. Reg. at 61,605—and will be in danger of losing their jobs in a few short days, *id.* at 61,607; there are

[2] Contrary to Defendants' claim (at 35), this Court has previously concluded that such allegations, when supported by evidence, can suffice to establish standing. *State v. Biden*, No. 2:21-CV-067-Z, 2021 WL 3603341, at *11-*12 (N.D. Tex. Aug. 13, 2021).

preexisting "endemic staff shortages for almost all categories of employees at almost all kinds of health care providers," *id.*; and disruption to healthcare services will cost $600 million in the first year, *id.* at 61,609 (Table 7). Texas has put additional evidence in the record demonstrating the harm to Texas, including to state-run facilities, *see, e.g.*, App.206-09, 217-19, 223-28, 235-39, 243-48, and will present further evidence at the preliminary-injunction hearing. And it cannot be overstated that there is irreparable harm in unlawfully forcing an individual to be vaccinated, as a vaccination cannot be undone. If Texas is likely to prevail on the merits, there is every reason to prevent the vaccine mandate from taking effect.

B. The balance of equities and public interest favor an injunction for the same reasons described in *Alabama Association of Realtors*, 141 S. Ct. at 2489-90. The CMS Vaccine Mandate threatens the economic and physical health and well-being of Texas residents. And while the public "has a strong interest in combating the spread of the COVID–19[,] . . . our system does not permit agencies to act unlawfully even in pursuit of desirable ends." *Id.* at 2490.

C. Finally, Defendants request that the Court sever the unlawful portions of the vaccine mandate and limit its injunction to facilities operated by Texas. But Defendants have not identified any portion of the CMS Vaccine Mandate that is lawful. Moreover, if the Court concludes that Defendants violated the APA when adopting the CMS Vaccine Mandate, then the mandate must be "set aside." 5 U.S.C. § 706(2). Thus, any injunction should enjoin all Defendants, regardless of who the plaintiffs are. At a minimum, however, the CMS Vaccine Mandate should be enjoined throughout Texas. *See Missouri*, 2021 WL 5564501, at *15 (enjoining CMS Vaccine Mandate in ten States).

Conclusion

For the foregoing reasons, the Court should grant Texas's request for a temporary restraining order and preliminary injunction.

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