IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

STATE OF LOUISIANA, *et al.*, Plaintiffs, v. XAVIER BECERRA, in his official capacity as Secretary of the United States Department of Health and Human Services, *et al.*, Defendants.	Civil Action No. 3:21-CV-03970

DEFENDANTS' MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

COVID-19 has "overtaken the 1918 influenza pandemic as the deadliest disease in American history." Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,556 (Nov. 5, 2021). By the time the rule at issue here was published three weeks ago, SARS-CoV-2, the virus that causes COVID-19, had infected over 44 million people, hospitalized more than 3 million people, and had claimed more than 720,000 lives in the United States. Those numbers continue to grow. *See* Centers for Disease Control ("CDC"), COVID Data Tracker Weekly Review, https://perma.cc/CU4F-GD9Q (updated Nov. 19, 2021). Because the virus is highly transmissible, it can easily pass from person to person at health care facilities. As a result, the pandemic has been devastating for health care facilities and for patients alike. Fortunately, the vaccines now approved or authorized for emergency use to protect against COVID-19 are safe and highly effective.

The Secretary of Health and Human Services reviewed this evidence and concluded that action was urgently needed to protect patients from infection with the virus while they receive care in facilities funded by Medicare and Medicaid. Congress has assigned the Secretary a statutory responsibility to ensure that the health and safety of patients are protected in these federally-funded facilities. To do so, he issued a rule requiring certain health care facilities, as a condition of their participation in these programs, to ensure that those members of their health care staffs who interact with patients, or who have contact with other staff who do so, receive vaccination for COVID-19, absent an exemption. These staff members are required to be vaccinated (or to obtain the first shot of a two-dose regimen) by December 6, or to request an exemption from this requirement from their employer. Non-exempt employees who follow a two-shot regimen must complete their second shot by January 4, 2022. The Secretary issued his rule on an emergency basis, and waived a comment period in advance of publication, because he foresaw an imminent need to protect patients against a spike in COVID-19 cases in the winter months. Although precise calculations are of course not possible, he found that his rule is likely to save hundreds, and possibly thousands, of lives each month, once it is implemented.

Plaintiffs are fourteen States that seek to prevent the Secretary from enforcing this rule. But this Court lacks jurisdiction over their claims. Congress has channeled jurisdiction over such claims

into an exclusive system for judicial review, under which a party must first present a particular claim for Medicare benefits, or dispute a particular sanction, to the agency for its resolution before that party may proceed to federal court. Plaintiffs have not met this prerequisite for this Court's jurisdiction.

Plaintiffs also fail to show they are entitled to emergency relief. They are unlikely to succeed on the merits. The Secretary has the statutory authority and responsibility to ensure that federal funds are used to protect, rather than harm, the health and safety of patients receiving care at facilities that voluntarily participate in Medicare and Medicaid. He reasonably exercised that authority to arrive at this rule. He explained his determination that the rule's potential to save several hundred to several thousand lives per month compelled him to act now. In so doing, he accounted for the rule's potential costs, including that some health care workers might seek other jobs rather than accept vaccination; he concluded, however, based on real-world experience with vaccination requirements, that relatively few would do so. Given that about a quarter of a health care facility's staff on average are new hires in any given year, he concluded that the effects of workers leaving for other jobs to avoid vaccination, and the countervailing effects of other employees newly seeking jobs in facilities that require vaccination, would be dwarfed by the effects of this regular churn in the health care workforce. The Secretary accordingly acted, on an emergency basis, to protect lives in the coming weeks and months.

Nor can Plaintiffs meet the remaining preliminary injunction factors. The only harm Plaintiffs might have standing to assert—an alleged economic loss—is entirely speculative, as another court recently concluded in a nearly identical suit. *Florida v. Dep't of Health & Human Servs.*, ---F. Supp. 3d---, 2021 WL 5416122 (N.D. Fla. Nov. 20, 2021). The equities and public interest weigh heavily against an injunction, which would undermine the public's significant interest in protecting the health of Medicare and Medicaid patients.

For all of these reasons, the Plaintiffs' motion for preliminary injunction should be denied.

BACKGROUND

I. The COVID-19 pandemic has had devastating effects on Medicare and Medicaid patients, and on health care workers.

The novel coronavirus SARS-CoV-2 causes a severe acute respiratory disease known as

COVID-19. 86 Fed. Reg. at 61,556-57. As of mid-October 2021, over 44 million COVID-19 cases, 3 million COVID-19 related hospitalizations, and 720,000 COVID-19 deaths had been reported in the United States, *id.*[1], including over 500,000 cases and 1,900 deaths among health care staff. *Id.* at 61,559.

Because the virus that causes COVID-19 is highly transmissible, it can readily spread among unvaccinated health care workers, and from these workers to patients, in health care facilities, even when infection control practices are followed. *Id.* at 61,557 n.16; 61,585 n.210. Unvaccinated health care workers are at increased risk for SARS-CoV-2 infection, and therefore risk exposing colleagues and patients to the virus. *Id.* at 61,558 n.42. Due to many of the factors that qualify them for enrollment (*e.g.*, age, disability, and/or poverty), Medicare and Medicaid patients are more likely to face high risk of developing severe disease and of experiencing severe outcomes from COVID-19 if infected by SARS-CoV-2. *Id.* at 61,566, 61,609. "[T]he available evidence for ongoing healthcare-associated COVID-19 transmission risk is sufficiently alarming in and of itself to compel CMS to take action." *Id.* at 61,558.

Unvaccinated staff also jeopardize patients' access to needed medical care and services. *Id.* 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 SARS-Cov-2 infections from health care workers. *Id.* Absenteeism from health care staff as a result of infection with the virus has also created staffing shortages that have disrupted patient access to recommended care. *Id.* at 61,559.

In June and July 2021, an especially contagious strain of SARS-CoV-2 known as the Delta variant drove dramatic increases in COVID-19 case and hospitalization rates in the United States. *Id.*. From June to September 2021, daily cases increased over 1200 percent, hospital admissions over 600 percent, and deaths over 800 percent. *Id.* at 61,583. Cases among health care workers have "grown in

[1] These figures likely underestimate the full impact of the COVID-19 pandemic, *id.* at 61,557 n.4, and fail to capture the widespread and devastating effects of post-acute illness from the virus, including long-term nervous system and neurocognitive disorders, cardiovascular disorders, and reduced quality of life. *Id.* at 61,557 n.5.

tandem with broader national incidence trends since the Delta variant's emergence." *Id.* at 61,585. The vast majority of cases during this period were among the unvaccinated population. *Id.*

In September and October 2021, reported cases began to trend downward, albeit still at highly elevated levels,[2] but at the time the Secretary issued his rule, there were troubling indications that a resurgence in the virus was coming in the next several weeks. *Id.* at 61,584. Respiratory viruses, like SARS-Cov-2, typically circulate more frequently during colder months, and the United States experienced a large spike in COVID-19 cases during the winter of 2020. *Id.* The 2021-2022 winter influenza season may be abnormally severe, given lower immunity levels to influenza. *Id.* The interaction between the COVID-19 virus and the influenza virus may lead to particularly severe outbreaks over the next several months. *Id.* at 61,584. "Accordingly, it is imperative that the risk for healthcare-associated COVID-19 transmission be minimized during the influenza season." *Id.*

II. Safe and effective vaccines are available to protect patients of health care facilities.

Currently, three manufacturers offer vaccines approved or authorized for emergency use in the United States by the Food and Drug Administration (FDA). *Id.* at 61,563. FDA reviewed safety and efficacy data, and issued emergency use authorizations in December 2020 for the Pfizer-BioNTech and Moderna vaccines, and in February 2021 for the Janssen (Johnson & Johnson) vaccine. *Id.* at 61,562, 61,564. On August 23, 2021, based on further safety and efficacy data, FDA fully approved the Pfizer-BioNTech COVID-19 vaccine. *Id.* at 61,564.

These vaccines are highly effective in preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death. *Id.* at 61,565 n.115. The evidence indicates that these vaccines continue to offer strong protection against the Delta variant. *Id.* at 61,565 n.116. The evidence also indicates that these vaccines offer better protection than infection-induced immunity alone does. *Id.* at 61,559-60; *see also id.* at 61,585 n.205. Recent studies indicate that vaccination of health care workers is 80 percent effective in preventing SARS-CoV-2 infection among frontline workers—more

[2] Those trends have reversed since the rule issued; since a nadir near the end of October, the moving 7 day case average has increased by nearly 50%, with a 16% increase over the last full week for which CDC reports data. *See* Centers for Disease Control, COVID Data Tracker Weekly Review, https://perma.cc/87MA-GNNV (updated Nov. 19, 2021).

effective in practice than are existing protocols, such as protocols for regular testing. *Id.* at 61,585 n.210. Like all vaccines, the COVID-19 vaccines are not 100 percent effective at preventing infection. However, the risk of developing COVID-19, including severe illness, remains much higher for unvaccinated than vaccinated people, and therefore could lead to higher absenteeism rates for unvaccinated staff in healthcare settings. *Id.* at 61,559, 61,565 n.120. Studies have also shown that vaccinated people with breakthrough infections may be less infectious than unvaccinated individuals with primary infections, resulting in fewer opportunities for transmission. *Id.* at 61,558 n.37.

III. The Social Security Act grants the Secretary the authority to protect the health and safety of patients in facilities funded by the Medicare and Medicaid programs.

Congress established the Medicare program "[a]s a means of providing health care to the aged and disabled." *Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993); *see* 42 U.S.C. § 1395 *et seq.* Congress also created the Medicaid program to "furnish medical assistance" (i.e., health care) on behalf of individuals "whose income and resources are insufficient to meet the costs of necessary medical services[.]" *Id.* § 1396-1. Under both programs, health care services are provided by private health care organizations and professionals who meet the statutory and regulatory requirements for participation.

To participate in Medicare, providers such as hospitals, home-health agencies, hospices, and skilled nursing facilities voluntarily enter into a provider agreement with the Centers for Medicare & Medicaid Services (CMS) after demonstrating that they meet the conditions for participation. *Id.* § 1395cc. Medicaid providers, likewise, voluntarily enter into provider agreements with State Medicaid agencies to be eligible for participation in that program. *Id.* § 1396a(a)(27). By entering into the provider agreement, a facility agrees that it will comply with the Medicare and Medicaid statutes and with the Secretary's regulations under these statutes. *See id.* §§ 1395cc(b)(2); 1396a(p)(1).

The Secretary has authority under the Social Security Act and the Medicare statute to issue such regulations "as may be necessary to the efficient administration of the functions with which" he is charged under each statute. 42 U.S.C. § 1302(a); *see also id.* § 1395hh(a)(1). He is charged with issuing regulations as he deems necessary to, *inter alia*, ensure that the health and safety of patients are protected while these individuals receive care that is funded by either program. *See, e.g.*, *id.* § 1395x(e)(9)

((a "hospital" must "meet[] such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution"); *id.* § 1395i-3(d)(4)(B) (same with respect to skilled nursing facilities). These regulations are alternatively known as "conditions of participation," "conditions for coverage," or "requirements for participation." The Secretary's long-standing conditions of participation include detailed requirements governing, among other things, the qualifications of professional staff, the condition of facilities, and other requirements that he deems necessary to protect patient health and safety. In particular, the regulations require that facilities maintain effective "infection prevention and control programs," and "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; *see also, e.g.*, *id.* §§ 482.42(a); 416.51(b).

The Secretary may enter into agreements with States under which a state health agency agrees to conduct periodic surveys to determine whether providers meet Medicare's conditions of participation. 42 U.S.C. § 1395aa(a); *see also* 42 C.F.R. § 488.10(a). A State's decision to enter into a state survey agreement is voluntary, *see* 42 U.S.C. § 1395aa(a), but by entering into such agreement, a State obliges itself to conduct surveys to "assess compliance with Federal health, safety and quality standards," 42 C.F.R. § 488.26(c)(1), using "the survey methods, procedures, and forms that are prescribed by CMS," *id.* § 488.26(d). State survey agencies review facilities for compliance and present findings to CMS, *see id.* § 488.12, but CMS has sole authority to determine noncompliance and impose remedies on Medicare providers, *see* 42 U.S.C. § 1395i-3(h)(2). If a provider fails to comply with conditions of participation, CMS may, upon notice, terminate the provider's participation in the Medicare program, *see* 42 U.S.C. § 1395cc(b)(2); 42 C.F.R. § 489.53, or in some circumstances, impose monetary penalties, *see, e.g.*, 42 U.S.C. § 1395bbb(e),(f); 42 C.F.R. § 488.820.

A facility may appeal an "initial determination" by CMS, including a "finding of noncompliance leading to the imposition of enforcement actions," 42 C.F.R. § 498.3(b)(13), and is entitled to a *de novo* hearing before an administrative law judge ("ALJ"). *Id.* §§ 498.40-498.79. A facility may appeal an ALJ's determination to the Departmental Appeals Board. *Id.* § 498.80. The Board's decision is the final decision of the Secretary, *id.* § 498.90. The Medicare statute allows a provider to

seek judicial review of the "final decision" of the Secretary. *See* 42 U.S.C. § 1395cc(h)(1)(A) (cross-referencing 42 U.S.C. § 405(g)). This avenue of judicial review is exclusive. 42 U.S.C. § 405(h) (incorporated into the Medicare statute by 42 U.S.C. § 1395ii); *see also Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 8 (2000).

IV. The Secretary issued the vaccination rule to protect the health and safety of patients at facilities funded by the Medicare and Medicaid programs.

On November 5, 2021, CMS published the interim final rule at issue here, which requires various categories of Medicare and Medicaid providers and suppliers to develop and implement plans and policies to "ensure staff are fully vaccinated for COVID-19, unless exempt, because 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.[3] The Secretary concluded that "it would endanger the health and safety of patients, and be contrary to the public interest to delay" issuance of a vaccine requirement for staff in healthcare settings, *id.* at 61,586, and that, accordingly, there was good cause to waive notice and comment procedures, *id.* at 61,583-86. Under the rule, all relevant staff must receive the first dose of a two-dose COVID-19 vaccine or a single-dose COVID-19 vaccine, or request or have been granted an exemption under the health care facility's exemption policies, by December 6, 2021. *Id.* at 61,573. By January 4, 2022, all non-exempt staff who are covered by the rule must be fully vaccinated. *Id.*

V. This litigation is brought.

Plaintiffs challenge the rule, asserting claims under the Administrative Procedure Act (APA), the Social Security Act, the Congressional Review Act, and the Constitution. Compl. ¶¶ 116-197. On November 15, 2021, they filed their Complaint, *see* Compl., and moved for a preliminary injunction. *See* Pls.' Mem. in Supp. of Mot. for Prelim. Inj., ECF No. 2-1 ("Br.").

STANDARD OF REVIEW

"A preliminary injunction is an extraordinary and drastic remedy" that should "never be awarded as of right." *Munaf v. Geren*, 553 U.S. 674, 689-90 (2008) (citation omitted). A plaintiff is

[3] Facilities must develop policies to permit their staff to request exemptions from the vaccination requirement "because of an ADA disability, medical condition, or sincerely held religious belief, practice, or observance." 86 Fed. Reg. at 61,572.

entitled to such an "extraordinary remedy" only "upon a clear showing" that it is "entitled to such relief." *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 22 (2008). A plaintiff must show (1) "a substantial threat of irreparable injury," (2) "a substantial likelihood of success on the merits," (3) "that the threatened injury if the injunction is denied outweighs any harm that will result if the injunction is granted," and (4) "that the grant of an injunction will not disserve the public interest." *Jordan v. Fisher*, 823 F.3d 805, 809 (5th Cir. 2016). A preliminary injunction should not be "granted unless the party seeking it has clearly carried the burden of persuasion on all four requirements." *Id.* (citation omitted); *see also, e.g.*, *Lake Charles Diesel, Inc., v. Gen. Motors Corp.*, 328 F.3d 192, 203 (5th Cir. 2003).

ARGUMENT

I. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THEIR CLAIMS BECAUSE THE MEDICARE STATUTE'S CHANNELING PROVISION DEPRIVES THIS COURT OF JURISDICTION OVER THEIR CLAIMS.

Plaintiffs dispute the validity of the vaccination rule, and argue that health care facilities in their States should not be subject to any sanction under Medicare for violating the rule. This Court lacks jurisdiction over these claims. Claims arising under the Medicare statute must be channeled through that statute's exclusive administrative review scheme, which bars pre-enforcement challenges.

The Medicare statute "channels most, if not all, Medicare claims through [a] special review system." *Illinois Council*, 529 U.S. at 8; *see also Sw. Pharmacy Sols., Inc. v. CMS*, 718 F.3d 436, 440 (5th Cir. 2013). Under 42 U.S.C. § 1395cc(h)(1), for example, a provider that disputes CMS's decision to impose a sanction, such as terminating its Medicare agreement, is entitled to a hearing before the agency and judicial review of the agency's decision, under 42 U.S.C. § 405(g). Congress made this avenue of judicial review exclusive, *see id.* § 405(h) (applicable to the Medicare statute by *id.* § 1395ii), foreclosing any alternative bases for jurisdiction, such as 28 U.S.C. § 1331, over any claim "arising under" the Medicare statute. *See Illinois Council*, 529 U.S. at 10; *Smith v. Berryhill*, 139 S. Ct. 1765, 1772 (2019).[4]

[4] Plaintiffs also invoke the Declaratory Judgment and Mandamus Acts, 28 U.S.C. §§ 2201 and 1361. But § 2201 is not an independent source of jurisdiction. *Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 767 (5th Cir. 2011). And mandamus is only available to order "a precise, definite act about which an official ha[s] no discretion whatever," *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 63 (2004) (cleaned up), not "to prohibit the defendants from acting in a certain manner in the future." *Family*

In *Illinois Council*, the Supreme Court concluded that the federal courts lacked jurisdiction over constitutional, statutory, and APA claims brought by an association of nursing home operators, which had sought pre-enforcement review of the validity of a Medicare regulation governing termination procedures for nursing homes found to be in violation of their conditions of participation. The Court held that claims involving the Medicare program may not be brought in federal court before a party first presents its claim to the agency; "the bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies,'" which are subject to established exceptions, and instead "demands the 'channeling' of virtually all legal attacks through the agency." *Illinois Council*, 529 U.S. at 12–13. The Supreme Court recognized that this stringent rule "comes at a price, namely, occasional individual, delay-related hardship." *Id.* at 13. But, the Court explained,

> In the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts, paying this price may seem justified.

Id. At least, "such was the judgment of Congress." *Id.*; *see also Heckler v. Ringer*, 466 U.S. 602, 627 (1984).

Illinois Council emphasized the channeling requirement's broad reach. The Court explained that its decisions "foreclose distinctions based upon the 'potential future' versus the 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge, the 'collateral' versus 'non-collateral' nature of the issues, or the 'declaratory' versus 'injunctive' nature of the relief sought." *Illinois Council*, 529 U.S. at 13–14. It also explained that the channeling requirement is not limited to particular types of relief. "Claims for money, claims for other benefits, *claims of program eligibility*, and *claims that contest a sanction or remedy*," the Court noted, "may all similarly rest upon individual fact-related circumstances, may all similarly dispute agency policy determinations, or may all similarly involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions." *Id.* at 14 (emphasis added). The Court found "no reason to distinguish among them in terms of the language or in terms of the purposes of § 405(h)." *Id.*; *see also Physician Hosps. of Am. v. Sebelius*, 691 F.3d

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Rehab., Inc. v. Azar, 886 F.3d 496, 505-06 (5th Cir. 2018) (citation omitted). Plaintiffs seek to invalidate a regulation, not to compel the performance of a ministerial duty.

649, 656 (5th Cir. 2012). Claims are subject to § 405(h), exclusively, if they arise under the Medicare statute, even if they also arise under the Constitution or another statute such as the APA. A claim "arises under" the Medicare statute if "both the standing and the substantive basis for" the claim is the statute, or if it is "inextricably intertwined with a claim for benefits." *Ringer*, 466 U.S. at 614-15; *see also Physician Hosps.* 691 F.3d at 656. The inquiry looks to the claim's "essence," and "not whether it lends itself to a 'substantive' rather than a 'procedural' label." *Ringer*, 466 U.S. at 614-15, 624.

All of Plaintiffs' claims plainly "arise under" the Medicare statute. Plaintiffs, acting purportedly on behalf of state-run health care facilities and as *parens patriae* for privately-run facilities, challenge the Secretary's authority under the Medicare statute to issue the vaccination rule. They seek to preclude him from imposing the Medicare statute's remedies of civil monetary penalties, payment withholding, or termination on facilities that violate the rule. The basis for these claims arises under the Medicare statute, and they are inextricably intertwined with facilities' claims that they should continue to receive the benefit of eligibility to participate in the Medicare program, without sanction, even if they do not comply with the vaccination rule. *See Blue Valley Hosp. v. Azar*, 919 F.3d 1278, 1283 (10th Cir. 2019).[5]

The Supreme Court has recognized a narrow exception to § 405(h)'s jurisdictional bar, when applying the bar "would not simply channel review through the agency, but would mean no review at all." *Illinois Council*, 529 U.S. at 19.[6] But Plaintiffs may not invoke this exception simply by alleging that financial hardship forecloses further review. *See id.* at 22; *see also Sw. Pharmacy Sols.*, 718 F.3d at 441. "[T]he 'channeling' of virtually all legal attacks through the agency . . . comes at a price, namely, occasionally individual, delay-related hardship," but Congress deemed that price "justified." *Illinois Council*, 529 U.S. at 13. The question instead is "whether, as applied generally . . . hardship likely found in many cases turns what appears to be simply a channeling requirement into *complete preclusion* of

[5] Conditions of participation are common Medicare and Medicaid regulations, enforced through a scheme that determines eligibility and penalties under both programs. Review of these determinations is "through the Medicare administrative appeals procedure"; thus, § 405(h) applies fully to challenges to these regulations. *Cathedral Rock of N. Coll. Hill, Inc. v. Shalala*, 223 F.3d 354, 366 (6th Cir. 2000); *see also In re Bayou Shores SNF, LLC*, 828 F.3d 1297, 1330 (11th Cir. 2016); 42 U.S.C. § 1396i(b)(2).

[6] A second narrow exception applies where a plaintiff has presented its claim to the agency, but it is inapplicable here. *See Illinois Council*, 529 U.S. at 15; *Affiliated Prof'l Home Health Care Agency v. Shalala*, 164 F.3d 282, 284 (5th Cir. 1999).

judicial review." *Id.* at 22-23 (emphasis added); *see also Physician Hosps.*, 691 F.3d at 659.

There is no "complete preclusion" of judicial review of the vaccination rule. A provider that is subject to an enforcement action could exhaust its remedies before the agency and then proceed to federal court. 42 U.S.C. § 1395cc(h). Such a facility, once it receives notice of a potential sanction and files an appeal before an ALJ, "shall have expedited access to judicial review" that will permit the facility to proceed directly to federal court to challenge the legality of the rule. *Id.* § 1395cc(h)(1)(B). The Medicare statute thus sets forth an orderly procedure for parties to contest the legality of sanctions that the Secretary imposes on them. *See Illinois Council*, 529 U.S. at 19.

It is true, of course, that State governments are not "dissatisfied" "institution[s] or agenc[ies]" under § 1395cc(h)(1), and thus States themselves could not use that statute's vehicle for judicial review, although individual state-operated facilities could if they are cited for a violation. But the same was true of the plaintiff in *Illinois Council*, and the Court held that that was immaterial. It is the "rights to review" of health care facilities subject to the rule "that are at stake," and "the statutes that create the special review channel adequately protect those rights." *Illinois Council*, 529 U.S. at 24; *see also Sw. Pharmacy Sols.*, 718 F.3d at 444-46; *Physician Hosps.*, 691 F.3d at 659. Facilities aggrieved by the rules' enforcement may seek review of that rule after following the jurisdictional requirements of § 405(h). State governments, however, may not skip the jurisdictional requirements to litigate on their behalf.

II. PLAINTIFFS ARE UNLIKELY TO SUCCEED ON THE MERITS OF THEIR CLAIMS.

A. CMS has statutory authority for the rule.

The Social Security Act grants the Secretary authority to issue rules and regulations "as may be necessary to the efficient administration of the functions with which" he is charged under the Act. 42 U.S.C. § 1302(a); *see also id.* § 1395hh(a)(1). This language grants "broad authority," *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356, 365 (1973) (quotation marks omitted), and a rule issued under statutes with this language "will be sustained so long as it is 'reasonably related to the purposes of the enabling legislation.'" *Id.* at 369 (quoting *Thorpe v. Hous. Auth. of City of Durham*, 393 U.S. 268, 280-81 (1969)). Section 1302(a) confers "broad rule-making powers . . . in substantially the same language" as

the provisions at issue in these cases. *See Thorpe*, 393 U.S. at 277 n.28; *see also Blum v. Bacon*, 457 U.S. 132, 140 n.8 (1982). The Fifth Circuit thus applies the same "reasonably related" standard in reviewing an attack on the Secretary's authority under § 1302(a). *See Baylor Univ. Med. Ctr. v. Heckler*, 758 F.2d 1052, 1062 (5th Cir. 1985).

The vaccination rule is well within the Secretary's authority under this standard. Congress created the Medicare and Medicaid programs to provide health care to the populations covered under each program. *See Good Samaritan Hosp.,* 508 U.S. at 404; *see also* 42 U.S.C. § 1396-1. The purpose of providing health care to these populations is to advance and maintain patients' health, not to harm them. It is therefore unsurprising that Congress instructed the Secretary to administer these programs so as to ensure that patients' health and safety is protected. Throughout the Medicare and Medicaid statutes, Congress directed him to use the various tools at his disposal to ensure that health care facilities do not harm their patients. *See, e.g.*, 42 U.S.C. § 1395aa(a); *id.* § 1396a(a)(36); *id.* § 1395bb(c).

Particularly relevant here, numerous provisions in the Medicare and Medicaid statutes charge the Secretary with the responsibility to issue regulations, as he deems necessary, conditioning facilities' eligibility for these programs on their ability to protect the health and safety of their patients while those patients are receiving care that is funded by either program. *See, e.g.*, 42 U.S.C. § 1395x(e)(9) (hospitals); *id.* § 1395i-3(d)(4)(B) (skilled nursing facilities); *id.* § 1395i-3(f)(1) (same). (A full listing of the Secretary's statutory authorities with respect to health and safety standards for the various types of facilities covered by the rule may be found at 86 Fed. Reg. at 61,567.) These provisions operate "capaciously," and "are broadly worded to give HHS significant leeway in deciding how best to safeguard [patients'] health and safety." *Northport Health Servs. of Ark., LLC v. U.S. Dep't of Health & Hum. Servs.*, 14 F.4th 856, 870 (8th Cir. 2021) (discussing § 1395i-3). The statutes thus direct the Secretary to impose conditions of participation on health care facilities so as to protect patients' health and safety—a responsibility that has taken on paramount importance during the pandemic.

Plaintiffs do not dispute that requiring vaccination of health care facility employees protects the "health and safety" of those facilities' patients, as those words are ordinarily understood. Instead, they contend, based on canons such as the "major question" doctrine, that the statutes' failure to

expressly address vaccination means that Congress did not grant the Secretary authority to protect patients' health and safety in this manner. Br. 10-14. But the interpretive canons on which Plaintiffs rely "may only be used where words are of obscure or doubtful meaning." *Iverson v. United States*, 973 F.3d 843, 853 (8th Cir. 2020) (citing *Russell Motor Car Co. v. United States*, 261 U.S. 514, 520 (1923)). Here, where "health and safety" has "a character of its own" that plainly encompasses preventing a deadly disease, these canons are inapplicable. *Russell Motor Car*, 261 U.S. at 519. And, in any event, these canons do not apply "unless it is fair to suppose that Congress considered the unnamed possibility and meant to say no to it." *Coastal Conservation Ass'n v. U.S. Dep't of Commerce*, 846 F.3d 99, 106 (5th Cir. 2017). Plaintiffs can point to no statutory text that would indicate that Congress meant "health and safety" to mean anything other than its natural implication, which includes the protection of patients from contracting highly infectious diseases at Medicare- and Medicaid-funded facilities.

For this reason, Plaintiffs' reliance on *Alabama Association of Realtors v. Department of Health & Human Services*, 141 S. Ct. 2485 (2021), is misplaced. The Court there rejected an eviction moratorium under a different statute, reasoning that a "downstream connection between eviction and the interstate spread of disease is markedly different from the direct targeting of disease that characterizes the measures identified in [that] statute." *Id.* at 2488. The Secretary here is not regulating the "downstream" effects of the pandemic. Rather, the statutes directly instruct him to protect the health and safety of patients while they receive care paid for by Medicare or Medicaid. Because the Secretary found that patients in these settings face a high risk of infection with SARS-CoV-2, and that vaccines are an effective means of reducing and preventing transmission of the virus, he discharged his statutory duty by issuing his vaccination rule. *See generally Merck & Co. v. U.S. Dep't of Health & Hum. Servs.*, 962 F.3d 531, 537-38 (D.C. Cir. 2020) (distinguishing an invalid rule with only "a hoped-for trickle-down effect on the regulated programs" from a valid rule with "an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs").

Plaintiffs argue that the Secretary's authority should be read narrowly, because the vaccination rule interferes with state authority over matters of public health, an area of "traditional state concern." Br. 12. But the Medicare and Medicaid statutes were enacted under the Spending Clause. The Secretary

has a duty to ensure that federal funds are used as Congress directed, in particular, by protecting patients' health and safety at facilities funded by these programs. "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 even when Congress legislates "in an area historically of state concern." *Id.* at 608 n.*. The rule does not intrude on state authority any more than do the long-standing rules conditioning federal funds on providers' commitment to prevent the spread of infection in their facilities. *See, e.g.*, 42 C.F.R. §§ 416.51(b), 482.42(a), 483.80.[7]

Plaintiffs also attempt to invoke the nondelegation doctrine to contend that Congress could not lawfully delegate to the Secretary the authority to protect the health and safety of Medicare and Medicaid patients. Br. 12. But "[d]elegations are constitutional so long as Congress lays down by legislative act an intelligible principle to which the person or body authorized to exercise the authority is directed to conform." *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 441 (5th Cir. 2020) (cleaned up), *cert. denied*, 141 S. Ct. 2746 (2021). The Secretary's statutory authority to protect Medicare and Medicaid patients' health and safety easily meets this minimal standard. *See Gundy v. United States*, 139 S. Ct. 2116, 2129 (2019) (plurality opinion) (citing cases and noting that Supreme Court had previously upheld delegations "to regulate 'in the public interest'"; "set 'fair and equitable' prices and 'just and reasonable' rates"; and "issue whatever air quality standards are 'requisite to protect the public health'").

Finally, Plaintiffs argue that the Secretary has purportedly asserted control over the selection of health care facility employees or the administration of health care institutions, in violation of 42 U.S.C. § 1395. This assertion, again, misconstrues the nature of the Medicare and Medicaid programs, and of the vaccination rule. Health care facilities voluntarily participate in Medicare and Medicaid. *See*

[7] For the same reason, Plaintiffs' invocations of the Fifth Circuit's grant of a stay application in *BST Holdings, L.L.C. v. OSHA*, ---F.4th---, 2021 WL 5279381 (5th Cir. Nov. 12, 2021), are entirely misplaced. That case involved a different statute, under which OSHA exercised regulatory power granted under the commerce power, and the court expressed concern about the reach of OSHA's general regulatory power. This case involves Congress's exercise of its power to place conditions on federal funds' use, and health care facilities' voluntary acceptance of those conditions when they participate in Medicare and Medicaid.

Burditt v. U.S. Dep't of Health & Hum. Servs., 934 F.2d 1362, 1376 (5th Cir. 1991). If they choose to do so, they must "meet certain conditions of participation established by the Secretary" in order to receive federal payments under these programs. *United States v. Baylor Univ. Med. Ctr.*, 736 F.2d 1039, 1044 (5th Cir. 1984). Those conditions have long included detailed rules addressing the qualifications of employees at health care facilities. *See, e.g.*, 42 C.F.R. § 482.22 (standards for medical staff at hospitals). The Secretary's vaccination rule, like these other rules addressing employee qualifications, ensures that federal funds are used only to pay for the purposes that Congress intended. Because the vaccination rule is not a legal mandate, but instead a condition imposed on the payment of federal funds, the rule does not assert "control" over the administration of institutions. *See Goodman v. Sullivan*, 891 F.2d 449, 451 (2d Cir. 1989); *Am. Acad. of Ophthalmology, Inc. v. Sullivan*, 998 F.2d 377, 387 (6th Cir. 1993).

B. The rule is the product of reasoned decisionmaking.

Plaintiffs contend that the Secretary acted arbitrarily by issuing a rule to protect the health and safety of Medicare and Medicaid patients. Even assuming that claims under the Social Security Act incorporate the APA's standard for arbitrary-and-capricious review, *but see Estate of Morris v. Shalala*, 207 F.3d 744, 745 (5th Cir. 2000), that standard is easily met here. This standard is "narrow and highly deferential." *Sierra Club v. U.S. Dep't of Interior*, 990 F.3d 909, 913 (5th Cir. 2021) (citation omitted). "[T]he 'court is not to substitute its judgment for that of the agency.'" *Id.* (citation omitted). Rather, it "consider[s] whether the decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Id.* (citation omitted); *see also FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). The Secretary considered all the relevant factors, and reasonably explained his decision, when he issued his rule to protect Medicare and Medicaid patients from the transmission of a deadly virus at facilities funded by these programs. The APA requires nothing more.

Protection of the Health and Safety of Medicare and Medicaid Patients. The Secretary's primary responsibility is to protect the health and safety of patients receiving care at Medicare- and Medicaid-funded facilities. He considered the available evidence and reasonably concluded that the rule would protect these patients' health and safety; indeed, the record overwhelmingly points to this conclusion.

SARS-CoV-2 is highly transmissible, and extremely dangerous. 86 Fed. Reg. at 61,556-57. By

the time this rule was published, COVID-19 had caused the deaths of at least 720,000 people in the United States, including at least 1,900 health care workers, and hospitalized at least 3 million people. *Id.* at 61,556, 61,569. It is "the deadliest disease in American history." *Id.* at 61,556. Given the virulence of this virus, it can be easily transmitted among health care workers, and from health care workers to patients, in health care facilities. *Id.* at 61,557 n.16. Unvaccinated health care workers are at increased risk for SARS-CoV-2 infection, and so exposing their colleagues and patients to the virus. *Id.* at 61,558 n.42. Due to many of the factors that qualify participants in the Medicare and Medicaid programs for enrollment (e.g., age, disability, and/or poverty), patients in facilities funded by these programs are more likely than the general population to suffer severe illness or death from COVID-19. *Id.* at 61,609. For these reasons, "the available evidence for ongoing healthcare-associated COVID-19 transmission risk is sufficiently alarming in and of itself to compel CMS to take action." *Id.* at 61,558.

Medicare and Medicaid beneficiaries' access to needed medical care is jeopardized by low rates of vaccination among health care workers at facilities funded by these programs. *Id.* Program patients have refused care from unvaccinated staff, or forgone care altogether, to avoid contracting the virus from health care workers. *Id.* Absenteeism due to SARS-CoV-2 infection and COVID-19 illness has contributed to staffing shortages that disrupt patient access to recommended care. *Id.* at 61,559.

Fortunately, the approved or authorized COVID-19 vaccines are safe, 86 Fed. Reg. at 61,562, and highly effective in preventing serious outcomes of COVID-19, *id.* at 61,565 n.115. They offer strong protection against known variants of the virus, including the Delta variant, particularly against hospitalization and death. *Id.* at 61,565 n.116. Recent studies show that the vaccines are highly effective in preventing SARS-CoV-2 infection among frontline workers. *Id.* at 61,585 n.205. Studies also show that vaccinated people with breakthrough infections may be less infectious than unvaccinated individuals with primary infections, resulting in fewer transmission opportunities. *Id.* at 61,558 n.37.

In short, evidence overwhelmingly points to the conclusion that SARS-CoV-2 is extremely dangerous for Medicare and Medicaid patients, and that health care staff vaccination is highly effective in preventing transmission among health care workers, and from the workers to patients. The Secretary, at minimum, reasonably so found, and he took action on that basis to fulfill his responsibility

to protect the health and safety of program beneficiaries while they receive care that these programs pay for. The APA requires nothing more than that. *See Prometheus Radio Project*, 141 S. Ct. at 1158.

Staff Shortages in Health Care Facilities. The Secretary also reasonably found that high rates of SARS-CoV-2 transmission among health care staff contribute to the health care worker shortage, and that the rule would alleviate this problem. Many health care workers have missed work due to SARS-CoV-2 infection, disrupting patient access to care. 86 Fed. Reg. at 61,559. At least 500,000 COVID-19 cases, and at least 1,900 COVID-19 deaths, have been reported among health care staff, with the true figures likely much higher. *Id.* The infection rate among health care staff has increased dramatically with the Delta variant's rise. *Id.* These trends are driven by health care staff vaccination rates that remain too low to protect staff and patients from the virus. *Id.* The Secretary thus fully explained that his rule would help to alleviate staffing shortages at health care facilities, "particularly during periods of community surges in SARS–CoV–2 infection, when demand for health care services is most acute," because "COVID-19 case rates among staff have also grown in tandem with broader national incidence trends since the Delta variant's emergence." *Id.* at 61,569-70, 61,585.

Plaintiffs posit that a substantial portion of health care workers will leave their jobs rather than be vaccinated, thereby threatening health care facilities' operation. Br. 17. The Secretary considered this possibility and rejected it, after reviewing recent empirical data regarding the effect of government- or privately-imposed vaccination requirements. Numerous health systems and health care employers nationwide have already implemented COVID-vaccine requirements. 86 Fed. Reg. at 61,566. These policies have had overwhelming success, even among health care workers previously hesitant to be vaccinated. *Id.* For example, after Houston Methodist implemented a vaccination requirement for practitioners at its facilities, it achieved a 99% compliance rate with that requirement among its employees and physicians. *Id.* at 61,566 n.131. Novant Health similarly achieved 98.6% compliance with its vaccination requirement for its staff. *Id.* at 61,566 n.132. The State of New York similarly reported a 92% compliance rate with its vaccine requirement. *Id.* at 61,569 n.159. Additional operators of more than 250 long-term care facilities around the country have achieved greater than 95%, and in some cases 100%, vaccination rates after imposing their own requirements. *Id.* at 61,569 n.158.

Based on this experience, a coalition of more than fifty professional health care associations, including the American Medical Association, the American Nurses Association, and the National Association for Home Care and Hospice, concluded that vaccination requirements are in the best interest of their members, of patients, and of health care facilities. *Id.* at 61,565. These organizations 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.* at 61,565 & n.122.

The Secretary recognized that there was some uncertainty as to how many employees would leave their jobs as a result of a vaccination rule, but concluded that it was more likely that any such effect would be more than offset by reduced staff absences from a reduction in illnesses, as well as a return to work of employees who have stayed out of the workforce for fear of contracting SARS-CoV-2. *Id.* at 61,608. Both effects, moreover, would be dwarfed by the ordinary degree of churn in the market of labor in the health care industry. In any given year, about 2.66 million employees in health care settings are typically new hires, in a total workforce of 10.4 million employees. *Id.* Health care providers are accustomed to regularly finding and replacing staff, and there is no reason to believe that this process would become any more onerous, even if some unvaccinated workers leave for other jobs. *Id.* at 61,608-09. In sum, after reviewing the real-world experience of vaccination requirements to date, the Secretary predicted that his rule would "result in nearly all health care workers being vaccinated." *Id.* at 61,569. This predictive judgment is owed deference. *See, e.g., Huawei Techs. USA, Inc. v. FCC*, 2 F.4th 421, 455 (5th Cir. 2021); *see also FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 521 (2009); *Newspaper Ass'n of Am. v. Postal Regul. Comm'n*, 734 F.3d 1208, 1216 (D.C. Cir. 2013).

Consideration of Alternatives. The Secretary reasonably considered alternatives to his vaccination rule. Plaintiffs contend that he failed to consider the possibility of requiring health care workers to be tested regularly. Br. 18. But he explicitly addressed, and rejected, this option, noting that he had "reviewed scientific evidence on testing and found that vaccination is a more effective infection control measure." 86 Fed. Reg. at 61,614. Plaintiffs complain that the Secretary did not cite the evidence underlying this determination, but the APA does not require this. *See* 5 U.S.C. § 553(c)

(requiring rules only to recite "a concise general statement of their basis and purpose"). In any event, the rule refers to evidence including studies showing that existing testing protocols are of limited effectiveness in preventing COVID-19 outbreaks, and that certain rapid COVID-19 tests will only detect approximately 40% of asymptomatic cases.[8] In contrast, recent studies of vaccine effectiveness among health care workers suggest that vaccinations prevent approximately 80% of infections in the first instance, and drastically reduce the risk of significant illness and hospitalization. 86 Fed. Reg. at 61,565. Moreover, the lone example Plaintiffs cite, from Utah, provides no evidence that the weekly testing that State conducts is as effective in preventing staff from spreading infection to patients as vaccination is. *Contra supra* n.8.

The Secretary also considered exempting people with prior SARS-CoV-2 infections from his rule. Although Plaintiffs cherry-pick one particular study of patients in Israel, which reported finding high immunity levels for previously-infected persons, Br. 19, the Secretary reasonably relied on CDC's analysis, upon a complete review of the scientific literature, that the best scientific evidence points against exempting individuals with prior infections, whose infection-induced immunity is highly variable, unlike vaccine-induced immunity. *See* 86 Fed. Reg. at 61,613; *id.* at 61,560. The weight of the evidence suggests that infection-induced immunity is not equivalent to vaccination for COVID-19, *id.* at 61,559, and that, even in persons with prior SARS-CoV-2 infections, vaccination provides strong protection against reinfection, *id.* at 61,585 n.205. In reviewing agency action, it "is generally not for the judicial branch to undertake comparative evaluations of conflicting scientific evidence." *Bellion Spirits, LLC v. United States*, 335 F. Supp. 3d 32, 42 (D.D.C. 2018), *aff'd*, 7 F.4th 1201 (D.C. Cir. 2021) (citation omitted). The Secretary's evaluation of the scientific literature is owed deference here.

Change in Position. The Secretary explained that, after vaccines became available to the general population, his initial approach was "to encourage rather than mandate vaccination." 86 Fed. Reg. at

[8] *See* Isaac See, et al., *Modeling Effectiveness of Testing Strategies to Prevent Coronavirus Disease 2019 (COVID-19) in Nursing Homes – United States, 2020*, 73 Clinical Infectious Diseases 792 (Aug. 2, 2021), https://perma.cc/96QK-C685; Ian W. Pray, et al., *Performance of an Antigen-Based Test for Asymptomatic and Symptomatic SARS-CoV-2 Testing at Two University Campuses – Wisconsin, Sept. – Oct. 2020*, 69 Morbidity and Mortality Weekly Report 1642 (Jan. 1, 2021), https://perma.cc/F483-K8A4.

61,583. It appeared at the time that "a combination of other Federal actions, a variety of public education campaigns, and State and employer-based efforts would be adequate." *Id.* Unfortunately, "vaccine uptake among health care staff has not been as robust as hoped for and ha[s] been insufficient to protect the health and safety of individuals receiving health care services" from covered providers. *Id.*; *see also id.* at 61,599. The Secretary determined that action was now needed to achieve the higher vaccination rates among health care workers necessary to protect patients. *Id.* at 61,583. He thus showed that he was aware that he was changing his policy on this issue, and explained his reasons for doing so. The APA requires no more. *See Fox Television Stations, Inc.*, 556 U.S. at 515.

Alleged Pretext. Nor are Plaintiffs correct that the Secretary's justification is pretextual. Br. 19. The rule recites that he is using his statutory authority to promote "[h]igher rates of vaccination . . . in health care settings," in light of his duty "to protect the health and safety of individuals providing and receiving care and services from Medicare- and Medicaid-certified providers." 86 Fed. Reg. at 61,560. Although Plaintiffs accuse the Secretary of a hidden agenda of also protecting the general community, he forthrightly explained his prediction that the rule would also have that positive, additional effect. *Id.* at 61,612. Unlike *Department of Commerce v. New York*, 139 S. Ct. 2551, 2575 (2019), there is not a "significant mismatch between the decision the Secretary made and the rationale he provided." The Secretary took action to protect patients at federally-funded facilities, as it was his statutory responsibility to do. *See also id.* at 2573 ("[A] court may not set aside an agency's policymaking decision solely because it might have been . . . prompted by an Administration's priorities.").

Asserted Reliance Interests. Plaintiffs wrongly contend that the Secretary failed to account for any reliance interests of states, healthcare providers, and their workers. Br. 20. To the contrary, he directly accounted for the costs that employers and some employees would incur under the rule. 86 Fed. Reg. at 61,607-10. He reasonably concluded, however, that the benefits far outweighed the costs. He calculated that the rule's benefits would outweigh its costs even if only 120 lives were saved, or 600 hospitalizations prevented. *Id.* at 61,612. The lives saved under the rule will probably be "many times higher" than that threshold: although these estimates are somewhat uncertain, "total lives saved under this rule may well reach several hundred a month or perhaps several thousand a month." *Id.* Nothing

in the APA required the Secretary to weigh the costs more heavily than the benefit of lives saved.

The Scope of the Rule. Finally, Plaintiffs contend that the rule is overbroad, either because it should have applied only to facilities that care for the elderly and infirm, or because it should have exempted personnel without direct patient contact. Br. 20-21. The Secretary reasonably explained both policy choices. *First*, Plaintiffs assert that the rule "reaches many categories of healthcare facilities, such as psychiatric residential treatment facilities [PRTFs] for individual[s] 21 years of age . . . that are not related to CMS's asserted interest in protecting elderly and infirm patients from the transmission of COVID-19." *Id.* at 20-21. But that misstates the Secretary's interest; his statutory duties do not extend *only* to the elderly or infirm; his duty is to protect the health and safety of each of the patient populations at health care facilities covered by this rule. *See, e.g.*, 42 U.S.C. § 1396d(h)(1). And he reasonably concluded that individuals in congregate care settings, such as PRTFs, are at greater risk of acquiring infections, including infection with the virus that causes COVID-19. 86 Fed. Reg. at 61,575.

Second, Plaintiffs contend that the rule is overbroad because it requires vaccination of staff that may come into contact with others at the site of care. Br. 21. But the Secretary explained at length why the rule should cover such personnel. *See, e.g.,* 86 Fed. Reg. at 61,570-71. He concluded that they may "encounter fellow employees . . . who will themselves enter a health care facility or site of care for their job responsibilities[.]" *Id.* at 61,568. Given SARS-CoV-2's high transmissibility and demonstrated transmission rates among health care workers, this conclusion was eminently reasonable. *See id.* at 61,557.[9] Plaintiffs' argument reduces to a dispute over where to draw the line for a vaccination rule. But an agency "is not required to identify the optimal threshold with pinpoint precision. It is only required to identify the standard and explain its relationship to the underlying regulatory concerns." *WorldCom, Inc. v. FCC*, 238 F.3d 449, 461-62 (D.C. Cir. 2001). The Secretary did so here.

C. The Secretary had good cause to issue the rule on an interim basis.

Notice-and-comment rulemaking is not required "when the agency for good cause finds (and

[9] At the same time, the rule exempts from the vaccine requirements those staff who "telework full-time," and vendors and other professionals who perform infrequent, non-healthcare services. 86 Fed. Reg. at 61,571. The Secretary also found that it would be "overly burdensome" to mandate that all providers and suppliers ensure COVID-19 vaccination "for all individuals who enter the facility." *Id.*

incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." 5 U.S.C. § 553(b)(B); 42 U.S.C. § 1395hh(b)(2)(C). This exception excuses notice and comment in emergency situations, or where delay could result in serious harm. *See Jifry v. FAA*, 370 F.3d 1174, 1179 (D.C. Cir. 2004). The Secretary's finding here more than meets that standard.

The Secretary explained that any further delay "would endanger the health and safety of additional patients and be contrary to the public interest." 86 Fed. Reg. at 61,584. He properly found that any delay for a comment period would be contrary to the public interest, given the rules' "life-saving importance." *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981); *see also Chambless Enters., LLC v. Redfield*, 508 F. Supp. 3d 101, 119 (W.D. La. 2020). The Secretary projected that the "total lives saved under this rule may well reach several hundred . . . or perhaps several thousand a month." 86 Fed. Reg. at 61,612. Any further delay in issuing the rule "would do real harm," *U.S. Steel Corp. v. U.S. EPA*, 595 F.2d 207, 214 (5th Cir. 1979), in the form of lives lost that would have been saved under the rule. *See also Sorenson Comm'ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014) (although good cause is rarely invoked, "we have approved an agency's decision to bypass notice and comment where delay would imminently threaten life"); *Chambless Enters.*, 508 F. Supp. 3d at 119.

Rather than grapple with this reality, Plaintiffs argue that the Secretary could have started his rulemaking earlier. Br. 9. But he explained that he initially chose a policy of "encourag[ing] rather than mandat[ing] vaccination," believing that a combination of other efforts would be "adequate," 86 Fed. Reg. at 61,583, and only issued the vaccination rule after first determining that such other efforts were insufficient. *See id.* at 61,559, 61,583. Given data showing that SARS–CoV–2 is highly transmissible between health-care workers and patients in hospitals, and the growth in case rates among health care workers, *id.* at 61,585, he found that delaying the rule "would contribute to additional negative health outcomes for patients including loss of life," *id.* at 61,584. And, although Plaintiffs fault the Secretary for not immediately issuing a rule when he announced his plans to do so in September, the fact that he completed a 73-page rule, with an analysis of over 200 cited sources, in less than 2 months shows

that he and his agency acted with appropriate dispatch in the face of the crisis.[10]

Plaintiffs also fault the Secretary for issuing his rule at a time when COVID-19 case rates were decreasing. Br. 9. (This is no longer the case. *See supra* n.2.) But he identified "emerging indications of potential increases," and foresaw that a renewed surge during the winter flu season would exacerbate the strain on the health care system. 86 Fed. Reg. at 61,584. Because flu incidence is highest in "December through March" and "COVID-19 vaccines require time after administration for the body to build an immune response," he reasonably found that "a staff COVID-19 vaccination requirement for the providers and suppliers identified in this rule cannot be further delayed." *Id.* Deference is owed to his predictive judgment on this score. *See Huawei Techs.*, 2 F.4th at 455. Taken together, the Secretary detailed his considered, supported reasons for why his rule is needed *right now* to save lives. If this case does not satisfy the good cause exception, it is hard to imagine when the exception ever might apply.

Because the Secretary had good cause to forgo notice and comment, Plaintiffs' three additional procedural arguments are unavailing. *First*, they contend that he violated 42 U.S.C. § 1395z, which provides that, "[i]n carrying out his functions, relating to determination of [some, but not all, of the] conditions of participation by providers . . . [of services at issue here], the Secretary shall consult with appropriate State agencies[.]" 86 Fed. Reg. at 61,567 (citation omitted). The Secretary found that "[a]ny delay in the implementation of this rule would result in additional deaths and serious illnesses among health care staff and consumers, further exacerbating the newly-arising, and ongoing, strain on the capacity of health care facilities to serve the public," *id.*, and thus there were no entities with which it would be "appropriate to engage in these consultations in advance of issuing" the rule, but noted that he would engage in consultations after the rule's issuance "in carrying out [his] functions." *Id.* That finding is owed deference, for the same reasons that the Secretary's decision to issue an interim final rule is so entitled. *See The GEO Grp., Inc. v. Newsom*, 15 F.4th 919, 930 (9th Cir. 2021) (statute authorizing agency to take "appropriate" action "is a hallmark of vast discretion"). *See also Kisor v. Wilkie*, 139 S. Ct. 2400, 2448 (2019) (Kavanaugh, J., concurring in the judgment) ("broad and open-

[10] *See* Anne Joseph O'Connell, *Agency Rulemaking and Political Transitions*, 105 N.W. L. Rev. 471, 513-19 (2011) (on average, federal rulemakings take 1.3 years to complete).

ended terms" like "'appropriate'" "afford agencies broad policy discretion"); *Alon Refin. Krotz Springs, Inc. v. EPA*, 936 F.3d 628, 655 (D.C. Cir. 2019), *cert. denied sub nom.*, *Valero Energy Corp. v. EPA*, 140 S. Ct. 2792 (2020) ("nor does the phrase 'as appropriate' itself specify a particular temporal dimension").

Second, Plaintiffs contend that the Secretary violated 42 U.S.C. § 1302(b), which requires the preparation of a regulatory impact analysis upon publication of a "notice of proposed rulemaking," *id.* § 1302(b)(1), or upon publication of a "final version of a rule or regulation with respect to which an initial regulatory impact analysis is required by paragraph (1)," *id.* § 1302(b)(2). This requirement does not apply here. The Secretary did not publish a notice of proposed rulemaking, and this is not the final version of a rule with respect to which an initial regulatory impact analysis was required. The Secretary accordingly reasonably found that the statute did not require an analysis under either paragraph; the plain text of the statute "only applies to final rules for which a proposed rule was published," 86 Fed. Reg. at 61,613, not to interim final rules that the Secretary publishes to address emergencies such as an imminent threat to patients' lives. *See Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council, Inc.*, 435 U.S. 519, 524 (1978) (courts may not impose additional procedural requirements on rulemakings beyond those expressed in statute); *Abubaker Abushagif v. Garland*, 15 F.4th 323, 332 (5th Cir. 2021).

Third, Plaintiffs contend that the agency violated 5 U.S.C. § 808. But that provision simply grafts the APA's good cause standard onto the Congressional Review Act. Moreover, 5 U.S.C. § 805 "denies courts the power to void rules on the basis of agency noncompliance with the [CRA]." *Montanans for Multiple Use v. Barbouletos*, 568 F.3d 225, 229 (D.C. Cir. 2009).

D. The rule is constitutional.

The vaccination rule does not, as Plaintiffs contend, Br. 21-22, violate either the Tenth Amendment or the Spending Clause. Congress spends hundreds of billions of dollars each year to pay for health care under the Medicare and Medicaid programs. *See Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). Most facilities that receive Medicare or Medicaid payments are privately owned and operated. State-operated facilities that choose to participate in Medicare or Medicaid must agree to abide by the same health and safety standards that apply to private facilities. Congress unquestionably has the authority to require health care facilities that receive Medicare or Medicaid payments to adhere

to standards that protect the health and safety of the patients, and that power exists regardless whether Congress acts "in an area historically of state concern." *Sabri v. United States*, 541 U.S. at 605, 608 n.*; *see also Helvering v. Davis*, 301 U.S. 619, 641 (1936); *Northport Health Servs.*, 14 F.4th at 869 n.5 (recognizing Congress's authority to control how Medicare funds are spent).

Plaintiffs contend that their state-run facilities lacked constitutionally adequate notice of the rule, because its requirements are not explicitly spelled out in the statute. Br. 21. This claim is meritless. Even when funding conditions apply to a State in its capacity as regulator (rather than, as here, in its capacity as facility operator), the Constitution does not demand this level of exactitude. *See, e.g., Bennett v. Ky. Dep't of Educ.*, 470 U.S. 656, 669 (1985). "Congress is not required to list every factual instance in which a state will fail to comply with a condition." *Mayweathers v. Newland*, 314 F.3d 1062, 1067 (9th Cir. 2002); *see also W. Virginia Dep't of Health & Hum. Res. v. Sebelius*, 649 F.3d 217, 223 (4th Cir. 2011).

Their alternative contention that their survey agencies are "commandeered" into enforcing the rule, Br. 21-22, has no bearing on the validity of the rule itself and, in any event, mischaracterizes the role of state survey agencies. The statute permits States to enter agreements with the Secretary to survey facilities' compliance with the conditions of participation in Medicare and Medicaid. These agreements are entirely voluntary. *See* 42 U.S.C. § 1395cc(a). Moreover, survey agencies do not "enforce" the conditions of participation, as Plaintiffs suggest, Br. 22; they instead report their findings to CMS, which has sole authority to determine noncompliance and impose remedies on Medicare providers. 42 C.F.R. §§ 488.10(a), 488.26(c)(1).

Plaintiffs' observation that they will not be compensated for surveys if they decline to perform them, Br. 21, is unremarkable. Plaintiffs cannot seriously contend that this consequence bears any resemblance to the "coercion" at issue in *NFIB*, which held that Congress could not make the entirety of a State's traditional Medicaid funding contingent on participation in a new program to provide health coverage for all low-income adults. Here, the Secretary is not "enlisting the States in a new health care program," *Nat'l Fed'n of Indep. Businesses v. Sebelius*, 567 U.S. 519, 584 (2012) ("*NFIB*"). *See Gruver v. La. Bd. of Supervisors for La. State Univ. Agric. & Mech. Coll.*, 959 F.3d 178, 184 (5th Cir.), *cert. denied*, 141 S. Ct. 901 (2020). He is simply applying the existing provisions of the Medicare and

Medicaid statutes to fulfill his statutory duty to protect the health and safety of beneficiaries of these programs. And the magnitude of federal funding at issue for surveys is miniscule compared to the funds that were at stake in *NFIB*.

III. PLAINTIFFS DO NOT MEET THE REMAINING INJUNCTION FACTORS.

A. Plaintiffs fail to establish irreparable harm.

Plaintiffs also cannot demonstrate likely irreparable harm. *See Florida v. Dep't of Health & Human Servs.*, ---F. Supp. 3d---, 2021 WL 5416122 (N.D. Fla. Nov. 20, 2021). This showing "is required for injunctive relief." *Motient Corp. v. Dondero*, 529 F.3d 532, 538 (5th Cir. 2008).

Plaintiffs suffer no cognizable harm to their "sovereign interests" at all, let alone a harm of the type required for equitable relief. Br. 23. Absent an allegation that the State's own enforcement activities are disrupted, they do not have a cognizable interest for Article III purposes in the abstract question whether a state law purporting to create immunities from federal regulation is preempted. *See Va. ex rel. Cuccinelli v. Sebelius*, 656 F.3d 253, 270 (4th Cir. 2011); *see also Florida*, 2021 WL 5416122 at *4 (rejecting this same argument as "lack[ing] merit"). And, as for their asserted quasi-sovereign interests or *parens patriae* interests, Br. 23-24, they lack standing to sue the federal government in that capacity, i.e., to protect its citizenry from the operation of federal law. *See Alfred L. Snapp & Son v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982) ("A State does not have standing as *parens patriae* to bring an action against the Federal Government"); *see also Massachusetts v. EPA*, 549 U.S. 497, 520 n.17 (2007) (noting the difference between a prohibited suit wherein a State seeks to protect its citizens from the operation of federal statutes, and a permitted suit whereby a State asserts its rights under federal law).

Although Plaintiffs allege "irreparable economic injuries" and a diversion of state resources, Br. 22-23, neither constitutes irreparable harm. *See Florida,* 2021 WL 5416122 at *3 ("[E]conomic loss such as the loss of funding is not irreparable."). Congress adjudged that, even though § 405's channeling provision "comes at a price, namely, occasional individual, delay-related hardship," that price is justified "[i]n the context of a massive, complex health and safety program such as Medicare."

Illinois Council, 529 U.S. at 13.

Plaintiffs' claims of economic harm as to certain state-run health care providers are also speculative, as the *Florida* court recognized. That court "disregarded as conclusory" and "speculative" the State's assertions (in declarations materially identical to those submitted here) "of how the various [state] agencies and institutions anticipate they may be adversely impacted by the mandate." *Florida*, 2021 WL 5416122 at *3. The court also noted that Florida's affidavits failed to "take . . . into account any impact from the availability of the exemption process," and concluded that Florida had failed to provide any "evidence to suggest that the anticipated loss of federal funding from the State agencies' noncompliance will occur immediately on December 6, 2021." *Id.*.

Plaintiffs' evidence here is equally lacking. They rely on conjecture that they *may* need to "reduce services and lose revenue." Br. 23. But "[t]here must be a likelihood that irreparable harm will occur. . . . [A] preliminary injunction will not be issued simply to prevent the possibility of some remote future injury." *United States v. Emerson*, 270 F.3d 203, 262 (5th Cir. 2001). As discussed, the Secretary acted against a backdrop in which many health care workers "already comply with employer or State government vaccination requirements." 86 Fed. Reg. at 61,567. He acknowledged concerns that some workers are reluctant to obtain vaccinations, but he found—based on real-world experience with COVID-19 vaccination requirements in a variety of settings—that the rule was likely to be highly successful, and that the vast majority of non-exempt individuals would obtain vaccination, even where they had expressed an initial unwillingness to do so. *Id.* at 61,569; *see also* Determination of the Acting OMB Director Regarding the Revised Safer Federal Workforce Task Force Guidance for Federal Contractors & the Revised Economy & Efficiency Analysis, 86 Fed. Reg. 63,418, 63,422 (Nov. 16, 2021) (Office of Management & Budget analysis noting that "Tyson Foods reported more than 96 percent of its workforce is now vaccinated" after imposing a vaccination requirement). Moreover, given the high degree of churn in the health care workforce—about one quarter of health care workers, on average, are new hires each year—the Secretary reasonably found that any effect of unvaccinated workers leaving jobs with health care facilities, or of vaccinated workers newly seeking employment there, would be dwarfed by this regular feature of the health care industry. 86 Fed. Reg. at 61,608.

Plaintiffs identify no concrete evidence demonstrating that large numbers of health care workers will actually leave their jobs if the rule remains in effect. They cite speculative declarations from health care agencies that providers "may lose significant percentages of their employees," Decl. of Stephanie McGee Azar, ¶ 11, ECF No. 2-4, but they have not identified any facilities that actually issued or were subject to vaccination requirements and lost significant numbers of employees. Absent such evidence, Plaintiffs cannot show that the harm they fear will *in fact* occur, or that it would in any way outstrip the regular and large-scale movement of workers in the health care workforce.

And critically, even if some facilities cannot immediately comply with the rule, Plaintiffs wrongly assume that immediate termination from the Medicare and Medicaid programs will result. CMS has published a set of FAQs detailing its implementation plans for the rule, which explains, "CMS's goal is to bring health care facilities into compliance. Termination would generally occur only after providing a facility with an opportunity to make corrections and come into compliance." CMS, Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (External FAQ), 10 (Nov. 24, 2021), https://perma.cc/85PY-SCL4. Thus, Plaintiffs cannot show that any injury is imminent.

B. Plaintiffs fail to establish that the balance of equities and public interest factors favor the requested injunction.

The third and fourth requirements for a preliminary injunction—the balance of harms and the public interest—"merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Here, these considerations tilt decisively in Defendants' favor. An injunction against the rule would harm the public interest in slowing the spread of COVID-19 among millions of health care workers and patients at federally-funded health care facilities. The Secretary projects that the vaccination rule may save hundreds, and potentially thousands, of lives each month. 86 Fed. Reg. at 61,612. In the context of this pandemic, "federal courts across the country have routinely concluded that undoing orders deemed necessary by public health officials and experts to contain a contagious and fast-spreading disease would result in comparatively more severe injury to the community." *Chambless Enters.*, 508 F. Supp. 3d at 123 (citation omitted). In evaluating the balance of harms, "courts properly decline to second-guess the judgments of public health officials." *Id.* (citations omitted).

By comparison, any theoretical harm "pales in comparison to the significant loss of lives that Defendants have demonstrated could occur" if the rule is enjoined. *Id.* (citation omitted). As explained above, Part III.A, Plaintiffs' claimed harms are both speculative and purely economic. Nowhere do they dispute the life-saving effects of vaccination; in fact, in discussing the public interest prong, they fail even to acknowledge the unparalleled American casualties from COVID-19. Although they argue that the rule will cause health care staff to leave their jobs in large numbers, they have set forth no evidence to show that the vaccination rule will actually have that effect. In fact, as noted in the rule, there are clear examples of requirements having exactly the effect that the Secretary intends—increasing the percentage of vaccinated staff to very high levels. 86 Fed. Reg. at 61,569.

Moreover, "[t]here is inherent harm to an agency in preventing it from enforcing regulations that Congress found it in the public interest to direct that agency to develop." *Cornish v. Dudas*, 540 F. Supp. 2d 61, 65 (D.D.C. 2008). Congress has charged the Secretary with the responsibility to protect the health and safety of individuals providing and receiving care and services from Medicare and Medicaid providers. *See, e.g.*, 42 U.S.C. §§ 1395x(e)(9); 1395i–3(d)(4)(B). The public interest favors allowing the Secretary to fulfill these responsibilities.

IV. ANY RELIEF SHOULD BE APPROPRIATELY LIMITED.

If the Court disagrees with Defendants' arguments, any relief should be no broader than necessary to remedy the demonstrated irreparable harms of these Plaintiffs. "A plaintiff's 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) (citation omitted).

In that regard, *first*, any injunction should apply only to those aspects of the rule for which the Court finds Plaintiffs have met their burden under the four-factor test for emergency relief. The Supreme Court has held a regulation severable where severance would "not impair the function of the statute as a whole, and there is no indication that the regulation would not have been passed but for its inclusion." *K Mart Corp. v. Cartier, Inc.*, 486 U.S. 281, 294 (1988) (invalidating only the provision of

a regulation that exceeded the agency's statutory authority). Severability clauses, such as the one in the rule, *see* 86 Fed. Reg. at 61,560, create a presumption that the validity of the entire regulation is not dependent on the validity of any specific unlawful provision if that unlawful provision would not impair the function of the regulation as a whole. *Alaska Airlines, Inc. v. Brock*, 480 U.S. 678, 686 (1987).

Second, any injunctive relief should be limited, at most, to facilities operated by Plaintiffs. "The Court's constitutionally prescribed role is to vindicate the individual rights of the people appearing before it." *Gill*, 138 S. Ct. at 1933; *see also id.* at 1934 (citing *Daimler Chrysler Corp. v. Cuno*, 547 U.S. 332, 353 (2006)); *Madsen*, 512 U.S. at 765. Indeed, Plaintiffs have no interest in whether facilities in other States are subject to the rule during the pendency of this lawsuit (and in fact, if their allegations concerning trends among health care workers are to be believed, they would benefit from relief being circumscribed within their own borders to facilities they themselves operate), nor standing to assert claims on behalf of facilities that Plaintiffs do not themselves operate. Thus, Plaintiffs' claims would be fully redressed through a preliminary injunction prohibiting the Secretary from "implementing" or "enforcing" the rule against only the facilities that Plaintiffs operate.

Nationwide relief would be particularly harmful here given that two other district courts are currently considering similar challenges, and a third recently decided one. A nationwide injunction would render the district court's order in *Florida*, as well as any additional orders that might follow from other courts considering similar claims, meaningless as a practical matter. It would also preclude appellate courts from testing Plaintiffs' claims against the rule in other jurisdictions. Moreover, many States are not challenging the vaccination rule. There is no reason why Plaintiffs' disagreements with it should govern the rest of the country. *See California v. Azar*, 911 F.3d 558, 583 (9th Cir. 2018) ("The detrimental consequences of a nationwide injunction are not limited to their effects on judicial decisionmaking. There are also the equities of non-parties who are deprived the right to litigate in other forums."); *see also id.* at 582-84 (vacating nationwide scope of injunction in facial APA challenge).

CONCLUSION

For the foregoing reasons, Plaintiffs' Motion should be denied.

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Respectfully submitted,

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