No. 21-14098

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

STATE OF FLORIDA,

Plaintiff-Appellant,

v.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, et al.,

Defendants-Appellees.

DEFENDANTS-APPELLEES' OPPOSITION TO MOTION FOR INJUNCTION PENDING APPEAL

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rule 26.1-1, counsel for defendants-appellees certify that the following have an interest in the outcome of this appeal:

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Florida v. HHS et al.
Eleventh Circuit Case No. 21-14098

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INTRODUCTION AND SUMMARY OF ARGUMENT

Congress spends hundreds of billions of dollars each year under the Medicare and Medicaid programs to protect the health of Americans. Congress specified that hospitals and other participating facilities must meet requirements set by the Secretary of Health and Human Services (HHS) to ensure the health and safety of patients. In the rule at issue here, the Secretary established a condition of participation requiring covered staff at such participating facilities to be vaccinated against COVID-19, to prevent transmission of the virus to patients. Because cases and deaths are expected to spike in the coming winter months, unvaccinated staff at participating facilities must receive their first vaccine dose by December 6, or request an exemption by that date. The Secretary projected that the rule will save hundreds and potentially thousands of lives every month.

More than 50 leading professional organizations representing health care workers—including the American Medical Association and the American Nurses Association—support COVID-19 vaccination requirements for health care workers. *Joint Statement in Support of COVID-19 Vaccine Mandates for All Workers in Health and Long-Term Care (Joint*

Statement).[1] These organizations emphasized that this step "is the logical fulfillment of 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*. As the Secretary explained, health care workers have long been required by employers to be vaccinated against diseases such as influenza, hepatitis B, and other infectious diseases.

The district court properly denied Florida's motion for a preliminary injunction, *see* Docs. 6, 18, and Florida has failed to establish any of the factors necessary for an injunction pending appeal. Florida failed even to establish district court jurisdiction, and its challenges to the vaccination rule are meritless. The Secretary has explicit statutory authority to require facilities voluntarily participating in Medicare and Medicaid to meet health and safety standards for the protection of patients. Longstanding regulations require these facilities to have infection-control programs that prevent the transmission of communicable disease. Funding conditions of this sort present no constitutional issue. And ample evidence supports the

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

Secretary's determination that the vaccination rule will provide crucial protections for patients in the coming winter months, when COVID-19 cases are expected to spike, and that there was good cause to make the rule effective without delay.

The Secretary comprehensively addressed the only practical concern that Florida identified: the risk that the vaccination requirement will prompt unvaccinated workers to quit in large numbers and exacerbate labor shortages. The Secretary found on the basis of recent empirical evidence that this concern is overstated and outweighed by other effects. The Secretary explained, for example, that after a large hospital system in Texas imposed a COVID-19 vaccine mandate, 99.5% of its 26,000 workers received the vaccine. Likewise, 98% of 33,000 workers complied with a Detroit-based system's vaccine mandate. More than 97% complied with vaccine mandates imposed by a Delaware-based health system with more than 14,000 employees and a North Carolina-based system with more than 35,000 employees. Furthermore, the Secretary found that the potential adverse effect of the vaccination rule in the labor market would be offset by reduced staff absenteeism and dwarfed by the regular churn of employees

in the health care workforce, where about a quarter of a health care facility's staff on average are new hires each year.

In short, Florida's claims are meritless, and the remaining factors overwhelmingly favor the federal government.

STATEMENT

A. The Medicare and Medicaid Programs

Under the Medicare and Medicaid programs, Congress spends hundreds of billions of dollars each year to pay for health care. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019) (noting that Medicare alone spends about $700 billion annually). Medicare, which is funded entirely by the federal government, covers individuals who are over age 65 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 National Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 583, 585 (2012).

The facilities that provide health care to Medicare and Medicaid beneficiaries are entities such as hospitals, skilled nursing facilities (also known as nursing homes or long-term care facilities), home-health agencies, and hospices. If a facility wishes to participate in these programs,

it enters into a provider agreement for the applicable program after demonstrating that it meets the conditions for participation. 42 U.S.C. §§ 1395cc, 1396a(a)(27).

Congress charged the Secretary with responsibility to ensure that facilities participating in these programs 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 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" 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 psychiatric hospitals, *see id.* § 1396d(h); rural health clinics, *id.* § 1396d(*l*)(1), and hospices, *id.* § 1396d(o).

Longstanding regulations establish detailed "Conditions of Participation" for participating facilities that address (among other things),

the qualifications of employees, the condition of the facilities, and other requirements that the Secretary deems necessary to protect patient health and safety. These regulations include the requirement that the facility maintain an effective "infection prevention and control program" to "provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections." *See, e.g.*, 42 C.F.R. § 483.80 (long-term care facilities); *id.* § 482.42(a) (hospitals); *id.* § 416.51(b) (ambulatory surgical centers).

B. The Vaccination Rule For Facilities That Participate In Medicare or Medicaid

The rule at issue here amended the infection-control regulations for facilities that participate in Medicare or Medicaid. To prevent health care workers from infecting patients with the virus that causes COVID-19, the rule requires facilities certified to participate in Medicare or Medicaid to ensure that their staff are fully vaccinated against COVID-19, unless exempt for medical or religious reasons. 86 Fed. Reg. 61,555, 61,561, 61,572 (Nov. 5, 2021).[2] Covered staff must receive the first dose of a two-dose

[2] The rule exempts staff who telework full-time, and vendors and other professionals who perform infrequent, non-healthcare services. 86 Fed. Reg. at 61,571.

vaccine or a single-dose vaccine by December 6, 2021, or otherwise request an exemption by that date. *Id.* at 61,573. Non-exempt covered staff must be fully vaccinated by January 4, 2022. *Id.*

The rule rests on the Secretary's comprehensive analysis and finding that "vaccination of staff is necessary for the health and safety of individuals to whom care and services are furnished." *Id.* at 61,561. While many health care workers are vaccinated against COVID-19, vaccination rates remain too low in many health care 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.*

Unvaccinated staff pose a threat to patients because the virus that causes COVID-19 is highly transmissible and dangerous. *Id.* at 61,556-57. Given the virulence of this virus, it is readily spread among health care workers and from health care workers to patients. *Id.* at 61,557 n.16. In particular, unvaccinated health care workers are highly susceptible to transmitting the virus to their colleagues and patients. *Id.* at 61,558 n.42. And due to many of the factors that qualify them for enrollment (such as age, disability, and/or poverty), Medicare and Medicaid patients are more

likely to face a high risk of developing severe disease and of experiencing severe outcomes from COVID-19 if infected. *Id.* at 61,566, 61,609.

Unvaccinated staff also jeopardize patients' access to needed medical care and services. *Id.* at 61,558. Out of a fear of exposure to the virus, patients are refusing care from unvaccinated staff, thereby limiting the ability of providers to meet the health care needs of their patients. *Id.* Patients also are forgoing medically necessary care altogether to avoid contracting the virus that causes COVID-19 from health care workers. *Id.* Absenteeism among health care staff as a result of infection with the virus has also created staffing shortages that have disrupted patient access to care. *Id.* at 61,559.

The Secretary explained that, in July 2021, more than 50 health care associations—including the American Medical Association and the American Nurses Association—jointly advocated for vaccine mandates for health care workers. *Id.* at 61,565 & n.122. The signatories represent millions of workers throughout the U.S. health care industry, including groups representing doctors, nurses, long-term care workers, home care workers, pharmacists, physician assistants, public health workers, hospice workers, and epidemiologists. *Id.* Due to "the recent COVID-19 surge and

the availability of safe and effective vaccines," these organizations urged that "all health care and long-term care employers require their workers to receive the COVID-19 vaccine." *Joint Statement*. The signatories explained that this step "is the logical fulfillment of 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*.

In issuing the rule, the Secretary acknowledged the concern that the vaccination requirement could prompt some health care workers to leave their jobs rather than be vaccinated, but concluded on the basis of recent empirical evidence that this concern was overstated and outweighed by other effects and countervailing considerations. 86 Fed. Reg. at 61,608. The Secretary explained, for example, that after a large hospital system in Texas imposed a vaccine mandate, 99.5% of its staff received the vaccine. *Id*. at 61,569. Only 153 of its 26,000 workers—that is, only 0.6%—resigned rather than receive the vaccine. *Id*. at 61,566, 61,569.[3] Similarly, a Detroit-based

[3] *See also More than 150 Employees Resign or Are Fired from Houston Hospital System After Refusing to Get Vaccinated*, Tex. Trib. (June 23, 2021), https://perma.cc/F2SA-53D6.

health system that imposed a vaccine mandate reported that 98% of its 33,000 workers were fully or partially vaccinated or in the process of obtaining a religious or medical exemption when the requirement went into effect, with exemptions comprising less than 1% of staff members. *Id*. at 61,569. A long-term care parent corporation established a vaccine mandate for its more than 250 facilities, leading to more than 95% of its workers being vaccinated; again, very few workers quit their jobs rather than be vaccinated. *Id*. A health care system that is the largest private employer in Delaware with more than 14,000 employees, and an integrated health system in North Carolina with more than 35,000 employees, instituted vaccination requirements and achieved vaccination rates of at least 97% among their staffs. *Id*. at 61,566. And when New York enacted a state-wide vaccine mandate for health care workers, it recorded a jump in vaccine compliance in the final days before the requirements took effect on October 1, 2021. *Id*. at 61,569.

Furthermore, the Secretary concluded that the potential adverse effect in the health care labor market would be offset by reduced absenteeism from lowered rates of infection, quarantine, and illness among staff, as well as a return to work of employees who have stayed out of the

workforce for fear of contracting the virus that causes COVID-19. *Id*. at 61,608. More generally, the Secretary explained that about a quarter of a health care facility's staff on average are new hires each year, and that this regular churn in the health care workforce would dwarf the effect of workers leaving for other employment as a result of the vaccination requirement. *Id.*

Based on his comprehensive analysis, the Secretary determined that "the available evidence for ongoing healthcare-associated COVID-19 transmission risk is sufficiently alarming in and of itself to compel [the agency] to take action," i*d*. at 61,558, and that the rule should be made effective without delay, *id*. at 61,583-85. The Secretary explained 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 have already been over half a million COVID-19 cases among health care 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 coming winter months, *id*. at 61,584; and that this spike will coincide with flu season, raising the additional danger of combined infections, *id*. The Secretary

predicted that the rule will save hundreds and potentially thousands of lives every month, and that "a further delay in imposing a vaccine mandate would endanger the health and safety of additional patients and be contrary to the public interest." *Id*. at 61,584.

ARGUMENT

To obtain the "extraordinary remedy" of an injunction pending appeal, a plaintiff must show (1) "a substantial likelihood that they will prevail on the merits of the appeal"; (2) "a substantial risk of irreparable injury . . . unless the injunction is granted"; (3) "no substantial harm to other interested persons"; and (4) "no harm to the public interest." *Touchston v. McDermott*, 234 F.3d 1130, 1132 (11th Cir. 2000) (en banc). "Failure to show any of the four factors is fatal." *United States v. Alabama*, 443 F. App'x 411, 419 (11th Cir. 2011) (unpub.) (quoting *American Civil Liberties Union of Fla., Inc. v. Miami-Dade Cty. Sch. Bd.*, 557 F.3d 1177, 1198 (11th Cir. 2009)). None of these factors supports Florida here.

A. Florida Failed to Establish District Court Jurisdiction.

Florida asked the district court to enjoin enforcement of the vaccination rule against facilities within Florida that participate in

Medicare or Medicaid. Such an injunction would have exceeded the district court's jurisdiction.

First, Florida lacks standing to sue the federal government on behalf of *privately-run* facilities or their health care workers. As the district court explained, a State cannot sue *parens patriae* "to shield employees who choose to work in a federally funded healthcare facility from the rules that govern administration of the federal program." Doc. 18, p. 7 (citing *Commonwealth of Mass. v. Mellon*, 262 U.S. 447, 485-86 (1923) ("It cannot be conceded that a state, as *parens patriae*, may institute judicial proceedings to protect citizens of the United States from the operation of the statutes thereof."); *Virginia ex rel. Cuccinelli v. Sebelius*, 656 F.3d 253, 271 (4th Cir. 2011) ("To permit a state to litigate whenever it enacts a statute declaring its opposition to federal law . . . would convert the federal judiciary into a forum for the vindication of a state's generalized grievances about the conduct of government.")).

Second, Florida's *state-run* facilities must follow the jurisdictional requirements of the Medicare statute which, as the Supreme Court explained in *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000), preclude pre-enforcement challenges to conditions of Medicare

participation. Such challenges may proceed only through the special review system that the Medicare statute provides.[4] Just as the trade association in *Illinois Council* could not circumvent that bar by bringing a pre-enforcement action on behalf of its members, neither can Florida do so on behalf of its state-run facilities.

B. Florida's Challenges to the Vaccination Rule Are Meritless.

The district court correctly concluded that Florida is unlikely to succeed on the merits. Doc. 18. The contrary rulings in *State of Louisiana v. Becerra*, No. 3:21-cv-03970 (W.D. La. Nov. 30, 2021), and *State of Missouri v. Biden*, No. 4:21-cv-01329 (E.D. Mo. Nov. 29, 2021), are incorrect and should not be followed here.

1. *The vaccination rule is within the Secretary's statutory authority and presents no constitutional issue.*

The Secretary has express statutory authority to require facilities participating in Medicare or Medicaid to adhere to standards that protect the health and safety of patients. For example, the Medicare statute

[4] Likewise, if a facility violates a rule that applies to both Medicare and Medicaid, the facility must seek review of the determination through the Medicare administrative appeals procedure. *In re Bayou Shores SNF, LLC*, 828 F.3d 1297, 1330 (11th Cir. 2016).

authorizes payments for "hospital services," 42 U.S.C. § 1395d(a), and defines a "hospital" as an institution that meets 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 supra*, p. 5 (similar provisions for other types of facilities). Requiring health care workers to become vaccinated against a highly transmissible and deadly disease is a straightforward example of a "requirement[]" that is "necessary in the interest of the health and safety" of the patients that medical facilities exist to serve.

Moreover, Congress vested the Secretary with authority to issue such regulations "as may be necessary to the efficient administration of the functions with which" he is charged under the Social Security Act, which include the Medicare and Medicaid programs. 42 U.S.C. § 1302(a). The Supreme Court has emphasized that § 1302(a) and similarly worded delegations confer "broad rule-making powers." *Thorpe v. Housing Auth. of City of Durham*, 393 U.S. 268, 277 n.28 (1969). "Where the empowering provision of a statute states simply that the agency may 'make . . . such rules and regulations as may be necessary to carry out the provisions of this Act,'" "the validity of a regulation promulgated thereunder will be

sustained so long as it is 'reasonably related to the purposes of the enabling legislation.'" *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356, 369 (1973) (quoting *Thorpe*, 393 U.S. at 280-81).

Contrary to the *Louisiana* court's premise, the CMS vaccination rule does not present an issue of "vast economic and political significance" or "radically readjust the balance of state and national authority." Op. 20, 29, *State of Louisiana v. Becerra*, No. 3:21-cv-03970 (W.D. La. Nov. 30, 2021) (*Louisiana* Op.). Congress spends hundreds of billions of dollars annually to pay for health care at facilities that participate in Medicare and Medicaid. "Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare" and "to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare." *Sabri v. United States*, 541 U.S. 600, 605 (2004). This power applies regardless of whether Congress legislates "in an area historically of state concern." *Id.* at 608 n.*.

The vaccination rule is a condition on federal funding for health care facilities. It does not intrude on state police powers or control the practice of medicine, 42 U.S.C. § 1395, any more than do the longstanding, unchallenged regulations requiring such providers to prevent the spread of

infection within their facilities. *See, e.g.*, 42 C.F.R. §§ 416.51(b), 482.42(a), 483.80. As the district court explained, Florida's contrary assertion "misconstrues the nature of the vaccination mandate" at issue here. Doc. 18, p. 15.

Nor does the vaccination rule violate the "liberty interests" of health care workers. *Louisiana* Op. 32. As the district court here noted, Doc. 18, p. 6, the Supreme Court has rejected the contention that there is an individual right to refuse vaccination for communicable disease, *see Jacobson v. Massachusetts*, 197 U.S. 11 (1905), and the Supreme Court recently refused to enjoin pending appeal Maine's COVID-19 vaccination mandate for health care workers, *see Does 1-3 v. Mills*, -- S. Ct. --, 2021 WL 5027177 (U.S. Oct. 29, 2021); *see also Klaassen v. Trustees of Indiana Univ.*, 7 F.4th 592, 593 (7th Cir. 2021) (Easterbrook, J.) (noting that vaccination requirements that are conditions of participation pose even less of a concern). Health care workers have no right to endanger their patients. As the leading organizations representing health care workers have explained, the requirement that such workers be vaccinated for COVID -19 "is the logical fulfillment of 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." *Joint Statement*. The "ethical duty of receiving vaccinations is not new, as staff have long been required by employers to be vaccinated against certain diseases, such as influenza, hepatitis B, and other infectious diseases." 86 Fed. Reg. at 61,569.

2. Ample evidence supports the Secretary's determination that the vaccination rule will provide crucial protections for patients.

There is likewise no merit to plaintiffs' contention that the vaccination rule is arbitrary and capricious. Ample evidence supports the Secretary's determination that staff vaccination at facilities participating in Medicare and Medicaid will provide important protections for patients. *See* Doc. 18, pp. 11-14.

More than 50 health care associations—including the American Medical Association and the American Nurses Association—jointly urged that "all health care and long-term care employers require their workers to receive the COVID-19 vaccine." *Joint Statement*. The signatories represent millions of workers throughout the U.S. health care industry, including groups representing doctors, nurses, long-term care workers, home care workers, pharmacists, physician assistants, public health workers, hospice

workers, and epidemiologists. 86 Fed. Reg. at 61,565 & n.122. For example, the American Nurses Association—which "represent[s] the interests of the nation's 4.2 million registered nurses"—"supports health care employers mandating nurses and all health care personnel to get vaccinated against COVID-19 in alignment with current recommendations for immunization by public health officials." *ANA Supports Mandated COVID-19 Vaccinations for Nurses and All Health Care Professionals* (July 26, 2021).[5]

The district courts in *Louisiana* and *Missouri* erred by substituting their views on epidemiology for the judgment of public health experts. The *Louisiana* court's discussion of "natural immunity" is illustrative. That court opined that health care workers previously infected with the virus that causes COVID-19 should be allowed to rely on "natural immunity," instead of vaccination, to prevent transmission of the virus to patients. *Louisiana* Op. 25-26. The Secretary relied on studies showing that infection-induced immunity is not equivalent to receiving vaccination for COVID-19, 86 Fed. Reg. at 61,559, and that even among those persons with prior infections, vaccination provides strong protection against reinfection, *id*. at

[5] https://perma.cc/MS5A-4WTU.

61,585 n.205. The Secretary accordingly followed the recommendations of the Centers for Disease Control & Prevention (CDC), which has found that the best academic evidence supports vaccination regardless of infection history. *Id*. at 61,560 & n.70.

3. Ample evidence supports the Secretary's determination that the rule's benefits for patients exceed the risks of causing labor shortages.

The Secretary specifically addressed the practical concern that Florida emphasizes: the risk that the vaccination requirement will prompt significant numbers of health care workers to quit rather than receive the vaccine and will exacerbate labor shortages. The Secretary found based on recent empirical data that any adverse impact on the labor market is likely to be small, offset by countervailing effects, and dwarfed by the regular churn in the health care workforce.

For example, after the Houston Methodist Hospital system imposed a COVID-19 vaccine mandate, only 153 of its more than 26,000 workers—that is, only 0.6%—resigned rather than receive the vaccine. *See supra*, pp. 9-10. Widespread compliance with vaccine mandates likewise occurred at a North Carolina-based health system with more than 35,000 employees, a Detroit-based health system with more than 33,000 employees, a Delaware-

based health system with more than 14,000 employees, and a long-term care corporation with more than 250 facilities. 86 Fed. Reg. at 61,566, 61,569. For example, at the North Carolina-based Novant 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.[6] Moreover, as the American Hospital Association emphasized, the vaccination rule at issue here "provides a level playing field across healthcare facilities," which further reduces the likelihood that health care workers will leave their jobs for other employment. *AHA Statement on CMS and OSHA Vaccine Mandate Rules* (explaining that the American Hospital Association "has been supportive of hospitals that call for mandated vaccination of health care workers in order to better protect patients and the communities we serve").[7]

Furthermore, the Secretary found that any adverse effect on the labor market caused by the rule would be offset by a reduction in COVID-19-induced staff absenteeism. 86 Fed. Reg. at 61,608. And more generally, such effects would be dwarfed by the ordinary churn in the market for

[6] *See* Novant Health, *About Us*, https://perma.cc/K4PH-EE66.
[7] https://perma.cc/H6D9-XEQK.

labor in the health care industry. In any given year, it is typical for about 2.66 million employees in health care settings to be new hires, out of a total workforce of 10.4 million employees. *Id*. Florida provided no basis to reject these findings.

4. Ample evidence supports the Secretary's determination that the vaccination rule should be established without delay.

There is likewise no basis to reject the Secretary's determination that there was good cause to make the vaccination rule effective immediately. *See* 86 Fed. Reg. at 61,583-85. The procedural statute on which Florida relies, 42 U.S.C. § 1395z, generally instructs the Secretary to consult with "appropriate State agencies" but does not require that such consultations occur in advance—particularly not in advance of an urgent, interim action like the rule here. *See* Doc. 18, p. 10 (citing 86 Fed. Reg. at 61,567). And the Secretary detailed why the rule's protections should be put in place before an anticipated surge in COVID-19 cases in the coming winter months. The Secretary explained 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 have already been more than half a million COVID-19 cases among health care staff, *id*.

at 61,585; that rates among staff have grown since the Delta variant's emergence, *id*.; that COVID-19 cases are expected to spike during the coming winter months, *id*. at 61,584, and that this spike will coincide with flu season, raising the additional danger of combined infections, *id*.

The Secretary determined that "a further delay in imposing a vaccine mandate would endanger the health and safety of additional patients and be contrary to the public interest." *Id*. The Secretary predicted that the rule will save hundreds and potentially thousands of lives every month, *id*. at 61,612, which is ample cause to proceed without advance notice and comment. *See Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014) ("[W]e have approved an agency's decision to bypass notice and comment where delay would imminently threaten life."). Florida's suggestion that the Secretary should have acted sooner, Mot. 12, would not, even if true, be reason to block a rule that will prevent many patient deaths in the coming months, *see* Doc. 18, p. 13.

C. The Balance of Equities and Public Interest Preclude an Injunction Pending Appeal.

The balance of equities and public interest overwhelmingly favor the federal government. If the rule is not implemented before the anticipated

COVID-19 surge, hundreds and potentially thousands of patients at hospitals, nursing homes, and other facilities participating in Medicare and Medicaid may die as the result of COVID-19 infections transmitted to them by staff.

That threat to human life and health far exceeds the potential indirect harms to patients resulting from workers who may quit rather than receive the vaccine. For the reasons already discussed, Florida provides no basis to reject the consensus of leading health care organizations and the judgment of the Secretary that the benefits of requiring health care workers to be vaccinated far outweigh any countervailing concerns. Indeed, Florida cannot speak for *privately-run* facilities or their workers, whose representatives have publicly supported vaccination requirements.

Moreover, as the district court explained, Florida's declarations did not demonstrate irreparable harm even as to *state-run* facilities. For example, one declaration states that Florida operates six psychiatric residential treatment facilities that employ more than 3,000 workers. Doc. 2-2 at 3. It further states: "As some employees will refuse the vaccination," the rule will amplify staffing shortages. *Id*. at 4. This statement is vague

and conclusory and, like Florida's other declarations, it fails to take into account the rule's exemptions.

The empirical evidence before the Secretary showed that the percentage of health care workers who actually resigned is very low even when health care employers have imposed such a mandate. Furthermore, as the American Hospital Association emphasized, the CMS vaccination rule "provides a level playing field across healthcare facilities," which further reduces the likelihood that health care workers will leave their jobs for other employment. American Hosp. Ass'n, *AHA Statement on CMS and OSHA Vaccine Mandate Rules* (Nov. 4, 2021)[8] (explaining that the American Hospital Association "has been supportive of hospitals that call for mandated vaccination of health care workers in order to better protect patients and the communities we serve").

Florida's alternative argument—that its state-run facilities will lose Medicare and Medicaid funding or face enforcement action if they do not comply with the vaccination rule, *e.g.*, Doc. 2-5, p. 3—is likewise no basis to enjoin the rule's enforcement against these facilities or anyone else. Under

[8] https://perma.cc/J2A8-S8NP.

Illinois Council, the exclusive means to challenge such sanctions is through the Medicare statute's special review system, which does not allow district courts to entertain pre-enforcement actions. Moreover, facilities face no imminent threat of enforcement action, and any sanctions that might eventually be imposed would not be irreparable because they are reviewable in court.

The balance of equities and public interest are unaltered by state laws purporting to restrict vaccine mandates. Even assuming that a sovereign's abstract interest in enforcing its law is a cognizable Article III interest, the federal government has a sovereign interest in enforcing the vaccination rule at issue here. Thus, the balance of equities and public interest do not depend on abstract notions of sovereignty, but on the real world impact of the CMS vaccination rule. And as already explained, the protections that the rule provides for the health and safety of patients vastly outweigh any countervailing concerns.

D. Any Relief Must Be Limited to Those State-Run Facilities in Florida that Established Irreparable Injury.

Assuming *arguendo* that any relief is appropriate, it must be limited to those state-run facilities in Florida that demonstrated irreparable injury.

The Supreme Court has emphasized that a "remedy must be tailored to redress the plaintiff's particular injury," *Gill v. Whitford*, 138 S. Ct. 1916, 1934 (2018), and "injunctive relief should be no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs," *Madsen v. Women's Health Ctr., Inc.*, 512 U.S. 753, 765 (1994). Here, as already explained, Florida cannot speak for privately-run facilities or their workers, whose leading professional associations strongly support vaccination requirements for staff. A "showing of irreparable injury is the *sine qua non* of injunctive relief." *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc). Thus, any injunctive relief would have to be narrowly tailored to those state-run facilities in Florida that demonstrated imminent irreparable harm.

CONCLUSION

Plaintiff's motion for an injunction pending appeal should be denied.

Respectfully submitted,

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December 2021

CERTIFICATE OF COMPLIANCE

This opposition complies with the type-volume limit of Federal Rule of Appellate Procedure 27(d)(2)(A) because it contains 5,197 words. This opposition 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.

s/ Laura E. Myron
Laura E. Myron

CERTIFICATE OF SERVICE

I hereby certify that on December 3, 2021, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Eleventh Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Laura E. Myron
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