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

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After months of choosing to "encourage" healthcare providers to receive the COVID-19 vaccination, the Centers for Medicare and Medicaid Services (CMS), at the direction of President Biden, moved the goalposts, now concluding that nothing less than a 100% vaccination rate is acceptable. The decision to mandate vaccinations for nearly every individual (other than a patient) who sets foot in a covered facility was uninformed, illogical, and without statutory authority. Congress never authorized CMS (under the guise of "administering" the Medicare and Medicaid programs) to mandate vaccinations for a wide swath of individuals who work at, volunteer at, or contract with covered facilities. In its rush to push out the mandate, and notwithstanding that CMS lacked the statutory authority to do so, CMS failed to follow the statutorily mandated procedures for adopting such a rule—procedures that would have demonstrated the harm the vaccine mandate will cause. Its decision was arbitrary and capricious on numerous levels. Requiring mandatory vaccinations at this time, almost a year since COVID-19 vaccines were first available in Texas, would disrupt the status quo—which for the duration of the pandemic has been to encourage, but not compel, vaccinations (and routine testing of individuals). To radically alter the playing field now will have devastating effects on the State of Texas.

Injunctive relief is necessary because implementation of CMS's mandate will lead to a reduction in the availability of healthcare services for those vulnerable individuals who rely on Medicare and Medicaid—facility staff shortages will be exacerbated, and some rural hospitals may have to discontinue certain services if they cannot replace their staff. Further, if facilities are faced with the termination of healthcare workers at this juncture of the pandemic, it will make an already difficult situation much worse, akin to a regulatory "bloodletting" of Texas and its healthcare services. CMS failed to acknowledge this reality, instead relying on a data-free discussion of

estimates and assumptions that everything will work out. But the evidence demonstrates otherwise. CMS's Vaccine Mandate is unlawful, and Defendants should be enjoined from implementing it.

I. FACTUAL BACKGROUND

A. The Healthcare Worker Crisis

Texas, like the rest of the nation, is currently facing a severe workforce shortage in the healthcare industry. Some sectors, such as nursing, had workforce shortages that predated the COVID-19 pandemic. App.008. The nursing shortage has been exacerbated by the pandemic, as many nurses have retired early or left the profession due to fatigue and burnout. App.011. One Texas hospital in a high-poverty and socially vulnerable community reported that its annual average for nurse turnover increased from 2 percent prior to the pandemic to a staggering 20 percent in 2020. App.034. Staffing shortages became so severe in some areas of Texas that the State began to recruit out-of-state medical workers to alleviate the situation. App.082. Even with the State's assistance, however, Texas healthcare providers continued to experience critical staffing shortages. App.083.

According to a HHSC report from May 2020, Texas is suffering from a statewide shortage of physicians that "is projected to increase from 6,218 full-time equivalents (FTEs) in 2018 to 10,330 FTEs in 2032." App.102. In particular, Texas is experiencing a critical shortage of psychiatrists, pediatricians, and family physicians. App.103. Current projections in medical school enrollment and resident positions indicate that Texas's graduate medical education system will not create a supply of physicians that can meet the projected demand. *Id.* Needless to say, the Texas healthcare industry cannot afford to lose more workers.

B. Federal Vaccine Mandates

President Biden previously indicated his administration would not impose vaccine mandates on the American people. As recently as July 23, 2021, the White House announced that mandating vaccines is "not the role of the federal government." App.156. But in an abrupt about-face, President Biden announced on September 9, 2021, that he would "require more Americans to be vaccinated." App.183. He blamed unvaccinated individuals for healthcare shortages, stating: "our patience is wearing thin. And your refusal has cost all of us." App.185. President Biden similarly cast aspersions on state officials—like those in Texas—who have adopted public-health policies with which he does not agree. App.187. Referring specifically to governors who oppose federal vaccine mandates, President Biden promised that "if these governors won't help us beat the pandemic, I'll use my power as President to get them out of the way." *Id.*

President Biden announced a series of federal vaccine mandates: (1) a mandate from the Occupational Safety and Health Administration ("OSHA") for companies with more than 100 employees; (2) a mandate for federal employees; (3) a mandate for employees of federal contractors and subcontractors; and (4) what would become the CMS Vaccine Mandate that is at issue in this case. App.184.

In response to President Biden's announcement, Governor Abbott issued Executive Order GA-40 on October 11, finding that COVID-19 vaccine mandates will "caus[e] workforce disruptions that threaten Texas's continued recovery from the COVID-19 disaster." App.251. He therefore ordered that "[n]o entity in Texas can compel receipt of a COVID-19 vaccine by any individual, including an employee or a consumer, who objects to such vaccination for any reason of personal conscience, based on a religious belief, or for medical reasons, including prior recovery from COVID-19." App.252.

C. The CMS Vaccine Mandate

1. Covered entities and individuals

On November 5, 2021—nearly two months after President Biden announced the federal mandates—CMS published its Interim Final Rule with Comment Period entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination." 86 Fed. Reg. 61,555 ("CMS Vaccine Mandate").

The CMS Vaccine Mandate covers fifteen categories of Medicare- and Medicaid-certified providers and suppliers, including rural health clinics, hospitals, long-term-care facilities ("LTCs"), and home health agencies. *Id.* at 61,569-70. Despite the diverse nature of the entities covered by the CMS Vaccine Mandate, CMS relied almost exclusively on data from LTCs—providers who serve mostly elderly and immunocompromised patients—to justify applying its mandate to the fourteen other categories of Medicare- and Medicaid-certified providers. *See id.* at 61,585, 61,604.

The CMS Vaccine Mandate is exceptionally broad, requiring the vaccination of virtually every full-time employee, part-time worker, trainee, student, volunteer, or contractor working at the covered facilities. *Id.* at 61,570. The mandate requires that all "facility staff" be vaccinated, which includes those "who provide any care, treatment, or *other services* for the facilities," "*regardless of . . . patient contact*." *Id.* (emphasis added). Thus, workers who perform purely administrative duties, those who provide housekeeping and food services, and those contracted to perform services at the facility must be vaccinated. *Id.* Exemptions from the vaccination requirement are allowed only to the extent necessary to "comply with applicable Federal anti-discrimination laws and civil rights protections" such as medical exemptions required by the Americans with

Disabilities Act ("ADA") and religious exemptions required by Title VII of the Civil Rights Act of 1964. *Id.* at 61,568.

CMS intended that its vaccine mandate be nearly universal in applicability to healthcare staff. *Id.* at 61,573. It estimated that approximately 10.3 million employees will fall under the mandate. *Id.* at 61,603.

2. Specific requirements

Covered providers must implement the CMS Vaccine Mandate in two thirty-day phases. *Id.* at 61,571. Phase 1 requires that staff receive the first dose of the vaccine or have requested or been granted a medical or religious exemption by December 6, 2021. *Id.* Phase 2 requires that non-exempt staff be fully vaccinated by January 4, 2022. *Id.*

The CMS Vaccine Mandate imposes numerous regulatory burdens on Medicare and Medicaid providers and suppliers—all of which must be implemented within 30 days of November 5, 2021. For example, these providers must "track and securely document the vaccination status of each staff member," including booster doses. *Id.* at 61,570-71. They must also implement procedures by which staff may request an exemption from the vaccination requirement. *Id.* at 61,572. And they are required to create "a process for ensuring implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19." *Id.* State surveyors (who will also have to be vaccinated) will be required to undergo training on how to assess compliance with the CMS Vaccine Mandate, including how to review records of staff vaccination and how to interview staff to verify vaccination status. *Id.* at 61,574; *see also* App.219, 226-27.

3. Failure to comply

Healthcare providers that fail to comply with the CMS Vaccine Mandate face a wide variety of potential penalties—including monetary penalties, denial of payment for new admissions, and even the termination of the Medicare/Medicaid provider agreement. 86 Fed. Reg. at 61,574. These potential penalties have real-life consequences to Texas healthcare providers and could impact their ability to serve their patients.

D. The CMS Vaccine Mandate's Impact on Texas

1. Impact on Texas healthcare workers

Considered heroes at the beginning of the pandemic for risking their lives to save others, healthcare workers who have chosen to decline a COVID-19 vaccine are now facing termination, further exacerbating preexisting staffing shortages. Kara Shepherd, for example, was a nurse at Houston Methodist Willowbrook Hospital who often had to perform multiple jobs at once due to staffing shortages. App.241. Shepherd previously contracted COVID-19, giving her natural immunity to the virus, and chose to decline the vaccine due to safety concerns. App.242. She was terminated for her choice. *Id.* Her story is just one of many—healthcare workers who choose not to be vaccinated for a variety of reasons and have been terminated. *See, e.g.*, App.213-14; App.216; App.232-34. And this, despite pervasive staffing shortages in the healthcare industry, including in state-run facilities. App.219, 227, 237-38. If the CMS Vaccine Mandate is permitted to stand, more healthcare workers will undoubtedly meet Shepherd's fate—terminated solely for choosing to decline a vaccine. Not only will this lead to additional staffing shortages, it may well prevent countless Texans from receiving medical care they desperately need. *See, e.g.*, App.218-19, 226.

2. Impact on rural Texas

Rural Texas will likely be hardest hit by the CMS Vaccine Mandate. Moore County, a rural community located in the Texas Panhandle, illustrates the devastating consequences of the CMS Vaccine Mandate on rural Texas.

The Moore County Hospital District ("MCHD") is a critical access hospital district that has cared for patients infected with COVID-19 since the initial surge in March 2020. App.244. Of MCHD's 372 fulltime employees, 99 remain unvaccinated. *Id.* Should the CMS Vaccine Mandate be implemented, MCHD will either have to terminate its unvaccinated employees or face punitive actions from CMS. App.244-45. But MCHD cannot afford either option. Medicare and Medicaid programs comprise 45% of MCHD's tax payer mix, so termination of the contracts would bankrupt MCHD. App.245. On the other hand, if MCHD were to lose a sizable number of employees, it would prevent MCHD from being able to fulfill its commitment to provide essential healthcare services to the community, such as EMS, trauma and acute care, surgical and obstetrical services, long-term care, home health and hospice, and physician and outpatient clinical ancillaries. *Id.* As stated by the CEO of MCHD, "[t]he [CMS Vaccine Mandate] puts rural hospitals in a no-win situation. Either we pay a penalty we cannot afford or we lose staff we cannot replace or afford to lose." *Id.*

The struggles facing MCHD were echoed by the CEO for Goodall-Witcher Healthcare ("GWH")—another hospital serving rural Texas. App.247. He has been personally informed by multiple GWH employees, including nurses in highly skilled areas, that they will resign if they are required to receive a vaccine. *Id.* If GWH loses even some staff, it may have to discontinue some healthcare services, like labor and delivery, forcing patients to potentially travel another 35 miles to receive those services. App.247-48. It is not feasible for GWH to simply replace its unvaccinated

workers, as the rural area in which GWH is located does not contain qualified individuals to fill those slots. App.248.

3. Impact on state-run healthcare institutions

The CMS Vaccine Mandate will detrimentally impact state-run institutions in Texas that participate in Medicare and Medicaid, including thirteen State Supported Living Centers ("SSLCs"), nine State Hospitals ("SHs") and one residential youth center for individuals with mental health issues. App.237. SSLCs provide crucial services to Texans with intellectual and developmental disabilities who are medically fragile or have behavioral problems. *Id.* SSLCs are heavily dependent on federal funding, receiving $515 million in Fiscal Year 2021, and they must meet CMS's conditions of participation to maintain their certification. *Id.* Texas State Hospitals provide psychiatric care to thousands of Texans with mental illness throughout the State. *Id.* The State Hospitals are already struggling to hire and retain adequate staffing levels. *Id.* Currently, they have 600 beds offline due to their staffing shortage. *Id.* In Fiscal Year 2021, State Hospitals received approximately $956,000 in revenue through Medicaid and approximately $24.6 million through Medicare billing. App.237-38.

Texas's Health and Human Services' Health and Specialty Care System ("HSCS") has historically experienced staffing shortages, and that issue was worsened by the COVID-19 pandemic. App.238. Fill rates for the HSCS have steadily dropped from 86% in March 2020 to 73% in September 2021. *Id.* Staffing challenges have strained daily operations of these facilities. *Id.* State Hospitals currently have 8,508 FTEs, of which only 6,351 positions are filled. *Id.* SSLCs have 13,863 FTEs, of which only 9,945 are filled. *Id.*

Staffing problems will be further exacerbated by the CMS Vaccine Mandate. *Id.* Many staff at these facilities have already expressed their opposition to mandatory vaccines. *Id.* Scott Schalchlin,

Deputy Executive Commissioner for Texas's HSCS, anticipates that staff will resign from their positions in lieu of complying with the CMS Vaccine Mandate. *Id.* Decreased staffing will increase the risk of injury or incident, require halting admission to HSCS facilities, overwork nurses (if their shift replacement does not come to work, for example), lead to closure of beds or units in the State Hospitals, expand the civil and forensic inpatient care waitlists for State Hospitals, and increase the likelihood of regulatory citation due to sub-minimal staffing levels. *Id.* It will also require additional resources and an increased workload to comply with the onerous regulatory requirements imposed by the CMS Vaccine Mandate. App.239. In short, the CMS Vaccine Mandate will further strain the already-struggling HSCS and prevent Texans from receiving the care they need.

II. ARGUMENT

A plaintiff seeking a temporary restraining order or preliminary injunction must establish (1) "that he is likely to succeed on the merits," (2) "that he is likely to suffer irreparable harm in the absence of preliminary relief," (3) "that the balance of equities tips in his favor," and (4) "that an injunction is in the public interest." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008). The standards for securing a temporary restraining order or preliminary injunction are substantively the same. *Whole Woman's Health v. Paxton*, 264 F. Supp. 3d 813, 818 (W.D. Tex. 2017). To preserve the status quo, federal courts have regularly enjoined federal agencies from implementing and enforcing new regulations pending litigation challenging them. *See, e.g.*, *Texas v. United States*, 787 F.3d 733 (5th Cir. 2015) (enjoining executive order inconsistent with immigration statutes). Here, Plaintiffs the State of Texas and the Texas Health and Human Services Commission (collectively, "Texas") satisfy each of the requirements for the issuance of

a temporary restraining order and preliminary injunction. Plaintiffs request that the Court issue a temporary restraining order that remains in effect until the Court has the opportunity to rule on Plaintiffs' motion for preliminary injunction. *See Forman v. Dallas Cnty., Tex.*, 193 F.3d 314, 323 (5th Cir. 1999) (explaining that "[a] temporary restraining order is a 'stay put,' equitable remedy that has as its essential purpose the preservation of the status quo while the merits of the case are explored through litigation.").

A. Texas Is Likely to Succeed on the Merits of Its Claims.

"[O]ur system does not permit agencies to act unlawfully even in pursuit of desirable ends." *Ala. Ass'n of Realtors v. Dep't of Health & Human Servs.*, 141 S. Ct. 2485, 2490 (2021). The CMS Vaccine Mandate violates multiple provisions of the Administrative Procedure Act, the Social Security Act, and other federal statutes that unambiguously delineate CMS's rulemaking authority and the procedural requirements that govern that rulemaking. Texas is likely to succeed on the merits of its claims because the CMS Vaccine Mandate (1) exceeds CMS's statutory authority; (2) was adopted without compliance with administrative procedures required by law; and (3) is arbitrary and capricious.

1. CMS lacked the statutory authority to issue a vaccine mandate.

"[A]n agency literally has no power to act . . . unless and until Congress confers power upon it." *La. Pub. Sev. Comm'n v. FCC*, 476 U.S. 355, 374 (1986). Thus, under the APA, a court must "hold unlawful and set aside agency action" that is "not in accordance with law" or "in excess of statutory . . . authority[] or limitations, or short of statutory right." 5 U.S.C. § 706(2)(A), (C). The CMS Vaccine Mandate far exceeds the statutory authority of CMS and, accordingly, this Court should hold it unlawful and set it aside.

CMS asserts that it has "broad statutory authority to establish health and safety regulations," including "the authority to establish vaccination requirements." 86 Fed. Reg. at 61,567. But it then cites two statutes that do not mention health, safety, or vaccines. *Id.* (referring to sections 1102 (42 U.S.C. § 1302) and 1871 (42 U.S.C. § 1395hh)). And the remaining facility-specific statutes cited by CMS do not grant it the authority to impose vaccination requirements on the nearly 10.4 million individuals who work for, volunteer at, or contract with healthcare facilities. Instead, Congress has explicitly forbidden the federal government from interfering in the selection of employees at healthcare facilities. 42 U.S.C. § 1395.

Under *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984), a court that is reviewing an agency's construction of a statute asks two questions. First, applying the ordinary tools of statutory construction, the court must determine "whether Congress has directly spoken to the precise question at issue." *Id.* at 842-43. If so, the court "must give effect to the unambiguously expressed intent of Congress." *Id.* But "if the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843. Here, whether decided at step one or two, the result is the same—the statutes cited by CMS do not give it the authority to mandate the COVID-19 vaccine at covered facilities.

a. Section 1102 (42 U.S.C. § 1302) gives the Secretaries of the Treasury, Labor, and Health and Human Services the authority to make rules "as may be necessary to the efficient administration of the functions with which each is charged." Section 1871 (42 U.S.C. § 1395hh) is similar: the Secretary may make rules "as may be necessary to carry out the administration of the insurance programs under this subchapter." Nothing about this general grant of authority includes

the ability to force healthcare providers to make their employees, interns, volunteers, and contractors choose between a vaccine and their jobs.

As the D.C. Circuit has explained, "for a regulation to be 'necessary' to the programs' 'administration,' the Secretary must demonstrate an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs." *Merck & Co., Inc. v. United States Dep't of Health & Human Servs.*, 962 F.3d 531, 537-38 (D.C. Cir. 2020) (internal citation omitted). The "operational focus" must be on the Medicare and Medicaid programs, and the effect of the regulation "must be more than tangential." *Id.* at 538.

Medicaid is a program through which "participating States may provide federally funded medical assistance to needy persons." *Beal v. Doe*, 432 U.S. 438, 440 (1977). Medicare similarly enables healthcare providers to "enter into agreements with the Secretary of Health and Human Services pursuant to which they are reimbursed for certain costs associated with the treatment" of the aged and disabled. *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993). The purpose of the programs, therefore, is primarily financial—to provide and pay for medical care for those in need. That does not require that all employees, volunteers, and contractors at participating facilities maintain a certain number of vaccines. "[T]he 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." *Merck*, 962 F.3d at 538. And as demonstrated by the absence of a vaccine mandate until now, it is not "necessary" to have a vaccine mandate in order to administer either program.[1]

[1] Indeed, if CMS's general authority were as wide-ranging as it believes, the grant of authority would violate the nondelegation doctrine, which requires Congress to "'lay down by legislative act

This is especially true considering the absence of any evidence showing that provider-to-patient transmission of COVID-19 is currently a problem. At most, CMS cites some evidence of transmission of COVID-19 in a healthcare setting during the early stages of the pandemic—before a vaccine even existed. 86 Fed. Reg. at 61,557. But it cites nothing to show that now—after nearly 60% of the population has been fully vaccinated, including 70% of all adults, App.193—that provider-to-patient transmission is so problematic that Medicare and Medicaid cannot be administered without a vaccine requirement.

Further, the scope of CMS's claimed authority also counsels against CMS's interpretation. As the Supreme Court has explained, it expects Congress to "speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.'" *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000)). Sometimes referred to as the "major questions doctrine," the principle is that "an agency's exercise of regulatory authority can be of such 'extraordinary' significance that a court should hesitate before concluding that Congress intended to house such sweeping authority in an ambiguous statutory provision." *Am. Lung Ass'n v. EPA*, 985 F.3d 914, 959 (D.C. Cir. 2021), *cert. granted* (U.S. Oct. 29, 2021) (citing, inter alia, *King v. Burwell*, 576 U.S. 473, 485-86 (2015)). "Where there are special reasons for doubt, the doctrine asks whether it is implausible in light of the statute and subject matter in question that Congress authorized such unusual agency action." *Id.*

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an intelligible principle to which the person or body authorized to [exercise the delegated authority] is directed to conform.'" *Gundy v. United States*, 139 S. Ct. 2116, 2123 (2019) (plurality op.).

Thus, for example, the Supreme Court rejected the CDC's claimed authority to issue an eviction moratorium when between 6 and 17 million people faced a risk of eviction. *Ala. Ass'n*, 141 S. Ct. at 2489. As CMS admits here, there are nearly 10.4 million individuals covered by its mandate with an additional 2.7 million individuals yet to be hired who will also be covered, 86 Fed. Reg. at 61,603 (Table 5), 61,606 (Table 6), and the first-year costs of implementation will be nearly $1.4 billion, with $600 million going to staffing and service disruptions alone, *id.* at 61,609 (Table 7). Congress would not have hidden the elephant of mandatory vaccines for all employees, leading to a severe disruption in the provision of healthcare services to an untold number of people, in the mousehole of "efficient administration" of Medicare and Medicaid. *See Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001).

One additional factor militating against CMS's broad interpretation of its authority is its attempt to shift authority to enact health-and-safety laws from the States to the federal government. "[H]ealth laws of every description" are within the States' "police" powers. *Mayor, Aldermen & Commonalty of City of New York v. Miln*, 36 U.S. (11 Pet.) 102, 133 (1837) (quoting *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 203 (1824)). Unlike the States however, the federal government does not possess the police power. *See, e.g.*, *Bond v. United States*, 572 U.S. 844, 854 (2014); *see also Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 38 (1905) (noting that the "safety and the health of the people" are for the State to "guard and protect" and are not matters that "ordinarily concern the national government"). Thus, transferring responsibility for health and safety generally from the States to the federal government has significant implications for federalism, and Supreme Court precedent requires Congress to use "exceedingly clear language if it wishes to significantly alter the balance between federal and state power." *United States Forest*

Serv. v. Cowpasture River Preservation Ass'n, 140 S. Ct. 1837, 1850 (2020); *see also Teltech Sys., Inc. v. Bryant*, 702 F.3d 232, 236 (5th Cir. 2012) (noting the "presumption that federal statutes do not supersede States' historic police powers, unless Congress clearly and manifestly intended to do so.").

Thus, again, in *Alabama Association of Realtors*, the Supreme Court did not find the CDC had the power to "intrude[] into an area that is the particular domain of state law." 141 S. Ct. at 2489. Here, health and safety laws are the province of the States. If Congress intended the "efficient administration" of Medicare and Medicaid to include health and safety regulations of employees, volunteers, and contractors, it would have said so in more specific terms than "efficient administration" and "administration of . . . insurance programs." Consequently, sections 1102 and 1871 do not provide CMS with the statutory authority to adopt a vaccine mandate.

b. CMS also relies on facility-specific regulations as a source for its authority, but none permit a vaccine mandate. 86 Fed. Reg. at 61,567 (Table 1). CMS repeatedly states that it has never imposed a vaccine requirement. *Id.* at 61,567 ("We have not previously required any vaccinations."), 61,568 ("[W]e have not, until now, required any health care staff vaccinations."). CMS also admits that its previous "health" and "safety" rules concerned only infection prevention and control standards. *Id.* at 61,558.

For example, regarding ambulatory surgical centers, CMS cites sections 1832(a)(2)(F)(i) and 1833(i)(1)(A). *Id.* Those sections refer to the ability to obtain benefits at an ambulatory surgical center that "meets health, safety, and other standards specified by the Secretary in regulations." 42 U.S.C. § 1395k(a)(2)(F)(i); *see also id.* § 1395l(i)(1)(A). And the standards previously adopted by CMS refer only to having a sanitary environment and an infection-control program—not

vaccinated employees. 42 C.F.R. § 416.51. CMS pulls its authority to impose vaccine mandates on hospitals from the definition of "hospital," which includes institutions that meet "such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution." *Id.* § 1395x(e)(9). But the only such requirements imposed on hospitals are, again "infection prevention and control" requirements, which are described as having an infection-control professional and maintaining a clean and sanitary environment, among other elements. *Id.* § 482.42. Other facilities are similarly regulated. *See, e.g.*, *id.* §§ 483.80 (infection-control standards at long-term care facilities), 483.430 (training requirements for staff at long-term care facilities); 485.640 (infection-control standards at critical access hospitals).

c. Finally, Congress has explicitly limited the federal government's ability to mandate who a healthcare provider hires and fires, as opposed to mandating facility standards. There is a significant difference in kind from requiring healthcare facilities to adopt infection-control standards and train their staff appropriately to requiring healthcare facilities to terminate the employment of anyone who does not have CMS's preferred vaccines. To that end, Congress has provided that "[n]othing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control . . . over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services." 42 U.S.C. § 1395. Mandating who healthcare facilities can hire and who they must fire is exercising "supervision or control" over the "selection" and "tenure" of employees. And, as discussed herein, this could include thousands of employees, causing severe disruptions to the provision of healthcare services in Texas. CMS's Vaccine Mandate is therefore contrary to statute.

For the same reasons that sections 1102 and 1871 do not authorize a vaccine mandate, the facility-specific regulations do not either: Congress would have spoken clearly if it intended to impact such a large group of people and significant portion of healthcare services, as well as to shift health-and-safety regulation from the States to the federal government. *See supra* pp.12-14. CMS has never before interpreted its statutory authority to include vaccine mandates, and its attempt to do so now should be rejected. Because it lacked statutory authority, CMS's Vaccine Mandate must be held unlawful and set aside. Texas is likely to prevail on Count One of its Complaint.

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

Even if *arguendo* CMS has the authority to adopt a vaccine mandate (which Texas contends that CMS does not have), CMS failed to follow the required administrative procedures when doing so by: failing to provide a notice and comment period, failing to consult with state agencies beforehand, and failing to prepare a regulatory impact analysis regarding rural hospitals. Because it did not observe the "procedure required by law," CMS's Vaccine Mandate violates the APA and must be held unlawful and set aside. 5 U.S.C. § 706(2)(D).

a. CMS failed to follow the notice-and-comment procedure.

CMS admits that the APA and SSA typically require it to publish notice of a proposed rule and wait sixty days for comments before it may finally adopt that rule. 86 Fed. Reg. at 61, 583; *see also* 5 U.S.C. § 553; 42 U.S.C. § 1395hh. But it claims that no such notice-and-comment period is required here under the statutory exception that applies when "the agency for good cause finds . . . that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 86 Fed. Reg. at 61,583; *see also* 5 U.S.C. 553(b)(B); 42 U.S.C. § 1395hh(b)(2)(C). CMS asserts that such "good cause" exists because of the emergency created by COVID-19 and possibility of negative health outcomes. 86 Fed. Reg. at 61,583-84. *But see Does 1–3 v. Mills*, No.

21A90, 2021 WL 5027177, at *3 (Oct. 29, 2021) (Gorsuch, J., dissenting from denial of application for injunctive relief) (noting that society's interest in slowing the spread of COVID-19 "cannot qualify as [compelling] forever," for "[i]f human nature and history teach anything, it is that civil liberties face grave risks when governments proclaim indefinite states of emergency").

"Generally, the 'good cause' exception to notice and comment rulemaking is to be 'narrowly construed and only reluctantly countenanced.'" *Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004) (citation omitted) (quoting *Tennessee Gas Pipeline Co. v. FERC*, 969 F.2d 1141, 1144 (D.C. Cir. 1992)). Properly understood, that exception does not apply here. CMS's own actions demonstrate the lack of emergency and its need for additional information (that could have been provided during a comment period) to properly determine the impact of its mandate. Because CMS failed to undertake its statutory obligation to notify the public and take comment before adopting such a momentous rule, Texas is likely to prevail on Counts Two and Three of its complaint.

i. Conducting notice and comment in these circumstances was not "impracticable." 5 U.S.C. § 553(b)(B). CMS's reason for ignoring the notice-and-comment process is based on its claim that an emergency exists—that it must act swiftly to "protect the health and safety of millions of people receiving critical healthcare services, the workers providing care, and our fellow citizens living and working in communities across the nation." 86 Fed. Reg. at 61,583.[2] But CMS's own actions belie that assertion.

CMS admits that it was not always concerned with obtaining a 100% vaccination rate among healthcare workers. The vaccines have been available for nearly a year, yet until this point, CMS

[2] CMS's desire to protect all "fellow citizens . . . across the nation" further underscores how far it has drifted from its statutory authorization to adopt rules regarding the "efficient administration" of Medicare and Medicaid. *See supra* pp.11-12.

sought only to "encourage" vaccination, *id.*, presumably accepting that not all healthcare workers would choose to be vaccinated. And even when President Biden announced in September that CMS needed to issue a vaccine mandate, it still waited nearly sixty days before taking this emergency action. "Good cause cannot arise as a result of the agency's own delay, because otherwise, an agency unwilling to provide notice or an opportunity to comment could simply wait . . . raise up the 'good cause' banner and promulgate rules without following APA procedures." *Nat. Res. Def. Council v. NHTSA*, 894 F.3d 95, 114-15 (2d Cir. 2018). As the Fifth Circuit recently observed with respect to OSHA's two-month delay in issuing its vaccine mandate, "[o]ne could query how an 'emergency' could prompt such a 'deliberate' response." *BST Holdings, LLC v. Occupational Health & Safety Admin.*, No. 21-60845, 2021 WL 5279381, at *3 n.11. (5th Cir. Nov. 12, 2021). Although delay is not conclusive, an agency's failure to act promptly is "evidence that a situation is not a true emergency." *Asbestos Info. Ass'n/N. Am. v. Occupational Safety & Health Admin.*, 727 F.2d 415, 423 (5th Cir. 1984).

Here, if anything, the situation has only improved. More and more individuals continue to be vaccinated, 86 Fed. Reg. at 61,604, and COVID-19 infections are trending downward, *id.* at 61,584. CMS offers nothing to explain why now—nearly a year after COVID-19 vaccines became available—the situation has become an emergency that requires 100% healthcare worker vaccination without even a period to reflect and comment. Given that CMS waited this long to issue its vaccine mandate, a period of comment is not impracticable. And given the comments CMS would have received about the mandate's impact on the healthcare industry, a period of comment would have been beneficial in explaining the crippling effect the mandate would have on the provision of healthcare in America.

ii. Notice and comment was not "unnecessary," either. 5 U.S.C. § 553(b)(B). "The more expansive the regulatory reach of these rules, of course, the greater the necessity for public comment." *Am. Fed'n of Gov't Emp., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981). As explained above, compliance with the vaccine mandate will impact millions of individuals, cost over $1 billion, and may disrupt the provision of healthcare across the country. As CMS admits, there are currently "endemic staff shortages for almost all categories of employees at almost all kinds of health care providers and supplier[s] and these may be made worse if any substantial number of unvaccinated employees leave health care employment altogether." 86 Fed. Reg. at 61,607.

CMS had no reliable data demonstrating how many healthcare workers would choose to leave their positions rather than comply with the vaccine mandate and what impact that will have on the provision of healthcare, especially in rural communities. Instead, its discussion of the anticipated costs of compliance is almost entirely free of evidence, substituting hard data with "estimates" and "assum[ption]s." *Id.* at 61,604-09. It refers to "uncertainties" in who will be in the labor market, noted that that its estimates are "highly dependent" on whether vaccination refusals were one percent or ten percent, and "welcome[s] comments on these issues." *Id.* at 61,607. And CMS admits that "it is possible there may be disruptions in cases where substantial numbers of health care staff refuse vaccinations . . . and are terminated, with consequences for employers, employees, and patients"—but that it does "not have a cost estimate for those, since there are so many variables and unknowns." *Id.* at 61,608.

Had CMS followed proper procedure, it would have learned that information during the comment period. As Texas has shown here, it is facing staffing shortages in healthcare facilities

across the State. App.237-38. And CMS's belief that a mandate will convince workers to be vaccinated is undermined by the multiple declarants who have already chosen to be terminated from their healthcare positions rather than be vaccinated, as required by their employer. App.213-14; App.216; App.232-34. This problem will be particularly acute in Texas's rural communities, which lack the ability to easily replace healthcare workers, leading to a decrease in healthcare services in areas with no nearby alternatives. App.207-09; App.243-48. CMS could not have reasonably determined whether mandating a COVID-19 vaccine would outweigh the disruption in healthcare services without this information. Notice and comment was not "unnecessary"; it was essential.

iii. Finally, given the potential impact on the provision of healthcare to millions of Americans, a period of notice and comment is not "contrary to the public interest." 5 U.S.C. § 553(b)(B). It cannot possibly be contrary to the public interest to fully learn all of the facts on whether a vaccine mandate will help or hurt those in need of care. While the public is certainly interested in limiting the spread of COVID-19, it is also interested in maintaining a safe level of healthcare, protecting the rights of those who choose not to be vaccinated, and holding the federal government to its constitutional and statutory limits. Indeed, prior interim rules issued by CMS concerning COVID-19 and long-term care facilities resulted in hundreds of public comments. 86 Fed. Reg. at 61,575. And the OSHA Vaccine Mandate has resulted in lawsuits across the country from both governmental and private parties. *See, e.g.*, *BST Holdings*, 2021 WL 5279381; *Bentkey Servs. LLC v. OSHA*, No. 21-4027 (6th Cir. Nov. 4, 2021); *Indiana v. OSHA*, No. 21-3066 (7th Cir. Nov 5, 2021); *Job Creators Network v. OSHA*, No. 21-3491 (8th Cir. Nov. 4, 2021). It blinks reality to claim

that allowing the public to comment on the CMS Vaccine Mandate is actually "contrary" to the public interest.

For these reasons, CMS had no authority to forego the statutorily required period of notice and comment. Texas is likely to prevail on Counts Two and Three of its Complaint.

b. CMS failed to consult with state agencies or provide a regulatory analysis regarding rural hospitals.

Relatedly, CMS ignored several other statutory requirements in its rush to issue the vaccine mandate—requirements that would have led it to specific evidence of the harms that the vaccine mandate will cause. These additional failures to follow the law provide yet more reasons that the vaccine mandate must be set aside, 5 U.S.C. 706(2)(D), and Texas is likely to prevail on counts Four and Five of its complaint.

i. In carrying out statutory functions, "relating to determination of conditions of participation by providers of services" regarding hospitals, long-term-care facilities, home health agencies, comprehensive outpatient rehabilitation facilities, hospices, critical access hospitals, and ambulatory surgical centers, "the Secretary shall consult with appropriate State agencies and recognized national listing or accrediting bodies, and may consult with appropriate local agencies." 42 U.S.C. § 1395z. Consultation is appropriate under section 1395z because "conditions prescribed under any of such subsections may be varied for different areas or different classes of institutions or agencies." *Id.*

CMS does not deny that it failed to consult with any state agency, accrediting body, or local agency. 86 Fed. Reg. at 61,567. Instead, it asserts that, because of the purported "urgent need" to adopt this rule, there is no entity "with which it would be appropriate to engage in these consultations." *Id.* But unlike notice-and-comment, section 1395z does not contain an exception

for consultations when they are impracticable, unnecessary, or contrary to the public interest. Thus, CMS is left to argue that the rule does not contain a temporal requirement, *id.* at 61,567, meaning that CMS is never obligated to consult with any government agency or accrediting body prior to adopting a rule. It could simply promise to do so at some point in the future. Congress did not enact a toothless requirement. If CMS enacts a rule with a severe detrimental impact on the provision of healthcare, it is of little comfort to those impacted that CMS would consult with relevant entities at some point.

Consultation here would have been fruitful, as there are a variety of local and regional implications of the vaccine mandate. For example, rural communities in Texas face particular hardship, as they lack easy access to healthcare workers to replace those whom they will have to terminate if they wish to keep Medicare and Medicaid funds. App.207-09; App.243-48. Even CMS recognizes that different sections of the country are being hit with COVID-19 at varying rates. 86 Fed. Reg. at 61,583-84 (noting the national downward trend, but possible increases in northern States). And CMS would have a better understanding of why individuals may choose not to be vaccinated, which calls into question its "belie[f] that the COVID-19 vaccine requirements . . . will result in nearly all health care workers being vaccinated." *Id.* at 61, 569.

ii. Similarly, whenever the Secretary proposes a rule that "may have a significant impact on the operations of a substantial number of small rural hospitals, the Secretary shall prepare and make available for public comment an initial regulatory impact analysis." 42 U.S.C. § 1302(b)(1). CMS does not deny that this provision applies but concluded that it did not need to prepare the required analysis because rural hospitals would not be significantly impacted by the vaccine mandate. 86 Fed. Reg. at 61,613. Yet CMS also recognized that "early indications are that rural hospitals are

having greater problems with employee vaccination refusals than urban hospitals, and we welcome comments on ways to ameliorate this problem." *Id.* As Texas has shown, the impact on rural hospitals may be significant. As several declarants testified, their rural hospital districts cannot afford to lose additional staff—and they lack the ability to compete with areas with larger populations to attract more staff. App.207-09; App.243-48. The hospitals cannot afford to turn down Medicare and Medicaid funding, as it makes up a significant portion of their revenue. App.207-09; App.243-48. Yet terminating unvaccinated staff could force them to discontinue certain healthcare services, leaving those in their community with no nearby alternatives. App.207-09; App.243-48. Had CMS followed the statutorily required procedures, it would have learned of this information and been able to provide the required analysis. Its failure to do so requires that the vaccine mandate be set aside. 5 U.S.C. § 706(2)(D).

3. The CMS Vaccine Mandate is arbitrary and capricious.

Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary and capricious." *See* 5 U.S.C. § 706 (2)(A). An agency action is arbitrary or capricious if it fails to "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). "Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely fails to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Id.* In reviewing an agency's action, the court may consider only the reasoning "articulated by the agency itself" at the time of the agency action and cannot consider post hoc rationalizations. *Id.* at 50 (citing *Burlington Truck Lines, Inc. v.*

United States, 371 U.S. 156, 168 (1962)); *see also Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1908 (2020).

Here, CMS's vaccine mandate, among other flaws, failed to consider important aspects of the issue before it, offered explanations counter to the evidence before it, and ultimately failed to articulate a rational connection between the facts it found and the choices it made.

a. Reliance on outdated, incomplete, or nonexistent data.

To justify its vaccine mandate, CMS surmised that "[f]ear of exposure to and infection with COVID-19 from unvaccinated health care staff can lead patients to themselves forgo seeking medically necessary care." 86 Fed. Reg. at 61,558. But to support this claim, CMS relied on data from 2020 before any COVID-19 vaccines were available. *See id.* at nn.44-48. CMS also cited unspecified anecdotal reports indicating that individuals are refusing care from unvaccinated staff, limiting the extent to which medical providers can properly care for their patients. *Id.* But CMS offers no details of these anecdotal reports nor evidence to support them. Notably, CMS does not cite any verifiable current evidence supporting its contention that in these final months of 2021, patients are forgoing medical care because of potential contact with unvaccinated medical providers. There have been tremendous shifts in societal actions and attitudes since the beginning days of the pandemic. Evidence of some people's attitudes during 2020—in the early days and height of the pandemic, when no vaccine was available and shutdowns existed across the country—cannot reasonably be said to accurately reflect prevalent attitudes in late 2021 when the landscape has significantly altered, both medically and societally.

Additionally, CMS cherry-picked data, creating an incomplete picture about the need for vaccination. CMS determined a vaccine mandate was necessary due to a stalling of vaccination rates among LTC facility staff—64% as of August 28, 2021. *Id.* at 61,575. CMS concluded a 64%

vaccination rate was "suboptimal" based on preliminary data from the CDC's National Healthcare Safety Network showing higher rates of COVID-19 infections at LTC facilities with a staff vaccination rate of less than 75%. *Id.* at 61,558. But that same data showed that the difference between infection rates at LTC facilities where 60-74% of staff were vaccinated, and those where 75-100% were vaccinated, was "not significant." App.200. CMS arbitrarily determined that a vaccination rate of 64% was suboptimal when the data it relied upon to make that determination suggested the opposite.

CMS's reliance on the 75% number makes even less sense when considering the staff vaccination rates at LTCs actually *exceeded* 75% at the time the vaccine mandate was implemented. As of October 31, 2021, the CDC weekly vaccine data relied on by CMS showed the complete and partial staff vaccination rates at LTC facilities was 78.2%, including 76% fully vaccinated.[3] And despite CMS's claim that the vaccination rate at LTC facilities had stalled, the rate of vaccination had increased by 37.18% in only a five-month period—from 55.4% on May 23, 2021 to 76% on October 31, 2021.[4]

CMS relied on old data, including data from before COVID-19 vaccines were available and data gathered at the height of the Delta variant, to justify an unprecedented vaccine mandate. The data relied on did not reflect the reality of vaccination rates when the mandate was implemented. *See Mo. Pub. Serv. Comm'n v. FERC*, 337 F.3d 1066, 1075 (D.C. Cir. 2003) (concluding that the agency's action was arbitrary and capricious because the agency "had adopted a new rationale premised on old facts that were no longer true."). Additionally, CMS's explanation that a 64%

[3] https://www.cdc.gov/nhsn/covid19/ltc-vaccination-dashboard.html
[4] *Id.*

vaccination rate is suboptimal runs counter to the evidence before it, which showed no significant difference in infection rates from LTCs where 60-74% of staff were vaccinated and LTCs where 75-100% of staff were vaccinated. *See State Farm*, 463 U.S. at 43.

b. Overbroad application

CMS implicitly admitted that the only comprehensive data it relied on to justify its vaccine mandate was data from LTCs:

> The best data come from long term care facilities, as early implementation of national reporting requirements have resulted in a comprehensive, longitudinal, high quality data set . . . . While similarly comprehensive data are not available for all Medicare- and Medicaid-certified provider types, the available evidence for ongoing healthcare-associated COVID-19 transmission risk is sufficiently alarming in and of itself to compel CMS to take action.

86 Fed. Reg. at 61,558. CMS did not explain what "available evidence" compelled it to take action. CMS further alleged, with no support, that despite a lack of comprehensive data set from any other provider types, that "the LTC facilities experience may generally be extrapolated to other settings." *Id.* at 61,585. It then used this conclusory, unsupported statement to justify a vaccine mandate that covered fifteen categories of Medicare- and Medicaid-certified providers. *See United Techs. Corp. v. U.S. Dep't of Def.*, 601 F.3d 557, 562 (D.C. Cir. 2010) (explaining that courts "do not defer to the agency's conclusory or unsupported suppositions."). These providers include, among others, rural health clinics, hospitals, home health agencies, and psychiatric residential treatment facilities. 86 Fed. Reg. at 61,569-70.

By applying the vaccine mandate to fifteen different types of providers, CMS ignored a number of important factors—such as the fundamental differences between LTCs and other providers. For example, while LTCs serve a population that is older and more vulnerable to COVID-19, psychiatric residential treatment facilities serve individuals under twenty-one years of

age. *Id.* at 61,576. Additionally, rural and other community-care oriented health centers serve the full age spectrum and a lower fraction of severely health-impaired individuals. *Id.* at 61,612. CMS even acknowledged that "risk of death from infection from an unvaccinated 75- to 84-year-old person is 320 times more likely than the risk for an 18- to 29-year-old person." *Id.* at 61,610 n.247. Despite this, CMS ignored these differences by applying a blanket mandate to all fifteen types of providers including, among others: Ambulatory Surgical Centers; Intermediate Care Facilities for Individuals with Intellectual Disabilities; Comprehensive Outpatient Rehabilitation Facilities; Community Mental Health Centers; Home Infusion Therapy Suppliers; and Rural Health Clinics. 86 Fed. Reg. 61,567, Table 1. CMS provided no justification for applying what it (wrongly) believed to be necessary for LTCs to other healthcare settings with seemingly little in common with LTCs. CMS provided no satisfactory explanation for why certain facilities with significantly lower-risk patients should be subjected to the same requirements as facilities that treat higher-risk patients. It also presented no facts demonstrating the other fourteen covered categories of providers should be treated like LTCs. *See State Farm*, 463 U.S. at 43.

Not only is the CMS Vaccine Mandate overbroad in the types of providers it covers—it is also overbroad in the categories of individuals subject to its requirements. The mandate requires vaccination for all "facility staff," which encompasses employees, trainees, students, volunteers, or contractors "who provide any care, treatment, or *other services* for the facility," "*regardless of patient contact*." 86 Fed. Reg. at 61,570 (emphasis added). The mandate would require vaccination of employees who predominantly telework, and those who perform exclusively administrative tasks and have no patient contact. *Id.* It also requires vaccination of employees who occasionally interact with a patient, resident, or client in any location—even locations outside of a health facility. *Id.*

The vaccine mandate extends even further than employees. It also covers contractors working at a site of care. As an example, CMS explained that an entire construction crew working at a site of care would have to be vaccinated if they used common areas, such as restrooms and cafeterias. *Id.* at 61,571.

CMS cited no data to justify such a sweeping measure. CMS provided no evidence, anecdotal or otherwise, suggesting that administrative staff, teleworkers, contracted construction crews, or any other individuals who have little or no patient contact are likely to spread COVID-19 to patients. CMS acted arbitrarily and capriciously by imposing a vaccination requirement on a wide variety of individuals without considering whether those individuals pose *any* risk to patients. *See State Farm*, 463 U.S. at 43.

c. Failure to consider the full impact of the vaccine mandate

CMS intended its vaccine mandate to be broad, acknowledging that the mandate had "near-universal applicability" to healthcare staff and estimated that over 10.3 million employees would be subject to the mandate. 86 Fed. Reg. at 61,573, 61,603. Despite the extreme ramifications of this mandate, CMS conducted only a brief, perfunctory analysis of the effect the mandate would have on staffing shortages and patient care.

CMS rightly acknowledged that there are currently "endemic staff shortages" for nearly all types of healthcare providers and supplies nationwide, *id.* at 61,607, and that there could be "disruptions" if a large number of unvaccinated employees are not granted an exemption and fired for not submitting to a vaccine. *Id.* at 61,608. But CMS dismissed these concerns because "there is insufficient evidence to quantify them." *Id.* at 61,569. It also optimistically reasoned, with no support, that the vaccine mandate "will result in nearly all health care workers being vaccinated." *Id.* CMS may not excuse its failure to seek out and consider critical information necessary to

determine the full impact that the vaccine mandate would have on the healthcare community, patients, and local communities, by merely asserting that insufficient evidence exists.

Had CMS attempted to consider the relevant information, it could easily have learned that the consequences of its mandate will be dire, especially in rural Texas. For example, the Hansford County Hospital District in rural Texas is already facing a staffing shortage. App.208. Approximately 56% of hospital staff are fully vaccinated, while many remain unvaccinated due to personal, medical, and religious concerns. *Id.* Many rural communities, like Hansford County, had problems recruiting and retaining staff that preceded the COVID-19 pandemic. *Id.* The CMS Vaccine Mandate would turn what is already a precarious situation in Hansford County into a catastrophic one. It would further strain the limited resources the hospital has at its disposal and prevent residents of rural communities from receiving the care they need.

While CMS acknowledged the vaccination rates are disproportionately low in rural locations—and that these healthcare workers are more likely to be members of racial and ethnic minority communities—it dismissed these concerns by surmising that unvaccinated employees could simply find other jobs in "physician and dental offices" that are not covered by the vaccine mandate. 86 Fed. Reg. at 61,566, 61,607. This conclusory analysis failed to consider the lack of alternative jobs in small, rural communities. It also failed to consider the disproportionate effect a mass resignation and/or termination of healthcare employees would have on the minority and underprivileged citizens served by rural healthcare providers.

While CMS naively believes almost all healthcare workers will comply with its mandate and submit to vaccination, that rosy outlook does not reflect reality. *See supra* pp. 6-7. The effects of terminations and resignations due to the mandate impact both the healthcare professionals

themselves and the members of the communities they serve. CMS acted arbitrarily and capriciously by failing to consider this probable result. *See State Farm*, 463 U.S. at 43.

d. Lack of flexibility

The CMS Vaccine Mandate is also arbitrarily and capriciously inflexible. For example, it fails to provide any alternative to vaccination that would be at least as effective in protecting against COVID-19. Regular testing of employees is a commonly provided alternative to vaccination, and it is an option provided by OSHA in its recently implemented ETS. *See* 86 Fed. Reg. 61,402. While CMS contends it "considered" regular mandatory testing instead of mandatory vaccination, it summarily concluded mandatory vaccination was the only option because "vaccination is a more effective infection control measure." 86 Fed. Reg. at 61,614. But CMS failed to explain how periodic testing was a less effective infection-control measure than vaccination. It also failed to acknowledge the disparity between its rejection of periodic testing and OSHA's adoption of it in its ETS.

CMS further failed to consider that many healthcare workers may have natural immunity to COVID-19 due to previously contracting the virus. CMS rejected the notion of natural immunity as an infection-control measure when explaining the mandate's vaccination requirement. *Id.* at 61,614. But elsewhere, CMS recognized the effectiveness of natural immunity by stating that those "recover[ing] from infection" are "no longer sources of future infections," which "reduce[s] the risk to both health care staff and patients substantially." *Id.* at 61,604. By acknowledging the effectiveness of natural immunity, yet dismissing it as a viable alternative to vaccination, CMS's reasoning runs contrary to the evidence before it. *See State Farm*, 463 U.S. at 43.

The inflexibility of CMS's vaccine mandate is perhaps best exemplified by the untenable deadline it set for workers to be vaccinated. Workers are required to receive their first shot by

December 6, 2021, and their second shot (if receiving either the Moderna or Pfizer vaccine) by January 4, 2022. 86 Fed. Reg. at 61, 574 (Table 2). In imposing this deadline, CMS wholly failed to consider the practical difficulties in obtaining vaccinations by that time period. Those receiving the Pfizer vaccine must wait 21 days between their first and second shots, and those receiving the Moderna vaccine must wait 28 days between their first and second shots. App.203. So, hypothetically if a person receives their first shot of the Moderna vaccine on November 30, 2021, they cannot get the second shot any earlier than December 28, 2021, but must get it before January 4, 2022. Taking this example further, if a person is suffering from COVID-19 at this time, they would not be able to take any shots until they recovered, did not have any symptoms and tested negative—even though this person is attempting to comply.

The inflexibility of this mandate also lacks practical application. CMS failed to consider the practical difficulties workers will face in obtaining vaccines during a window of time when many, including doctors and religious leaders who could provide an exemption, may be unavailable due to the holiday season. It also failed to consider that vaccines may not be as readily available as in the past due to an increased emphasis on vaccinating children 5 to 11 years and older after the CDC approved this age group for vaccination on November 2, 2021.

CMS acted arbitrarily and capriciously by imposing an excessive, one-size-fits-all solution to a purported problem that is not supported by the evidence it cites. It repeatedly failed to consider important issues, relied on outdated and insufficient data, misinterpreted that data, misapplied that data, and offered explanations that run contrary to the evidence. It failed to consider the full impact of the vaccine mandate—ignoring evidence of the devastating impact that the CMS Vaccine Mandate would have on the healthcare community, patients, and local communities—especially

in rural America. Finally, the CMS acted arbitrarily and capriciously by imposing the vaccine mandate in an inflexible manner that will exacerbate what will already be a massive disruption of the nation's healthcare system.

The CMS Vaccine Mandate fails to "articulate a satisfactory explanation for its action including a rational connection between the facts found and the choice made." *See State Farm*, 463 U.S. at 43 (1983). It is arbitrary and capricious and must be set aside. *See* 5 U.S.C. § 706 (2)(A). Texas is likely to prevail on Count Six of its complaint.

B. Texas Is Likely to Suffer Irreparable Harm in the Absence of Preliminary Relief.

Texas, and its residents, will suffer irreparable harm from the CMS Vaccine Mandate absent preliminary relief from this Court. As has been discussed, implementation of the mandate will (1) exacerbate staffing shortages, and (2) significantly impact rural areas which lack access to alternative healthcare options. Moreover, by purporting to preempt state laws, the CMS Vaccine Mandate harms Texas's sovereign interests in the enforcement of its laws—which include a ban on vaccine mandates.

1. CMS has admitted that the country is facing "endemic staff shortages for almost all categories of employees at almost all kinds of health care providers and supplier[s]." 86 Fed. Reg. at 61,607. One in five hospitals "report that they are currently experiencing a critical staffing shortage." *Id.* at 61,559. In addition, "approximately 23 percent of [long-term-care] facilities report[] a shortage in nursing aides; 21 percent report[] a shortage of nurses; and 10 to 12 percent report[] shortages in other clinical and non-clinical staff categories." *Id.* And "[o]ver half (58 percent) of nursing homes participating in a recent survey . . . indicated that they are limiting new admissions due to staffing shortages." *Id.*

These shortages have impacted Texas, as well. According to a HHSC report from May 2020, Texas is suffering from a statewide shortage of physicians that "is projected to increase from 6,218 full-time equivalents (FTEs) in 2018 to 10,330 FTEs in 2032." App.102. These shortages include physicians who practice general internal medicine, family medicine, pediatrics, and psychiatry. App.103. Texas has also experienced shortages in nursing, even before the pandemic began, that have only been exacerbated during the pandemic, as many nurses have left due to burnout and retirement. App.011.

And the declarations provided by Texas uniformly note that Texas facilities face consistent staff shortages. App.212-14; App.220-22; App.229-34; App.235-39; App.240-42. Requiring healthcare facilities to terminate unvaccinated staff or risk losing Medicare and Medicaid funds will only exacerbate the problem. And a lack of staffing will make it more difficult for vulnerable Texans who rely on Medicare and Medicaid to receive the healthcare they need. Texas has a quasi-sovereign or *parens patrie* interest in protecting its vulnerable citizens from the harm caused by the CMS Vaccine Mandate. *See Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607 (1982). This is especially true where, as here, the "injury to the health and welfare of [the State's] citizens . . . is one that the State, if it could, would likely attempt to address through its own sovereign lawmaking powers." *Id.*

2. The CMS Vaccine Mandate will likely severely disrupt care in Texas's rural communities. As several declarants testified, Medicare and Medicaid funds make up a significant percentage of revenue for these rural hospital districts. App.206-09; App.243-48. And, despite efforts to encourage vaccination, a percentage of staff remain unvaccinated. App.206-09; App.243-48. Being

forced to terminated unvaccinated staff may require those hospitals to discontinue some healthcare services, leaving their communities without the full range of care. App.206-09; App.243-48.

3. The Governor of Texas has issued an executive order prohibiting mandatory vaccination requirements by entities in Texas. App.251-52. But the CMS Vaccine Mandate purports to "preempt[] inconsistent State and local laws as applied to Medicare- and Medicaid-certified providers and suppliers." 86 Fed. Reg. at 61,568; *see also id.* at 61,572, 61,613. Consequently, Texas faces a direct sovereign injury from the CMS Vaccine Mandate. Numerous courts have made clear that preventing the State from enforcing its laws is itself an irreparable harm. *See, e.g.*, *Abbott v. Perez*, 138 S. Ct. 2305, 2324 n.17 (2018) ("[T]he inability to enforce its duly enacted plan clearly inflicts irreparable harm on the State."); *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) ("Any time [a State is blocked] from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury."); *Org for Black Struggle v. Ashcroft*, 978 F.3d 603, 609 (8th Cir. 2020). When the State is blocked from implementing its laws, "the State necessarily suffers the irreparable harm of denying the public interest in the enforcement of its law." *Planned Parenthood of Greater Tex. Surgical Health Servs. v. Abbott*, 734 F.3d 406, 419 (5th Cir. 2013); *Coal. For Econ. Equity v. Wilson*, 122 F.3d 718, 719 (9th Cir. 1997).

Not only would the CMS Vaccine Mandate block Texas from enforcing its own laws—it would also force Texas to administer a federal mandate. It is well-established that the federal government cannot use Congress's spending power to "commandeer[] a State's . . . administrative apparatus for federal purposes." *NFIB v. Sebelius*, 567 U.S. 519, 577 (2012). Yet that is precisely what CMS has done. It compels state surveyors to enforce its mandate by ensuring healthcare providers' compliance. 86 Fed. Reg. at 61,574. It has also forced Texas officials presiding over

state-run health facilities to become administrators of a federal mandate. And if they choose to not enforce the mandate, they risk losing Medicare and Medicaid funds essential to the operation of their facilities. The CMS Vaccine Mandate is "a gun to the head" compelling Texas healthcare institutions to submit to its requirements. *See NFIB*, 567 U.S. at 581.

C. The Balance of Equities Favors Texas, and the Injunction Is in the Public Interest.

When governmental action is implicated, the third and fourth *Winter* factors merge for consideration. *Nken v. Holder*, 556 U.S. 418, 435 (2009). In order to preserve the relative positions of the parties until a trial on the merits can be held, federal courts have regularly enjoined federal agencies from implementing and enforcing new regulations pending litigation challenging them. *See, e.g.*, *Texas v. United States*, 787 F.3d 733 (5th Cir. 2015). Here, the status quo has been to encourage, but not mandate vaccination against COVID-19. Texas healthcare institutions have a reliance interest on the federal government's previous policy of not requiring vaccines, which CMS either ignored or unreasonably rejected by changing its long-standing policy and requiring almost instant compliance with its new policy. *See Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2126-27 (2016); *DHS v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1914-15 (2020). As explained throughout this motion, there is no justification for CMS to unilaterally decide that millions of healthcare works at thousands of facilities must receive the vaccine or lose their jobs—regardless of the harm to the healthcare industry's ability to provide care.

For those same reasons, injunctive relief is undoubtedly in the public interest. In addition to the economic and healthcare interests discussed, the liberty interests at stake here "are not reducible to dollars and cents." *BST Holdings*, 2021 WL 5279381, at *8. "The public interest is also served by maintaining our constitutional structure and maintaining the liberty of individuals

to make intensely personal decisions according to their own convictions—even, or perhaps *particularly*, when those decisions frustrate government officials." *Id.*

III. CONCLUSION

For the foregoing reasons, the Court should grant Texas's motion for a temporary restraining order to preserve the status quo until the Court has had an opportunity to rule on Texas's motion for preliminary injunction, and grant Texas's motion for preliminary injunction.

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Certificate of Service

I certify that a true and accurate copy of the foregoing document was filed electronically (via CM/ECF) on November 16, 2021. The foregoing document was also served electronically on counsel for Defendants on November 16, 2021, although counsel for Defendants has not agreed to accept electronic service. I further certify that a true and accurate copy of the foregoing document will be served by mail on the following recipients on November 17, 2021:

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