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

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

PLAINTIFF STATES' MEMORANDUM IN SUPPORT
OF MOTION FOR PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

Other Authorities

INTRODUCTION

Plaintiffs, the States of Missouri, Nebraska, Arkansas, Kansas, Iowa, Wyoming, Alaska, South Dakota, North Dakota, and New Hampshire, challenge the Centers for Medicare and Medicaid Services' ("CMS") Interim Final Rule with Comment Period ("IFC") entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination." 86 Fed. Reg. 61,555 (Nov. 5, 2021). That IFC, also referred to as the "CMS vaccine mandate," "CMS mandate," or "mandate," imposes an unprecedented federal vaccine mandate on nearly every employee, volunteer, and third-party contractor working at a wide range of healthcare facilities.

This mandate threatens to exacerbate an alarming shortage of healthcare workers, particularly in rural communities, that has already reached a crisis point. Indeed, the circumstances in the Plaintiff States—facts that CMS, which skipped notice-and-comment rulemaking, did not meaningfully consider—foreshadow an impending disaster in the healthcare industry. By ignoring the facts on the ground and unreasonably dismissing concerns about workforce shortages, the CMS vaccine mandate jeopardizes the healthcare interests of rural Americans.

This mandate is unlawful for at least five reasons. First, it is arbitrary and capricious under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706. Second, it exceeds CMS's statutory authority and conflicts with law. Third, it violates the U.S. Constitution. Fourth, it violates numerous procedural requirements of the APA and the Social Security Act. And fifth, CMS failed to prepare a required regulatory impact analysis ("RIA") on the impact the IFC will have on the operations of Plaintiff States' small rural hospitals. Because the CMS mandate is unlawful, and because it threatens to devastate healthcare throughout the country, the Court should enjoin it pending final resolution on the merits.

STATEMENT OF FACTS

A. The Healthcare Worker Shortage Crisis in the Plaintiff States.

"[C]urrently there are endemic staff shortages," CMS admits, "for almost all categories of employees at almost all kinds of health care providers and supplier[s]." 86 Fed. Reg. at 61,607. "1 in 5 hospitals," CMS notes, "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.* It is thus not surprising, CMS relayed, that "[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.*

The Plaintiff States' experience confirms this. Healthcare facilities through the Plaintiff States affirm that they have been and still are experiencing serious workforce shortages. *See, e.g.*, Strong Decl. ¶ 4 (Ex. F); Kahl Decl. ¶ 7 (Ex. Q); McNea Decl. ¶ 9 (Ex. S); Barber Decl. ¶ 11 (Ex. N); Mazanec Decl. ¶ 11 (Ex. R); Glaubke Decl. ¶ 11 (Ex. U); Sroczynski Decl. ¶¶ 4–7 (Ex. T); Johansson Decl. ¶¶ 2, 5–6 (Ex. DD). A recent study shows that 97 of Missouri's 114 counties have a nursing shortage. Lori Schneidt, Anne Heyen & Tracy Greever-Rice, *Show Me the Nursing Shortage: Location Matters in Missouri Nursing Shortage*, 12 J. Nursing Reg. 52 (2021). In addition, staff nurse turnover in Missouri is the highest it has been in 20 years. *See* Missouri Hospital Association, *2021 Workforce Report* (2021), *available at* https://www.mhanet.com/mhaimages/Workforce/2021/2021_WF_report.pdf. Thus, to fill open positions, there has been a boom in demand for travel nurses, but this further harms small rural hospitals that cannot afford to pay their nurses more to stay and cannot afford the exorbitant rates of travel nurses. *See* Leticia Miranda, *Rural hospitals losing hundreds of staff to high-paid*

traveling nurse jobs (Sept. 15, 2021), https://www.nbcnews.com/business/business-news/rural-hospitals-losing-hundreds-staff-high-paid-traveling-nurse-jobs-n1279199.

The staffing shortages have gotten so bad that it has prompted emergency measures by state officials. Just a few months ago, on August 27, 2021, Missouri Governor Michael L. Parson signed Executive Order 21-09 declaring a targeted State of Emergency for Missouri's healthcare system. Mo. Exec. Order 21-09 (Aug. 27, 2021), *available at* https://www.sos.mo.gov/library/reference/orders/2021/eo9 (last visited Nov. 8, 2021). The Order, which remains in effect until December 31, 2021, declared that "a state of emergency exists relative to *staff shortages in the State's healthcare system* and the State's recovery efforts from the COVID-19 public health threat." *Id.* (emphasis added). Likewise, on August 26, 2021, Nebraska Governor Pete Ricketts issued Executive Order No. 21-12 declaring that "Nebraska hospitals, clinics, and other health care facilities are facing a shortage of health care professionals" and that "a hospital capacity emergency exists." Neb. Exec. Order 21-12 (Aug. 26, 2021), *available at* https://www.dropbox.com/s/sm3dpu7t094ymum/Executive%20Order%2021-12%20-%20Additional%20Healthcare%20Workforce%20Capacity.pdf?dl=0. Governor Ricketts issued the order, which temporarily waived certain regulations governing healthcare workers and which remains in effect until December 31, 2021, to "protect[] the citizens of Nebraska from the public health threat of a hospital capacity and workforce emergency." *Id.* In addition, on September 21, 2021, Wyoming Governor Mark Gordon activated the Wyoming National Guard to provide temporary assistance to healthcare facilities throughout Wyoming. Governor Gordon called approximately 97 soldiers to provide additional staffing for "Wyoming hospitals, long term care facilities, and public health departments statewide." Johansson Decl. ¶ 3 (Ex. DD).

B. President Biden's September 9, 2021 Speech Announcing Vaccine Mandates.

For the first six months of President Biden's Administration, none of his agencies sought to 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." Press Briefing by Press Secretary Jen Psaki (July 23, 2021), The White House, https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/23/press-briefing-by-press-secretary-jen-psaki-july-23-2021/.

Yet on September 9, 2021, amid flagging poll numbers due to the crisis in Afghanistan and on the southern border, the Administration's policy on federal vaccine mandates underwent a dramatic about-face. That day, President Biden gave a speech announcing his six-point Plan to "turn the tide on COVID-19." Joseph Biden, Remarks at the White House (Sept. 9, 2021), https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ ("Biden Speech"). He announced the first plank of his plan: to "require more Americans to be vaccinated." *Id.* Toward that end, the President called for several 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) the CMS vaccine mandate challenged here. *Id.* The stated purpose of these mandates was to increase the number of vaccinated people by any coercive power available to the federal government. *Id.*

President Biden also expressed a dismissive view of States that have used their constitutionally guaranteed police powers to adopt contrary public-health policies. *Id.* He stated: "Let me be blunt. My plan also takes on elected officials and states that are undermining . . . these

lifesaving actions." *Id.* Speaking scornfully of "governor[s]" who oppose the new federal mandates, he 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.*

C. CMS's November 5, 2021 Vaccine Mandate.

On November 5, 2021, nearly two months after President Biden announced his federal vaccine mandates, CMS published the IFC challenged here. 86 Fed. Reg. 61,555. In creating that rule, however, CMS did not comply with notice-and-comment requirements or consult with the States. *See* 5 U.S.C. § 553(b)–(c) (APA requirements), 42 U.S.C. § 1395hh(b)(1) (Social Security Act requirements), 42 U.S.C. § 1395z ("Secretary shall consult with appropriate State agencies").

CMS openly recognized that its action was unprecedented—never before had the agency mandated vaccination. *See, e.g.*, 86 Fed. Reg. at 61,567 ("We have not previously required any vaccinations"); *see also* Compl. ¶ 121 (collecting other cites). CMS nevertheless took this action to nationalize the COVID-19 vaccination response, explaining that "the inconsistent web of State, local, and employer COVID-19 vaccination requirements have established a pressing need for a consistent Federal policy mandating staff vaccination in health care settings." 86 Fed. Reg. at 61,584. And the agency chose the draconian course of mandating vaccines because it determined that the "most important inducement [for vaccination] will be the fear of job loss." *Id.* at 61,607.

The CMS vaccine mandate covers fifteen categories of Medicare- and Medicaid-certified providers and suppliers, including Rural Health Clinics ("RHCs"), Critical Access Hospitals ("CAHs"), other hospitals, Psychiatric Residential Treatment Facilities ("PRTFs") for individuals under age 21, and long-term-care ("LTC") facilities. *Id.* at 61,556. By expanding its reach in this way, the mandate broadly sweeps in a "diverse" set of healthcare providers. *Id.* at 61,602.

CMS applies its vaccine mandate to practically every full-time employee, part-time worker, trainee, student, volunteer, or third-party contractor working at covered facilities. The mandate requires vaccination for all "facility staff"—a term that includes employees, trainees, students, volunteers, and contractors—"who provide any care, treatment, or *other services* for the facility," "*regardless of . . . patient contact*." *Id.* at 61,570 (emphasis added). This includes "administrative staff" and "housekeeping and food services." *Id.* CMS also imposed its mandate on "any individual that . . . has the *potential* to have contact with anyone at the site of care." *Id.* at 61,571 (emphasis added). This includes "staff that primarily provide services remotely via telework" but "occasionally encounter fellow staff . . . who will themselves enter a health care facility." *Id.* at 61, 570. Illustrating its breadth, the mandate also covers a "crew working on a construction project whose members use shared facilities (restrooms, cafeteria, break rooms) during their breaks[.]" *Id.* at 61,571. CMS allows exemptions 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.

Recognizing the mandate's breadth, CMS acknowledges its "near-universal applicability" to health-care staff and its demand that "virtually all health care staff in the U.S. [must] be vaccinated for COVD-19." *Id.* at 61,573. CMS estimates that approximately 10.3 million employees will fall under the mandate. *Id.* at 61,603.

CMS expressly rejected the option of allowing workers to undergo "daily or weekly [COVID-19] testing" instead of mandatory vaccination, and it did so for only one reason: because the agency believes that "vaccination is a more effective infection control measure" than regular testing. *Id.* at 61,614.

CMS was "aware of concerns about health care workers choosing to leave their jobs rather than be vaccinated" and knew that "there might be a certain number of health care workers who choose to do so." *Id.* at 61,569. But CMS dismissed these concerns because "there is insufficient evidence to quantify" that risk and balance it against others. *Id.* Instead, based on the experiences of a few private healthcare facilities that implemented vaccine mandates in mostly urban areas, CMS optimistically "believe[d] that the COVID-19 vaccine requirements . . . will result in *nearly all* health care workers being vaccinated." *Id.* (emphasis added); *see also id.* at 61,609 (finding that only a "relatively small fraction" of turnover "will be due to vaccination").

The IFC was immediately effective on November 5, 2021—the day it was published. *Id.* at 61,555. Covered providers must implement the vaccine mandate in two 30-day phases. *Id.* at 61,571. Phase 1 requires staff to receive the first vaccine dose or request a medical or religious exemption by December 6, 2021. *Id.* And Phase 2 mandates that non-exempt staff be fully vaccinated by January 4, 2022. *Id.* Covered healthcare providers that do not comply are subject to termination of their Medicare/Medicaid provider agreement. *Id.* at 61,574; *see also* Compl. ¶ 127 (citing other support). Because the decision to get vaccinated must occur by December 6, the Plaintiff States need relief before that date.

D. The CMS Vaccine Mandate's Commandeering of the States.

The CMS mandate overrides state laws and commandeers state officials at every turn. The agency repeatedly says that it intends for the mandate to preempt any arguably inconsistent state and local laws. *See, e.g.*, 86 Fed. Reg. at 61,568 ("We intend . . . that this nationwide regulation preempts inconsistent State and local laws"); *see also* Compl. ¶ 121 (collecting cites).

CMS also requires "State-run facilities that receive Medicare and Medicaid funding" to enforce and administer the vaccine mandate by "imposing [it] on their employees." 86 Fed. Reg.

at 61,613. This includes complying with overbearing record-keeping obligations, such as "tracking [the] vaccination status" of staff who are not covered by the mandate, and documenting the "vaccination status of any staff who have obtained any booster doses" even though the mandate does not require boosters. *Id.* at 61,571. The Plaintiff States operate many state-run hospitals. *See, e.g.*, Huhn Decl. ¶¶ 3, 6–12, 15–18 (Ex. J); York Decl. ¶¶ 1–3 (Ex. B); Johansson Decl. ¶¶ 1–2, 6 (Ex. DD); Kahl Decl. ¶¶ 8–10 (Ex. Q); White Decl. ¶¶ 3–4 (Ex. C); Ringling Decl. ¶ 3 (Ex. CC); Jones Decl. ¶ 3 (Ex. AA).

CMS additionally coopts "State surveyors . . . to assess compliance with" the mandate. 86 Fed. Reg. at 61,574. Those surveyors are employed by the States. *See* Bollin Decl. ¶ 5 (Ex. H); Gayhart Decl. ¶ 3 (Ex. A); Wehbi Decl. ¶ 4 (Ex. BB). They must "review[] the entity's records of staff vaccinations" and "interview[] staff to verify their vaccination status." 86 Fed. Reg. at 61,574. And they must "cite providers and suppliers when noncompliance is identified." *Id.*

E. The CMS Vaccine Mandate's Disruptive Impact on Healthcare.

Vaccination rates, as CMS admits, "are disproportionately low among nurses and health care aides" in rural locations and other "communities that experience social risk factors," 86 Fed. Reg. at 61,566, and "rural hospitals are having greater problems with employee vaccination . . . than urban hospitals," *id.* at 61,613. A recent survey also shows that a substantial portion of "unvaccinated workers"—a whopping 72%—"say they will quit" rather than submit to a vaccine mandate. Chris Isidore and Virginia Langmaid, *72% of unvaccinated workers vow to quit if ordered to get vaccinated*, CNN.com (Oct. 28, 2021), https://www.cnn.com/2021/10/28/business/covid-vaccine-workers-quit/index.html. The confluence of these developments have created the perfect storm for healthcare calamity in rural America.

Healthcare facilities throughout the Plaintiff States confirm this. The leadership at Callaway District Hospital—a Small Rural Hospital and Critical Access Hospital in Callaway, Nebraska—is deeply distressed. Eggleston Decl. ¶¶ 1, 4–5 (Ex. L). Around 20 members of its 65-person staff are not vaccinated, and over half of those unvaccinated workers are nurses. *Id.* at 12, 14. Sadly, Callaway "project[s] [the] loss of approximately 30% of [its] staff" from the CMS mandate—losses that "will almost certainly lead to closure of [the] facility" and "leave [that] rural community without essential healthcare services." *Id.* at ¶¶ 16–17.

Likewise, Cherry County Hospital in rural Valentine, Nebraska fears that it will not survive CMS's mandate. Kellum Decl. ¶¶ 1, 4, 15 (Ex. P). Sixty-six of its 159 staff members are not vaccinated, and the hospital projects that the mandate will force 50 of those 66 to leave their positions. *Id.* at ¶¶ 11, 13–14. That will result in closing its dialysis and chemotherapy departments, dramatically reducing its ability to provide needed surgeries, and perhaps even shutting down the hospital. *Id.* at ¶ 15. In the CEO's words, "I cannot express the extent of what is about to happen." *Id.* at ¶ 16. Patients in that community "will not have the primary care services needed to stay healthy," and they "will not have the staff to care for them in an emergency." *Id.*

Similar evidence from Box Butte General Hospital, a Small Rural Hospital and Critical Access Hospital in Alliance, Nebraska, illustrates the systemic staffing issues. Mazanec Decl. ¶¶ 1, 4–5 (Ex. R). Box Butte has had open positions "since 2019 with no applications received" due to "existing health care worker shortages" and "challenges of the rural location." *Id.* at ¶ 11. Currently, 42% of Box Butte's 289 employees are unvaccinated, and those employees include senior leadership, physicians, and nurses. *Id.* at ¶¶ 10, 12. The hospital expects "to lose 15 percent of its total employees" from the CMS mandate, and those losses will "impact[] nearly all . . . departments," including emergency medicine. *Id.* at ¶ 13. Box Butte thus anticipates needing to

close departments, reduce services, and turn patients away. *Id.* at ¶ 14. And because the remaining employees "will be forced to work extended hours," this will feed a vicious cycle as they "experience an even greater amount of burnout" and will be likely to "leave health care" altogether. *Id.* at ¶ 15.

Community Hospital—which is in rural McCook, Nebraska, serves people from Southwest Nebraska and Northwest Kansas, and is 70 miles from the next closest facility providing similar services—also faces severe consequences from the CMS mandate. Bruntz Decl. ¶¶ 1, 9–10 (Ex. W). Seventy-eight of its 330 employees (24%) are unvaccinated, and 76 of the unvaccinated staff "have indicated they will not or are seriously considering not receiving the vaccination." *Id.* at ¶ 13. The hospital thus expects that it will "lose well more than 10% of its staffing," that its patients "will be harmed" when the facility is "forced to limit or close services," and that many of the remaining vaccinated staff "will resign due to the stress and burn out that will inevitably exist." *Id.* at ¶¶ 14–16.

The experience of Franciscan Care Services, a Small Rural Hospital and Critical Access Hospital in Northeast Nebraska, illustrates the interconnectedness of the healthcare industry. Toline Decl. ¶¶ 1, 4–5, 9 (Ex. Y). Just a few months ago, in June 2021, it experienced "increased volumes" after the closure of a critical access hospital 15 miles away. *Id.* at ¶ 9. Now it fears for the future since 23% of its staff are unvaccinated. *Id.* at ¶ 14. If it loses many of them as it expects, Franciscan will need "to reduce services in the clinic" to provide care for "emergency patients." *Id.* at ¶ 15. In turn, "[e]mergency room patient volumes . . . will increase due to inability to care for [patients] in the clinic setting." *Id.*

The leadership at a slightly larger hospital—Great Plains Health in North Platte, Nebraska—is also troubled by the vaccine mandate. It has a total staff of 1,197, and 311 of them

are not vaccinated. McNea Decl. ¶¶ 1, 8, 10 (Ex. S). The hospital projects that it will "lose a high percentage of these unvaccinated employees," in addition to already having 231 vacancies. *Id.* at ¶¶ 9–10. Such losses, which would lead to "a dangerously reduced number of staffed ICU beds," would have "negative effects" on patients. *Id.* at ¶ 11. Great Plains also fears that it will "need to close or reduce" its "behavioral health unit," requiring it to send patients to a different facility that "is nearly three hours away and itself facing staffing concerns." *Id.* at ¶ 12.

What's more, Scotland County Hospital in Memphis, Missouri, a 25-bed, non-profit Critical Access Hospital serving rural Northeast Missouri and Southeast Iowa, has "at least" five essential workers in critical areas who have "stated emphatically they will not be vaccinated," and the hospital's CEO believes the CMS vaccine mandate will cause these workers to quit or he'll have to fire them. The hospital has already "suffered staff resignations by 18%" during the pandemic, and the loss of "additional employees will cause significant difficulty in the continued quality and safe operations of SCH." Tobler Decl. ¶¶ 1–2, 4, 6–7 (Ex. G).

Evidence also shows that CMS's mandate will have substantially negative effects on hospitals with successful voluntary vaccination efforts. St. Anthony Regional Hospital, in rural Carroll, Iowa, has about 87% of its 750-person staff vaccinated. Smith Decl. ¶¶ 3, 4, 6 (Ex. D). But a recent survey of its unvaccinated employees shows that 40 employees are likely to resign rather than comply with CMS's mandate. *Id.* at ¶ 8. Given the hospital's significant struggles with filling and recruiting staff, the loss of 40 employees will force it "to evaluate the availability of needed healthcare services to the people" it serves. *Id.* at ¶ 5, 9, 11.

The mandate's unsettling effects on the healthcare industry reach beyond rural hospitals to skilled nursing and long-term-care ("LTC") facilities. Many long-term-care facilities in Missouri "have indicated that they would have to close their facilities" under the mandate. Strong Decl. ¶

6 (Ex. F). That "would displace thousands of residents across the state and affect the entire health care system" by "inundat[ing] hospital capacity" and "leaving little room for others in the community to receive the care they need." *Id.*

The Missouri Department of Health and Senior Services ("DHSS") echoed these concerns in a November 12, 2021 emergency amendment to Mo. Code Regs. Ann. tit. 19, § 30-82.010. *See* Emergency Amendment, Missouri Department of Health and Senior Services (Nov. 12, 2021), https://www.sos.mo.gov/CMSImages/AdRules/main/EmergenciesforInternet/19c30-82.010IE.pdf. According to DHSS, approximately 44% of staff working at Missouri's long-term-care facilities are not fully vaccinated. *Id.* DHSS anticipates that "many of the [44%] of unvaccinated staff working at these long term facilities will not choose to get vaccinated, even with this vaccine mandate from CMS." *Id.* DHSS thus predicts that because of the CMS vaccine mandate, some long-term-care facilities—namely, skilled nursing facilities and intermediate care facilities—"will not have enough staff to care for the residents in their facilities and be in compliance with federal and state law." *Id.* These facilities may be forced to temporarily close or consolidate until the staffing shortages are fixed. *Id.* The emergency amendment thus creates a temporary closure procedure for facilities should they need to "make plans to begin discharging residents and pursing temporary closures before" CMS's deadlines. *Id.*

Specific examples throughout the Plaintiff States support these broader concerns about long-term-care facilities. One troubling situation involves Kimball County Manor and Assisted Living, a nursing home in rural Nebraska. Monheiser Decl. ¶ 1 (Ex. V). Of that facility's 55 employees, 31 are unvaccinated, and at least 27 of them "have informed management that they will resign or be terminated rather than be vaccinated." *Id.* at ¶ 8. "Losing potentially 48% of [its] workforce, including a substantial percentage of [its] already depleted nursing staff[,] will force"

the manor to reduce its services and transfer "current patients" to facilities further away. *Id.* at ¶ 9. It will also jeopardize the manor's "very existence." *Id.* at ¶ 9. Fearing its impending doom, the manor has already placed "a hold on admitting new patients in anticipation of [the] loss of staff." *Id.* at ¶ 7.

A similar situation faces Monroe City Manor Care Center, a nursing home in Missouri. It has an employee vaccination rate under 50%, and "[w]hen surveyed, a majority of the[] unvaccinated staff stated they would choose to leave healthcare completely over being forced to get [a] covid-19 vaccine." Vanlandingham Decl. ¶ 7 (Ex. E). That loss of 25% of its total staff "will cause significant difficulty in the continued operation" of the facility. *Id.* at ¶ 8.

Scotland County Care Center ("SCCC"), another nursing home in Missouri, is similarly situated. SCCC, a political subdivision of the State of Missouri, derives 50% of its total operational revenues from CMS, and is currently experiencing a shortage of nursing staff. This has already led SCCC to contract-out nursing services at a substantial premium. And now, the CMS vaccine mandate will cause SCCC to "lose more staff, struggle to fill those vacancy spots with agency staffing, causing even more financial hardship." Twenty out of 65 of SCCC's employees are "vehemently opposed to taking the vaccine and if the CMS mandate is indeed imposed, they will quit working at SCCC." "If that happens," SCCC "will lose about 30% of [its] workforce"—a loss that will cause SCCC to cease its operations. Schrage Decl. ¶¶ 1–2, 4–5, 7, 9 (Ex. I).

Emerald Health Care, which operates four skilled nursing facilities throughout Nebraska, anticipates that the CMS mandate will cause it to lose between 25% and 10% of its staff at each of its locations. Sroczynski Decl. ¶¶ 4–7 (Ex. T). Considering that the staffing at these facilities is already extremely deficient, Emerald's long-term prospects are quite grim. *Id.* Even if it survives, the mandate "will result in each [Emerald] facility turning away patients." *Id.* at ¶ 8.

State-run healthcare facilities will also be significantly impacted. The Alaska Psychiatric Institute ("API") estimates that "[d]espite the availability of medical and religious exemptions," it "is likely to lose approximately 20 employees (8% of [its] workforce) as a result of the vaccine mandate." York Decl. ¶ 9 (Ex. B). "Losing even 5% of its workforce would cause substantial harm to API because it would be extremely difficult to fill those positions." *Id.* at ¶ 10. Similarly, 37% of the staff at Arkansas's seven state-run healthcare facilities are unvaccinated, and the State "expects that the CMS vaccine mandate will result in increased staffing shortages" for those providers. White Decl. ¶¶ 8–9 (Ex. C). South Dakota likewise expects staff loss at its state-run psychiatric hospital and fears that it might result in "individuals needing emergency inpatient psychiatric treatment [being] held in jail settings or emergency rooms until capacity is available." Ringling Decl. ¶¶ 3, 7–8 (Ex. CC).

That the CMS mandate would ignite these healthcare catastrophes was not a secret. In Missouri, for example, it has been publicly discussed and widely anticipated for the last few months that vaccine mandates will prompt widespread resignations and intensify existing staffing shortages in the healthcare sector—as healthcare facilities described their prospects under the threatened mandate as "dangling by a thread."[1] National media also covered this issue. *See, e.g.*, *As Vaccine Deadlines Approach, Hospitals Fear Staffing Shortages Will Occur*, NPR.org (Sept. 27, 2021), https://www.npr.org/sections/coronavirus-live-updates/2021/09/27/1041047608/

[1] *See, e.g.*, Emily Manley, *Missouri Health Care Association says vaccine mandate will worsen staffing shortage*, Fox 2 News (Sept. 14, 2021), https://fox2now.com/news/missouri/missouri-health-care-association-says-vaccine-mandate-will-worsen-staffing-shortage/; Allison Kite and Tessa Weinberg, *'Dangling by a thread': Nursing home industry warns of staff exodus over vaccine mandates*, Missouri Independent (Sept. 15, 2021), https://missouriindependent.com/2021/09/15/dangling-by-a-thread-nursing-home-industry-warns-of-staff-exodus-over-vaccine-mandates/; Mike Stunson, *Missouri hospital fears staff may quit over Biden vaccine mandate*, Kansas City Star (Oct. 14, 2021), https://www.kansascity.com/news/coronavirus/article254948037.html.

vaccine-deadlines-hospitals-fear-staffing-shortages. All this shows that these adverse impacts, especially in rural and underserved areas, have been widely anticipated for many weeks.

ARGUMENT

Courts consider four factors in determining whether to grant a preliminary injunction: "(1) the likelihood of the movant's success on the merits; (2) the threat of irreparable harm to the movant in the absence of relief; (3) the balance between that harm and the harm that the relief would cause to other litigants; and (4) the public interest." *Watkins Inc. v. Lewis*, 346 F.3d 841, 44 (8th Cir. 2003) (citing *Dataphase Sys., Inc. v. C.L. Sys., Inc*., 640 F.2d 109, 114 (8th Cir. 1981) (en banc)). Here, all four factors favor Plaintiff States.

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

The Plaintiff States are likely to succeed on the merits of their claims that (1) the CMS vaccine mandate is arbitrary and capricious, (2) it exceeds CMS's statutory authority and conflicts with law, (3) it violates the Constitution, (4) it contravenes multiple procedural rulemaking requirements, and (5) CMS failed to produce a required regulatory impact analysis.

A. The CMS Vaccine Mandate Is Arbitrary and Capricious in Violation of the APA.

The CMS vaccine mandate is arbitrary and capricious under the APA. As an initial matter, the APA undoubtedly applies to this case. The United States Department of Health and Human Services ("HHS"), which delegated its authority to and acted through CMS, is a federal agency. *See Soucie v. David*, 448 F.2d 1067, 1073 (D.C. Cir. 1971) ("[T]he APA . . . confers agency status on any administrative unit with substantial independent authority in the exercise of specific functions."). And the IFC is final agency action because (1) it "mark[s] the consummation of the agency's decisionmaking process," and (2) it is a pronouncement "by which rights or obligations have been determined, or from which legal consequences will flow." *Bennet v. Spear*, 520 U.S.

154, 177–78 (1997). Indeed, the IFC directly determines which healthcare facilities will be eligible to receive Medicare and Medicaid funding. In CMS's words, "[p]rovider and supplier compliance with the Federal rules issued under these statutory authorities are mandatory for participation in the Medicare and Medicaid programs." 86 Fed. Reg. at 61,560.

Under the APA, a court must "hold unlawful and set aside agency action" that is "arbitrary" or "capricious." 5 U.S.C. § 706(2)(A). "The APA's arbitrary-and-capricious standard requires that agency action be reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). Courts must ensure that "the agency has acted within a zone of reasonableness and, in particular, has reasonably considered the relevant issues and reasonably explained the decision." *Id.* "[T]he agency must examine the relevant data and 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). The arbitrary-and-capriciousness standard also requires the agency "to assess whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1915 (2020). Under these principles, the IFC establishing the CMS vaccine mandate is arbitrary and capricious for at least seven reasons.

First, CMS failed to reasonably explain its decision to impose its vaccine mandate despite the alarming healthcare workforce shortages and the obvious risk that the mandate will exacerbate an already unstable situation. In fact, CMS's analysis goes a long way toward showing that the vaccine mandate will indeed throw gasoline on the fire.

CMS repeatedly admits that the current "endemic staff shortages" in the healthcare industry "may be made worse if any substantial number of unvaccinated employees leave health care

employment altogether." 86 Fed. Reg. at 61,607; *see also id.* at 61,608 ("[T]here may be disruptions in cases where substantial numbers of health care staff refuse vaccination and are not granted exemptions and are terminated, with consequences for employers, employees, and patients"); *id.* at 61,609 ("[I]t is true that compliance with this rule may create some short-term disruption of current staffing levels for some providers or suppliers in some places."). And CMS went further by acknowledging that "[e]ven a small fraction" of unvaccinated healthcare workers leaving their jobs "could disrupt facility operations." *Id.* at 61,612.

CMS also discussed facts showing that potential calamity awaits rural communities in particular. For instance, CMS acknowledged that "vaccination rates are disproportionately low among nurses and health care aides" in rural locations and other "communities that experience social risk factors." *Id.* at 61,566. And it admitted that "early indications are that rural hospitals are having greater problems with employee vaccination . . . than urban hospitals." *Id.* at 61,613.

Despite these acknowledged concerns about intensifying an already-existing healthcare crisis, CMS decided to move forward anyway. It did so because it thought that the unvaccinated employees would get jobs in other healthcare positions, such as "physician and dental offices," that are not covered by the CMS vaccine mandate. *Id.* at 61,607. Yet this speculation does nothing to abate the debilitating harm soon to be inflicted upon the *healthcare facilities* falling under this mandate. Indeed, it does not suggest that the healthcare worker shortage will improve but only that shortages will be further concentrated among the covered healthcare facilities.

CMS also conjectured that staffing deficiencies at facilities covered by the mandate "might be offset by persons returning to the labor market who were unwilling to work at locations where some other employees are unvaccinated." *Id.* at 61,607. This was pure speculation. CMS cited no evidence that such vaccinated workers exist, and it strains credulity to suggest that they do. A

worker who harbors such fears would still have to regularly work with unvaccinated *patients*, and it is irrational to assume that they would be willing to work with unvaccinated patients but not unvaccinated coworkers.

In the end, CMS dismissed the concerns about staffing because, it believed, "there is insufficient evidence to quantify" those concerns and balance them against other risks. *Id.* at 61,569. Instead, based on the experiences of a few private healthcare facilities that implemented vaccine mandates in mostly urban settings, which have much larger labor-market pools and higher community vaccination rates, CMS optimistically "believe[d] that the COVID-19 vaccine requirements . . . will result in *nearly all* health care workers being vaccinated." *Id.* (emphasis added). But CMS did not reference data on any past efforts to mandate COVID-19 vaccines in rural areas. Making such a rosy across-the-board projection based on nothing more than the experiences of a few cherry-picked healthcare providers is decidedly unreasonable.

The arbitrariness is particularly apparent in CMS's decision to act based on such scant and inapposite anecdotes instead of soliciting public comment and state input, as applicable statutes required the agency to do. *See* 5 U.S.C. § 553(b)–(c) (APA), 42 U.S.C. § 1395hh(b)(1) (Social Security Act), 42 U.S.C. § 1395z ("Secretary shall consult with appropriate State agencies"). Obtaining insight from those sources would have provided the agency with important information on the looming healthcare disaster. Had CMS sought public comment, it would have heard about countless situations like those recounted in the declarations supporting this motion (and in Section E under the Statement of Facts above). With the fate of our strained national healthcare industry hanging in the balance, it is the height of arbitrariness not to solicit input from key stakeholders.

Despite the obvious concerns about the vaccine mandate upending significant sectors of the healthcare industry, CMS remarkably concluded that existing staffing shortages are actually *a*

reason to impose the mandate. In CMS's words, "the urgent need to address COVID-related staffing shortages that are disrupting patient access to care[] provides strong justification as to the need to issue this" mandate. 86 Fed. Reg. at 61,567. Because "unvaccinated staff" are purportedly "at greater risk for infection" and "absenteeism," CMS elaborated, allowing providers to continue hiring them might "create staffing shortages." *Id.* at 61,559. But this speculation irrationally ignores the obvious: that maintaining a larger pool of potential workers, even if some might have a bout with COVID-19, is better than categorically excluding an entire class of individuals. In short, CMS's discussion of the mandate's projected effect on the existing healthcare crisis is unreasonable from beginning to end.

Second, CMS failed to consider the reliance interests of healthcare providers (including state-run facilities) and healthcare workers. For years, CMS has had regulations setting the conditions for Medicare and Medicaid participation. *See id.* at 61,555 (listing the regulations amended by the IFC). Yet never before had CMS mandated any vaccines for staff members. And six months ago, when CMS adopted an IFC requiring two groups of healthcare providers covered by this mandate—long-term-care ("LTC") facilities and Intermediate Care Facilities for Individuals with Intellectual Disabilities ("ICFs-IID")—to educate their staff on COVID-19 vaccines, it did not go so far as to mandate them. *See* Medicare and Medicaid Programs; COVID-19 Vaccine Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) Residents, Clients, and Staff, 86 Fed. Reg. 26306-01 (May 13, 2021). So when CMS adopted the vaccine mandate, the agency was "not writing on a blank slate," and thus it needed to consider reliance interests. *Regents*, 140 S. Ct. at 1915.

Many healthcare providers relied on CMS's prior rules by hiring staff members regardless of their vaccination status. *See, e.g.*, McNea Decl. ¶ 9 (Ex. S); Naiberk Decl. ¶ 11 (Ex. M); Sharp Decl. ¶ 12 (Ex. X); Kahl Decl. ¶ 13 (Ex. Q). In fact, Nebraska specifically sought out unvaccinated applicants because the State's executive-branch officials decided that they would not mandate vaccination as a condition of working in state-run healthcare facilities. Kahl Decl. ¶ 13 (Ex. Q). By relying on the then-existing regulations, many healthcare facilities assembled workforces without concern for vaccination. But now those facilities stand to abruptly lose significant portions of their staff because of CMS's change in course. And the impact of that will reach far beyond the providers themselves and directly harm the people in the communities they serve. CMS did not discuss these reliance interests when adopting its mandate.

Nor did CMS consider any of the reliance interests of healthcare workers. Those individuals have "embarked on careers" and taken jobs in reliance on the prior CMS rules. *Regents*, 140 S. Ct. at 1914. Now they stand to lose those jobs because of CMS's mandate. And the consequences of that would "radiate outward" to injure not only those workers' families but also the very people they once cared for. *Id.* "These are certainly noteworthy concerns," and it was CMS's duty to consider them, "but the agency failed to do it." *Id.* Ignoring these critical worker-focused reliance interests violates the APA.

Third, CMS completely "failed to consider" other "important aspects of the problem" before it. *Id.* at 1910 (quoting *State Farm*, 463 U.S. at 43) (cleaned up). Critically, CMS did not acknowledge that it was infringing on a well-established area of state sovereignty. "[T]he police power of a state" includes the authority to adopt regulations seeking to "protect the public health," including the topic of mandatory vaccination. *Jacobson v. Massachusetts*, 197 U.S. 11, 24–25 (1905). Though these matters "do not ordinarily concern the national government," *id.* at 38, CMS

never recognized that it was trampling on traditional State prerogatives and disrupting the existing federal-state balance of authority. Instead, CMS made explicit its desire to override contrary state law on vaccine issues. *See, e.g.*, 86 Fed. Reg. at 61,568 ("We intend . . . that this nationwide regulation preempts inconsistent State and local laws").

Fourth, CMS's own discussion betrays the illogic of its refusal to exempt healthcare workers who have been previously "infected by SARS-CoV-2" and thus have developed infection-induced immunity, also called natural immunity. *Id.* at 61,614. The agency cast aside that option because it perceives "uncertainties about [sic] as to the strength and length of [natural] immunity." *Id.* But CMS similarly acknowledges that vaccine "immunity decreases" over time "after the primary vaccine series." *Id.* at 61,562. And the agency elsewhere recognized the value of natural immunity when it said that each day 100,000 people are "recover[ing] from infection," that they "are *no longer sources of future infections*," and that their natural immunity "reduce[s] the risk to both health care staff and patients substantially." *Id.* at 61,604 (emphasis added). Simply put, CMS's inconsistencies on natural immunity demonstrate the unreasonableness of its decision.

CMS also ignored key evidence indicating that natural immunity effectively guards against the Delta variant. A widely publicized study of a large population of patients in Israel found that *vaccinated* people who had not been previously infected had 13 times higher odds of experiencing a breakthrough infection with the Delta variant than patients who had recovered from COVID but were never vaccinated. Sevan Gazit et al., *Comparing SARS-CoV-2 natural immunity to vaccine-induced immunity: Reinfections versus breakthrough infections*, medRxiv Preprint (2021), https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1). It is unreasonable for CMS to pretend that this evidence does not exist.

Fifth, CMS's pronouncement about the necessity of the vaccine mandate is an impermissible "*post hoc* rationalization." *Regents*, 140 S. Ct. at 1908 (citation omitted). The agency did not first identify the mandate as necessary to protect public health and then produce the rule. Rather, the President directed CMS to impose the mandate as part of a comprehensive plan to federalize the public-health response to COVID-19, and then the agency spent nearly two months reverse-engineering a justification for it. Such *post hoc* rationalizations cannot satisfy APA review.

Sixth, the exceedingly broad scope of healthcare providers covered by the CMS vaccine mandate is arbitrary. The mandate reaches categories of healthcare facilities, such as Psychiatric Residential Treatment Facilities ("PRTFs") for individuals under age 21, *see* 86 Fed. Reg. at 61576, that are not related to CMS's asserted interest in protecting elderly and infirm patients from COVID-19. Indeed, CMS recognizes that "risk of death from infection from an unvaccinated 75- to 84-year-old person is 320 times more likely than the risk for an 18- to 29-years old person." *Id.* at 61,610 n.247. CMS provides no reasoned explanation for this overbroad approach.

Seventh, the vast range of workers, volunteers, and third-party contractors compelled by the mandate is inexplicable. It applies to onsite "administrative staff" and "housekeeping and food services" staff "*regardless of . . . patient contact*." *Id.* at 61,570 (emphasis added). It also reaches "any individual that . . . has the *potential* to have contact with anyone at the site of care." *Id.* at 61,571 (emphasis added). This includes "staff that primarily provide services remotely via telework" but "occasionally encounter fellow staff . . . who will themselves enter a health care facility." *Id.* at 61, 570. And the mandate also covers a third-party vendor's "crew working on a construction project whose members use shared facilities (restrooms, cafeteria, break rooms) during their breaks." *Id.* at 61,571. The sheer breadth of this mandate is far removed from the

purported purpose of protecting patient safety. For all these reasons, the CMS vaccine mandate is arbitrary and capricious under the APA.

B. The CMS Vaccine Mandate Exceeds Statutory Authority And Is Not In Accordance With Law.

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 violates this command in two ways. First, the mandate exceeds statutory authority because the statutes that CMS cites do not support imposing a vaccine mandate. Second, the mandate conflicts with 42 U.S.C. § 1395 by impermissibly authorizing CMS officials to control the selection of healthcare workers.

1. The mandate exceeds CMS's statutory authority.

CMS's purported statutory authority for its vaccine mandate rests on two sets of laws. *See* 86 Fed. Reg. at 61,567. First, the agency relies on two statutes that give general rulemaking power to HHS. *See* 42 U.S.C. § 1302(a) ("the Secretary of Health and Human Services . . . shall make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which [he] is charged under this Act"); 42 U.S.C. § 1395hh(a)(1) (providing that the "Secretary shall prescribe such regulations as may be necessary to carry out the administration of the insurance programs under" Title 18 of the Social Security Act). Second, CMS invokes other more specific statutes that supposedly give it authority to impose the mandate on the covered classes of healthcare facilities. 86 Fed. Reg. at 61,567.

Before analyzing the statutory text, it is important to assess the magnitude of what CMS has done. Amidst an ongoing political debate about whether governments should mandate COVID-19 vaccines, President Biden announced that his administration would implement a slew of them, including CMS's mandate. *See* Biden Speech, *supra*. This is a brazen attempt to

federalize a national public-health response to COVID-19, and it is something that CMS admits it has never done before. These statutes do not give CMS that kind of power.

Start with three important background principles of statutory construction often referred to as clear-statement rules. First, courts "expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance." *Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021) (per curiam); *see also Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) (Congress does not "hide elephants in mouse-holes"). Exercising power of vast economic and political significance is precisely what CMS has done here. It seeks to settle a federal-state struggle on politically controversial public-health matters by implementing a heavy-handed policy that threatens to inflict economic ruin on significant segments of the healthcare industry.

Second, "'it is incumbent upon the federal courts to be certain of Congress' intent before finding that federal law overrides' the 'usual constitutional balance of federal and state powers.'" *Bond v. United States*, 572 U.S. 844, 858 (2014) (quoting *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991)). CMS's mandate seeks to usurp the police power of the States to "protect the public health" by addressing mandatory vaccination—a topic that "do[es] not ordinarily concern the national government." *Jacobson*, 197 U.S. at 24–25, 38.

Third, "[w]here an administrative interpretation of a statute invokes the outer limits of Congress' power," courts "expect a clear indication that Congress intended that result." *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Engineers*, 531 U.S. 159, 172 (2001). As explained in the constitutional argument below, affording a federal agency the power to mandate vaccines reaches beyond even the outer limits of Congress's power.

For all these reasons, Congress must speak unambiguously to authorize CMS to mandate vaccines. Yet it has not done so, as an examination of the relevant statutory texts demonstrates.

Turning to that text, the two general rulemaking statutes that CMS invokes do not suffice. Those statutes give CMS the authority to create regulations "necessary to the efficient administration" of its functions, 42 U.S.C. § 1302(a), or "necessary to carry out the administration" of Title 18 of the Social Security Act, 42 U.S.C. § 1395hh(a)(1). But CMS may exercise this authority only if it is connected to a specific aspect of the agency's duties. That is why CMS attempts to tie each part of the vaccine mandate to a more specific statute. *See* 86 Fed. Reg. at 61,567. Thus, CMS's supposed authority under these general statutes piggy-backs entirely on its reliance on the more specific statutes. And those specific statutes do not grant CMS the power it has exercised here.

The specific statutes are best divided into two groups. The first includes statutes stating that CMS may set "standards," "criteria," or "requirements" for certain facilities.[2] But those laws do not connect the referenced standards, criteria, or requirements to vaccines specifically or even to health or safety in general. *See* Compl. ¶¶ 136–39, 143. By their own terms, then, they do not remotely authorize a vaccine mandate.

The second group includes statutes indicating that CMS may create rules or conditions

[2] *See* 42 U.S.C. § 1396d(h)(1)(B)(i) (governing Psychiatric Residential Treatment Facilities ("PRTFs") and mentioning "standards as may be prescribed in regulations by the Secretary"); 42 U.S.C. § 1396d(d)(1) (governing Intermediate Care Facilities for Individuals with Intellectual Disabilities ("ICFs-IID") and mentioning "standards as may be prescribed by the Secretary"); 42 U.S.C. § 1395i–4(e) (governing Critical Access Hospitals ("CAHs") and mentioning "criteria as the Secretary may require"); 42 U.S.C. § 1395rr(b)(1)(A) (governing End-Stage Renal Disease ("ESRD") facilities and mentioning "requirements as the Secretary shall by regulation prescribe"); 42 U.S.C. § 1395x(iii)(3)(D)(i)(IV) (governing Home Infusion Therapy ("HIT") suppliers and mentioning "requirements as the Secretary determines appropriate").

concerning the health and safety of the individuals served. Most of these statutes permit regulations that "ensure," or are "necessary" for, the "health and safety" of patients or recipients of services,[3] while a few generically authorize CMS to adopt health and safety "standards" or "conditions" without mentioning necessity.[4] Though these statutes mention health and safety, they too fail to authorize vaccine mandates.

A statute's surrounding words and sentences inform an agency's "grant of authority by illustrating the kinds of measures that could be necessary." *Alabama Ass'n of Realtors*, 141 S. Ct. at 2488. Under "the doctrine of *noscitur a sociis*," courts apply the rule that "a word is known by the company it keeps" to "avoid ascribing to one word" or phrase "a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995) (cleaned up). Surrounding nearly all

[3] *See* 42 U.S.C. § 1395eee(f) (addressing Programs of All-Inclusive Care for the Elderly ("PACE") facilities and allowing provisions "provisions to ensure the health and safety of individuals enrolled"); 42 U.S.C. § 1395x(aa)(2)(K) (addressing Rural Health Clinics ("RHCs") and mentioning "requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services"); 42 U.S.C. § 1395x(ff)(3)(B) (addressing Community Mental Health Centers ("CMHCs") and mentioning "conditions as the Secretary shall specify to ensure . . . the health and safety of individuals being furnished such services"); 42 U.S.C. § 1395x(e)(9) (addressing hospitals and mentioning "requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services"); 42 U.S.C. § 1395x(dd)(2)(g) (addressing hospices and mentioning "requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services"); 42 U.S.C. § 1395x(cc)(2)(J) (addressing Comprehensive Outpatient Rehabilitation Facilities ("CORFs") and mentioning "conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services"); 42 U.S.C. § 1395i–3(d)(4)(B) (addressing LTC facilities and mentioning "requirements relating to the health, safety, and well-being of residents . . . as the Secretary may find necessary"); 42 U.S.C. § 1396r(d)(4)(B) (same); 42 U.S.C. § 1395x(o)(6) (addressing Home Health Agencies ("HHAs") and mentioning "conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services").

[4] *See* 42 U.S.C. § 1395k(a)(2)(F)(i) (addressing Ambulatory Surgical Centers ("ASCs") and mentioning "health, safety, and other standards"); 42 U.S.C. § 1395x(p) (addressing facilities that provide outpatient physical therapy and speech-language pathology services and mentioning "conditions relating to the health and safety of individuals who are furnished services").

the health and safety language in the statutes that CMS cites are explicit statutory standards, conditions, and requirements. Those express conditions, as one statute illustrates, generally address topics like administrative matters ("maintain[ing] clinical records"), staff qualifications (nurses must be "licensed"), and the services that the facility provides ("24-hour nursing service"). *See* 42 U.S.C. § 1395x(e) (listing conditions for hospitals).

Yet those kinds of requirements are entirely unlike vaccine mandates in at least three ways. First, vaccines seek to safeguard patients by keeping staff members from getting sick in the first instance. Second, vaccines require staff members to submit to a personal medical intervention. Third, as CMS acknowledges, vaccines entail some risks of "[s]erious adverse reactions" to staff members even though "they are rare." 86 Fed. Reg. at 61,565. No other statutory condition expressly listed in CMS's statutes exhibits any, much less all, of these characteristics. Because vaccine mandates differ in kind (and not merely degree) from the statutory conditions, CMS's cited statutes do not afford the vast power the agency claims.

Finally, reading these statutes to give CMS the authority to mandate vaccines throughout the healthcare field would create a serious nondelegation problem. The nondelegation doctrine requires Congress to "lay down by legislative act an intelligible principle to which the person or body authorized to fix such rates is directed to conform." *Panama Ref. Co. v. Ryan*, 293 U.S. 388, 429–30 (1935). But if nondescript language about health and safety requirements is so broad that it allow CMS to mandate vaccines, the intelligible principle that precedent demands is nowhere to be found. For all these reasons, CMS exceeded its statutory authority in adopting its mandate.

2. The Mandate conflicts with 42 U.S.C. § 1395 by authorizing CMS officials to control the selection of healthcare workers.

The CMS vaccine mandate not only exceeds the agency's lawful authority but also violates a provision in the Social Security Act. That statute—42 U.S.C. § 1395—states:

> Nothing in [Title 18 of the Social Security Act] shall be construed to authorize any Federal officer or employee *to exercise any supervision or control* over the practice of medicine or the manner in which medical services are provided, or *over the selection, tenure, or compensation of any officer or employee* of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

42 U.S.C. § 1395 (emphases added). The CMS vaccine mandate violates 42 U.S.C. § 1395 because it authorizes federal officials at CMS to exercise "supervision" and "control" over the "selection" and "tenure" of employees (including state employees) and other persons "providing health services." *Id.* It does so by prohibiting covered healthcare facilities from hiring unvaccinated employees and forcing those facilities to terminate—and thus end the "tenure" of—unvaccinated employees. *Id.* In addition, CMS's mandate violates this statute because it authorizes CMS officials to exercise "supervision" and "control" over the "administration" and "operation" of institutions, agencies, and persons that provide health services (including state facilities and employees). *Id.* Indeed, the mandate controls the administration and operation of these institutions by dictating their hiring and firing policies. Thus, CMS's actions conflict directly with the plain meaning of 42 U.S.C. § 1395 and are not in accordance with law.

C. The CMS Vaccine Mandate Unconstitutionally Infringes on the Authority of the States and Exceeds Congress's Enumerated Powers.

"[E]ven in a pandemic, the Constitution cannot be put away and forgotten." *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 68 (2020). The Constitution "leaves to the several States a residuary and inviolable sovereignty, reserved explicitly to the States by the Tenth Amendment." *New York v. United States*, 505 U.S. 144, 188 (1992) (cleaned up). As that Amendment says, "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people." U.S. Const. amend. X.

As already discussed, "the police power of a state" includes the authority to adopt

regulations seeking to "protect the public health," including the topic of mandatory vaccination. *Jacobson*, 197 U.S. at 24–25. The States "did not surrender" these powers "when becoming . . . member[s] of the Union." *Id.* at 25. Thus, in our constitutional order, "[t]he safety and the health of the people . . . are, in the first instance, for [the States] to guard and protect." *Id.* at 38. To the extent that health measures like vaccine mandates "can be [implemented] by any government, they depend, primarily, upon such action as the state, in its wisdom, may take." *Id.*

By seeking to impose its vaccine mandate on millions of state and private healthcare workers, CMS is arrogating to itself powers that belong to the States. CMS admits that it never before has attempted to mandate vaccines on state or private employees. 86 Fed. Reg. at 61,568 ("[W]e have not, until now, required any health care staff vaccinations"). Often "the most telling indication of a severe constitutional problem is the lack of historical precedent" for it. *NFIB v. Sebelius*, 567 U.S. 519, 549 (2012). That is certainly true here.

Confirming the Tenth Amendment violation, nothing in the Constitution gives the federal government the power CMS seeks to exercise. While Congress has Spending Clause authority, U.S. Const. art. I, § 8, cl. 1, that power does not support the CMS mandate for two reasons.

First, the federal government cannot use Congress's spending power to "commandeer[] a State's . . . administrative apparatus for federal purposes," *NFIB*, 567 U.S. at 577, or "conscript state [agencies] into the national bureaucratic army," *id.* at 585; *see also Printz v. United States*, 521 U.S. 898, 926, 933 (1997) (explaining that Congress "may not compel the States to . . . administer a federal regulatory program," and holding that Congress cannot require state officials to conduct a background check on prospective gun purchasers). But that is exactly what CMS has done—forcing "State surveyors" to enforce the mandate by verifying healthcare providers' compliance with it. 86 Fed. Reg. at 61,574. If States instruct their surveyors not to enforce the

mandate, that will disqualify Medicare- and Medicaid-certified providers and suppliers in their States. Kahl Decl. ¶ 12 (Ex. Q). Forcing States to administer the mandate or jeopardize *all Medicare and Medicaid funds flowing into their States* (even to private healthcare providers) is "a gun to the head" that compels States to participate against their will. *NFIB*, 567 U.S. at 581.

It is not only state surveyors that must enforce the vaccine mandate; it is also the state officials who run state-run healthcare facilities. Those officials now must demand that their employees get vaccinated and fire them if they demur. They have become administrators of this federal COVID-19 mandate. Nor is it possible for all the state-run health facilities in the Plaintiff States to immediately forego all Medicare and Medicaid funding. That money often amounts to a substantial percentage of a facility's annual budget. *See, e.g.*, Huhn Decl. ¶ 22 (Ex. J) (89% of the Missouri Department of Mental Health's budget); Kahl Decl. ¶ 10 (Ex. Q) (62% of one state facility's expenditures). But States have been given a mere month to either give up all that funding (and thereby imperil the people served by those facilities) or submit to this federal strong-arming by demanding that their employees get vaccinated. Forcing this choice on such an abrupt timeline is another way in which CMS is compelling the States to enforce this unconstitutional mandate.

Second, CMS's claimed statutory authority for its mandate did not provide "clear notice" to the States that the agency could impose vaccine requirements. *See Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006). "[W]hen Congress attaches conditions to a State's acceptance of federal funds, the conditions must be set out 'unambiguously.'" *Id.* (quoting *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981)). But as explained above, the relied-upon statutes do not authorize CMS's unprecedented action, must less did they furnish clear

notice of that power. *See NFIB*, 567 U.S. at 584 ("[T]he spending power . . . does not include surprising participating States with post-acceptance . . . conditions.").

Just as the Spending Clause does not authorize CMS's mandate, neither does the Commerce Clause. Art. I, § 8, cl. 3. Indeed, the mandate does not "regulate Commerce"—that is, it does not regulate ongoing commercial activity. *Id.* Rather, it demands action—in the form of compulsory vaccines—from millions of people. *NFIB*, 567 U.S. at 555 ("The Framers gave Congress the power to *regulate* commerce, not to *compel* it"). But the Commerce Clause is not a license to act "whenever enough [people] are not doing something the [federal] Government would have them do." *Id.* at 553. Much like Congress lacks authority under the Commerce Clause to directly mandate the purchase of personal health insurance, so also it lacks authority to directly mandate vaccination. *See id.* Moreover, Defendants' mandate does not merely require *activities* in the workplace; it intrudes upon a deeply *personal* health decision that transcends commerce and work issues. "Any police power to regulate individuals as such, as opposed to their activities, remains vested in the States" and has not been given to the federal government. *Id.* at 557. Defendants have thus exceeded their authority by attempting to impose their mandate.

D. The CMS Vaccine Mandate Violates Procedural Notice-and-Comment and State-Consultation Requirements.

Under the APA, a court must "hold unlawful and set aside agency action" that is "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). The APA requires federal agencies to publish "notice of proposed rule making . . . in the Federal Register" and then "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." 5 U.S.C. § 553(b)–(c). The Social Security Act similarly requires CMS to "provide for notice of [a] proposed regulation in the Federal Register and a period of not less than 60 days for public comment thereon." 42 U.S.C. § 1395hh(b)(1).

Before promulgating its vaccine mandate, CMS admittedly did not publish notice of proposed rulemaking in the Federal Register or give all interested members of the public an opportunity to comment. Thus, the agency violated the governing notice-and-comment requirements unless it showed "good cause" that those procedural regularities "are impracticable, unnecessary, or contrary to the public interest" under the circumstances. 5 U.S.C. § 553(b)(B) (APA); 42 U.S.C. § 1395hh(b)(2)(C) (incorporating 5 U.S.C. § 553(b)(B) into the Social Security Act). But CMS failed to demonstrate that "good cause" excuses its procedural failures.

"The burden is on the agency 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). "[J]udicial review of a rule promulgated under an exception to the APA's notice-and-comment requirement must be guided by Congress's expectation that such exceptions will be narrowly construed and only reluctantly countenanced." *Nw. Airlines, Inc. v. Goldschmidt*, 645 F.2d 1309, 1321 (8th Cir. 1981) (citation omitted). "The public interest prong of the good cause exception is met only in the rare circumstance when ordinary procedures—generally presumed to serve the public interest—would in fact harm that interest." *Mack Trucks, Inc. v. E.P.A.*, 682 F.3d 87, 95 (D.C. Cir. 2012).

Under these circumstances, notice-and-comment procedures would not have harmed the public interest. Far from it. Those procedural requirements would have created a vital forum for States, healthcare providers, and healthcare workers to submit critical information showing that the CMS vaccine mandate portends disaster for the healthcare industry, particularly in rural communities. This is one of the key purposes that notice-and-comment procedures serve. *See Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005) (recognizing that the purpose of the procedural requirements is "to give affected

parties an opportunity to develop evidence in the record to support their objections" and "ensure that agency regulations are tested via exposure to diverse public comment"). By dispensing with those requirements, CMS plugged its ears and ignored the mountain of evidence showing that the mandate threatens devastating consequences to healthcare providers throughout the nation.

CMS purported to find "good cause to waive notice of proposed rulemaking" because it supposedly "would be impracticable and contrary to the public interest . . . to undertake normal notice and comment procedures." 86 Fed. Reg. at 61,586. Though CMS mentioned the alleged impracticability of fulfilling notice-and-comment requirements, the focus of its reasoning was on the public interest. CMS offered two different groups of justifications, but neither suffices.

First, CMS's good-cause discussion spills much ink rehashing its justifications for the mandate itself—reasons such as the efficacy of the COVID-19 vaccines, CMS's displeasure with current "levels of vaccination based on voluntary efforts," and "FDA's full licensure of the Pfizer-BioNTech's Comirnaty vaccine." *Id.* at 61,584. But it is not enough under the good-cause standard to recite the reasons for the rule itself; the agency must "point to something specific that illustrates a particular harm that will be caused by the delay required for notice and comment." *United States v. Brewer*, 766 F.3d 884, 890 (8th Cir. 2014) (citation omitted). These general reasons thus do not advance CMS's good-cause argument.

Second, CMS places much weight on "[t]he emergence of the Delta variant" in May and June 2021. 86 Fed. Reg. at 61,583; *see also id.* at 61,584 (mentioning "Delta-variant-driven surging case counts beginning in summer 2021"). But CMS undermines that reason when it acknowledges that "newly reported COVID-19 cases, hospitalizations, and deaths have begun to trend downward at a national level." *Id.* at 61,583. CMS nonetheless claims, without citing any support, that "there are emerging indications of potential increases" in case counts arising in

"northern states where the weather has begun to turn colder." *Id.* at 61,584. CMS's undocumented and unexplained pronouncement of "emerging indications" cannot carry the day.

CMS also raises its concern that "the 2021–2022 influenza season" will soon begin. *Id.* Yet the agency simultaneously concedes that "the intensity of the upcoming 2021–2022 influenza season cannot be predicted" and that "influenza activity during the 2020–2021 season was low throughout the U.S." *Id.* Moreover, one would naturally assume that the onset of the flu season would be a reason to *avoid* critical staffing shortages at healthcare facilities for underserved communities—not to exacerbate them. For a "risk of future harm" to "justify a finding of good cause," the "risk must be more substantial than a mere possibility." *Brewer*, 766 F.3d at 890. Because CMS's influenza concerns raise no more than a "mere possibility" of harm, they are insufficient to establish good cause.

Another consideration further weakens CMS's good-cause claim: the agency's professed need to immediately implement the rule is "undermined" by its own "delay in promulgating the [IFC]." *Id.* President Biden announced the CMS mandate nearly two months before the agency released it. That delay hardly suggests a situation so dire that CMS may dispense with notice-and-comment procedures and the important purposes they serve.

Not only did CMS violate notice-and-comment requirements under the APA and Social Security Act, it also flouted the statutory obligation to "consult with appropriate State agencies" before issuing rules like this. The relevant statute—42 U.S.C. § 1395z—provides that "the Secretary shall consult with appropriate State agencies . . . and may consult with appropriate local agencies" when "carrying out his functions, relating to determination of conditions of participation by providers of services, under subsections (e)(9), (f)(4), (j)(15), (o)(6), (cc)(2)(I), and[] (dd)(2), and (mm)(1) of section 1395x of this title, or by ambulatory surgical centers under section

1395k(a)(2)(F)(i) of this title." This statute gives the States a direct procedural interest in being consulted before decisions such as this.

The statute applies to CMS's mandate because this agency action purports to establish "conditions of participation" for many of the referenced "providers of services." These include hospitals under 42 U.S.C. § 1395x(e)(9), long-term-care facilities (also known as skilled nursing facilities) under 42 U.S.C. § 1395x(j) and 42 U.S.C. § 1395i–3, Home Health Agencies ("HHAs") under 42 U.S.C. § 1395x(o)(6), Comprehensive Outpatient Rehabilitation Facilities ("CORFs") under 42 U.S.C. § 1395x(cc)(2), hospices under 42 U.S.C. § 1395x(dd)(2), Critical Access Hospitals ("CAHs") under 42 U.S.C. § 1395x(mm)(1) and 42 U.S.C. § 1395i–4(e), and Ambulatory Surgical Centers ("ASCs") under 42 U.S.C. § 1395k(a)(2)(F)(i).

CMS admitted that it did not comply with the requirement to "consult with appropriate State agencies." 86 Fed. Reg. at 61,567. By failing to seek that input before issuing the mandate, CMS violated 42 U.S.C. § 1395z.

CMS counters that it has not violated the statute because it "intend[s] to engage in consultations with appropriate State agencies . . . following the issuance of th[e] rule." 86 Fed. Reg. at 61,567. This position is baseless. The statute plainly requires that the consultation with States occur *before* a rule is issued. Consultation *after* a rule is finalized is essentially meaningless—allowing the States to discuss a *fait accompli*. Accordingly, the statute's text demands the consultation when the Secretary is "carrying out his functions[] relating to determination of conditions of participation by providers of services." 42 U.S.C. § 1395z. The Secretary, via CMS, already made the determination that the vaccine mandate should be a condition of participation. It was at that time CMS was required to consult with the States. Indeed, the whole purpose of this consultation requirement is to enable States, which are so intimately involved with and affected

by these Medicare and Medicaid rules, to provide the agency critical information that it might be ignoring. Allowing this to occur after the rule takes effect defeats the point. Since CMS did not consult with the States ahead of time, the agency ran afoul of 42 U.S.C. § 1395z.

E. CMS Failed to Prepare the Regulatory Impact Analysis Required Under 42 U.S.C. § 1302.

CMS violated another mandatory obligation when it failed to prepare a regulatory impact analysis ("RIA") under 42 U.S.C. § 1302. That statute requires that whenever the Secretary publishes a rule—and, therefore, "publishes a general notice of proposed rulemaking"—"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) (emphases added).

Congress's use of the word "shall" in statutes indicates mandatory action. "The first sign that the statute impose[s] an obligation is its mandatory language: 'shall.'" *Maine Cmty. Health Options v. United States*, 140 S. Ct. 1308, 1320 (2020). "Unlike the word 'may,' which implies discretion, the word 'shall' usually connotes a requirement." *Id.* (citation omitted). This explains why courts in the Eighth Circuit have construed § 1302(b)(1)'s use of the word "shall" as a requirement. *See Ashley Cty. Med. Ctr. v. Thompson*, 205 F. Supp. 2d 1026, 1067 (E.D. Ark. 2002) ("[T]he Social Security Act provides that when HHS publishes a proposed rule under the Medicaid statute that may have a significant impact on the operations of a substantial number of rural hospitals, HHS *must* prepare a regulatory impact analysis.") (emphasis added) (citing 42 U.S.C. § 1302(b)(1)).

It is indisputable that § 1302(b)(1) applies to the CMS vaccine mandate because CMS's cited statutory authority falls under Titles 18 and 19 of the Social Security Act. 86 Fed. Reg. at 61,567. It's also indisputable that the IFC would cover small rural hospitals located in the Plaintiff

States. *See id*. at 61,613 (defining a "small rural hospital" as one "located outside of a metropolitan statistical area and has fewer than 100 beds"); Bruntz Decl. ¶ 4 (Ex. W); Tobler Decl. ¶ 2 (Ex. G). And it's also indisputable that the mandate *will*—not just "may"—have a significant impact on the operations of a substantial number of small rural hospitals. *See* Statement of Facts, *supra*, at § E. The plain language of § 1302(b)(1) does not require certainty of a significant impact; it merely requires possibility. The evidence the Plaintiff States have submitted readily meets that standard: The CMS vaccine mandate threatens to exacerbate already devastating shortages in healthcare staffing by forcing small rural hospitals to terminate their unvaccinated workers. That, in turn, will compel those hospitals to close certain divisions, cancel certain services, or shutter altogether. Eggleston Decl. ¶¶ 16–17 (Ex. L); Mazanec Decl. ¶ 14 (Ex. R).

These dire consequences stretch across rural America, and their collective force required CMS to prepare a regulatory impact analysis—something it failed to do. That critical procedural step would have forced CMS to "describe"—and thus address—"the impact of the proposed rule" on the Plaintiff States' small rural hospitals. 42 U.S.C. § 1302(b)(1). Thus, this RIA (along with commentary from key stakeholders) could have helped CMS address "important aspects of the problem" and consider legitimate reliance interests, as required under the APA. *Regents*, 140 S. Ct. at 1910, 1913. But CMS did not do that. And just as CMS's failure to comply with the APA's notice-and-comment requirements was "prejudicial error," so too was its "complete failure" to prepare a regulatory impact analysis under § 1302(b)(1). *Brewer*, 766 F.3d at 890–91 (cleaned up). For these reasons, CMS violated 42 U.S.C. § 1302(b)(1).

II. The Balancing of Harms and the Public Interest Support an Injunction.

The remaining preliminary-injunction factors include "(2) the threat of irreparable harm to the movant in the absence of relief; (3) the balance between that harm and the harm that the relief

would cause to other litigants; and (4) the public interest." *Watkins, Inc.*, 346 F.3d at 44. These factors also favor the States.

A. The States Face Irreparable Harm to Their Sovereign, Quasi-Sovereign, and Proprietary Interests.

Without an injunction, the States will suffer irreparable harm to their sovereign, quasi-sovereign, and proprietary interests. These injuries not only establish irreparable harm but also demonstrate why the States have standing to bring their claims.

First, the States face direct sovereign injuries from CMS's mandate. As noted above, the mandate expresses CMS's intent to preempt any contrary state statute or policy. *See* Compl. ¶ 121 (collecting cites). If not enjoined, the mandate will supersede all these sovereign state choices.

This includes numerous statutes and policies of the Plaintiff States. For example, Missouri has a statute that prohibits public health orders, including vaccine mandates, if they are not approved by the governing bodies of political subdivisions, Mo. Rev. Stat. § 67.265, and that statute may be partially preempted if the vaccine mandate goes into effect. CMS's mandate also ostensibly preempts an Alaska statute that (1) broadly protects the right to object to COVID-19 vaccines "based on religious, medical, or *other* grounds" and (2) forbids any person from "requir[ing] an individual to provide justification or documentation to support the individual's decision to decline a COVID-19 vaccine." 2021 Alaska Sess. Laws ch. 2, § 17 (emphasis added). Similarly, the mandate purportedly preempts Ark. Code § 20-7-143, which is currently in effect and prohibits public entities in the State from requiring vaccines, and Ark. Code § 11-5-118, which will go into effect in January and require that private employees be given a testing option in lieu of a vaccine mandate.

Preempting, and thus partially invalidating, duly enacted state statutes inflicts *per se* irreparable injury on the States as sovereigns. "Any time" a State is blocked "from effectuating

statutes enacted by representatives of its people, it suffers a form of irreparable injury." *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) (citing *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351 (1977) (Rehnquist, J., in chambers)). In other words, when a State is blocked from implementing its statutes, "the State necessarily suffers the irreparable harm of denying the public interest in the enforcement of its law." *Planned Parenthood of Greater Texas Surgical Health Servs. v. Abbott*, 734 F.3d 406, 419 (5th Cir. 2013); *Coalition for Economic Equity v. Wilson*, 122 F.3d 718, 719 (9th Cir. 1997).

Second, the States face irreparable injuries to their quasi-sovereign or *parens patriae* interests in protecting substantial segments of their population. The Supreme Court has recognized that each State has "a quasi-sovereign interest in the health and well-being—both physical and economic—of its residents in general." *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607 (1982). This quasi-sovereign interest arises when a defendant's conduct threatens harm to a "sufficiently substantial segment of [a State's] population," especially where 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 sovereign lawmaking powers." *Id.* As noted above, several States have already enacted statutes to protect their citizens from vaccine mandates.

The States' quasi-sovereign interests manifest themselves in at least two ways. More broadly, the States seek to maintain the viability of healthcare providers within their borders. But the CMS mandate threatens to cripple healthcare in the States (especially in rural areas), create a critical shortage of services, and jeopardize the lives and wellbeing of vulnerable citizens. All this easily constitutes irreparable harm. *See Kai v. Ross*, 336 F.3d 650, 656 (8th Cir. 2003) ("danger to plaintiffs' health, and perhaps even their lives, gives them a strong argument of irreparable injury"). In addition, the States are home to tens of thousands of healthcare workers who are now

forced to accept an unwanted medical intervention or give up their livelihood. Illustrating the irreparable harm to these workers, the mere announcement of CMS's mandate has already compelled some to resign. Shackett Decl. ¶ 8 (Ex. Z).

Third, the States face irreparable injury to their proprietary interests. Those harms are readily apparent when the States operate their own healthcare facilities. They are forced to impose the CMS mandate on their own employees, and the resulting compliance costs, labor losses, disruptions in day-to-day operations, and decreased revenue from turning away patients are all irreparable injuries. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220–21 (1994) (Scalia, J., concurring) ("[A] regulation later held invalid almost always produces the irreparable harm of nonrecoverable compliance costs."). Irreparable injury to further proprietary interests also occurs when States direct their surveyors to spend time and resources "assess[ing] compliance" with the vaccine mandate by "reviewing . . . records of staff vaccinations," "interview[ing] staff to verify their vaccination status," and "cit[ing] providers and suppliers when noncompliance is identified." 86 Fed. Reg. at 61,574. In addition, States will incur irreparable pocketbook harm in the form of (1) lost tax revenue because of reduced healthcare services in the States and (2) a diversion of state resources to supply "State immunization" records to healthcare providers needing to document staff vaccination status. *Id*. at 61,572. All these irreparable harms show why the Plaintiff States need immediate relief.

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

When the party opposing the injunction is the federal government, the balance-of-harms factor "merge[s]" with the public-interest factor. *Nken v. Holder*, 556 U.S. 418, 436 (2009). That balance weighs heavily in the States' favor. On the one hand, as explained above, the States stand to suffer all sorts of irreparable harms absent an injunction. But on the other hand, an order

preventing CMS from enforcing its unlawful mandate will inflict no cognizable injury on the agency because government officials "do[] not have an interest in the enforcement of an unconstitutional law." *N.Y. Progress & Prot. PAC v. Walsh*, 733 F.3d 483, 488 (2d Cir. 2013). Similarly, the public interest supports an injunction because "[t]here is generally no public interest in the perpetuation of unlawful agency action." *League of Women Voters of United States v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016).

The mandate's anticipated adverse impact on the healthcare worker shortage also shows that the public interest calls for an injunction. The Plaintiff States have shown that many healthcare providers, particularly in rural areas, will be forced to fire desperately needed workers, cancel vital services, and even shut down completely. *See* Eggleston Decl. ¶¶ 16–17 (Ex. L); Mazanec Decl. ¶ 14 (Ex. R); Bruntz Decl. ¶¶ 14–16 (Ex. W); Naiberk Decl. ¶ 14 (Ex. M). All that directly harms the patients they serve and public health interests in their communities. *See* Eggleston Decl. ¶¶ 16–17 (Ex. L); McNea Decl. ¶ 11 (Ex. S); Bruntz Decl. ¶ 15 (Ex. W); Monheiser Decl. ¶¶ 7, 9 (Ex. V); Shackett Decl. ¶ 9 (Ex. Z); Cyboron Decl. ¶ 16 (Ex. K) ("This mandate will . . . create disparities in care quality and access here in our rural community."); Petik Decl. ¶ 15 (Ex. O) ("[The hospital] will be put in an almost impossible position to provide the same level and quality of services" as before). Given the interconnectedness of the healthcare industry, service reductions in one facility will place added burdens on other providers. *See* Toline Decl. ¶¶ 9, 14–15 (Ex. Y); Monheiser Decl. ¶ 9 (Ex. V); York Decl. ¶ 13 (Ex. B); McNea Decl. ¶ 12 (Ex. S). And the loss of staff will further burden remaining workers and risk driving them out of their jobs due to burnout. *See* Mazanec Decl. ¶ 15 (Ex. R); Bruntz Decl. ¶ 16 (Ex. W). The situation threatens to devolve quickly, absent immediate relief from this Court.

The public interest also favors vindicating the traditional balance of power between the federal government and the States. "[A] healthy balance of power between the States and the Federal Government will reduce the risk of tyranny and abuse from either front." *Gregory*, 501 U.S. at 458. Casting aside these safeguards, CMS seeks to overtake an area of traditional state authority by imposing an unprecedented and oppressive demand to federally dictate the private medical decisions of millions of Americans. In our nation, the public interest favors federalism, and it favors freedom. The CMS vaccine mandate should be enjoined.

CONCLUSION

The Court should grant Plaintiffs' motion for a preliminary injunction.

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CERTIFICATE OF SERVICE

I hereby certify that, on November 12, 2021, a true and correct copy of the foregoing and any attachments were filed electronically through the Court's CM/ECF system, to be served on counsel for all parties by operation of the Court's electronic filing system and to be served on those parties that have not appeared who will be served in accordance with the Federal Rules of Civil Procedure by mail or other means agreed to by the party.

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