No. 21-3725

IN THE UNITED STATES COURT OF APPEALS
FOR THE EIGHTH CIRCUIT

STATE OF MISSOURI, et al.,
Plaintiffs-Appellees,
v.

JOSEPH R. BIDEN, JR., 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)

On Appeal from the United States District Court
for the Eastern District of Missouri

OPENING BRIEF FOR APPELLANTS

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SUMMARY OF THE CASE AND STATEMENT REGARDING ORAL ARGUMENT

To protect patients at facilities that choose to participate in the Medicare and Medicaid programs, the Secretary of Health and Human Services issued an interim final rule requiring such facilities to ensure that their covered staff are vaccinated against COVID-19 (subject to medical and religious exemptions). The district court entered a preliminary injunction that prohibited the enforcement of the rule within the plaintiff States. A divided panel of this Court denied the federal government's motion for a stay pending appeal.

The federal government applied to the Supreme Court for a stay pending further review. After hearing oral argument, the Supreme Court granted the government's application. In so ruling, the Supreme Court resolved the merits of the States' challenge to the rule in the government's favor. *See Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam). The Supreme Court's reasoning requires that the preliminary injunction be vacated. We respectfully submit that oral argument is unnecessary.

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STATEMENT OF JURISDICTION

Plaintiffs invoked the district court's jurisdiction under 28 U.S.C. §§ 1331, 1361, 2201. App. 6; R. Doc. 1, at 6.[1] On November 29, 2021, the district court entered a preliminary injunction. Add. 1-32; R. Doc. 28, at 1-32. On November 30, 2021, defendants filed a timely notice of appeal. App. 225; R. Doc. 29. This Court has jurisdiction under 28 U.S.C. § 1292(a)(1).

STATEMENT OF THE ISSUE

To protect patients at facilities that choose to participate in the Medicare and Medicaid programs, the Secretary of Health and Human Services (Secretary) issued an interim final rule requiring such facilities to ensure that their covered staff are vaccinated against COVID-19 (subject to medical and religious exemptions). The district court entered a preliminary injunction that prohibited the enforcement of the rule within the plaintiff States. The Supreme Court granted the federal government's application for a stay of the preliminary injunction pending further review and, in so ruling, the Court resolved the merits of the States' challenge to

[1] Citations to the government's Appendix are abbreviated App.__. Citations to the Addendum are abbreviated Add.__.

the rule in the federal government's favor. The question presented is whether the preliminary injunction should be vacated.

The most apposite authority is: *Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam).

STATEMENT OF THE CASE

A. The Medicare and Medicaid Programs

Congress spends hundreds of billions of dollars each year to pay for healthcare under the Medicare and Medicaid programs. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). Medicare, which is funded entirely by the federal government, covers individuals who are age 65 or older or who have specified disabilities. *See id.* Medicaid, which is funded by the federal government and States, covers eligible low-income individuals, including those who are elderly, pregnant, or disabled. *See Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 650-51 & n.5 (2003).

Medicare and Medicaid beneficiaries receive care at a variety of medical facilities, including hospitals, skilled nursing facilities (also known as nursing homes or long-term care facilities), and hospices. To participate in the Medicare or Medicaid program, each of those facilities must enter

into a provider agreement and meet specified conditions of participation. *E.g.*, 42 U.S.C. §§ 1395cc, 1396a(a)(27).

Congress charged the Secretary with ensuring that facilities participating in Medicare and Medicaid adequately protect the health and safety of their patients. For example, the Medicare statute authorizes payments for "hospital services," 42 U.S.C. § 1395d(a), and defines a "hospital" as an institution that meets, *inter alia*, such "requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution," *id.* § 1395x(e)(9); *see also, e.g.*, *id.* § 1395i-3(d)(4)(B) (providing that a "skilled nursing facility must meet," *inter alia*, such "requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary"). The Medicaid statute also imposes health and safety requirements, *see, e.g.*, *id.* § 1396r(d)(4)(B), or incorporates by cross-reference analogous Medicare standards for certain types of facilities, *see, e.g.*, *id.* § 1396d(h) (psychiatric hospitals); *id.* § 1396d(*l*)(1) (rural health clinics); *id.* § 1396d(o) (hospices).

The Secretary has exercised those authorities to promulgate regulations establishing detailed conditions of participation in Medicare

and Medicaid. The regulations address, for example, the qualifications of staff, the condition of the facilities, and other requirements that the Secretary deems necessary to protect patient health and safety. *E.g.*, 42 C.F.R. pt. 482 (conditions of participation for hospitals). The regulations also "focus a great deal on infection prevention and control standards, often incorporating guidelines as recommended by CDC and other expert groups." 86 Fed. Reg. 61,555, 61,568 (Nov. 5, 2021). The regulations have long included a requirement that facilities maintain an "infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections." 42 C.F.R. § 483.80 (long-term care facilities); *see, e.g.*, *id.* § 482.42(a) (hospitals); *id.* § 416.51(b) (ambulatory surgical centers).

B. The Vaccination Rule for Facilities That Participate in Medicare or Medicaid

On September 9, 2021, President Biden announced that the government would be undertaking "new steps to fight COVID-19," including a plan being developed by the Secretary to require vaccinations for workers "who treat patients on Medicare and Medicaid." *Remarks on*

the COVID-19 Response and National Vaccination Efforts, Daily Comp. Pres. Docs., 2021 DCPD No. 00725, at 1-2. On November 5, 2021, the Secretary issued an interim final rule amending existing infection-control regulations and related conditions of participation in Medicare and Medicaid to require that participating facilities ensure that their covered staff are vaccinated against COVID-19 to reduce the transmission from staff to patients. 86 Fed. Reg. at 61,561; *see id.* at 61,616-27 (text of amendments). The rule requires facilities to provide medical and religious exemptions. *Id.* at 61,572. It also contains exceptions for staff who telework full-time and others who perform infrequent, non-healthcare services. *Id.* at 61,571. Covered staff were originally required to receive the first dose of a vaccine by December 6, 2021, or to request an exemption by that date. *Id.* at 61,573. Non-exempt covered staff were to be fully vaccinated by January 4, 2022. *Id.*

1. In issuing the rule, the Secretary explained that he had determined that "vaccination of staff is necessary for the health and safety of individuals to whom care and services are furnished." 86 Fed. Reg. at 61,561. He observed that vaccination rates remain low in many healthcare facilities. *Id.* at 61,559. For example, as of mid-September 2021, COVID-19

vaccination rates for hospital staff and long-term care facility staff averaged 64% and 67%, respectively. *Id.*

The Secretary found that unvaccinated staff at healthcare facilities pose a serious threat to the health and safety of patients because the virus that causes COVID-19 is highly transmissible and dangerous. 86 Fed. Reg. at 61,556-57. He explained that, unless appropriate protections are implemented, the virus can spread among healthcare workers and from workers to patients. *See id.* at 61,557 & n.16. He further explained that vaccination substantially diminishes the risk of such transmission by reducing infection and, according to "[e]merging evidence," by lowering the risk of transmission even in the event of "breakthrough infections." *Id.* at 61,558. By contrast, unvaccinated healthcare workers are at increased risk for infection and therefore at increased risk of exposing their patients and colleagues to the virus. *See id.* at 61,558 & nn.42-43 (discussing studies linking unvaccinated staff to increased risk of COVID-19 infection). And because eligibility for the Medicare and Medicaid programs turns on factors such as advanced age and disability, patients covered by those programs frequently face a higher risk of developing severe disease and of

experiencing severe outcomes from COVID-19 if infected. *Id.* at 61,566, 61,609.

The Secretary also found that "[f]ear of exposure to and infection with COVID-19 from unvaccinated health care staff can lead patients to themselves forgo seeking medically necessary care," 86 Fed. Reg. at 61,558, which creates a further "risk[] to patient health and safety," *id.* The Secretary noted reports that individuals are "refusing care from unvaccinated staff," which limits "the extent to which providers and suppliers can effectively meet the health care needs of their patients and residents." *Id.* The Secretary also noted that absenteeism by healthcare staff as a result of "COVID-19-related exposures or illness" has created staffing shortages that have further disrupted patient access to care. *Id.* at 61,559.

The Secretary emphasized that a vaccination requirement for the facilities covered by the rule is consistent with the recommendation of "more than 50 health care professional societies and organizations," including the American Medical Association and the American Nurses Association, which had released a joint statement supporting vaccination requirements for healthcare workers. 86 Fed. Reg. at 61,565. Those various

organizations "represent[] millions of workers throughout the U.S. health care industry," including "doctors, nurses, pharmacists, physician assistants, public health workers, and epidemiologists as well as long term care, home care, and hospice workers." *Id.* In the joint statement, the organizations urged that "all health care and long-term care employers require their workers to receive the COVID-19 vaccine." *Joint Statement in Support of COVID-19 Vaccine Mandates for All Workers in Health and Long-Term Care*.[2] The organizations explained that this step fulfills "the ethical commitment of all health care workers to put patients as well as residents of long-term care facilities first and take all steps necessary to ensure their health and well-being." *Id.*

2. Notwithstanding that broad support, the Secretary acknowledged the risk that the rule could prompt some healthcare workers to leave their jobs rather than be vaccinated. 86 Fed. Reg. at 61,608. But he found that "many COVID-19 vaccination mandates have already been successfully initiated in a variety of health care settings," and that those examples showed that "very few workers quit their jobs rather than be vaccinated."

[2] https://perma.cc/ECD8-ARE2.

Id. at 61,569. The Secretary explained, for example, that after the Houston Methodist Hospital system imposed a vaccine requirement, 99.5% of its staff received the vaccine. *Id.* Only 153 of its 26,000 workers resigned rather than receive the vaccine. *See id.* at 61,569 n.155 (citing article with the relevant figures). Widespread compliance with vaccine mandates likewise occurred at a Detroit-based health system with more than 33,000 employees and a Delaware-based health system with more than 14,000 employees. *Id.* at 61,566, 61,569. And at a North Carolina-based health system, only 375 of 35,000 employees across 15 hospitals, 800 clinics, and hundreds of outpatient facilities—that is, only 1% of the workforce—failed to comply. *See id.* at 61,566 n.132 (link to press release containing those figures).

The Secretary also noted that any departures by staff to avoid vaccination ought to be "offset by reductions in current staffing disruptions caused by staff illness and quarantine once vaccination is more widespread." 86 Fed. Reg. at 61,608. And although the net effect could not be predicted with certainty given the "many variables and unknowns," the Secretary judged that any disruption from a vaccine requirement would

likely be minor in comparison to normal patterns of healthcare worker turnover. *Id.*

3. The Secretary issued the rule as an interim final rule with a comment period, finding "good cause" to make the rule effective immediately, without prior notice and comment. 86 Fed. Reg. at 61,586; *see* 5 U.S.C. § 553(b)(B). In doing so, he determined that "it would endanger the health and safety of patients, and be contrary to the public interest," to delay the vaccination rule. 86 Fed. Reg. at 61,586. The Secretary noted that patients in facilities funded by the Medicare and Medicaid programs are more likely than the general population to suffer severe illness or death from COVID-19, *id.* at 61,609; that there had already been more than half a million COVID-19 cases among healthcare staff, *id.* at 61,585; that COVID-19 case rates among staff have grown since the Delta variant's emergence, *id.*; that COVID-19 cases are expected to spike during the winter, *id.* at 61,584; and that this spike will coincide with flu season, raising the additional danger of combined infections and increased pressure on the healthcare system, *id.* The Secretary predicted that the rule will save "several hundred . . . or perhaps several thousand" lives every month. *Id.* at 61,612.

C. Prior Proceedings

On November 10, 2021, plaintiffs—a group of ten States led by Missouri—brought this action challenging the rule in the U.S. District Court for the Eastern District of Missouri. App. 3-6; R. Doc. 1, at 3-6.

1. On November 29, 2021, the district court preliminarily enjoined enforcement of the rule within those States. Add. 32; R. Doc. 28, at 32. The court noted that, in considering a motion for a preliminary injunction, "the probability of success factor is the most significant." Add. 3 (quoting *Home Instead, Inc. v. Florance*, 721 F.3d 494, 497 (8th Cir. 2013)) R. Doc. 28, at 3. The court ruled that plaintiffs were likely to succeed on the merits of their claims that the Secretary lacked statutory authority to issue the vaccine rule, Add. 3-8; R. Doc. 28, at 3-8; that the rule was arbitrary and capricious, Add. 14-23; R. Doc. 28, at 14-23; and that the Secretary did not have good cause to proceed without notice and comment, Add. 8-13; R. Doc. 28, at 8-13. The court also concluded that the remaining factors supported a preliminary injunction. Add. 23-31; R. Doc. 28, at 23-31. The court later denied the government's motion for a stay pending appeal. Add. 33-35; R. Doc. 35, at 1-3.

2. The federal government filed an emergency motion in this Court to stay the preliminary injunction pending appeal. A divided panel issued an order denying the stay motion. *See* Order, Dec. 13, 2021.

3. The federal government filed applications in the Supreme Court for stays pending further review of both the preliminary injunction in this case and a second preliminary injunction issued in *Louisiana v. Becerra*, -- F. Supp. 3d --, No. 3:21-CV-03970, 2021 WL 5609846 (W.D. La. Nov. 30, 2021), which was based on largely identical reasoning but covered a different set of States. After hearing oral argument, the Supreme Court granted the stay applications and, as explained in detail below, resolved the merits of the challenges in the federal government's favor. *See Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam).

Accordingly, in parallel litigation, the State of Texas recently dismissed its complaint in light of the Supreme Court's ruling. *See* Plaintiffs' Motion for Dismissal, *Texas v. Becerra*, No. 2:21-cv-00229 (N.D. Tex. Jan. 18, 2022); Order, *Texas*, No. 2:21-cv-00229 (N.D. Tex. Jan. 19, 2022). Similarly, the State of Florida dismissed its appeal from the denial of a preliminary injunction. *See* Unopposed Motion for Voluntary Dismissal,

Florida v. Department of Health & Human Servs., No. 21-14098 (11th Cir. Jan. 21, 2022); Order, *Florida*, No. 21-14098 (11th Cir. Jan. 25, 2022).

SUMMARY OF ARGUMENT

The Supreme Court's opinion in this case requires that the preliminary injunction be vacated. The preliminary injunction rested on the district court's conclusion that plaintiffs are likely to succeed on claims that the Supreme Court has now rejected. Specifically, the district court reasoned that plaintiffs are likely to succeed in showing that the vaccination rule exceeds the Secretary's statutory authority, that the rule is arbitrary and capricious, and that the Secretary lacked good cause to issue the rule without notice and comment. The Supreme Court resolved each of those issues in the federal government's favor. *See Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam). The preliminary injunction therefore must be vacated.

STANDARD OF REVIEW

A preliminary injunction is reviewed for abuse of discretion. *Miller v. Honkamp Krueger Fin. Servs., Inc.*, 9 F.4th 1011, 1013 (8th Cir. 2021). A preliminary injunction that rests on erroneous legal conclusions is an abuse of discretion. *Id.* at 1013-14; *see, e.g.*, *Trump v. Hawaii*, 138 S. Ct. 2392, 2423

(2018) ("Because plaintiffs have not shown that they are likely to succeed on the merits of their claims, we reverse the grant of the preliminary injunction as an abuse of discretion.").

ARGUMENT

The Supreme Court's decision in this case shows that the preliminary injunction rests on errors of law. The district court reasoned that plaintiffs are likely to succeed on the merits of their claims that (1) the vaccination rule exceeds the Secretary's statutory authority, (2) the rule is arbitrary and capricious, and (3) the Secretary lacked good cause to proceed without notice and comment. The Supreme Court resolved each of these challenges in the federal government's favor. Plaintiffs therefore cannot show that they are "likely to succeed on the merits" and thus cannot defend the entry of a preliminary injunction. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see, e.g., Barr v. Lee*, 140 S. Ct. 2590, 2591 (2020) (vacating preliminary injunction because plaintiffs had not "established that they are likely to succeed on the merits"); *Trump v. Hawaii*, 138 S. Ct. 2392, 2423 (2018) (same); *Munaf v. Geren*, 553 U.S. 674, 690 (2008) (same). Finally, although the Court need not reach the issue, the "balance of equities"

confirms that a preliminary injunction is unwarranted. *Winter*, 555 U.S. at 20.

A. The Rule Is Within The Secretary's Authority

The Supreme Court first ruled that "the Secretary's rule falls within the authorities that Congress has conferred upon him." *Biden v. Missouri*, 142 S. Ct. 647, 652 (2022) (per curiam). The Court noted that the Secretary is granted the "general statutory authority to promulgate regulations 'as may be necessary to the efficient administration of the functions with which [he] is charged.'" *Id.* at 650 (alteration in original) (quoting 42 U.S.C. § 1302(a)). "One such function—perhaps the most basic, given the Department's core mission—is to ensure that the healthcare providers who care for Medicare and Medicaid patients protect their patients' health and safety." *Id.* "To that end, Congress authorized the Secretary to promulgate, as a condition of a facility's participation in the programs, such 'requirements as [he] finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.'" *Id.* (quoting 42 U.S.C. § 1395x(e)(9)). "While this provision pertains only to hospitals, the Secretary has similar statutory powers with respect to most

other categories of healthcare facilities covered by the interim rule." *Id.* at 652 n.*.[3]

The Supreme Court cited the Secretary's findings that the vaccine rule "will substantially reduce the likelihood that healthcare workers will contract the virus and transmit it to their patients," and that "a vaccine mandate is necessary to promote and protect patient health and safety in the face of the ongoing pandemic." *Biden v. Missouri*, 142 S. Ct. at 652 (quotation marks omitted) (citing 86 Fed. Reg. at 61,557-58, 61,613). The Court concluded that "[t]he rule thus fits neatly within the language of the statute." *Id.* "After all, ensuring that providers take steps to avoid transmitting a dangerous virus to their patients is consistent with the fundamental principle of the medical profession: first, do no harm." *Id.*

[3] The Supreme Court noted that for five such kinds of facilities, the relevant statute does not contain express "health and safety" language, but the Court explained that "employees at these facilities—which include end-stage renal disease clinics and home infusion therapy suppliers—represent less than 3% of the workers covered by the rule." *Biden v. Missouri*, 142 S. Ct. at 652 n.*. "And even with respect to them, the pertinent statutory language may be read as incorporating the 'health and safety' authorities applicable to the other 97%. *Id.* (citing, *e.g.*, 42 U.S.C. § 1396d(d)(1)). The Supreme Court also saw "no reason to let the infusion-clinic tail wag the hospital dog, especially because the rule has an express severability provision." *Id.* (citing 86 Fed. Reg. at 61,560).

The Court emphasized that it "would be the 'very opposite of efficient and effective administration for a facility that is supposed to make people well to make them sick with COVID-19.'" *Id.* (quoting *Florida v. Department of Health & Human Servs.*, 19 F.4th 1271, 1288 (11th Cir. 2021)). The Court concluded that the vaccination rule "is a straightforward and predictable example of the 'health and safety' regulations that Congress has authorized the Secretary to impose." *Id.* at 653.

The Supreme Court rejected the argument that the rule runs afoul of the directive in 42 U.S.C. § 1395 that federal officials may not "exercise any supervision or control over the ... manner in which medical services are provided, or over the selection [or] tenure ... of any officer or employee of" any facility. *Biden v. Missouri*, 142 S. Ct. at 654 (alterations in original). The Court observed that plaintiffs' "reading of section 1395 would mean that nearly every condition of participation the Secretary has long insisted upon is unlawful." *Id.*

In sum, the Supreme Court squarely "conclude[d] that the Secretary did not exceed his statutory authority in requiring that, in order to remain eligible for Medicare and Medicaid dollars, the facilities covered by the interim rule must ensure that their employees be vaccinated against

COVID-19." *Biden v. Missouri*, 142 S. Ct. at 653; *see id.* (holding that "Congress has authorized the Secretary to impose" the rule).

B. The Rule Is Not Arbitrary And Capricious

The Supreme Court "disagree[d] with" the "remaining contentions in support of the injunctions entered below." *Biden v. Missouri*, 142 S. Ct. at 653. The Court concluded that "the interim rule is not arbitrary and capricious." *Id.* "Given the rulemaking record, it cannot be maintained that the Secretary failed to 'examine the relevant data and articulate a satisfactory explanation for' his decisions to (1) impose the vaccine mandate instead of a testing mandate; (2) require vaccination of employees with 'natural immunity' from prior COVID-19 illness; and (3) depart from the agency's prior approach of merely encouraging vaccination." *Id.* at 653-54 (quoting *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)) (citing 86 Fed. Reg. at 61,583, 61,559-61, 61,614).

"Nor is it the case that the Secretary 'entirely failed to consider' that the rule might cause staffing shortages, including in rural areas." *Biden v. Missouri*, 142 S. Ct. at 654 (first quoting *State Farm*, 463 U.S. at 43; and then citing 86 Fed. Reg. at 61,566, 61,569, 61,607-09). "As to the additional flaws

the District Courts found in the Secretary's analysis, particularly concerning the nature of the data relied upon," the Supreme Court emphasized that "the role of courts in reviewing arbitrary and capricious challenges is to 'simply ensur[e] that the agency has acted within a zone of reasonableness.'" *Id*. (alteration in original) (quoting *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021)).

C. The Secretary Had Good Cause To Issue The Rule Without Advance Notice And Comment

The Supreme Court likewise rejected plaintiffs' procedural claims. Addressing the Secretary's "finding of good cause to delay notice and comment," the Supreme Court concluded that "the Secretary's finding that accelerated promulgation of the rule in advance of the winter flu season would significantly reduce COVID-19 infections, hospitalizations, and deaths" constitutes "the 'something specific'" that is "required to forgo notice and comment." *Biden v. Missouri*, 142 S. Ct. at 654 (citing 86 Fed. Reg. at 61,584-86). The Court also rejected the contention that "the two months the agency took to prepare a 73-page rule constitutes 'delay' inconsistent with the Secretary's finding of good cause." *Id*.

Similarly, the Supreme Court agreed "with the Secretary that he was not required to 'consult with appropriate State agencies,' 42 U.S.C. § 1395z, in advance of issuing the interim rule," *Biden v. Missouri*, 142 S. Ct. at 654. "Consistent with the existence of the good cause exception, which was properly invoked here, consultation during the deferred notice-and-comment period is permissible." *Id*. The Court likewise concurred "with the Secretary that he need not prepare a regulatory impact analysis discussing a rule's effect on small rural hospitals when he acts through an interim final rule," a requirement that "applies only where the Secretary proceeds on the basis of a 'notice of proposed rulemaking' followed by a 'final version of [the] rule." *Id*. (citation omitted) (quoting 42 U.S.C. § 1302(b)(1), (2)).

* * *

In sum, the Supreme Court already resolved the merits of plaintiffs' challenge to the rule in the federal government's favor. Plaintiffs therefore cannot show that they are "likely to succeed on the merits" and thus cannot defend the entry of a preliminary injunction. *Winter*, 555 U.S. at 20; *see, e.g.*, *Lee*, 140 S. Ct. at 2591 (vacating preliminary injunction because plaintiffs had not "established that they are likely to succeed on the merits"); *Trump*

v. Hawaii, 138 S. Ct. at 2423 ("Because plaintiffs have not shown that they are likely to succeed on the merits of their claims, we reverse the grant of the preliminary injunction as an abuse of discretion."); *Munaf*, 553 U.S. at 690 ("[A] party seeking a preliminary injunction must demonstrate, among other things, a likelihood of success on the merits.") (quotation marks omitted).[4]

D. The Remaining Factors Confirm That The Preliminary Injunction Must Be Vacated

Finally, although the Court need not reach the issue, the "balance of equities" confirms that the preliminary injunction should be vacated. *Winter*, 555 U.S. at 20. "COVID-19 is a highly contagious, dangerous, and—especially for Medicare and Medicaid patients—deadly disease." *Biden v. Missouri*, 142 S. Ct. at 652. Given that the virus "can spread rapidly among healthcare workers and from them to patients, and that such spread is more likely when healthcare workers are unvaccinated," *id.* at 651 (citing 86 Fed. Reg. at 61,558-61, 61,567-68, 61,585-86), the vaccination of healthcare

[4] As explained above, in parallel actions, Texas voluntarily dismissed its complaint in light of the Supreme Court's ruling, and Florida voluntarily dismissed its appeal from the denial of a preliminary injunction. *See supra* pp. 12-13.

workers is "'necessary for the health and safety of individuals to whom care and services are furnished,'" *id.* (quoting 86 Fed. Reg. at 61,561). Unsurprisingly, "healthcare workers and public-health organizations overwhelmingly support the Secretary's rule." *Id.* at 653 (first citing 86 Fed. Reg. at 61,565-66; then citing Brief for American Medical Ass'n et al. as Amici Curiae in Support of Applicants, *Biden v. Missouri*, No. 21A240 (U.S. Dec. 21, 2021); Brief for American Public Health Ass'n et al. as Amici Curiae in Support of Applicants, *Biden v. Missouri*, Nos. 21A240 & 21A241 (U.S. Dec. 23, 2021); and then citing Brief for Secretaries of Health and Human Services et al. as Amici Curiae in Support of Applicants, *Biden v. Missouri*, Nos. 21A240 & 21A241 (Dec. 27, 2021)).

The Secretary reasonably determined that this direct threat to human life and health greatly outweighs the indirect effects if some workers quit rather than receive the vaccine, "including in rural areas." *Biden v. Missouri*, 142 S. Ct. at 654 (citing 86 Fed. Reg. at 61,566, 61,569, 61,607-09). Nor did plaintiffs identify any other irreparable harm that could justify the preliminary injunction. As the Supreme Court has emphasized, the "role of courts" is limited to providing "relief to claimants, in individual or class actions, who have suffered, or will imminently suffer, actual harm." *Lewis*

v. Casey, 518 U.S. 343, 349 (1996). The only claimants before the Court are the ten plaintiff States. They do not speak for healthcare workers, whose representatives strongly support COVID-19 vaccination requirements. *See Biden v. Missouri*, 142 S. Ct. at 653. They cannot bring suit on behalf of private providers or other private parties, because "[a] State does not have standing as parens patriae to bring an action against the Federal Government." *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 610 n.16 (1982). And even with respect to their own state-run facilities, plaintiffs cannot demonstrate irreparable harm, because any sanctions that might be imposed against such facilities for failing to comply with conditions of Medicare or Medicaid participation would be subject to judicial review. *See Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 8-9 (2000) (describing the Medicare statute's special review system).

The balance of equities and public interest are unaltered by the rule's preemption of state laws purporting to restrict vaccine mandates. *Cf.* Add. 24 (citing such state laws); R. Doc. 28, at 24. It is not unusual for federal regulations to preempt state law. *See, e.g., Fidelity Fed. Sav. & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 153 (1982) (noting that "[f[ederal regulations have no less pre-emptive effect than federal statutes"); *Norfolk*

S. Ry. Co. v. Shanklin, 529 U.S. 344, 358 (2000) (holding that regulations addressing "the adequacy of warning devices installed with the participation of federal funds" preempted state law). The federal government has a compelling interest in enforcing the vaccination condition in facilities it pays to care for Medicare and Medicaid patients. The district court correctly recognized that the Secretary "would face irreparable harm *if* it is unable to enforce a *properly authorized* and *enacted* regulation." Add. 31; R. Doc. 28, at 31. And the Supreme Court has since concluded that the challenged rule was properly authorized and enacted.

CONCLUSION

The preliminary injunction should be vacated.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a)(7)(B) because it contains 4,702 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Book Antiqua 14-point font, a proportionally spaced typeface.

Pursuant to Circuit Rule 28A(h)(2), I further certify that the brief has been scanned for viruses, and the brief is virus free.

/s/ Laura E. Myron
Laura E. Myron

CERTIFICATE OF SERVICE

I hereby certify that on January 31, 2022, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Eighth Circuit by using the appellate CM/ECF system. Service will be accomplished by the appellate CM/ECF system.

/s/ Laura E. Myron
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