Nos. 21A240 & 21A241

IN THE SUPREME COURT OF THE UNITED STATES

JOSEPH R. BIDEN, JR., PRESIDENT OF THE UNITED STATES, ET AL., APPLICANTS

v.

STATE OF MISSOURI, ET AL.

XAVIER BECERRA, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL., APPLICANTS

v.

STATE OF LOUISIANA, ET AL.

REPLY IN SUPPORT OF APPLICATIONS FOR STAYS OF THE INJUNCTIONS ISSUED BY THE UNITED STATES DISTRICT COURTS FOR THE EASTERN DISTRICT OF MISSOURI AND WESTERN DISTRICT OF LOUISIANA PENDING APPEALS TO THE UNITED STATES COURTS OF APPEALS FOR THE EIGHTH AND FIFTH CIRCUITS AND FURTHER PROCEEDINGS IN THIS COURT

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Hospitals, nursing homes, and other healthcare providers that choose to participate in Medicare and Medicaid have long been subject to detailed conditions adopted by the Secretary of Health and Human Services (HHS) -- including rules issued under the Secretary's express statutory authority to protect the health and

safety of Medicare and Medicaid patients. In response to an unprecedented pandemic, the Secretary adopted an additional health and safety condition requiring covered facilities to ensure that their staff are vaccinated against COVID-19 (subject to medical and religious exemptions). Such vaccine requirements had already been adopted by many healthcare providers and public-health agencies around the country and are overwhelmingly supported by the medical community. And the Secretary determined that vaccination of healthcare staff is the most effective way to prevent the transmission of a highly communicable and dangerous virus to patients who are especially vulnerable to its deadly effects.

As the Eleventh Circuit concluded in a comprehensive published opinion, respondents' various challenges to the rule are unlikely to succeed. Most importantly, the rule falls squarely within the Secretary's statutory authority. Respondents scarcely dispute that requiring facilities to ensure that staff are vaccinated against COVID-19 qualifies as a measure to protect patients' "health and safety" within the plain meaning of those terms. 42 U.S.C. 1395x(e)(9); see pp. 5-6, infra (additional statutes conferring authority). Instead, respondents ask this Court to depart from ordinary principles of statutory interpretation by demanding a clear statement specifically authorizing a vaccination requirement. That approach has no foundation in this Court's precedents. This is not a case where an agency is acting outside its expertise or regulating in an area Congress has not

authorized. Nor do these cases involve any federal intrusion into matters reserved to the States. Instead, a federal healthcare agency adopted a familiar health and safety requirement to protect patients in the federal healthcare programs the agency administers, pursuant to express statutory authority to do just that.

The equities overwhelmingly support stays pending appeal. The ongoing COVID-19 surge has driven case rates to new highs -- up more than fourfold since the Secretary issued the rule in early November and nearly threefold since the government filed its applications just over two weeks ago. See Centers for Disease Control and Prevention (CDC), COVID Data Tracker, https://go.usa.gov/xeFyx. The rule has never been more necessary than it is now, as the virtually unanimous support of healthcare organizations demonstrates. Absent stays, the preliminary injunctions will likely result in hundreds or thousands of deaths and serious illnesses from COVID-19 that could otherwise be prevented. Respondents' speculative assertions about the rule's effect on staffing pale in comparison to the overwhelming public interest in saving lives and preventing serious illness. Stays pending appeal are both wholly warranted and urgently needed.

I. This Court Would Likely Grant Review If Either Court Of Appeals Affirmed One Of The Preliminary Injunctions

This Court would likely grant review if a court of appeals upheld one of the preliminary injunctions. Respondents do not seriously dispute that the validity of the rule is a question of

exceptional national importance. Cf. Missouri Opp. 9 & n.7; Louisiana Opp. 39. Nor do they deny that the Fifth and Eighth Circuits' orders denying stays directly conflict with a published decision of the Eleventh Circuit holding that "the Secretary was authorized to promulgate the interim rule." Florida v. HHS, 19 F.4th 1271, 1287 (2021). And a rule to protect patients in the nationwide Medicare and Medicaid programs in response to an ongoing public health emergency is in effect in only half the States. That is a paradigmatic basis for review.[1]

II. The Government Is Likely To Succeed On The Merits

The rule is squarely within the Secretary's express statutory authority, constitutionally sound, thoroughly explained, and procedurally valid.

A. The Rule Falls Within The Agency's Statutory Authority

Respondents' central argument (Missouri Opp. 10-24; Louisiana Opp. 14-16, 22-26) is that requiring facilities that accept federal Medicare and Medicaid funds to ensure their staff are vaccinated against COVID-19 exceeds the Secretary's statutory authority. They are mistaken.

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[1] The Louisiana respondents note (Opp. 39) that Florida has tried to renew its request for an injunction pending appeal before the en banc Eleventh Circuit. But that court has neither called for a response nor taken any other action on Florida's request in the more than two weeks since it was filed.

1. The rule is authorized by the plain text of the relevant statutes

a. The rule invokes the Secretary's statutory authority to make "rules and regulations * * * as may be necessary to the efficient administration of the functions with which [he] is charged under" the Medicare and Medicaid programs. 42 U.S.C. 1302(a); see 42 U.S.C. 1395hh(a)(1). But respondents err in implying (e.g., Louisiana Opp. 24) that the rule rests exclusively -- or even primarily -- on that general authority. To the contrary, the Secretary also invoked additional authorities specifically applicable to each category of facility covered by the rule. 86 Fed. Reg. 61,555, 61,567 (Nov. 5, 2021); see ibid. (table setting forth statutes); id. at 61,575-61,583 (detailed discussion). And the statutory provisions applicable to the vast majority of those facilities expressly authorize the Secretary to impose requirements to protect the "health" and "safety" of patients.

The provision governing hospitals, for example, provides authority to impose "requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution." 42 U.S.C. 1395x(e)(9) (emphasis added); see 42 U.S.C. 1395i-3(d)(4)(B), 1396r(d)(4)(B) (analogous authority for long-term care facilities); 42 U.S.C. 1395k(a)(2)(F)(i), 1395l(i)(1)(A) (ambulatory surgery centers); 42 U.S.C. 1395x(dd)(2)(G) (hospices); 42 U.S.C. 1395x(o)(6) (home health agencies); 42 U.S.C. 1395x(ff)(3)(B) (community mental

health centers); 42 U.S.C. 1395eee(f)(4) (programs of all-inclusive care for the elderly); 42 U.S.C. 1395x(cc)(2)(J) (comprehensive outpatient rehabilitation facilities); 42 U.S.C. 1395x(p)(4)(A)(v) (providers of certain outpatient therapies); 42 U.S.C. 1395x(aa)(2)(k) (rural health clinics). For some of those facilities, Congress conferred on the Secretary not only the authority to impose health and safety requirements, but a "duty and responsibility" to do so. 42 U.S.C. 1395i-3(f)(1) (long-term care facilities); see 42 U.S.C. 1395bbb(b) (home health agencies).

The rule's vaccination "requirement[]" protects "the health and safety of" patients within the plain meaning of those statutes. 42 U.S.C. 1395x(e)(9). Most immediately -- and most importantly -- requiring facilities to ensure that healthcare workers are vaccinated against COVID-19 substantially reduces the likelihood that those workers will contract the virus and transmit it to patients. 86 Fed. Reg. at 61,558; see ibid. (citing study finding that vaccination was "80 percent effective in preventing * * * infection among frontline workers"). That protection is especially important for Medicare and Medicaid beneficiaries, who are disproportionately vulnerable to severe negative outcomes from COVID-19. Id. at 61,566, 61,568. And it is particularly necessary in healthcare facilities, where close contact is inevitable and physical distancing is often impossible, id. at 61,577 -- and where patients typically have no practical ability to avoid exposure to unvaccinated staff members. Requiring facilities to ensure staff

vaccination also protects patient health and safety by eliminating a basis for patients to defer other medical care to avoid exposure to unvaccinated staff. Id. at 61,558. And it reduces staff infections and the resulting "absenteeism due to COVID-19-related exposures or illness," which can "create staffing shortages that disrupt patient access to recommended care." Id. at 61,559.

Those direct and vital protections for patient health and safety explain the nearly universal support for the rule expressed by medical and public-health organizations in the joint statement relied upon by the Secretary, 86 Fed. Reg. at 61,565, and the multiple amicus briefs filed in support of the government's applications from a variety of perspectives, see American Medical Ass'n (AMA) Amici Br. (more than a dozen associations representing medical professionals and patients); American Public Health Ass'n (APHA) Amici Br. (wide range of public-health scholars and deans); Former Federal Health Officials Amici Br. (leaders of HHS and the Centers for Medicare & Medicaid Services during the Clinton, George W. Bush, and Obama Administrations); Service Employees Int'l Union (SEIU) Amici Br. (labor representatives of hundreds of thousands of healthcare workers).

b. Respondents offer no reason to doubt that requiring facilities to ensure that healthcare workers are vaccinated against COVID-19 advances patient "health" and "safety" within the plain meaning of the relevant statutes. The Missouri respondents contend (Opp. 14-18) that the statutory requirement that a hospital comply

with "such other requirements as the Secretary finds necessary in the interest of [patient] health and safety," 42 U.S.C. 1395x(e)(9), must be construed in light of the other requirements in Section 1395x(e). And they assert (Opp. 17) that the rule "is materially unlike the requirements listed in the preceding eight provisions" of that statute because those provisions "impose structural requirements on hospitals themselves" not on "hospital staff." But the rule likewise operates on the hospital, not its staff: "The hospital must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19." 42 C.F.R. 482.42(g) (emphasis added). And to the extent respondents mean that the rule requires hospitals to ensure that their staff meet a specified standard or take specified actions, that does not distinguish it from many other requirements imposed by and under the authority of Section 1395x(e).[2]

c. Respondents also observe (e.g., Missouri Opp. 13 & n.8) that a few of the facility-specific statutes the Secretary invoked -- which apply to less than three percent of all workers covered

[2] See, e.g., 42 U.S.C. 1395x(e)(1) (requiring that care be provided "by or under the supervision of physicians," who are defined in Section 1395x(r) as doctors meeting specified licensing and other requirements); 42 U.S.C. 1395x(e)(5) (requiring hospitals to have "a licensed practical nurse or registered professional nurse on duty at all times"); 42 C.F.R. 482.15(d)(1)(i) (requiring hospitals to provide "training in emergency preparedness policies and procedures to all new and existing staff"); 42 C.F.R. 482.42(c)(2)(iv) (requiring training of "hospital personnel and staff" on "infection prevention and control guidelines, policies, and procedures").

by the rule -- do not expressly refer to health and safety.[3] But the statutes respondents cite (ibid.) include broadly worded delegations of authority for the Secretary to set, e.g., "standards" or "requirements" for the facilities' participation in Medicare or Medicaid. See 42 U.S.C. 1396d(h)(1) (authority to set "standards" for psychiatric residential treatment facilities); 42 U.S.C. 1396d(d)(1) (authority to set "standards" for intermediate care facilities for individuals with intellectual disabilities (ICFs-IID)); 42 U.S.C. 1395rr(b)(1)(A) (authority to set "requirements" for end-stage renal disease (ESRD) facilities); 42 U.S.C. 1395x(iii)(3)(D)(i)(IV) (authority to set "requirements" for home infusion therapy suppliers).

Because, as shown above, the Secretary's authority to set health and safety requirements includes authority to require vaccination of staff at covered Medicare and Medicaid facilities, the broadly worded authorities conferred by the statutes that respondents cite do as well. Indeed, the Secretary has long exercised the authorities in those statutes to impose health and safety requirements for the covered facilities generally -- and, in some

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[3] Respondents point to four categories of facilities covered by statutes that do not include express health and safety language: (1) psychiatric residential treatment facilities, which have an estimated total of 30,000 staff; (2) intermediate care facilities for individuals with intellectual disabilities, which have an estimated total of 80,000 staff; (3) end-stage renal disease facilities, which have an estimated total of 170,000 staff; and (4) home infusion therapy suppliers, which have an estimated total of 20,000 staff. 86 Fed. Reg. at 61,603.

cases, infection-control requirements in particular. See, e.g., 42 C.F.R. 483.470(l)(1) (infection-control requirements for ICFs-IID); 42 C.F.R. 494.30 (same for ESRD facilities). The requirement at issue here falls comfortably within those same authorities.[4]

2. Respondents offer no basis to depart from the plain meaning of the statutory text

Because the requirement that Medicare and Medicaid facilities ensure that their staff are vaccinated against a highly transmissible and deadly virus is so readily understood as an exercise of the "health and safety" and other statutory authorities conferred on the Secretary, respondents repeatedly return to the assertion that the Court should impose on Congress a heightened-specificity requirement demanding an express reference to vaccination. There is no basis for that departure from the text.

a. Respondents principally rely (Missouri Opp. 22-23; Louisiana Opp. 22-23) on what they call the "major-questions doctrine." But this case lacks the hallmarks of the decisions respondents invoke, all of which grounded their analysis in the text, structure, and context of the relevant statutes. Here, HHS is not asserting regulatory power that is "markedly different" from the type of authority that Congress expressly identified in the relevant provision, Alabama Ass'n of Realtors v. HHS, 141 S. Ct. 2485,

[4] Even if it did not, that would at most justify an injunction against enforcement of the few portions of the rule that rest on statutes without express health and safety language. See 86 Fed. Reg. at 61,560 ("To the extent a court may enjoin any part of the rule, the Department intends that other provisions or parts of provisions should remain in effect.").

2488 (2021) (per curiam); or trying to regulate in an area Congress has affirmatively rendered off-limits in more specific legislation directly addressing the issue, cf. FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 143 (2000); or claiming authority that would "render the statute 'unrecognizable to the Congress that designed' it," Utility Air Regulatory Grp. v. EPA, 573 U.S. 302, 324 (2014) (citation omitted); see id. at 321, 324 (observing that under EPA's interpretation, "annual permit applications would jump from about 800 to nearly 82,000," causing "construction projects to grind to a halt nationwide"). Nor is this a case where an agency responsible for public health has attempted to regulate "the landlord-tenant relationship," Alabama Ass'n, 141 S. Ct. at 2489, or a tax agency has made "health insurance policy," King v. Burwell, 576 U.S. 473, 486 (2015). Instead, the federal agency primarily responsible for health care is setting health and safety requirements for facilities participating in federally funded healthcare programs, pursuant to an express statutory authorization to do just that.

The Secretary's exercise of that authority to require Medicare and Medicaid facilities to ensure their workers are vaccinated in no way renders the relevant statutes "unrecognizable." Utility Air, 573 U.S. at 324 (citation omitted). To the contrary, Congress authorized the Secretary to adopt health and safety requirements he finds necessary precisely because it understood that it could not foresee and "include in the legislation" all requirements that

might prove necessary to protect patients from hazards like "contagion." H.R. Rep. No. 213, 89th Cong., 1st Sess. 25-26 (1965). Nor is there anything "breathtaking," Alabama Ass'n, 141 S. Ct. at 2489, or "extravagant," Utility Air, 573 U.S. at 324, about the Secretary's determination that requiring Medicare- and Medicaid-funded facilities to adopt the measure most likely to prevent transmission of a potentially deadly virus to vulnerable patients is necessary for those patients' health and safety.

Respondents rely heavily on the asserted "economic and political significance" of the rule. Louisiana Opp. 22 & n.6 (citations omitted); see Missouri Opp. 1, 20. But this Court regularly decides challenges to agency actions of major economic and political significance under the usual rules of statutory interpretation, without imposing heightened-specificity requirements. See, e.g., Collins v. Yellen, 141 S. Ct. 1761, 1776 (2021); Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2380-2381 (2020); Department of Commerce v. New York, 139 S. Ct. 2551, 2571-2572 (2019); cf. Trump v. Hawaii, 138 S. Ct. 2392, 2408 (2018). Likewise, although the scope of the Medicare program inevitably means that the Secretary's determinations may involve billions of dollars, see Azar v. Allina Health Servs., 139 S. Ct. 1804, 1808 (2019), this Court has never treated that as a reason to demand a specific authorization in a Medicare case. Respondents thus err in presuming that the mere fact that a rule

could be called "economically and politically significant" requires Congress to have specifically referred to the precise regulatory measures in the statute authorizing the agency action.

Respondents also emphasize (e.g., Missouri Opp. 21) that HHS has not previously exercised the statutory authorities at issue here to condition funding on policies requiring vaccination. But HHS has never before faced a situation like this one: a pandemic driven by an infectious disease that poses especially lethal threats to patients at healthcare facilities, that can be prevented through widely available and highly effective vaccines, and for which near-universal vaccination has not already been achieved through other means (such as the ubiquitous vaccination requirements imposed by schools). 86 Fed. Reg. at 61,567-61,569. In the context of that unprecedented threat to patient health and safety, a vaccination requirement is simply a specific, urgently needed application of HHS's longstanding requirements that facilities take active measures to prevent the spread of "infections and communicable diseases." 51 Fed. Reg. 22,010, 22,027 (June 17, 1986); see, e.g., 42 C.F.R. 482.42 (current infection-control requirements for hospitals); 42 C.F.R. 483.80 (long-term care facilities); 42 C.F.R. 484.70(b) (home health agencies); 42 C.F.R. 416.51 (outpatient surgery centers); 42 C.F.R. 418.60 (hospices); 42 C.F.R. 494.30 (ESRD facilities).

Vaccination requirements are, moreover, familiar measures that have long been common in a variety of contexts. See Missouri

Appl. 22-23. "Healthcare facilities across the country" require workers to be vaccinated for other infectious diseases, including hepatitis B, influenza, and measles, mumps, and rubella. CDC, State Healthcare Worker and Patient Vaccination Laws (Feb. 28, 2018), https://go.usa.gov/xtxxT; see 86 Fed. Reg. at 61,567-61,568; Florida, 19 F.4th at 1288. Those common requirements to prevent the spread of dangerous infectious disease in healthcare settings reflect the "ethical duty" of healthcare workers "to protect those they encounter in their professional capacity," 86 Fed. Reg. at 61,569 -- a modern fulfillment of the ancient admonition that a healer should first do no harm. The vaccination requirement here rests on those deep foundations and thus is in no way "unprecedented" as a health and safety measure. Alabama Ass'n, 141 S. Ct. at 2489.

It is instead respondents who seek an unprecedented result here -- a holding that, even though the text of the relevant statutory authorities clearly covers the health and safety requirement at issue, some heightened measure of specificity is required simply because the rule has engendered some undefined measure of political disagreement. Agencies are not permitted "to act unlawfully even in pursuit of desirable ends," Alabama Ass'n, 141 S. Ct. at 2490, but neither are they disabled from acting lawfully simply because some find the ends undesirable. To rely on such "extratextual sources" would "risk amending statutes outside the legislative process reserved for the people's representatives,"

thereby undermining, not furthering, separation-of-powers principles. Bostock v. Clayton County, 140 S. Ct. 1731, 1738 (2020); accord id. at 1824 (Kavanaugh, J., dissenting).

b. Respondents also rely on the proposition that extra statutory clarity is required when an agency seeks to "significantly alter the balance between federal and state power." Louisiana Opp. 22 (citation omitted); see Missouri Opp. 20-21, 23-24. That argument is misplaced. The rule is a condition on facilities participating in federal spending programs, and States have no power to set conditions on federal activities. See, e.g., McCulloch v. Maryland, 17 U.S. (4 Wheat.) 316, 436 (1819). The rule accordingly does not alter or override the "constitutional balance of federal and state powers." Missouri Opp. 20 (citation omitted).

Respondents observe (e.g., Missouri Opp. 24) that this Court has held that the federal government's spending power does not allow it to coerce States into adopting regulatory policies or to impose conditions on States' acceptance of federal funds without clear notice. But those constitutional limitations (which, as discussed below, are in no way exceeded here) do not imbue the States with any power over federal spending programs. See, e.g., Sabri v. United States, 541 U.S. 600, 608 n.* (2004) (explaining that the federal spending power applies with equal force when Congress legislates "in an area historically of state concern"). Because conditions on federal spending programs are in no sense

"the particular domain of state law," Alabama Ass'n, 141 S. Ct. at 2489, respondents' federalism-canon arguments fail.

c. For similar reasons, respondents' argument that a heightened-specificity requirement applies because the rule "invokes the outer limits of Congress' power," Missouri Opp. 20 (citation omitted) -- and their related argument that the rule violates the Constitution, see Louisiana Opp. 26-28 -- are meritless.

As previously explained (see, e.g., Missouri Appl. 28-29), the vaccination condition at issue here -- like countless other conditions of participation in Medicare and Medicaid -- reflects a straightforward exercise of Congress's spending power. Respondents do not seem to dispute that basic point. And respondents cannot deny that protecting patients in federally funded healthcare programs from a deadly virus furthers the "general Welfare of the United States." U.S. Const. Art. I, § 8, Cl. 1; see, e.g., South Dakota v. Dole, 483 U.S. 203, 206–207 (1987).

The Louisiana respondents instead invoke the principle that the conditions of federal grants to States must be clear. Opp. 26-27 (citing Pennhurst State Sch. & Hosp. v. Halderman, 451 U.S. 1, 17 (1981)). The conditions at issue here fully comply with that principle. As an initial matter, the vast majority of the facilities subject to the condition are private entities participating in Medicare and Medicaid -- not States. Those conditions apply to state-run hospitals and other facilities only in the same manner as they apply to federally funded facilities generally.

And in any event, the relevant statutes make perfectly clear that participation in Medicare and Medicaid is conditioned on compliance with, e.g., "requirements [that] the Secretary finds necessary in the interest of the health and safety" of patients. 42 U.S.C. 1395x(e)(9) (hospitals).

Respondents seem to suggest that Congress was required not only to clearly condition participation on compliance with health and safety conditions adopted by the Secretary, but also to clearly set forth all the detailed conditions in the statute itself. But this Court has never imposed such a requirement, which would radically alter the administration of Medicare, Medicaid, and countless other spending programs. Medicare's "Conditions of Participation" for hospitals alone span some 48 pages in the Code of Federal Regulations. 42 C.F.R. Pt. 482. To take just a few examples, those conditions address such matters as hospital governance, hiring, staffing, and budgeting, 42 C.F.R. 482.12, 482.22; patients' rights, including grievance procedures and limits on the use of restraints, 42 C.F.R. 482.13; emergency preparedness, 42 C.F.R. 482.15; recordkeeping, 42 C.F.R. 482.24; and the hospital's physical environment, down to the placement of hand sanitizer, 42 C.F.R. 482.41(b)(8). On respondents' view, all of those conditions are invalid because they are not specifically set forth in the statute.[5]

[5] To the extent respondents suggest that the rule coerces them in any way (cf. Louisiana Opp. 27), they are mistaken. Unlike the Medicaid expansion the Court held to be impermissibly coercive

The Louisiana respondents' cursory assertion (Opp. 27) that any statutory provision authorizing the vaccination rule is "an unconstitutional delegation of legislative authority" is similarly baseless. As noted above, the rule is an exercise of the Secretary's statutory authorities to impose conditions -- including, in most cases, "requirements * * * necessary in the interest of [patient] health and safety," 42 U.S.C. 1395x(e)(9) -- for entities participating in Medicare and Medicaid. Those statutes readily provide the "intelligible principle[s]" required by this Court's non-delegation decisions. Whitman v. American Trucking Ass'ns, 531 U.S. 457, 474 (2001) (citation omitted); see id. at 475 (finding that direction to regulate "to protect the public health" sufficiently guided the agency's exercise of discretion); see also Gundy v. United States, 139 S. Ct. 2116, 2129 (2019) (plurality opinion) (collecting examples). Respondents do not attempt to reconcile their claim with those precedents.

d. In one final effort to justify a departure from the statutory text, respondents contend (Missouri Opp. 18-19, 23; Louisiana Opp. 14-16) that the rule conflicts with 42 U.S.C. 1395.

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in National Federation of Independent Business v. Sebelius, 567 U.S. 519, 541-542 (2012), the rule regulates Medicare and Medicaid facilities, not States. And contrary to the Missouri respondents' assertion (Opp. 6), HHS does not "force[] 'State surveyors . . . to assess compliance with'" the vaccination requirement. A State's decision to enter into a survey agreement with the Secretary is voluntary. See 42 U.S.C. 1395aa(a) ("The Secretary shall make an agreement with any State which is able and willing to do so[.]") (emphasis added).

But respondents misread Section 1395. That provision, titled "Prohibition against any Federal interference," provides that federal officials may not exercise "supervision or control over," inter alia, "the practice of medicine," the "selection, tenure, or compensation of" healthcare workers, or "the administration or operation" of healthcare facilities. Ibid. The rule does none of those things. It instead imposes a condition on the acceptance of Medicare and Medicaid funds, thereby "regulating a federal program." Florida, 19 F.4th at 1287 (emphasis added; citation omitted). The condition here no more violates Section 1395's prohibition on regulating the practice of medicine or the selection of healthcare workers than do countless other conditions of Medicare and Medicaid participation, such as detailed staff-qualification and patient-treatment requirements. See, e.g., 42 C.F.R. 482.22-482.27.[6]

B. The Rule Is Not Arbitrary And Capricious

Respondents alternatively contend that the vaccination rule is arbitrary and capricious on various grounds. None has merit.

1. Both district courts focused on one of respondents' challenges in particular, which respondents renew here: that the

[6] The Louisiana respondents assert (Opp. 13-15) that the government forfeited its right to contest the district court's contrary interpretation of Section 1395, as well as certain other issues, by not raising them in its stay application. That is mistaken. The Fifth Circuit did not endorse any of those alternative grounds for the preliminary injunction and instead rested solely on circuit precedent addressing what the court called the "major questions" doctrine. Louisiana Appl. App. 2a.

Secretary allegedly failed to consider whether the rule will cause staffing shortages. Missouri Opp. 27-32; Louisiana Opp. 28-31. But the Secretary extensively discussed the possible effects of the rule on the labor market and ultimately found any risk of short-term staffing shortages insufficient to outweigh the benefits of the rule. See 86 Fed. Reg. at 61,607-61,609. Respondents identify no sound basis to reject that judgment.

In particular, the Secretary recognized the possibility that the rule may cause "staffing and service disruptions" in cases where "substantial" numbers of staff members refuse vaccination and are not granted an exemption. 86 Fed. Reg. at 61,608. But he emphasized that such widespread departures had not actually come to pass at healthcare facilities that had adopted vaccination requirements. Id. at 61,566, 61,569. And he explained that any such departures would be offset to some extent by reduced COVID-related absenteeism and by the return to the labor force of individuals previously unwilling to work with unvaccinated colleagues. Id. at 61,607, 61,609. He also explained that any short-term disruptions must be viewed in the overall context of the healthcare labor market, where "it is normal for there to be roughly 2.66 million new hires" each year out of a labor force of 10.4 million. Id. at 61,608. He therefore concluded that "there is no reason to think" that the rule will cause "a net minus" in staffing levels "even in the short term." Id. at 61,609. That conclusion was amply supported by the evidence before the Secretary and accords

with the views of leading organizations of healthcare professionals, none of which have supported respondents' efforts to enjoin the rule. See Missouri Appl. 32-33; 86 Fed. Reg. at 61,565; see also AMA Amici Br. 1-7; SEIU Amici Br. 1-2.

Respondents contend (Missouri Opp. 28-29; Louisiana Opp. 29 & n.9) that declarations they submitted in litigation show that the Secretary overlooked a distinct risk of staffing shortages in rural areas. But those declarations do not identify even a single example of a vaccination requirement that triggered the sort of widespread staff departure respondents predict. The declarations instead consist largely of reports indicating that some facilities estimate or have been told that a subset of their unvaccinated staff members would rather quit than be vaccinated. See, e.g., Missouri Opp. App. 39a, 43a, 45a. As the Secretary explained, however, real-world experience shows that employees generally "respond[] to mandates by getting vaccinated" rather than leaving their jobs. 86 Fed. Reg. at 61,569.

Respondents are mistaken in asserting that the evidence of successful vaccination requirements involved only "urban areas." Missouri Opp. 29; see Louisiana Opp. 29. For example, the Secretary discussed the Novant Health system in North Carolina, see 86 Fed. Reg. at 61,566 n.132, which includes the "primary location[s] for emergency and specialized services for people in rural communities" in that State, see Gina DiPietro, Novant Health, 5 Things To Know (Feb. 1, 2021), https://perma.cc/L399-5VXC. Similarly,

the Secretary relied in part on evidence that a nursing facility in "rural Alabama" that imposed a vaccine mandate "lost only six of its 260 employees." Jack J. Barry et al., Half of Unvaccinated Workers Say They'd Rather Quit Than Get a Shot -- But Real-World Data Suggest Few Are Following Through (Sept. 24, 2021), https://perma.cc/UDY2-F9ML; see 86 Fed. Reg. at 61,569 n.155.[7]

That said, the Secretary seriously considered the concerns respondents raise, acknowledging some "early indications" that "rural hospitals are having greater problems with employee vaccination refusals than urban hospitals," and inviting "comments on ways to ameliorate this problem." 86 Fed. Reg. at 61,613. At the same time, the Secretary noted that the need for the rule was particularly strong in rural communities, where patients are especially at risk from COVID-19, id. at 61,566, and he ultimately determined that the rule struck the appropriate balance based on the evidence before him. That quintessential policy judgment was one for the Secretary, not States or the courts. And the Secretary was not required to wait for "perfect empirical or statistical data" about the effects of the rule in rural areas before taking steps to protect patients. FCC v. Prometheus Radio Project, 141

[7] Public reports continue to confirm that concerns about employees quitting en masse in response to COVID-19 vaccine mandates are generally overstated -- including in the respondent States. See, e.g., Dave Muoio, Fierce Healthcare, How Many Employees Have Hospitals Lost to Vaccine Mandates? (Dec. 28, 2021), https://perma.cc/E8LC-SQ4K (collecting reports of minimal staff departures from healthcare facilities in Louisiana, Indiana, Kansas, Kentucky, Ohio, South Carolina, and elsewhere).

S. Ct. 1150, 1160 (2021); see, e.g., FCC v. Fox Television Stations, Inc., 556 U.S. 502, 521 (2009) (explaining that an "agency's predictive judgment * * * merits deference").

2. This Court is also likely to reject respondents' other arbitrary-and-capricious challenges.

First, respondents assert (Missouri Opp. 26; Louisiana Opp. 30) that the Secretary failed to adequately consider "testing" and "natural immunity" (i.e., from a prior infection) as alternatives to a vaccination requirement. The Secretary explicitly considered both, and his decision to reject those alternatives was fully explained and reasonable. For example, the Secretary found that the "scientific evidence on testing" demonstrated that "vaccination is a more effective infection control measure," 86 Fed. Reg. at 61,614, and respondents have adduced no evidence to the contrary. Likewise, the evidence before the Secretary supported his conclusion that experiencing a COVID-19 infection is not equivalent to receiving vaccination for COVID-19, and that, among those persons with prior infections, vaccination provides stronger protection against reinfection. Id. at 61,559-61,560 & n.69. That conclusion is not undermined by the Secretary's separate statement that individuals who recover from COVID-19 are unlikely to be "sources of future infections." Id. at 61,604; see Missouri Opp. 26. The question before the Secretary was whether vaccination provides superior protection. Substantial scientific evidence

supported his decision not to carve out from the vaccine requirement healthcare staff who previously contracted COVID-19. See 86 Fed. Reg. at 61,614 (noting that any such carve-out would be contrary to CDC recommendations and would require "standards that do not now exist for reliably measuring the declining levels of antibodies over time in relation to risk of reinfection").

Second, the Secretary also acknowledged and fully explained the agency's change from its prior approach of merely encouraging vaccination, which experience had shown to be "insufficient to protect the health and safety of individuals receiving health care services" from covered facilities. 86 Fed. Reg. at 61,583. The fact that the Secretary issued the rule after the President announced multiple measures designed to combat the COVID-19 pandemic in specific contexts within federal authority through requirements encouraging or requiring vaccination hardly shows that the rule is "pretextual." Missouri Opp. 27; Louisiana Opp. 30. Respondents provide no reason to doubt the Secretary's conclusion that the rule will protect vulnerable Medicare and Medicaid patients. The fact that the rule will also protect the general public -- as the Secretary forthrightly explained, see 86 Fed. Reg. at 61,612 -- is an additional virtue, not impermissible pretext.

Finally, there is no merit to the Missouri respondents' claim (Opp. 25-26) that the Secretary relied only on evidence from long-term-care facilities. Although the Secretary explained that such

facilities have produced the most extensive data on COVID-19 transmission in healthcare settings, see 86 Fed. Reg. at 61,585, he also relied on hospital data, see ibid.; see also id. at 61,557-61,558. And he explained that those facilities illustrated the danger of COVID-19 transmission in healthcare settings more broadly because they "engage many, if not all, of the same health care professionals and support services" as the other covered facilities. Id. at 51,585. The Secretary was entitled to draw such inferences from the available data, particularly in the "absence of any countervailing evidence." Prometheus Radio Project, 141 S. Ct. at 1159.

C. The Secretary Validly Promulgated The Rule

This Court is also likely to reject respondents' attacks on the procedures the Secretary employed to issue the rule.

1. In light of the ongoing pandemic and urgent danger to patients, the Secretary had good cause to issue the rule as an interim final rule with a comment period, rather than delaying it for advance notice and comment. Missouri Appl. 36-37. Respondents do not identify any sound reason to reject the Secretary's finding that the rule is "the minimum regulatory action necessary" to protect the health and safety of Medicare and Medicaid patients, 86 Fed. Reg. at 61,613, or that "further delay in imposing a vaccine mandate would endanger the health and safety of additional patients," id. at 61,584. Indeed, even before the emergence of the Omicron variant, the Secretary correctly anticipated that time

was of the essence because of the "potential for new variants" to cause outbreaks of the kind that had devastated Medicare- and Medicaid-participating facilities earlier in the pandemic. Id. at 61,583-61,584.

Respondents also do not dispute that Medicare and Medicaid beneficiaries are especially at risk. Although "COVID-19 can affect anyone," "[a]ge remains a strong risk factor for severe COVID-19 outcomes." 86 Fed. Reg. at 61,566. The population aged 65 or older accounts for more than 80% of U.S. COVID-19 related deaths. See ibid. Social determinants of health such as poverty also "increase risk of severe illness and death from COVID-19," ibid., and Medicaid beneficiaries are by definition in low-income households. And "individuals seeking health care services are more likely to fall into the high-risk category." Id. at 61,568. Those considerations all underscore the need for urgency.

Respondents nonetheless assert (Louisiana Opp. 31-33; Missouri Opp. 33) that the two-month "delay" between the President's announcement in September and the issuance of the interim final rule in November precludes any invocation of the good-cause exception. In that timeframe, the Secretary prepared and issued a 73-page rule -- including a detailed cost-benefit analysis, 86 Fed. Reg. at 61,586-61,615 -- while also continuing to manage the agency's other efforts to address the country's worst pandemic in a century. Respondents' assertion (Louisiana Opp. 33) that the

agency could have prepared the rule, solicited comments, and reviewed and responded to those comments in two months seriously misunderstands the demands of the rulemaking process. See, e.g., Anne Joseph O'Connell, Agency Rulemaking and Political Transitions, 105 N.W. L. Rev. 471, 513-514 (2011) (finding that the average notice-and-comment rulemaking takes more than a year).

Respondents also fail to demonstrate any prejudice from the lack of a comment period because the Secretary already considered the issues they raise. Compare Missouri Opp. 33-34 (arguing that lack of comment period prejudiced the States by depriving them of the opportunity to submit information on potential staffing shortages), with 86 Fed. Reg. at 61,608-61,609 (considering, at length, the issue of "staffing and service disruptions").

2. The Louisiana respondents' reliance (Opp. 18-22) on 42 U.S.C. 1395z is equally unavailing. That provision instructs the Secretary to "consult with appropriate State agencies and recognized national listing or accrediting bodies" in determining conditions of Medicare participation for some of the facilities covered by the rule, 42 U.S.C. 1395z, but it does not require that such consultations occur in advance of any rulemaking. See Florida, 19 F.4th at 1290 n.3. To the contrary, the consultation requirement should be construed in light of the Medicare statute's express authority for the Secretary to adopt "interim final regulations," which may be made effective immediately for good cause. 42 U.S.C. 1395hh(a)(3)(C); see 42 U.S.C. 1395hh(b)(2)(C). The

Secretary expressly found that delaying the vaccination rule -- including for advance consultations with States -- would jeopardize the lives and health of patients. 86 Fed. Reg. at 61,567. The Secretary therefore reasonably determined to engage in the requisite consultations after issuing the rule. See ibid.

3. The Louisiana respondents also err in relying (Opp. 16-18) on 42 U.S.C. 1302(b), which requires the preparation of a regulatory impact statement for some rules that may affect a substantial number of small rural hospitals. By its terms, that statute does not apply to interim final rules like the one at issue here. Section 1302(b)(2) requires the preparation of a final regulatory impact analysis "[w]henever the Secretary promulgates a final version of a rule or regulation with respect to which an initial regulatory impact analysis is required by paragraph (1)," 42 U.S.C. 1302(b)(2), which in turn applies only to the publication of proposed rules. And in any event, the Secretary determined that the rule "will not have a significant impact on the operations of a substantial number of small rural hospitals." 86 Fed. Reg. at 61,613.

III. The Remaining Factors Overwhelmingly Favor A Stay

The remaining considerations overwhelmingly favor granting a stay to allow the rule to protect Medicare and Medicaid patients while the appeals are pending. The preliminary injunctions were imposed right as the highly transmissible Omicron variant emerged

and at the beginning of the winter holiday season, with its predictable increases in travel and indoor social gatherings. The explosion in COVID-19 cases that has resulted from those developments has severely strained the Nation's healthcare system and heightened the danger to vulnerable Medicare and Medicaid patients.

On the other side of the ledger, it bears repeating that the rule has been challenged only by States, not any private facilities impacted by the rule -- or their workers, who may seek medical or religious exemptions. And the interests the States assert do not support the sweeping relief granted by the district courts. Respondents focus almost exclusively on an asserted risk of labor shortages in "rural" areas (e.g., Missouri Opp. 1, 2, 6, 7, 29, 37). But that risk is, at best, highly speculative. See pp. 20-23, supra. And it would be profoundly inequitable to deprive all Medicare and Medicaid patients in the respondent States of the rule's protection based on speculative concerns about some rural labor markets.

The Louisiana respondents also err in asserting (Opp. 35-37) that a stay pending appeal would be tantamount to granting "ultimate relief," on the theory that employees who become vaccinated during litigation cannot be unvaccinated afterwards if respondents prevail. That assertion misapprehends the operation of the rule, which specifies a condition of participation for facilities. A facility that wishes to challenge the mandate may do so -- subject

to the statutory channeling provision, see Missouri Appl. 39 -- and the "ultimate relief" available to the facility if it were to prevail would be the reversal of any sanctions imposed for non-compliance. In short, granting a stay pending appeal may save hundreds or thousands of lives and would not preclude granting meaningful relief in the unlikely event that respondents ultimately prevail.

* * * * *

For the foregoing reasons and those stated in the government's applications, the injunctions should be stayed pending appeal and, if the Fifth or Eighth Circuit affirms the relevant injunction, pending the filing and disposition of a petition for a writ of certiorari and any further proceedings in this Court. At a minimum, the injunctions should be stayed as to all facilities other than those operated by respondents.

Respectfully submitted.

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