No. 21-3725

United States Court of Appeals for the Eighth Circuit

STATE OF MISSOURI, STATE OF NEBRASKA, *et al.*,
Plaintiffs-Appellees,

v.

JOSEPH R. BIDEN, JR., in his official capacity as the President of the United States of America, *et al.*,
Defendants-Appellants.

Reliant Care Management Company, L.L.C.,
Amicus Curiae,
American Academy of Family Physicians, *et al.*,
Amici on Behalf of Appellant(s).

Appeal from the United States District Court
for the Eastern District of Missouri, Eastern Division
The Honorable Matthew T. Schelp, United States District Judge

BRIEF OF APPELLEES

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STATEMENT WITH RESPECT TO ORAL ARGUMENT

Plaintiffs-Appellees Missouri, Nebraska, et al. (the "States") face a crisis in the provision of rural healthcare, caused by the Center for Medicaid and Medicare's vaccine mandate for healthcare workers, 86 Fed. Reg. 61,555-61,627 ("Mandate"). One of the States' declarants aptly summarized this crisis:

> I cannot express the extent of what is about to happen. Healthcare in this community and beyond … will never look the same. Patients will not have the primary care services needed to stay healthy, will not have the staff to care for them in an emergency, and will not have an ambulance service to respond to calls in an emergent manner…. Very highly skilled providers, nurses, ancillary, and support personnel will walk away from healthcare for good; this is not a maybe, this is an absolute. Patients needing life saving measures … will need to drive a minimum of two and three hours to receive the same services they are receiving locally today. This, however, is assuming the overburdened healthcare system in those organizations two and three hours away have the capacity to accept them as patients; which they will not be able to do. I simply cannot put into words what this mandate will do to our community and our healthcare system.

App. 160-161, R. Doc. 9-16, at 6-7. This crisis is unfolding *now*. The district court's preliminary injunction is stayed pending the outcome of this appeal. *Biden v. Missouri*, 142 S. Ct. 647, 654-55 (2022) (per curiam). Rural healthcare facilities are already closing and cutting services as they feel the Mandate's effect. The States respectfully request expedited consideration of this appeal by whatever method the Court prefers, to obtain a decision on the merits as quickly as possible. The Government has waived oral argument. App. Br. i. The States agree to waive oral argument, or they request highly expedited oral argument and an expedited decision.

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STATEMENT OF THE CASE

A. The Biden Administration Admits That Mandating Vaccines Is "Not the Role of the Federal Government."

Until September 9, 2021, the Biden Administration consistently declined to impose federal COVID-19 vaccine mandates. "In December of 2020, the President was quoted as saying, 'No I don't think [vaccines] should be mandatory.'" *BST Holdings, L.L.C. v. Occupational Safety & Health Admin.*, 17 F.4th 604, 614 n.17 (5th Cir. 2021). In 2021, both the Occupational Safety and Health Administration (OSHA) and the Centers for Medicare and Medicaid Services (CMS) issued major COVID-19-related regulatory actions, without imposing any vaccine mandate. 86 Fed. Reg. 26,306 (CMS); 86 Fed. Reg. 3276 (OSHA). On May 13, 2021, CMS published an IFC related to COVID-19, 86 Fed. Reg. 26,306, which "required offering vaccination to residents and staff, but did not mandate vaccination." 86 Fed. Reg. 61,601; *see also id.* 61,583. On July 23, 2021, the White House Press Secretary stated that mandating vaccines is "not the role of the federal government." The White House, *Press Briefing by Press Secretary Jen Psaki, July 23, 2021*, *at* https://www.whitehouse.gov/briefing-room/press-briefings/2021/07/23/press-briefing-by-press-secretary-jen-psaki-july-23-2021/.

B. President Biden Announces Federal Vaccine Mandates Designed To Increase Vaccination Rates by Any Means Available.

On September 9, 2021, that policy underwent a radical about-face. The President gave a major speech announcing several federal vaccine mandates intended to increase the number of vaccinated Americans by any available means. The White House, *Remarks by President Biden on Fighting the COVID-19 Pandemic* (Sept. 9, 2021), *at* https://www.whitehouse.gov/briefing-room/speeches-remarks/2021/09/09/remarks-by-president-biden-on-fighting-the-covid-19-pandemic-3/ ("Speech"). At the outset of the Speech, the President announced that his goal was to "raise our vaccination rate." *Id.* He expressed that "[m]any of us are frustrated with the nearly 80 million Americans who are still not vaccinated," and described COVID-19 as a "pandemic of the unvaccinated." *Id.* Having blamed the unvaccinated for the pandemic's woes, the President said, "[a]s your President, I'm announcing tonight a new plan *to require more Americans to be vaccinated*, to combat those blocking public health." *Id.* (emphasis added). He asserted that federal vaccine mandates would "reduce the number of unvaccinated Americans." *Id.* "First," the President announced, "we must *increase vaccinations among the unvaccinated with new vaccination requirements*." *Id.* (emphasis added). For this purpose, he announced several new federal mandates, including OSHA's mandate for private employers, a mandate for federal employees, a mandate for federal contractors, and a mandate for "those who work in hospitals, home healthcare facilities, or other medical facilities." *Id.* The purpose of these mandates was to

compel vaccination in as many Americans as possible: "vaccine requirements in my plan will affect about 100 million Americans – two thirds of all workers." *Id.*

The same day, September 9, 2021, the White House unveiled its "COVID-19 Action Plan." *See* The White House*, Path Out of the Pandemic: President Biden's COVID-19 Action Plan*, at https://www.whitehouse.gov/covidplan/ ("Plan"). Like the Speech, the Plan openly stated that its purpose was to compel vaccination of as many Americans as possible, by whatever federal powers were available. *See id.* The first point of the six-point Plan is "Vaccinating the Unvaccinated." *Id.* Like the Speech, the Plan announced that it "will reduce the number of unvaccinated Americans *by using regulatory powers … to substantially increase the number of Americans covered by vaccination requirements*." *Id.* (emphasis added). The Plan intended that "these requirements will become dominant in the workplace." *Id.* The Plan described the healthcare-workers mandate in terms of how many workers it would require to be vaccinated: "Requiring COVID-19 Vaccinations for Over 17 Million Health Care Workers…." *Id.* The Plan boasted that CMS would mandate vaccination for the overwhelming majority of healthcare workers: "These requirements will apply to approximately 50,000 providers and cover a majority of health care workers across the country." *Id.*

Two days later, on September 11, 2021, the White House Chief of Staff candidly retweeted a description of the vaccine mandates as "the ultimate work-

around for the Federal govt to require vaccinations." *BST Holdings*, 17 F.4th at 612 n.13.

C. CMS Imposes a Nationwide Vaccine Mandate on Healthcare Workers.

In the next two months, comprehensive surveys—which CMS would ignore—predicted that many unvaccinated workers would quit rather than comply with a vaccine mandate. *See, e.g.,* Chris Isidore, et al., *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.

On November 5, 2021—the same day the OSHA mandate was announced—CMS published its mandate for healthcare workers at virtually all healthcare facilities that receive Medicare or Medicaid funds. 86 Fed. Reg. 61,555-61,627 (the "Mandate"). CMS admitted that the Mandate is unprecedented. CMS has never before mandated vaccines for healthcare workers: "We have not previously required any vaccinations." 86 Fed. Reg. 61,567. "[W]e have not, until now, required any health care staff vaccinations." 86 Fed. Reg. 61,568. Even during the COVID-19 pandemic, before September 9, 2021, CMS admitted that it "chose … to encourage rather than mandate vaccination." 86 Fed. Reg. 61,583.

The Mandate requires vaccination against COVID-19 for nearly all workers in 15 kinds of federally funded healthcare facilities. 86 Fed. Reg. 61,567. It mandates vaccination for all "facility staff, regardless of clinical responsibility or

patient contact," including "[f]acility employees; licensed practitioners; students, trainees, and volunteers; and individuals who provide care, treatment, or other services for the facility and/or its patients, under contract or other arrangement." 86 Fed. Reg. 61,570. Even "a crew working on a construction project whose members use shared facilities … would be subject to these requirements." *Id.* at 61,571. CMS estimated that the Mandate covers 10.3 million workers. *Id.* at 61,603.

For statutory authority, CMS scoured the U.S. Code and provided 51 overlapping citations of definitional and ancillary statutory provisions applicable to 15 different facility types, as well as two provisions providing general administrative authority to CMS. 86 Fed. Reg. 61,567 tbl.1. CMS did not specify what language in what specific provisions purportedly authorized its vaccine mandate. *Id.*

To enforce the Mandate, CMS relied exclusively on *state* surveyors in state health departments. 86 Fed. Reg. 61,574. CMS announced that it will "advise and train State surveyors on how to assess compliance with the new requirements among providers and suppliers." *Id.* "The guidelines will also instruct surveyors to conduct interviews [of] staff to verify their vaccination status." *Id.*

CMS possessed scant evidence of staff-to-patient transmission of COVID-19 in most facilities. To find a risk of transmission, it relied heavily on two sources. First, the Mandate noted that "[a] retrospective analysis from England found up to 1 in 6 SARS-CoV-2 infections among hospitalized patients with COVID-19 in

England *during the first 6 months of the pandemic* could be attributed to healthcare-associated transmission." 86 Fed. Reg. 61,557 (emphasis added). Second, CMS relied on evidence of patient infections in long-term care facilities (LTCs), and "extrapolated" from those high-risk facilities to conclude that patients faced an infection risk from staff at 14 other kinds of facilities. 86 Fed. Reg. 61,585. CMS admitted that "similarly comprehensive data" on staff-to-patient transmission "are not available for all Medicare- and Medicaid-certified provider and supplier types," but it concluded, without further evidence, that the "LTC facilities[']' experience may generally be extrapolated to other settings." 86 Fed. Reg. 61,585.

CMS's other evidence, however, indicated that the risk of staff-to-patient transmission is minimal in the vast majority of facilities. CMS admitted that source-control measures other than vaccines—such as physical distancing, use of PPE, periodic testing, ventilation, and patient isolation or quarantine—"have been highly effective" in preventing transmission of COVID-19 in healthcare facilities. 86 Fed. Reg. 61,557. And CMS noted that "the most effective precautions other than vaccination—masks, social distancing, and ventilation—have been essentially universal in the health care sector during all of 2021." 86 Fed. Reg. 61,612.

CMS also admitted that no solid science supported its Mandate, stating that "the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] *not currently known*." 86 Fed. Reg. 61,615 (emphasis added).

In addition, CMS acknowledged that "endemic" staffing shortages are already afflicting every sector of the healthcare industry. It noted that "1 in 5 hospitals report that they are currently experiencing a critical staffing shortage." 86 Fed. Reg. 61,559. "[A]pproximately 23 percent of LTC facilities reported a shortage in nursing aides; 21 percent reported a shortage of nurses; and 10 to 12 percent reported shortages in other clinical and non-clinical staff categories." *Id.* "Over half (58 percent) of nursing homes … indicated that they are limiting new admissions due to staffing shortages." *Id.* In short, according to CMS, "currently there are endemic staff shortages for almost all categories of employees at almost all kinds of health care providers and suppliers and these may be made worse if any substantial number of unvaccinated employees leave health care employment altogether." 86 Fed. Reg. 61,607.

Nevertheless, CMS concluded that the Mandate presents a low risk of exacerbating existing staffing shortages. CMS admitted that it was basically guessing how many workers might quit rather than comply with the Mandate; CMS conceded that "there might be a certain number of health care workers who choose to do so," but claimed that "there is insufficient evidence to quantify … temporary staffing losses due to mandates." 86 Fed. Reg. 61,569. CMS also stated that "it is possible there may be disruptions in cases where substantial numbers of health care

staff refuse vaccination," but "there are so many variables and unknowns" that CMS could not predict them. 86 Fed. Reg. 61,608.

CMS ultimately concluded that the risk of staff shortages was low by relying solely on the experience of massive private health-care systems with large presences in heavily populated areas that had imposed private vaccine mandates, such as "a health care system that is the largest private employer in Delaware with more than 14,000 employees, a health care system and academic medical center with over 26,000 employees in Texas, and an integrated health system in North Carolina with more than 35,000 employees." 86 Fed. Reg. 61,566; *see also* 86 Fed. Reg. 61,569 ("a large hospital system in Texas," "[a] Detroit-based health system" with "33,000 workers," and "a LTC parent corporation" with "250 LTC facilities"). Every example referred to a massive private health care system with tens of thousands of employees and a strong footprint in heavily populated areas. *Id.* No small rural healthcare systems were included. *Id.*

CMS was undoubtedly aware that America contains many small, rural, community-based healthcare systems and facilities, with tiny staffs drawn heavily from the local communities; and CMS admitted that staffing shortages raise a particularly pressing concern for such facilities, but it collected and cited no evidence relating to them. Instead, it explicitly deferred consideration of rural providers' plight until later, after notice-and-comment. CMS acknowledged that

"early indications are that rural hospitals are having greater problems with employee vaccination refusals than urban hospitals," and stated that CMS "welcome[s] comments on ways to ameliorate this problem." 86 Fed. Reg. 61,613. Further, CMS admitted that "[e]ven a small fraction of recalcitrant unvaccinated employees could disrupt facility operations," 86 Fed. Reg. 61,612—which is especially true for small, rural, community-based facilities.

D. The States Challenge the Mandate.

On November 10, 2021, a coalition of ten States (the "States") challenged the Mandate. App. 1-58, R. Doc. 1. Their Complaint raised ten claims, including claims that the Mandate is unconstitutional under the Spending Clause, the anti-commandeering doctrine, and the Tenth Amendment. *Id.* at 52-55. The Complaint also alleged that CMS arbitrarily and capriciously failed to consider reliance interests. *Id.* at 44.

On November 12, 2021, the States moved for a preliminary injunction. R. Doc. 9. The States contended that the Mandate is arbitrary and capricious under the APA, *id.* at 15-23; that it exceeds CMS's statutory authority, *id.* at 23-28; that it violates notice-and-comment procedures, *id.* at 31-37, and that it is unconstitutional, *id.* at 28-31. The States also argued that "CMS failed to consider the reliance interests of healthcare providers … and healthcare workers." R. Doc. 9, at 19-20.

E. The Mandate Disrupts Legitimate Reliance Interests.

In support of their Motion for Preliminary Injunction, the States submitted thirty declarations, including 27 declarations from administrators of healthcare facilities (seven state-run and 20 privately run or run by local government), and three from State agencies overseeing state surveyors. App. 89-224, R. Docs. 9-1 to 9-30.

1. Small healthcare facilities in remote locations.

Unlike the massive private healthcare systems in Detroit and Houston that CMS considered, the States' declarants operate small facilities in rural and underserved locations. *See, e.g.,* App .99, R. Doc. 9-3, at 3 (Arkadelphia, Arkansas); App. 102, R. Doc. 9-4, at 2 (Carroll, Iowa); App. 114, R. Doc. 9-7, at 2 (Memphis, Missouri); App. 156, R. Doc. 9-16, at 2 (Valentine, Nebraska); App. 179, R. Doc. 9-20, at 3 (Cozad, Nebraska); App. 205, R. Doc. 9-26, at 2 (Belknap County, New Hampshire); App. 211, R. Doc. 9-27, at 3 (Stutsman County, North Dakota); App. 219, R. Doc. 9-29, at 2 (Yankton, South Dakota).

Most of these facilities are tiny compared to those cited by CMS, with workforces of a few dozen employees. *See, e.g.,* App. 106, R. Doc. 9-5, at 2 (60 employees); App. 124, R. Doc. 9-9, at 2 (65 employees); App. 136, R. Doc. 9-11, at 3 (103 employees); App. 141, R. Doc. 9-12, at 3 (65 employees); App. 145, R. Doc. 9-13, at 3 (134 employees); App. 187, R. Doc. 9-22, at 3 (55 employees).

These tiny facilities serve enormous geographic areas. *See, e.g,* App. 149, R. Doc. 9-14, at 3 (2,500 square miles); App. 153, R. Doc. 9-15, at 3 (8,100 square

miles); App. 157, R. Doc. 9-16, at 3 ("twenty-one thousand people in nineteen different zip codes"); App. 169, R. Doc. 9-18, at 3 ("10 panhandle counties" in Nebraska); App. 174, R. Doc. 9-19, at 2 ("67,832 square miles, about the size of the state of Pennsylvania"); App. 192, R. Doc. 9-23, at 3 ("7 to 10 counties"); App. 197, R. Doc. 9-24, at 3 (seven counties); App. 219, R. Doc. 9-29, at 2 ("the only state-run inpatient psychiatric hospital in South Dakota").

These facilities draw their workforces from local communities, where qualified healthcare workers are scarce, and the labor pool is less vaccinated than in urban centers. *See, e.g.,* App. 126, R. Doc. 9-9, at 4 ("In our rural areas, the pool of qualified workers for specific skills and knowledge is much smaller than the [n]on-rural areas. We face immense difficulties filling 'key,' 'essential' positions."); App. 157, R. Doc. 9-16, at 3 ("Being in a remote area is very challenging for recruitment."); App. 171, R. Doc. 9-18, at 5 ("The current rate of eligible individuals vaccinated in the Nebraska Panhandle is 40 percent."); App. 194, R. Doc. 9-23, at 5 ("it is nearly impossible to recruit clinical staff today"); App. 212, R. Doc. 9-27, at 4 (staffing from counties with vaccination rates of 56.4 percent, 61.4 percent, and 56.6 percent); App. 224, R. Doc. 9-30, at 4 (Wyoming healthcare facilities "operate in rural and frontier areas with small or limited labor markets").

2. High-risk, vulnerable patients.

Many facilities in the States treat high-risk, vulnerable patients. For example, the state-run facilities treat state-committed psychiatric patients and intellectually disabled individuals who have no one else to take care of them. App. 95-96, R. Doc. 9-2, at 3-4 (Alaska Psychiatric Institute); App. 99, R. Doc. 9-3, at 3 ("some of Arkansas' most vulnerable populations including the elderly, children, intellectually disabled individuals, and the mentally ill"); App. 129-133, R. Doc. 9-10, at 2-6 (Missouri's 12 state-run psychiatric facilities serving adults and children with severe psychiatric problems, and children with developmental disabilities); App. 165, R. Doc. 9-17, at 4 ("adults with intellectual and developmental disabilities requiring comprehensive, specialized support"); App. 206-207, R. Doc. 9-26, at 3-4 (the "most needy elderly" and "vulnerable, elderly residents"); App. 211, R. Doc. 9-27, at 3 ("sexually dangerous individuals," "people with intellectual and developmental disabilities … whose needs exceed community resources," and "children with serious emotional disturbance"); App. 220, R. Doc. 9-29, at 3 ("individuals needing emergency inpatient psychiatric treatment"). Patients in remote, rural, and underserved areas are also high-risk because of the difficulties in accessing care. *See, e.g.*, App. 115-116, R. Doc. 9-7, at 3-4 ("Our healthcare services provided in a remote and underserved area are critical to our communities.").

3. Already facing critical staffing shortages.

Without exception, these facilities were already facing critical staffing shortages *before* CMS announced its vaccine mandate. *See, e.g.*, App. 100, R. Doc. 9-3, at 4 (Arkansas' state-run facilities had "over 1,000 positions—representing over 40% of total positions—classified as being 'open' or unfilled"); App. 103, R. Doc. 9-4, at 3 (134 open positions out of 750 staff); App. 110-111, R. Doc. 9-6, at 2-3 ("Nearly all" of 350 nursing homes in Missouri "are currently facing a staffing crisis and barely able to meet minimum staffing levels to keep their doors open."); App. 125, R. Doc. 9-9, at 3 ("We are facing a workforce shortage like never before"); App. 133, R. Doc. 9-10, at 6 ("54% vacancy rate for licensed practical nurses"); App. 136-137, R. Doc. 9-11, at 3-4 ("[P]ositions are extremely difficult to fill…. We are already functioning in crisis mode."); App. 169-170, R. Doc. 9-18, at 3-4 (43 vacancies of 289 staff); App. 175, R. Doc. 9-19, at 3 (231 vacancies of 1197 total staff); App. 179, R. Doc. 9-20, at 3 ("This facility is in dire straits in terms of staffing…"); App. 197, R. Doc. 9-26, at 3 ("experiencing a severe employment crisis"); App. 212, R. Doc. 9-27, at 4 ("critical staff shortages").

4. Reliance on CMS's prior policy of *not* mandating vaccines.

To address such critical staffing shortages, these facilities relied heavily on CMS's longstanding policy of *not* mandating vaccines, and hired unvaccinated workers to fill much-needed positions. For example, Nebraska specifically relied on CMS's prior policy when it hired unvaccinated workers for its state-run psychiatric

facilities: "Beginning on or about August 2021 the State of Nebraska attempted to hire unvaccinated health care workers to help staff its state-run facilities *specifically relying upon prior CMS rules allowing this practice*." App. 166, R. Doc. 9-17, at 5 (emphasis added). This led to significant proportions of unvaccinated staff. *Id.* at 4-5, App. 165-166.

Likewise, the Butler County Health Center in rural Nebraska relied on CMS's previous policies to address its critical staffing shortages: "*Butler County Health Care Center has relied upon prior CMS rules that did not require COVID-19 vaccination for hiring staff.*" App. 145, R. Doc. 9-13, at 3 (emphasis added). This reliance resulted in 43 percent of the "active medical staff" unvaccinated, including "sixty six percent (66%) of physicians that provide obstetric services." *Id.* Similarly, Boone County Health Center in rural Nebraska "*relied on prior CMS rules that did not require vaccination in attempting to fill existing vacancies*." App. 197, R. Doc. 9-24, at 3 (emphasis added). This has resulted in 24 percent of staff unvaccinated. *Id.*

In fact, all such facilities relied on CMS's prior policies by hiring significant numbers of unvaccinated staff to address their critical staffing shortages. *See, e.g.,* App. 107, R. Doc. 9-5, at 3 ("The vaccination rate of [the facility's] employees is under 50%"); App. 130-132, R. Doc. 9-10, at 3-5 (describing Missouri state-run psychiatric facilities with staff vaccination rates (among others) of 34.6 percent, 52.6

percent, 43.9 percent, 55.1 percent, 29.6 percent, and 41.4 percent); App. 137, R. Doc. 9-11, at 4 (49 of 103 employees are unvaccinated); App. 154, R. Doc. 9-15, at 4 (44 percent of employees unvaccinated); App. 157, R. Doc. 9-16, at 3 (66 of 159 employees are unvaccinated); App. 164, R. Doc. 17, at 3 (101 of the 196 nursing homes in Nebraska (51.8%) had staff vaccination rates under 75%); App. 170, R. Doc. 9-18, at 4 (42 percent of staff unvaccinated); App. 175, R. Doc. 9-19, at 2 ("311 [staff] are known to have not been vaccinated"); App. 187, R. Doc. 22, at 3 (among "55 employees, 31 are known to be unvaccinated"); App. 192, R. Doc. 9-23, at 3 ("78 out of 330" staff unvaccinated).

In addition to reliance by healthcare *facilities*, healthcare *workers* also relied heavily on CMS's prior policy by taking jobs that CMS would later forbid. *See, e.g.,* App. 179, R. Doc. 9-20, at 3 (noting that the facility received job application "because it was not mandating vaccination"). CMS's reversal dramatically disrupts such reliance interests, and as a result, such workers face the daunting prospect of a mid-career change: "Very highly skilled providers, nurses, ancillary, and support personnel *will walk away from healthcare for good*; this is not a maybe, this is an absolute." App. 160, R. Doc. 9-16, at 6 (emphasis added). Moreover, even *vaccinated* staff relied on CMS's prior policy—they relied on their unvaccinated coworkers to prevent understaffing, overscheduling shifts, and burnout: "With anticipated limited service offerings, remaining employees will experience an even

greater amount of burnout, ultimately risking their own health and livelihood[;] *they, too, will leave healthcare*. They will be forced to work extended hours, take significant call hours and shifts, resulting in a risk in patient safety." App. 171, R. Doc. 9-18, at 5 (emphasis added); *see also, e.g.,* App. 183, R. Doc. 9-21, at 3 (expected losses of unvaccinated workers put "undue stress on our employees"); App. 193-194, R. Doc. 9-23, at 4-5 ("[E]ven if we can technically staff services with extra shift and call, we are already doing that, have been doing that for more than a year, and our vaccinated staff will not be capable of doing it for much longer.… *[M]ore will resign* due to the stress and burnout that will inevitably exist.") (emphasis added).

5. No heightened risk of COVID-19 transmission.

In these facilities, there is no evidence that the mix of vaccinated and unvaccinated staff presents any heightened risk to patients of COVID-19 transmission. None of the States' thirty declarants attested to any such risk, and the Government submitted no evidence of any such risk. *See* App. 89-224, R. Docs. 9-1 to 9-30. On the contrary, these facilities have taken universal precautions to avoid COVID-19 transmission by unvaccinated workers—the very precautions that CMS admits "have been highly effective" in preventing transmission of COVID-19, 86 Fed. Reg. 61,557, and "have been essentially universal in the health care sector during all of 2021," 86 Fed. Reg. 61,612.

Typical experiences include an Iowa hospital that "instituted a policy that requires employees declining the vaccine to wear an N95 mask and in some cases be tested prior to working each shift. This policy … has resulted in *no infections occurring within our workplace*." App. 103, R. Doc. 9-4, at 3 (emphasis added). A Nebraska hospital explained, "[p]atients are and will continue to be safe in our hospital whether our team is vaccinated or not vaccinated…. *Patients are not coming to the hospital for services and becoming ill with COVID.*" App. 171, R. Doc. 9-18, at 5 (emphasis added). Another facility noted, "[w]ith our enhanced precautions we have in place currently, allowing [a testing] alternative to a vaccine mandate *would not sacrifice patient or staff safety*." App. 176, R. Doc. 9-19, at 4 (emphasis added).

6. Expected staffing losses from the Mandate.

Virtually all declarants anticipated painful staffing losses from the Mandate. For example, the leader of a 350-facility association of Missouri nursing facilities reported that "[a] significant number facilities across [Missouri] … could lose up to 25% of their employees or more if CMS were to issue a vaccine mandate," while they "cannot afford to lose even 1% of their employees." App. 111, R. Doc. 9-6, at 3. Another facility reported that it "does not have enough staffing for the absence of nurses who are not willing to be vaccinated. We will be facing a huge problem!" App. 125, R. Doc. 9-9, at 3. Another Nebraska hospital "stands to lose 15 percent

of its total employees from all across the organization," including "key leadership positions in physicians, nursing…." App. 170, R. Doc. 9-18, at 4.

Unlike CMS's speculative approach, in these small facilities, administrators gauged their risk of staffing losses by the natural and reliable method of *actually talking to unvaccinated healthcare workers*—something CMS never did. *See, e.g.,* App. 103, R. Doc. 9-4, at 3 ("40 [of 750] employees said they would resign rather than comply"); App. 107, R. Doc. 9-5, at 3 (surveyed all 60 employees, and "a majority of these unvaccinated staff stated they would chose to leave healthcare completely"); App. 115, R. Doc. 9-7, at 3 ("20 … are weighing whether to comply and at least 5 stated emphatically that they will not be vaccinated"); App. 126, R. Doc. 9-9, at 4 ("Out of about 65 employees, about 20 employees tell me they are vehemently opposed to taking the vaccine … and will quit working at [the facility]."); App. 137, R. Doc. 9-11, at 4 (identifying ten employees and seven clinical personnel who will leave under the Mandate); App. 146, R. Doc. 9-13, at 4 (prediction of staff losses "has been determined through surveying the current staff that is unvaccinated"); App. 175, R. Doc. 9-19, at 3 ("Based on direct conversations with staff … Great Plains Health stands to lose a high percentage of these unvaccinated employees"); App. 179, R. Doc. 9-20, at 3 ("This facility … stands to lose an additional 25% of its employees … based on conversations with this facility's staff."); App. 193, R. Doc. 9-23, at 4 ("We have had discussions with our

unvaccinated staff, and … have strong evidence of the potential impact on our services."); App. 213, R. Doc. 9-27, at 5 ("eight to twelve current staff … have clearly stated they will quit").

7. Loss of critical healthcare services.

As a result of these additional staffing shortages, facilities universally predict that they will be forced to cut critical healthcare services for vulnerable and underserved populations, or (in some cases) close facilities entirely. One facility stated: "Of the 35 Med/Surg staff that we have, we may have to terminate 20 of them …. *Who is going to care for our patients?*" App. 202, R. Doc. 9-25, at 4 (emphasis added); *see also id.* ("We will have to reduce services in the clinic, in outpatient services and in surgery," "to divert emergency patients," and to increase "[w]ait times for critical care patients," thus "making nursing ratios unsafe for the rest of the acute care patients").

At Cherry County Hospital in Valentine, Nebraska, "[p]atients will not have the primary care services needed to stay healthy, will not have the staff to care for them in an emergency, and will not have an ambulance service to respond to calls in an emergent manner…. Patients needing life saving measures such as chemotherapy, cardiac rehabilitation, and dialysis (to name a few), will need to drive a minimum of two and three hours to receive the same services they are receiving locally today." App. 160, R. Doc. 9-16, at 6. That facility also forecasts "the loss of OB and both

planned and emergency C-section delivery…. This will, without a doubt, result in poor outcomes for mom and newborn." App. 159, R. Doc. 9-16, at 5.

Box Butte General Hospital, serving Nebraska's panhandle, anticipates "closure of departments, reduction of services, inability to accept patients and/or staff beds, increased wait times for services, need to access care possibly outside state lines, dramatic increase in our inability to transfer to alternative hospitals, or even loss of services altogether." App. 171, R. Doc. 9-18, at 5.

The only state-run inpatient psychiatric hospital in South Dakota will likely "reduce the patient population, limit admissions, and potentially take additional treatment unit offline," which "could require that individuals needing emergency inpatient psychiatric treatment be held in jail settings or emergency rooms until capacity is available." App. 220, R. Doc. 9-29, at 3. North Dakota, too, anticipates that, without adequate staffing, it "will not be able to provide statewide safety services for its most vulnerable population." App. 213, R. Doc. 9-27, at 5.

Scotland County Care Center in Memphis, Missouri predicts that the "emergency regulation will have dramatic and devastating consequences…. [T]here is no way we can continue to operate…. We will be forced to close our doors and displace the residents." App. 126-127, R. Doc. 9-9, at 4-5. Great Plains Health in North Platte, Nebraska predicts "a dangerously reduced number of staffed ICU beds, a reduced ability to obtain timely surgeries or surgery altogether due to loss of an

anesthesiologist and nursing staff, reduced ability … to provide cardiac stenting, and an inability to receive forensic sexual assault exams due to loss of SANE-qualified nurses." App. 175-176, R. Doc. 9-19, at 3-4.

Many other facilities in the States made similarly dire predictions of loss of services, closing departments, or shuttering healthcare facilities. *See, e.g.,* App. 107, R. Doc. 9-5, at 3 ("The loss of … employees will cause significant difficulty in the continued operation of MCMCC."); App. 111, R. Doc. 9-6, at 3 ("Without a sufficient number of staff, skilled nursing care facilities cannot stay open and will be forced to close."); App. 115, R. Doc. 9-7, at 3 (the Mandate "will cause significant difficulty in the continued quality and safe operations of SCH"); App. 137, R. Doc. 9-11, at 4 ("[I]f we lose even one nurse … our 24/7 nursing floor and emergency room services could collapse."); App. 142, R. Doc. 9-12, at 4 ("The projected loss of approximately 30% of our staff … will almost certainly lead to closure of our facility," which "would leave our rural community without essential healthcare services"); App. 146, R. Doc. 9-13, at 4 (the Mandate would "make it very difficult to continue operations," and require cutting "emergency department services, obstetric services, laboratory services, and acute nursing care"); App. 149, R. Doc. 9-14, at 3 (anticipating potential "closure of departments, reduction of services, inability to accept patients, increased wait times for services, [and] inability to staff beds"); App. 154, R. Doc. 9-15, at 4 (the medical center "will be put in an almost

impossible position to provide the same level and quality of services"); App. 183, R. Doc. 9-21, at 3 (predicting "potential closure of some departments" and the need to "divert many of our emergency patients to other facilities; the closest one is 45 miles away"); App. 188, R. Doc. 9-22, at 4 (the Mandate "jeopardiz[es] the very existence" of the facility); App. 193, R. Doc. 9-23, at 4 ("we will be forced to limit or close services such as cardiopulmonary rehabilitation and home health and hospice services"); App. 198, R. Doc. 9-24, at 4 (predicting potential "reduction of services, closure of satellite clinic locations, … increased wait time in the ER, [and] inability to staff hospital beds safely").

8. Loss of services compounded across rural America.

In addition to predicting cuts and closures of their own services, the States' declarants pointed out that other rural facilities—to whom they would otherwise refer patients—face the exact same problems from the Mandate. As one facility stated, because all rural facilities face the same problems, "the CMS vaccine mandate threatens rural healthcare infrastructure not only in Custer County but throughout Nebraska." App. 142, R. Doc. 9-12, at 4. The same is true in the other States.

Speaking more specifically, another facility explained, "[i]f someone is having a heart attack or a stroke, they may not make it to the other critical access hospital down the road 30 miles. This is assuming the critical access hospital 30

miles away is going to be able to keep their services going. During these surges of COVID we have also struggled terribly getting bed acceptance at larger facilities." App. 137, R. Doc. 9-11, at 4. Another stated that, as a result of the Mandate, "[p]atients needing life saving measures … will need to drive a minimum of two and three hours to receive the same services they are receiving locally today. This, however, is assuming the overburdened healthcare systems in those organizations two and three hours away have the capacity to accept them as patients; which they will not be able to do." App. 160, R. Doc. 9-16, at 6. Similarly, "other long-term care or assisted living facilities in rural areas will likely close due to … a limited pool of qualified staff. Closures of other facilities will only compound the inability of [the facilities] to care for patients in rural areas." App. 180, R. Doc. 9-20, at 4. *See also, e.g.,* App. 149, R. Doc. 9-14, at 3 (the facility "is already experiencing an inability to transfer patients to alternative hospitals facing similar staffing challenges"); App. 171, R. Doc. 9-18, at 5 (predicting a "dramatic increase in our inability to transfer to alternative hospitals" that have "ongoing ripple effects"); App. 193, R. Doc. 9-23, at 4 ("[T]ransfers will be needed much more frequently and to communities hours away at best."); App. 198, R. Doc. 9-24, at 3 (predicting the loss of "the ability to transfer when needed since we are all having the same issues"); App. 202-203. R. Doc. 9-25, at 4-5 (a nursing home "will most likely need to discharge residents because of the lack of staffing necessary to take care of them,"

which will "in turn fill up the hospital beds with residents that should reside in a nursing home").

F. The District Court Enters a Preliminary Injunction, Which the Supreme Court Stays.

The district court granted the States' motion for preliminary injunction. Add.1-32, R. Doc. 28. The district court held that the States were likely to prevail on their claims that the Mandate exceeds CMS's statutory authority, *id.* at 3-8; that CMS had violated notice-and-comment requirements, *id.* at 8-13; that the Mandate is arbitrary and capricious, *id.* at 14-23; and that the Mandate is pretextual, *id.* at 20 n.24. The district court held that "CMS did not properly consider *all* necessary reliance interests of facilities, healthcare workers, and patients." *Id.* at 21. The district court declined to reach the States' constitutional claims. *Id.* at 7 n.8.

The Government sought a stay of the injunction from this Court, which was denied. The Government then sought a stay pending appeal from the Supreme Court, which it granted on January 13, 2021. *Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam) ("*Missouri*"). In its stay opinion, the Supreme Court did not address the States' constitutional claims, whether the Mandate is impermissibly pretextual, or whether CMS adequately considered the States' and healthcare facilities' legitimate reliance interests. *Id.*

STANDARD OF REVIEW

"Review of a preliminary injunction is layered: fact findings are reviewed for clear error, legal conclusions are reviewed de novo, and the ultimate decision to grant the injunction is reviewed for abuse of discretion." *Comprehensive Health of Planned Parenthood Great Plains v. Hawley*, 903 F.3d 750, 754 (8th Cir. 2018) (cleaned up). In reviewing a preliminary injunction, courts consider: "(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).

SUMMARY OF THE ARGUMENT

The States are likely to prevail on the merits for six reasons.

First, the Government's *sole* argument on the merits—that the Supreme Court's stay opinion supposedly "resolved the merits" of this appeal, App. Br. 1—contradicts black-letter law. "The Court's stay order is not a decision on the merits." *Merrill v. Milligan*, 142 S. Ct. 879, 879 (2022) (Kavanaugh, J., concurring). Further, this appeal raises several grounds for affirmance that the Supreme Court did not address. And the Government has forfeited any other basis to challenge the district court's ruling by failing to raise them in its opening brief.

Second, the Mandate arbitrary and capriciously failed to consider "legitimate reliance" on CMS's longstanding earlier policy of *not* mandating vaccines. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1913 (2020). State-run and private healthcare facilities relied on that policy by hiring unvaccinated workers to address critical staffing shortages, and healthcare workers relied on it by taking jobs and embarking on careers that CMS would later prohibit. CMS considered *none* of these reliance interests—the words "reliance," "rely," and "relied" do not appear in the 73-page Mandate.

Third, the Mandate's entire patient-protection justification is a *post hoc* rationalization and unlawful pretext for the President's openly announced policy of compelling vaccination of Americans by any available federal power. As the

President openly stated, the Mandate's purpose is to promote vaccination for vaccination's sake, with patient protection as an afterthought at best.

Fourth, the Mandate violates the Spending Clause because the dozens of scattered statutory provisions cited by CMS as justifying the Mandate fail to provide "clear notice" that accepting Medicare/Medicaid funds would subject the States and healthcare providers to a vaccine mandate. CMS had never mandated vaccines for healthcare workers in any form, and the Supreme Court held for over 100 years that compulsory vaccination falls within the States' police powers.

Fifth, the Mandate violates both the Spending Clause and the anti-commandeering doctrine because it "dragoon[s]" hundreds of state surveyors into enforcing it by threatening all Medicaid/Medicare reimbursement funds to providers in the States. *Printz v. United States*, 521 U.S. 898, 928 (1997). That threat is an economic "gun to the head" that leaves States "with no real option but to acquiesce." *NFIB v. Sebelius*, 567 U.S. 519, 581-82 (2012) (plurality op.).

Sixth, the Mandate is unlawful for additional reasons cited by the district court and addressed in preliminary fashion by the Supreme Court—*i.e.*, the Mandate exceeds CMS's statutory authority, it is arbitrary and capricious on grounds in addition to those discussed above, and it unlawfully dispensed with notice-and-comment.

The balancing of harms and the public interest also support the States. The Mandate inflicts irreparable injury on the States in their sovereign, quasi-sovereign, and proprietary capacities. By contrast, the Government has no cognizable interest in enforcing an unlawful Mandate. And the public interest favors enjoining the Mandate to prevent the crisis in rural healthcare that is currently unfolding. Moreover, because the existing vaccines required by the Mandate have proven ineffective in preventing transmission of the Omicron variant, the Mandate's entire justification is now obsolete.

The preliminary injunction should be affirmed.

ARGUMENT

I. The States Are Likely to Succeed on the Merits.

The States are likely to succeed on the merits for six reasons.

A. The Supreme Court's Stay Opinion Did Not "Resolve the Merits."

The Government argues that, in the Supreme Court's stay opinion, "the Court *resolved the merits* of the States' challenge to the rule." App. Br. 1-2 (emphasis added). In fact, this is the sole argument that the Government makes on the merits. *Id.* at 1, 13, 14, 15-20. It is incorrect for at least two reasons.

First, the Supreme Court's "stay order is not a ruling on the merits, but instead simply stays the District Court's injunction *pending a ruling on the merits*." *Merrill*, 142 S. Ct. at 879 (Kavanaugh, J., concurring). "To reiterate: The Court's stay order is not a decision on the merits." *Id.* The "historic office" of a stay pending appeal "is to hold the matter under review in abeyance because the appellate court lacks sufficient time to decide the merits." *Nken v. Holder*, 556 U.S. 418, 432 (2009). In granting a stay, the appellate court does not "*decide[]* the merits," as that would be "something that does not look remotely like a stay." *Id.* at 432-33.

To obtain a stay from the Supreme Court, the movant need only show a "fair prospect" that the injunction will be reversed—not a certainty that it *will* be reversed. *Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010). This "fair prospect" standard has been often reaffirmed. *See, e.g., Merrill*, 142 S. Ct. at 879 (Kavanaugh, J.,

concurring); *Little v. Reclaim Idaho*, 140 S. Ct. 2616 (2020) (Roberts, C.J., concurring); *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 572 U.S. 1301, 1301 (2014) (Roberts, C.J.); *Maryland v. King*, 567 U.S. 1301, 1302 (2012) (Roberts, C.J., in chambers).

The "fair prospect" standard is part of "the well-settled standard for this form of relief." *Little*, 140 S. Ct. at 2616 (Roberts, C.J., concurring). Nothing in *Missouri*'s stay opinion purported to revise it. On the contrary, both dissents cited this well-established standard, without dispute from the majority. *Missouri*, 142 S. Ct. at 655 (Thomas, J., dissenting); *id.* at 659 (Alito, J., dissenting) ("[T]oday's ruling means only that the Federal Government is likely to be able to show that this departure is lawful, not that it actually is so.").

Second, the Supreme Court did not consider or address multiple alternative grounds for affirming the district court's injunction. For example, the States challenged the Mandate as impermissibly pretextual, as failing to consider reliance interests, and as unconstitutional under the Spending Clause, the anti-commandeering doctrine, and the Tenth Amendment. R. Doc. 9, at 19-20, 28-31. The district court ruled in the States' favor on the former issues, and declined to reach the constitutional issues. Add. 7 n.8, 20 n.24, 21, R. Doc. 28. The Supreme Court did not address any of them. *See Missouri*, 142 S. Ct. at 652-55.

The stay opinion follows the Supreme Court's universal rule that "we express no view on issues not addressed in this opinion." *Nat'l Fed'n of Indep. Bus. v. Dep't of Lab., Occupational Safety & Health Admin.*, 142 S. Ct. 661, 666 n.1 (2022) ("*OSHA*"). When an issue "was not ... raised in the briefs or argument nor discussed in the opinion of the Court," then "the case is not a binding precedent on this point." *United States v. L.A. Tucker Truck Lines, Inc.*, 344 U.S. 33, 38 (1952); *see also Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 91 (1998); *Lewis v. Casey*, 518 U.S. 343, 352 n.2 (1996). This Court may consider issues not addressed by the Supreme Court on a clean slate. And this Court "may affirm a judgment on any ground supported by the record." *Hamner v. Burls*, 937 F.3d 1171, 1176 (8th Cir. 2019).

Thus, the stay opinion does not "resolve the merits" of this lawsuit. And yet that is the *only* argument on the merits that the Government raises in its opening brief. App. Br. 1, 13, 14, 15-20. The Government's "Statement of the Issue" proclaims that "the [Supreme] Court resolved the merits of the States' challenge to the rule," as the sole reason that "the preliminary injunction should be vacated." App. Br. 1. That is the only argument in its 10-line "Summary of Argument": "The Supreme Court resolved each of those issues in the federal government's favor." App. Br. 13; *see also* App. Br. 14 (arguing only that "[t]he Supreme Court resolved each of these challenges in the federal government's favor"). It is the only argument in the Government's discussion of the merits of the statutory-interpretation question.

App. Br. 15-18. It is the only argument in the Government's cursory discussion of whether the rule is arbitrary and capricious. App. Br. 18-19. And it is the only argument in the Government's discussion of whether the Secretary had "good cause" to suspend notice-and-comment. App. Br. 19-20. The Government aptly summarizes its own argument: "In sum, the Supreme Court already resolved the merits of the plaintiffs' challenge to the rule in the federal government's favor." App. Br. 20.

Issues not raised in the opening brief are forfeited. *Chong Toua Vue v. Barr*, 953 F.3d 1054, 1058 (8th Cir. 2020) ("Although [appellant] raised this argument before the Board, he has forfeited it now by failing to raise it in his opening brief."); *Jenkins v. Winter*, 540 F.3d 742, 751 (8th Cir. 2008) ("Claims not raised in an opening brief are deemed waived."). The Government, therefore, has forfeited any ground to challenge the merits of the district court's preliminary injunction other than the erroneous argument that the merits were finally resolved by the Supreme Court's stay opinion.

B. The Mandate Is Arbitrary and Capricious Because It Failed to Consider Legitimate Reliance Interests.

The Mandate is arbitrary and capricious because it did not consider legitimate reliance interests of States, healthcare facilities, and their workers. The district court held that the Mandate was arbitrary and capricious on this ground. Add. 20-23, R.

Doc. 28. The Supreme Court did not address whether CMS adequately considered reliance interests in its stay opinion. *Missouri*, 142 S. Ct. 647, 653-54.

1. The Mandate did not consider *any* reliance interests.

In 2020, the Supreme Court held that it is arbitrary and capricious for an agency not to consider "legitimate reliance" on its prior policy. *Dep't of Homeland Sec. v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1913 (2020). Yet CMS did not consider *any* reliance interests of any regulated healthcare facilities or workers. Though the Mandate spans 73 pages of the Federal Register, a text search reveals that it does not contain the words "reliance," "rely," or "relied." 86 Fed. Reg. 61,555-61,627.

Healthcare facilities and healthcare workers both relied heavily on CMS's longstanding previous policy of *not* mandating vaccines. For over 50 years, CMS had *never* imposed any vaccine mandate on healthcare workers. 86 Fed. Reg. 61,567-68. During the COVID-19 pandemic, as recently as May 13, 2021, *see* 86 Fed. Reg. 26,306, CMS reaffirmed this longstanding policy, choosing "to encourage rather than mandate vaccination." 86 Fed. Reg. 61,583.

Healthcare facilities relied heavily on this longstanding, consistent policy. *Supra*, Part E.4. They were already facing critical staffing shortages before the Mandate was announced. *Id.* These facilities universally relied on CMS's policy to meet their staffing shortfalls, by hiring and retaining significant numbers of

unvaccinated workers. *Id.* Many of these facilities noted their express reliance on CMS's policies. *Id.*

Healthcare workers, too, heavily relied on CMS's prior policy of not mandating vaccines in Medicare- and Medicaid-funded facilities. *Id.* Unvaccinated workers took jobs in such facilities in reliance on the policy of permitting the unvaccinated to work—sometimes transferring from facilities with private vaccine mandates. *Id.* Those individuals "embarked on careers" and took jobs in specific reliance on CMS's prior policy. *Regents*, 140 S. Ct. at 1914. Now they stand to lose those jobs because of CMS's mandate. The consequences of those job losses—with attendant service reductions and facility closures—"radiate outward" to injure not only those workers' families, but also patients, facilities, and local economies. *Id.*; *see also* Add. 28, R. Doc. 28 ("[T]he mandate also would have a negative effect on the economies in Plaintiff states, especially, once again, in rural areas."). Vaccinated workers, likewise, relied heavily on their unvaccinated coworkers to fill up critical staffing shortfalls to avoid excessive shifts and burnout. *Supra*, Part E.4.

CMS considered none of these reliance interests. There is literally no mention of them in the IFC. CMS's conduct resembles that in *Regents*, where the Secretary of DHS cancelled Deferred Action for Childhood Arrivals without considering whether DACA "may have 'engendered serious reliance interests that must be taken into account.'" *Regents*, 1490 S. Ct. at 1913 (quoting *Encino Motorcars, LLC v.*

Navarro, 136 S. Ct. 2117, 2126 (2016), and *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009)). CMS "failed to address whether there was 'legitimate reliance' on" its prior policy of encouraging, but not mandating, vaccination. *Id.* (quoting *Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 742 (1996)). "It would be arbitrary and capricious to ignore such matters. Yet that is what [the Mandate] did." *Id.* (citation omitted).

2. The Mandate gave no meaningful consideration to the plight of state-run and rural healthcare facilities.

The Government will no doubt contend that CMS gave some minimal consideration to the risk of *staffing shortages* at rural healthcare facilities. The Supreme Court's stay opinion stated, without further elaboration, that CMS did not "entirely fail[] to consider that the rule might cause staffing shortages, including in rural areas." *Missouri*, 142 S. Ct. at 654 (citation omitted). But considering whether the Mandate would cause prospective *staffing shortages* is not the same as considering whether the prior policy had "engendered serious *reliance* interests." *Regents*, 140 S. Ct. at 1913 (emphasis added). As noted above, the word "reliance," "relied," and "rely" do not appear in the Mandate, and the Government cannot now pretend that it considered such interests. "Stating that a factor was considered ... is not a substitute for considering it." *Texas v. Biden*, 10 F.4th 538, 556 (5th Cir. 2021) (citation omitted).

In any event, while the Supreme Court gave CMS minimal credit for at least raising the issue of staffing shortfalls, CMS gave virtually no *meaningful* consideration to the unique plight of rural and state-run facilities inflicted by the Mandate. In discussing staffing shortages, CMS exclusively cited the experience of massive healthcare systems with tens of thousands of employees drawing staff from highly populated urban areas with high vaccination rates. *See* 86 Fed. Reg. 61,566, 61,569. These facilities bear no resemblance to small, rural, critical-access hospitals and community health centers that draw their workforces from heavily unvaccinated local communities. *Supra*, Part E.1. Yet in rural America, healthcare is provided principally by such small providers. CMS is certainly aware of small rural healthcare facilities, 86 Fed. Reg. 61,613, but it did not give their plight any meaningful consideration. On the contrary, it effectively admitted that it did *not* do so by indicating that it would consider their concerns *later*, in the Rule's final version, and inviting comments on the issue for later consideration instead of addressing it now. *Id.* At best, CMS "put a rock on one side of the scale and a feather on the other." Add. 22, R. Doc. 28. This is worse than a poor substitute for considering legitimate reliance interests—it is no substitute at all.

C. The Mandate Is a *Post Hoc* Rationalization and a Pretext for the President's Plan to Mandate Vaccination for Vaccinations' Sake.

COVID-19 presented a concern for patients in healthcare facilities long before September 9, 2021, and vaccines were widely available long before that date as well.

Yet CMS never adopted a sweeping vaccine mandate before then. Indeed, before the Mandate, CMS never required vaccination for healthcare workers in any context. 86 Fed. Reg. 61,567-61,568.

But on September 9, 2021, the President gave the Speech, and the White House announced the Plan. Both the Speech and the Plan were open and explicit about the Mandate's purpose: To require Americans to get vaccinated by using any power available to the federal government. The Speech announced "a new plan to require more Americans to be vaccinated," emphasizing that its purpose was to "increase vaccinations among the unvaccinated with new vaccination requirements." Speech, *supra*. The Plan was equally explicit, stating that its purpose was to *"reduce the number of unvaccinated Americans by using regulatory powers and other actions to substantially increase the number of Americans covered by vaccination requirements."* Plan, *supra*.

Having been instructed by the President to mandate vaccination for as many workers as possible, CMS produced an elaborate justification spanning 73 pages of the Federal Register. 86 Fed. Reg. 61,555-61,627. These 73 pages studiously ignore real reason for the mandate—the Administration's announced goal to require as many Americans as possible to be vaccinated. The reason for CMS's omission is obvious—CMS lacks authority to mandate vaccination to protect healthcare workers *from themselves*. Instead, CMS claimed to be adopting the Mandate to protect

patients from becoming infected by unvaccinated healthcare workers. This patient-protection rationale, however, received barely a mention in the Speech and the Plan, and it never moved CMS to adopt such any such mandate in the many months before September 9, 2021.

In assessing agency's reasons, this Court is not required to ignore obvious realities that the Administration broadcasted to all of America. "In reviewing agency pronouncements, courts need not turn a blind eye to the statements of those issuing such pronouncements," *BST Holdings*, 17 F.4th at 614, and this Court is "not required to exhibit a naiveté from which ordinary citizens are free." *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2575 (2019) (quoting *United States v. Stanchich*, 550 F.2d 1294, 1300 (2d Cir. 1977) (Friendly, J.)).

In adopting an elaborate justification for the Mandate that fundamentally differs from its actual purpose and motivation, CMS violated two well-established principles of administrative law. First, the entire Mandate is an "impermissible '*post hoc* rationalization.'" *Regents*, 140 S. Ct. at 1896 (quoting *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 420 (1971)). Second, the Mandate is impermissibly "pretextual." *Dep't of Commerce*, 139 S. Ct. at 2573. The district court found that the States were likely to succeed on this claim, Add. 20 n.24, R. Doc. 28, and the Supreme Court did not address it. *Missouri*, 142 S. Ct. 653-54.

1. The Mandate is a *post hoc* rationalization.

Here, CMS did not identify a danger to patients from COVID-19 and then fashion a standard to protect them. Instead, the White House dictated the standard to CMS in advance, and then CMS reverse-engineered an elaborate justification for that standard. The President devised a policy for purposes that *lie outside the agency's power to address*, and directed the agency to find a rationale *within its powers* to justify that policy. CMS has no power to compel vaccination for vaccination's sake, which was the President's openly stated goal. So it adopted the President's rule based entirely on a different rationale—patient protection—that the President barely mentioned. The entire Mandate is thus a quintessential *post hoc* rationalization—a justification invented afterward for a predetermined conclusion.

Here, the elaborate reasons provided in CMS's Mandate "can be viewed only as impermissible *post hoc* rationalizations." *Regents*, 140 S. Ct. at 1909. Such "*post hoc* rationalizations ... cannot serve as a sufficient predicate for agency action." *Id.* (quoting *American Textile Mfrs. Institute, Inc. v. Donovan*, 452 U.S. 490, 539 (1981)).

2. The Mandate's justification is a pretext for increasing the numbers of vaccinated Americans.

For similar reasons, the Mandate is impermissibly pretextual. Just as with the OSHA mandate, CMS "pursued its regulatory initiative only as a legislative 'work-around.'" *OSHA*, 142 S. Ct. at 668 (Gorsuch, J., concurring) (quoting *BST Holdings*, 17 F.4th at 612). "After the President voiced his displeasure with the country's

vaccination rate in September," CMS "pored over the U.S. Code in search of authority, or a 'work-around,' for imposing a national vaccine mandate." *BST Holdings*, 17 F.4th 612. It settled on "a constellation of statutory provisions that each concern one of the 15 types of medical facilities that the rule covers." *Missouri*, 142 S. Ct. at 656 (Thomas, J., dissenting). But this was sheer pretext. "In reviewing agency pronouncements, courts need not turn a blind eye to the statements of those issuing such pronouncements," *BST Holdings*, 17 F.4th at 614—especially when the speaker is the President, who has final authority over the agency. "In fact, courts have an affirmative duty *not* to do so." *Id.*

The level of pretext here exceeds that in *Department of Commerce*, 139 S. Ct. at 2567-76. There, the Secretary provided a detailed justification for his decision to reinstate the citizenship question on the decennial census. *Id.* at 2569-71. The Supreme Court held that this decision, on its own terms, was not arbitrary or capricious and did not exceed his statutory authority. *Id.* at 2569-73. Nevertheless, the Supreme Court invalidated the decision "because it rested on a pretextual basis." *Id.* at 2573. The Supreme Court emphasized that the Secretary had treated reinstating the citizenship question as a foregone conclusion, and then directed his staff to search for a justification. *Id.* at 2575. As a result, the Court held, "the evidence tells a story that does not match the explanation the Secretary gave for his decision." *Id.* "The reasoned explanation requirement of administrative law, after

all, is meant to ensure that agencies offer genuine justifications for important decisions." *Id.* at 2575-76.

Here, the evidence of pretext is far more overt and undeniable than in *Department of Commerce*. In that case, the Court inferred pretext from extra-record discovery indicating that the Secretary had a hidden motivation for his decision—one that was never identified. *See id.* at 2574. Here, by contrast, there is no such hidden motivation that must be teased out. The actual motivation for the CMS Mandate was proclaimed to the world, loud and clear, on September 9, 2021. This case is like an alternative version of *Department of Commerce* in which the Secretary publicly stated in advance, "I am going to reinstate the citizenship question. I want to do so for reasons that lie outside my Department's authority. Accordingly, I'm directing my staff to find different reasons for this decision that lie within our authority." As in *Department of Commerce*, the Speech and the Plan "reveal a significant mismatch between the decision the Secretary made and the rationale he provided." 139 S. Ct. at 2575,

"In order to permit meaningful judicial review, an agency must "disclose the basis" of its action." *Dep't of Commerce*, 139 S. Ct. at 2573 (quoting *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 167–69 (1962)). The CMS Mandate runs afoul of this principle. Like the OSHA mandate, it has a "pretextual basis,"

which is the "hallmark[] of unlawfully agency action." *BST Holdings*, 17 F.4th at 614.

D. The Mandate Violates the Spending Clause.

The Mandate is also unconstitutional on multiple grounds, including that it violates the Spending Clause. The States raised its constitutional claims before the district court, but it declined to reach them, Add. 7 n.8, R. Doc. 28, and the Supreme Court did not address them. *Missouri*, 142 S. Ct. at 653-54.

"Determining whether legislation is a permissible use of Congress's spending power requires a consideration of several limiting factors," including, among others: (1) "conditions on the state's receipt of federal funds must be set out unambiguously so that the state's participation is the result of a knowing and informed choice," (2) "conditions must not be prohibited by other constitutional provisions," and (3) "the circumstances must not be so coercive that 'pressure turns into compulsion.'" *Van Wyhe v. Reisch*, 581 F.3d 639, 649–50 (8th Cir. 2009) (quoting *South Dakota v. Dole*, 483 U.S. 203, 207-11 (1987)). The Mandate runs afoul of these three factors.

1. CMS's "hodgepodge" of statutes does not provide "clear notice" of vaccine mandates as a condition of federal funding.

First, the Mandate's rule of compulsory vaccination is a surprising and unprecedented requirement that no informed reader of the relevant statutes—including CMS itself—could have reasonably anticipated. For over 100 years, the Supreme Court held that compulsory-vaccination policies "are matters that do not

ordinarily concern the national government." *Jacobson v. Commonwealth of Massachusetts*, 197 U.S. 11, 38 (1905). "Vaccine mandates … fall squarely within a State's police power, … and, until now, only rarely have been a tool of the Federal Government." *Missouri*, 142 S. Ct. at 658 (Thomas, J., dissenting)) (citing *Zucht v. King*, 260 U.S. 174, 176 (1922)). Consistent with this history, for over 50 years, CMS *never* mandated vaccines for healthcare workers, despite issuing copious health-and-safety regulations for decades.

Notwithstanding this longstanding policy, CMS suddenly purported to discover statutory authority for an industry-wide vaccine mandate in many widely scattered statutory provisions—two generic provisions granting CMS administrative authority over Medicare and Medicaid, and dozens of definitional and ancillary citations relating to fifteen categories of health-care facilities. *See* 86 Fed. Reg. 61,567. CMS never identified what specific language in which specific provisions purported to authorize the Mandate, but justified its transformative policy by citation *en masse*. *Id.* In the face of decades of contrary understanding and practice, this "hodgepodge of provisions," *Biden*, 142 S. Ct. at 656 (Thomas, J., dissenting), falls far short of the constitutionally required "clear notice" that the Spending Clause requires for such funding conditions. *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 the many scattered statutes CMS invoked could not have furnished "unambiguous" notice of CMS's authority to mandate vaccination. *Id.* Nothing in federal law gave the States clear notice that forcing their employees at state-run hospitals to get a COVID-19 vaccine or forcing their state surveyors to enforce the CMS vaccine mandate would be a condition of accepting federal funds. And no State or private provider reasonably anticipated vaccine mandates when it accepted Medicare/Medicaid funds.

CMS's longstanding course of conduct prior to the Mandate fatally undermines its claim that the statutes provide clear notice. "This 'lack of historical precedent,' coupled with the breadth of authority that the Secretary now claims, is a 'telling indication' that the mandate extends beyond the agency's legitimate reach." *OSHA*, 142 S. Ct. at 666 (quoting *Free Enterprise Fund v. Public Company Accounting Oversight Bd.*, 561 U.S. 477, 505 (2010)).

No one—much less the States—could have anticipated the COVID-19 pandemic or CMS's response to it. Even CMS itself evidently did not anticipate that it would mandate vaccines across the healthcare industry, until the President directed it to do so. CMS's unprecedented use of a vaccine mandate as a condition of participation is a "surprising … post-acceptance … condition[]" on the States that

"the spending power ... does not include[.]" *NFIB v. Sebelius*, 567 U.S. 519, 584 (2012) (plurality opinion).

CMS may argue, as it did below, that the vaccine mandate "bears some relationship" to federal spending on Medicaid and Medicare. But the relationship is so tenuous that this goes even beyond *NFIB*, where the Supreme Court found a clear violation of the Spending Clause. 567 U.S. at 584. And here, the "clear notice" requirement is buttressed by the fact that the Mandate intrudes upon an area traditionally reserved for the States in the exercise of their police powers. As *Jacobson* noted, vaccine mandates "do not ordinarily concern the national government." 197 U.S. at 38. That has been the Nation's unbroken historical tradition for over 100 years.

Further, as in *NFIB*, the vaccine mandate "accomplishes a shift in kind, not merely degree." 567 U.S. at 583. Under the Mandate, Medicaid/Medicare is "no longer a program to care for the neediest among us, but rather an element of a comprehensive national plan to provide universal" vaccination of Americans. *Id.* at 583. "A State could hardly anticipate that" the statutes cited by CMS "included the power to transform [Medicare and Medicaid] so dramatically." *Id.*

2. The Mandate violates other constitutional provisions.

Further, spending "conditions must not be prohibited by other constitutional provisions." *Van Wyhe*, 581 F.3d at 650. Here, the Mandate violates both the anti-

commandeering doctrine and the Tenth Amendment, as discussed below. *See infra*, Parts I.E-F.

3. The Mandate is unconstitutionally coercive.

Third, under the Spending Clause, "the circumstances must not be so coercive that 'pressure turns into compulsion.'" *Van Wyhe*, 581 F.3d at 650 (citation omitted). Here, the Mandate threatens *all* Medicare and Medicaid funding for provider reimbursements in the States if the States do not deploy their surveyors to enforce it. This is unconstitutionally coercive for the reasons discussed in the anti-commandeering section below, Part I.E.

E. The Mandate Violates the Anti-Commandeering Doctrine and Is Unconstitutionally Coercive.

CMS 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. The States cannot be compelled to "administer" or "implement" "federal regulatory programs." *Printz*, 521 U.S. at 925-26, 933, 935. The Constitution does not tolerate the federal government "dragoon[ing]" state employees "into administering federal law." *Id.* at 928. "That is true whether Congress directly commands a State to regulate or indirectly coerces a State to adopt a federal regulatory system as its own." *NFIB*, 567 U.S. at 578.

But that is exactly what CMS has done here. CMS lacks its own federal enforcement apparatus for the Mandate; instead, the Mandate will be enforced by *state* surveyors in state health departments—including hundreds of surveyors who are officials of the Plaintiff States. App. 91-92, R. Doc. 1, at 3-4; App. 119-122, R. Doc. 8, at 3-6; App. 166, R. Doc. 17, at 5; App. 217, R. Doc. 28, at 3; App. 224, R. Doc. 30, at 4. CMS presses "State surveyors" into federal service to enforce the Mandate. 86 Fed. Reg. 61,574. If States instruct their surveyors not to enforce the Mandate, that will disqualify Medicare- and Medicaid-certified providers in their States. App. 166, R. Doc. 9-17, at 4 ("These surveys must be completed in order for facilities to continue to be certified for participation in Medicare and Medicaid."). It is hard to imagine a more coercive condition. Forcing States to administer the Mandate or jeopardize *all Medicare and Medicaid funds flowing into their States* is "a gun to the head" that compels States to participate against their will. *NFIB*, 567 U.S. at 581. It is "economic dragooning" that leaves States "with no real option but to acquiesce." *Id.* at 582. Thus, the Mandate is both unconstitutionally coercive under the Spending Clause, and independently unconstitutional under *Printz*'s anti-commandeering doctrine. *Id.*

It is not only state surveyors that must enforce the vaccine mandate; it is also 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 state-run health facilities 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.*, App. 132, R. Doc. 9-10, at 5 (89% of the Missouri Department of Mental Health's budget); App. 165, R. Doc. 9-17, at 4 (62.44% of one Nebraska state facility's expenditures). Forcing this choice on a series of arbitrary timelines is practically coercive. And because the States must ensure sufficient funding to care for ailing patients in need, this does not present States with a realistic choice.

CMS may argue, as it did below, that it isn't commandeering anyone because conditions on federal spending fall on healthcare providers, not on the States directly. That not only elevates form over substance, but also ignores state-run facilities. And it disregards the States' "stake in protecting [their] quasi-sovereign interests." *Massachusetts v. EPA*, 549 U.S. 497, 520 (2007). Moreover, to the extent CMS may argue that no commandeering occurs when CMS charges state surveyors with enforcing the vaccine mandate because the States voluntarily agreed to operate as surveyors, the state surveyors never agreed to enforce a vaccine mandate. Because "[p]revious Medicaid [regulations] simply do not fall into the same category as the one at stake here," *NFIB*, 567 U.S. at 585, any prior agreement by state surveyors does not encompass this demand.

F. The Mandate Violates the Tenth Amendment.

The Mandate also violates the Tenth Amendment because it attempts to exercise a police power reserved to the States. Vaccine mandates "do not ordinarily concern the national government." *Jacobson*, 197 U.S. at 38. "So far as they can be reached by any government," they lie within the police power of the States, and "depend, primarily, upon such action as the state, in its wisdom, may take." *Id.* "The safety and health of the people of" each State "are, in the first instance, for that commonwealth to guard and protect." *Id.* This "police power" is "a power which the state did not surrender when becoming a member of the Union under the Constitution." *Id.*

"[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) (per curiam). 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.

By seeking to impose its vaccine mandate on millions of healthcare workers, CMS arrogates to itself powers that have belonged exclusively to the States for centuries. CMS admits that it never before has attempted to mandate vaccines on

state or private employees. 86 Fed. Reg. 61,567-68. "This lack of historical precedent … is a telling indication that the mandate extends beyond the agency's legitimate reach." *OSHA*, 142 S. Ct. at 666 (quotation omitted).

G. The Mandate Exceeds CMS's Statutory Authority, Violates the APA, and Was Unlawfully Issued Without Notice-and-Comment.

The Mandate is also invalid for the other reasons identified by the district court, which the Supreme Court did address preliminarily in its stay opinion. *Missouri*, 142 S. Ct. at 653-54.

Statutory Authority. The Mandate exceeds CMS's statutory authority and violates 42 U.S.C. § 1395. *See* Add. 3-8, R. Doc. 28; *Missouri*, 142 S. Ct. at 655-69 (Thomas, J., dissenting); R. Doc. 9, at 23-28. The Mandate presents a question "vast economic and political significance" that "alter[s] the balance between state and federal power," and thus requires "exceedingly clear language." *Alabama Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, 141 S. Ct. 2485, 2489 (2021). CMS's "hodgepodge" of provisions fails to provide such a clear statement, especially when "context … inform[s] the scope of the provision." *Missouri*, 142 U.S. at 657 (Thomas, J., dissenting). And the Mandate violates the plain meaning of 42 U.S.C. § 1395 by controlling the "selection" and "tenure" of healthcare employees.

Arbitrary and Capricious. In addition to CMS's failure to consider reliance interests, which the Supreme Court did not address in its stay opinion, the Mandate is arbitrary and capricious for the reasons identified by the district court that the

Supreme Court did address. Add. 14-23, R. Doc. 28. First, the "record is devoid of evidence regarding the covered healthcare facilities," *id* at 14, because CMS simply "extrapolated" from LTCs to fourteen other kinds of facilities. Second, CMS "failed to consider or rejected obvious alternatives to a vaccine mandate without evidence," *id.* at 16, such as frequent testing or an exemption for those with natural immunity. In the process, CMS admitted "that it lacks solid evidence regarding transmissibility of COVID by the vaccinated," *id.* at 17 (citing 86 Fed. Reg. 61,612, 61,615). And CMS "plainly contradicts itself regarding the value of natural immunity," *id.* at 17 (citing 86 Fed. Reg. 61,604). Third, the Mandate is arbitrarily overbroad because it covers virtually all facilities and all staff "regardless of patient contact." *Id.* at 18 (citing 86 Fed. Reg. 61,571). And fourth, "CMS failed to adequately explain its contradiction to its long-standing practice of encouraging rather than forcing—by government mandate—vaccination." *Id.* at 19. In particular, CMS admits that "the vaccines' effectiveness to prevent disease transmission by those vaccinated [is] not currently known." 86 Fed. Reg. 61,615.

Lack of Notice-and-Comment. CMS unlawfully failed to provide notice-and-comment. Add. 8-13, R. Doc. 28 (citing 5 U.S.C. § 553 and 42 U.S.C. § 1395hh(b)(1)); *Missouri*, 142 S. Ct. at 658-660 (Alito, J., dissenting). CMS's months-long delay before issuing the Mandate undermines its claim of "good cause." Add. 9-10, R. Doc. 28. This is especially true given "the unprecedented,

controversial, and health-related nature of the mandate." *Id.* at 12. "[E]xceptions to notice-and-comment must be narrowly construed and only reluctantly countenanced." *Missouri*, 142 S. Ct. at 659 (Alito, J., dissenting) (quotation omitted). By refusing to accept comments, CMS willfully blinded itself to the concerns raised by the States' declarants. *Id.* CMS cannot "regulate first and listen later." *Id.*

II. The Balancing of Harms and the Public Interest Favor the States.

The other equitable factors also favor the States. Add. 23-31, R. Doc. 28.

A. The States Face Grievous Irreparable Injury.

The Mandate inflicts irreparable injury on the States in their sovereign, quasi-sovereign, and proprietary interests. It interferes with States' sovereignty by preempting their laws rejecting compulsory vaccination, *see id.* at 24 (citing Mo. Rev. Stat § 67.265; 2021 Alaska Sess. Laws ch. 2, § 17; Ark. Code § 20-7-143; and Ark. Code § 11-5-118). "State[s] . . . suffer irreparable harm" when they are "precluded from applying [their] duly enacted legislation." *Org. for Black Struggle v. Ashcroft*, 978 F.3d 603, 609 (8th Cir. 2020); *see also Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers). The Mandate also interferes with state sovereignty by "dragoon[ing]" hundreds of state surveyors into enforcing the unlawful mandate. *Printz*, 521 U.S. at 928. And it unlawfully arrogates to the

federal government the States' traditional police power over compulsory vaccination. *Jacobson*, 197 U.S. at 25.

The Mandate grievously injures each State's "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).[1] Each State contains significant rural areas where healthcare is provided by independent small hospitals and local clinics that draw their staff from heavily unvaccinated local populations. *Supra*, Part E.1. These facilities were already facing a staffing crisis when the Mandate was announced. *Id.* They face imminent closures and/or cutbacks to patient services from the Mandate. *Id.* By its compounded effect, the Mandate threatens a crisis in the provision of healthcare services across rural America. *Id.* As the district court found, "[s]taff reductions due to implementing the mandate … will cause a cascade of consequences," and "will decrease the quality of care provided at facilities, compromise the safety of

[1] The Government claims that the States cannot assert quasi-sovereign interests against the federal Government. App. Br. 23. The Supreme Court rejected that very argument in *Massachusetts v. EPA*, 549 U.S. 497, 520 n.17 (2007). "[T]here is a critical difference between allowing a State to protect her citizens from the operation of federal statutes … and allowing a State to assert its rights under federal law (which it has standing to do)." *Id.* By claiming that the Mandate violates the APA and the Constitution, the States merely "assert [their] rights under federal law," *id.*, and thus each State may assert its quasi-sovereign interest in defending the health and welfare of a "sufficiently substantial segment of its population." *Alfred L. Snapp*, 458 U.S. at 607.

patients, and place even more stress on remaining staff." Add. 25, R. Doc. 28. "[T]he loss of staffing in many instances will result in *no care at all*." *Id.* at 27.

The Mandate injures States in their proprietary interests, too, because "Plaintiffs themselves operate healthcare facilities that CMS's mandate reaches." Add. 27, R. Doc. 28. The States, like private employers, will be forced to fire well-qualified healthcare workers and desperately scramble to staff shifts and keep services going. *Id.* And the closure of facilities will injure local economies within the States, as the district court found. Add. 27 & n.32, R. Doc. 28.

B. The Government Faces No Cognizable Injury.

By contrast, the Government faces no cognizable injury because it "does 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). "There is generally no public interest in the perpetuation of an unlawful agency action." *League of Women Voters v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016).

C. The Public Interest Favors Enjoining the Mandate.

The public interest favors enjoining the Mandate. The Government argues that the Mandate will protect patients from severe health outcomes from COVID-19. App. Br. 22. But the Mandate itself undermines this argument, because it concedes that precautions other than vaccination have been "*highly effective*" in preventing transmission of COVID-19 in healthcare facilities, and that such

"effective precautions other than vaccination … have been *essentially universal* in the health care sector during all of 2021." 86 Fed. Reg. 61,557, 61,612 (emphases added). As discussed above, CMS cited no recent evidence of significant staff-to-patient COVID-19 transmission in the vast majority of facilities in 2021, when such "effective precautions other than vaccination" became "essentially universal." *Id.* By contrast, the States' declarants attested, without contradiction, that "no infections [are] occurring within our workplace," App. 103, R. Doc. 9-4, at 3, and "[p]atients are not coming to the hospital for services and becoming ill with COVID," App. 171, R. Doc. 9-18, at 5.

Moreover, since the Mandate was issued, the Delta variant has been replaced by the milder Omicron variant, which now accounts for 100 percent of COVID-19 cases in America. CDC COVID Data Tracker, *Variant Proportions*, https://covid.cdc.gov/covid-data-tracker/#variant-proportions (updated Feb. 22, 2022). The existing vaccines mandated by CMS, while they continue to protect against severe health outcomes, have proven ineffective in preventing *transmission* of the Omicron variant. *See, e.g., No Omicron Immunity Without Booster, Study Finds*, THE HARVARD GAZETTE (Jan. 7, 2022), https://news.harvard.edu/gazette/story/2022/01/no-omicron-immunity-without-booster-study-finds/ ("[T]raditional dosing regimens of COVID-19 vaccines available in the United States do not produce antibodies capable of recognizing and

neutralizing the Omicron variant."); Christian Holm Hansen et al., *Vaccine effectiveness against SARS-CoV-2 infection with the Omicron or Delta variants following a two-dose or booster BNT162b2 or mRNA-1273 vaccination series: A Danish cohort study*, medRxiv (Dec. 23, 2021), https://www.medrxiv.org/content/10.1101/2021.12.20.21267966v3.full-text. The Mandate—crafted for a world where Delta was dominant—has become entirely obsolete in today's Omicron-dominant world. There is no public interest in enforcing it.

CONCLUSION

The district court's preliminary injunction should be affirmed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned hereby certifies that this brief complies with the typeface and formatting requirements of Fed. R. App. P. 32, that it is written in Times New Roman 14-point font, and that it contains 12,898 words as determined by the word-count feature of Microsoft Word. Both the brief and addendum have been scanned for viruses and are virus-free.

/s/ D. John Sauer

CERTIFICATE OF SERVICE

I hereby certify that on February 28, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the CM/ECF system.

/s/ D. John Sauer