IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MISSOURI

STATE OF MISSOURI, *et al.*, Plaintiffs, v. JOSEPH R. BIDEN, JR., *et al.*, Defendants.	Civil Action No. 4:21-cv-1329

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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

The United States is in the midst of the most serious public health crisis it has ever faced. As of the time of the issuance two weeks ago of the rule at issue in this case, 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 alone. Those numbers have only grown since. *See* Centers for Disease Control ("CDC"), COVID Data Tracker Weekly Review, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html (updated Nov. 19, 2021). More than a year and a half into the COVID-19 pandemic, approximately 68,000 new cases and over 1,000 new deaths are reported in the United States every day. *See id.* Included among the tremendous human cost are at least half a million reported cases and 1,900 reported deaths among health care staff. Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,559 (Nov. 5, 2021). The pandemic has been devastating for health care facilities and for patients alike. Because the virus is highly transmissible, it can easily pass from person to person at health care facilities. Beneficiaries of the Medicare and Medicaid programs, in particular, are more likely than the general population to suffer serious outcomes, including hospitalization or death, from contracting the disease.

Fortunately, there are three vaccines that have now been approved or authorized for emergency use in the United States to combat the COVID-19 pandemic. These vaccines are safe and highly effective. In health care settings in particular, the weight of the scientific evidence shows that vaccinated people are less likely to become infected with SARS-CoV-2, and are less likely to pass it along to others, than are those who have not been vaccinated.

The Secretary of Health and Human Services reviewed this evidence and concluded that action was urgently needed to protect Medicare and Medicaid beneficiaries from the possibility that they would become infected with the virus while they receive care in facilities funded by these programs. Congress has assigned the Secretary a statutory responsibility to ensure that the health and safety of patients are protected in these federally-funded facilities. He accordingly issued a rule to do so.

The Secretary's rule requires 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 issuing the rule, because he foresaw an imminent need to protect Medicare and Medicaid beneficiaries against a spike in COVID-19 cases in the coming winter months. Although precise calculations on this score are of course not possible, he determined that his rule was likely to save hundreds, and possibly thousands, of lives each month, once it is implemented.

The Plaintiffs are ten States, who now seek a preliminary injunction to prevent the Secretary from enforcing this rule. But this Court lacks jurisdiction over their claims. Congress has withdrawn federal-question jurisdiction over claims like this one that arise under the Medicare statute. Instead, Congress has established by statute an exclusive system for judicial review, under which a party must first present a particular claim for benefits, or dispute a particular sanction, to the agency for its resolution before that party may proceed to federal court. The Plaintiffs have not met this statutory prerequisite for this Court's jurisdiction.

In addition, the Plaintiffs fail to satisfy any of the requirements for a preliminary injunction. In particular, the Plaintiffs are unlikely to succeed on the merits of their claims. 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 who receive care in facilities that voluntarily participate in the Medicare and Medicaid programs. He reasonably exercised that authority to arrive at his vaccination rule. He explained his determination that the life-saving potential of the rule compelled him to take action now. In so doing, he took into account the rule's potential costs, including the possibility that some health care workers would seek other employment rather than accept vaccination, but he concluded, on the basis of real-world experience with vaccination requirements, that relatively few health care workers 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 employment 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 reasonably chose to take action, on an emergency basis, to protect lives in the coming weeks and months.

Nor can the Plaintiffs meet the remaining preliminary injunction factors. They have not shown that they are likely to suffer irreparable harm absent preliminary relief. The only harm the Plaintiffs might even have Article III standing to assert—an alleged economic loss—is entirely speculative, as the Northern District of Florida recently concluded. *Florida v. Dep't of Health & Human Servs.*, No. 3:21-cv-02722-MCR-HTC (N.D. Fla. Nov. 20, 2021), Order at 8, ECF No. 6 (denying preliminary injunction motion in a nearly identical suit for the State's failure to show irreparable harm). And the equities and the public interest weigh heavily against the entry of preliminary injunctive relief. Granting the requested injunction would harm the public's significant interest in protecting the health of Medicare and Medicaid patients. An injunction would increase the likelihood that health care staff will infect those patients with the virus and thus the likelihood that they will suffer COVID-19 illness or death. It will also increase the risks to the health of health care staff and exacerbate some known causes of staffing shortages at Medicare- and Medicaid-participating facilities. These compelling interests easily outweigh the speculative economic harm that might befall the Plaintiffs absent preliminary relief.

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. The virus is highly transmissible, *id.* at 61,557, and extremely dangerous, *id.* at 61,556. As of mid-October 2021, over 44 million COVID-19 cases, 3 million COVID-19 related hospitalizations, and 720,000 COVID-19 deaths have been reported in the United

States. *Id.* Over half a million COVID-19 cases and 1,900 deaths have been reported among health care staff alone. *Id.* at 61,559. COVID-19 has now "overtaken the 1918 influenza pandemic as the deadliest disease in American history." *Id.* at 61,556.

Recent estimates of undiagnosed infections and under-reported deaths indicate that these figures likely underestimate the full impact of the COVID-19 pandemic. *Id.* at 61,557 n.4 (citing Seyed M. Moghadas and Alison P. Galvani, *The Unrecognized Death Toll of COVID-19 in the United States*, Lancet Regional Health Americas (Sept. 1, 2021), https://doi.org/10.1016/j.lana.2021.100033). These figures also 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 (citing Destin Groff, et al., *Short-Term and Long-Term Rates of Postacute Sequelae of SARS-CoV-2 Infection*, JAMA Network Open (Oct. 13, 2021), https://doi:10.1001/jamanetworkopen.2021.28568).

Because the virus that causes COVID-19 is highly transmissible, it is easily spread among health care workers, and from health care workers to patients, in health care facilities. *Id.* at 61,557 n.16 (citing, *e.g.*, Jonne J. Sikkens, et al., *Serologic Surveillance and Phylogenetic Analysis of SARS-CoV-2 Infection among Health Care Workers*, JAMA Network Open (July 28, 2021), http://doi.org/10.1001/jamanetworkopen.2021.18554). Unvaccinated health care workers are highly susceptible to transmitting the virus to their colleagues and to their patients. *Id.* at 61,558 n.42 (citing, *e.g.*, Scott C. Roberts, et al., *Correlation of Healthcare Worker Vaccination with Inpatient Healthcare-Associated Coronavirus Disease 2019 (COVID-19)*, 2021 Infection Control & Hospital Epidemiology 1 (Sept. 21, 2021)). Participants in the Medicare and Medicaid programs are more likely to face high risk of contracting COVID-19 and of experiencing severe outcomes from the disease. *Id.* at 61,609. In short, "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.

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. At nursing homes in particular, overall staffing levels, as measured on the basis of nursing hours per resident day, have remained stable; however, this appears to be a function of the reduced demand for medical care associated with patients' fears of contracting the virus from health care facility settings. *Id.*

In June and July 2021, the United States began to experience a dramatic increase in COVID-19 case and hospitalization rates, driven by an especially contagious strain of SARS-CoV-2 known as the Delta variant. *Id.* at 61,559. COVID-19 cases among staff of health care facilities have grown substantially since the emergence of the Delta variant. For example, cases among long-term care facility and end-stage renal disease facility staff have increased by over 1400 percent and 850 percent, respectively, between June and September 2021. *Id.* Over the same time period, daily cases of COVID-19 increased over 1200 percent, new hospital admissions increased over 600 percent, and daily deaths increased over 800 percent. *Id.* at 61,583. The vast majority of cases during this time period were among the unvaccinated population. *Id.*

In September and October 2021, newly reported cases began to trend downward, albeit still at highly elevated levels,[1] but there are troubling indications that a resurgence in the virus is coming in the next several weeks, particularly in northern states. *Id.* at 61,584. Respiratory virus infections, like the virus that causes COVID-19, typically circulate more frequently during the winter 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 an abnormally severe one, 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 n.190 (citing Sonja J. Olson,

[1] Those trends have reversed in the two weeks since the issuance of the rule; case rates are now climbing substantially. *See* Centers for Disease Control, COVID Data Tracker Weekly Review, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html (updated Nov. 19, 2021).

et al., *Changes in Influenza and Other Respiratory Virus Activity During the COVID-19 Pandemic – United States, 2020-2021*, 70 Morbidity and Mortality Weekly Report 1013 (July 23, 2021)). "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 has authority to review and approve "biological products," including vaccines, as safe and effective for their intended uses. *See* 42 U.S.C. § 262(a)(1), (i)(1). Under § 564 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3, FDA also may issue an "emergency use authorization" (EUA) during a public health emergency, which authorizes the marketing of vaccines (and other products) "intended for use" in responding to the emergency.

In March 2020, the Secretary determined that "circumstances exist justifying the authorization of emergency use of drugs and biological products during the COVID-19 pandemic[.]" EUA Declaration, 85 Fed. Reg. 18,250, 18,250–51 (Apr. 1, 2020). Based on that determination, FDA issued EUAs in December 2020 for the Pfizer-BioNTech and Moderna vaccines, and a third EUA in February 2021 for the Janssen (Johnson & Johnson) vaccine. 86 Fed. Reg. at 61,564. The EUAs for the three vaccines are based on FDA's review of extensive safety and efficacy data, including data from clinical trials involving tens of thousands of people. *Id.* at 61,562.

On August 23, 2021, the Pfizer-BioNTech COVID-19 vaccine obtained FDA approval, under the name Comirnaty, for people aged 16 years and older. *Id.* at 61,564. In approving Comirnaty, FDA determined that the vaccine was 91.1% effective in preventing COVID-19 disease and between 95% and 100% effective in preventing severe COVID-19 disease, based on an analysis of effectiveness data from approximately 20,000 vaccine and 20,000 placebo recipients. FDA, Comirnaty Approved Prescribing Information at 7, 15–18 (revised Aug. 20, 2021), https://perma.cc/53H8-UG3C. FDA concluded the product is safe based on data from approximately 12,000 vaccine recipients who were followed for safety outcomes for at least six months after their second dose, as well as safety

information from the millions of vaccine doses administered under the EUA. *Id.* at 12.

COVID-19 vaccines currently approved or authorized by FDA are highly effective in preventing serious outcomes of COVID-19, including severe disease, hospitalization, and death. 86 Fed. Reg. at 61,565 n.115 (citing https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/work.html). The available evidence indicates that these vaccines continue to offer strong protection against known variants of the virus, including the Delta variant (B.1.617.2), particularly against hospitalization and death. *Id.* at 61,565 n.116 (citing Mark W. Tenforde, et al., *Sustained Effectiveness of Pfizer-BioNTech and Moderna Vaccines Against COVID-19 Associated Hospitalizations Among Adults — United States, March–July 2021*, 70 Morbidity and Mortality Weekly Report 1156 (Aug. 27, 2021)).

The available evidence indicates that COVID-19 vaccines offer better protection than infection-induced immunity alone does. *Id.* at 61,559-60. Even among those persons with prior SARS-CoV-2 infections, vaccination helps prevent reinfection. *Id.* at 61,585 n.205 (citing Alyson M. Cavanaugh, *Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021*, 70 Morbidity and Mortality Weekly Report 1081 (Aug. 13, 2021)); *see also* CDC, *Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced immunity*, https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html (updated Oct. 29, 2021).

Recent studies indicate that, in addition to protection from hospitalization and death, the vaccines are 80 percent effective in preventing SARS-CoV-2 infection among frontline workers. *Id.* at 61,585 n.210 (citing Ashley Fowlkes, et al., *Effectiveness of COVID-19 Vaccines in Preventing SARS-CoV-2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance — Eight U.S. Locations, December 2020–August 2021*, 70 Morbidity and Mortality Weekly Report 1167 (Aug. 27, 2021)). Vaccination of health care workers is more effective in preventing the transmission of the virus than are other protocols, such as protocols for masking or regular testing. *Id.* at 61,585 n.210 (citing, *e.g.*, Michael Klompas, et al., *Transmission of SARS-CoV-2 From Asymptomatic and Presymptomatic Individuals in Healthcare Settings Despite Medical Masks and Eye Protection*, 73 Clinical Infectious Diseases 1693 (Nov. 2, 2021)).

Like all vaccines, the COVID-19 vaccines are not 100 percent effective at preventing infection,

and some breakthrough cases are expected among people with full vaccination. However, the risk of developing COVID-19, including severe illness, remains much higher for unvaccinated than vaccinated people. Vaccinated people with breakthrough COVID-19 cases are less likely to develop serious disease, be hospitalized, and die than those who are unvaccinated and get COVID-19. *Id.* at 61,565 n.120 (citing https://www.cdc.gov/coronavirus/2019-ncov/vaccines/effectiveness/why-measure-effectiveness/breakthrough-cases.html). Studies have 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 (citing, *e.g.*, Marc M. Shamier, et al., *Virological Characteristics of SARS-CoV-2 Vaccine Breakthrough in Health Care Workers* (Aug. 21, 2021), http://doi.org/10.1101/2021.08.20.21262158).

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, which is a cooperative state and federal 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[.]" 42 U.S.C. § 1396-1. Both programs were adopted in the 1965 amendments to the Social Security Act. Both are administered by the Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services (CMS). Under both Medicare and Medicaid, health care services are provided by private organizations and health care professionals who meet the statutory and regulatory requirements for participation. Participation in either Medicare or Medicaid is voluntary.

To participate in the Medicare program and receive payment for services furnished to Medicare beneficiaries, providers such as hospitals, home-health agencies, hospices, and skilled nursing facilities must enter into a provider agreement with CMS after demonstrating that they meet the conditions for participation. 42 U.S.C. § 1395cc. Medicaid providers, likewise, voluntarily enter into provider agreements with State Medicaid agencies to be eligible for participation in that program.

42 U.S.C. § 1396a(a)(27). By voluntarily entering into a provider agreement, a facility agrees that it will comply with the requirements of the Medicare and Medicaid statutes and the regulations that the Secretary issues under these statutes. *See* 42 U.S.C. § 1395cc(b)(2); *see also id.* § 1396a(p)(1).

The Secretary has broad authority under the Social Security Act and, in particular, under 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). In particular, the Secretary is charged with issuing regulations as he deems necessary to—among other things—ensure that the health and safety of Medicare and Medicaid patients are protected while these individuals receive care that is funded by either program. *See, e.g.*, 42 U.S.C. § 1395x(e)(9) (defining a "hospital" as an institution which "meets 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) ("A skilled nursing facility must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary."). These regulations are alternatively known as "conditions of participation," "conditions for coverage," or "requirements for participation."

The Secretary's long-standing regulations 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, Medicare and Medicaid providers and suppliers have long been required to maintain effective "infection prevention and control programs," to "provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections." 42 C.F.R. § 483.80 (long-term care facilities); *see also, e.g.*, *id.* §§ 482.42(a) (hospitals); 416.51(b) (ambulatory surgical centers).

The Medicare statute directs the Secretary to enter into agreements with the States under which each state health agency (or other appropriate state or local 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) (authorizing agreements with "any State which is able and willing to do so").

If the State enters into such an agreement, however, it 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). If a provider is accredited by a national accrediting organization's CMS-approved accreditation program, CMS may deem that provider to have met the applicable Medicare conditions of participation. *See* 42 U.S.C. § 1395bb(a); 42 C.F.R. §§ 488.4, 488.10(b). In such a case, however, the Medicare statute authorizes CMS to rely on state health agencies (or other appropriate state or local agencies) to conduct "validation surveys" of an accredited provider to "validate" the accrediting organization's determination. *See* 42 U.S.C. § 1395aa(c); 42 C.F.R. § 488.10(c). These surveys are conducted on a "representative sample" basis or "in response to substantial allegations" of deficiencies that would adversely affect the health and safety of patients (in which case they are often referred to as "complaint surveys"). 42 C.F.R. § 488.9(a); *see also* 42 U.S.C. § 1395aa(c). If such a validation or complaint survey reveals significant deficiencies on the part of a provider, that provider will no longer be deemed to meet the conditions of participation and will be subject to ongoing review by the state survey agency until the provider demonstrates compliance. *See* 42 U.S.C. § 1395bb(c); 42 C.F.R. §§ 488.9(c), 488.10(d).[2]

After completing a survey, the State survey agency provides its certification of substantial compliance or noncompliance, which is a recommendation to CMS. *See* 42 C.F.R. § 488.12. 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.

[2] Contrary to the Plaintiffs' assertion, Br. at 29-30, a state survey agency's failure to review for provider compliance does not "disqualify" providers in that state from program participation. All Medicare and Medicaid certified facilities are assumed to be in compliance until a survey (which could be performed by a CMS contractor, by an accreditation organization, or—if a State voluntarily takes on this role—by a state survey agency) makes an initial finding of a violation. Even then, the facility would remain certified while CMS pursues a plan of correction with the agency. *See* 42 C.F.R. § 488.11 (state survey agency functions do not include enforcement).

§ 489.53, or in certain circumstances, impose other remedies, *see, e.g.*, 42 U.S.C. § 1395bbb(e),(f); 42 C.F.R. § 488.820 (additional remedies for home-health agencies).

Providers have a vehicle for administrative review of these remedies. Specifically, a facility may appeal an "initial determination" by CMS, including a "finding of noncompliance leading to the imposition of enforcement actions" specified in the regulations. 42 C.F.R. § 498.3(b)(13). The facility is entitled to a *de novo* hearing before an administrative law judge ("ALJ"), at which it may present evidence and witnesses. 42 C.F.R. §§ 498.40-498.79. A facility that is dissatisfied with an ALJ's determination may appeal that decision to the Appellate Division of the Departmental Appeals Board (the "Board"). 42 C.F.R. § 498.80.

The Board's decision is the final decision of the Secretary. *See 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)). As explained by the Supreme Court in *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 8 (2000), the Medicare statute makes this avenue of judicial review exclusive. The statute provides that "[n]o findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided." 42 U.S.C. § 405(h) (incorporated into the Medicare statute by 42 U.S.C. § 1395ii). And the same provision further provides that "[n]o action against the United States, the [Secretary], or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under [the Medicare Act]." *Id.*

IV. The Secretary has acted in response to the pandemic, but recent developments have revealed an urgent need for further action to protect the health of Medicare and Medicaid patients.

Since the onset of the COVID-19 pandemic, the Secretary has taken numerous actions to address the public health emergency. Among other things, he issued a rule waiving certain regulatory requirements requiring that medical encounters be held in person. 85 Fed. Reg. 19,230 (Apr. 6, 2020). He also instituted new data-reporting requirements for certain providers and implemented new statutory requirements that providers make public the prices for COVID-19 diagnostic tests. *See* 85

Fed. Reg. 54,820 (Sept. 2, 2020); 85 Fed. Reg. 71,142-205 (Nov. 6, 2020).

In May 2021, the Secretary exercised his authority to issue regulations for the protection of beneficiaries' health and safety by issuing a rule that established enhanced infection control requirements for long-term care facilities and other facilities. 86 Fed. Reg. 26,306 (May 13, 2021). This rule required, among other things, that the covered facilities offer COVID-19 vaccination and education about the vaccine to both residents and staff. *Id.*

As noted above, the emergence of the Delta variant over the summer months led to a dramatic spike in cases, hospitalizations, and deaths caused by COVID-19, a resurgence that has been driven by the spread of infection among the unvaccinated population. The Secretary's initial policy approach, after vaccines became available to the general population during the early months of 2021, was "to encourage rather than mandate vaccination." 86 Fed. Reg. at 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, that turned out not to be the case—"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.* Vaccination rates among health care workers average 67%, 64%, or 60% for long-term care facility staff, hospital staff, and end-stage renal disease facility staff, respectively. *Id.* at 61,599. In September 2021, the President announced his COVID-19 Action Plan, which announced a series of regulatory actions that federal agencies were planning to undertake in response to the pandemic. As relevant here, the announcement described CMS's plans to require vaccinations for health care workers at Medicare- and Medicaid-participating facilities. The White House, Path Out of the Pandemic, https://www.whitehouse.gov/covidplan (last visited Nov. 19, 2021).

V. The Secretary issued the vaccination rule to protect the health and safety of Medicare and Medicaid patients from the transmission of the COVID-19 virus in health care facilities.

On November 5, 2021, CMS issued the interim final rule that is the subject of this case. Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg.

61,555 (Nov. 5, 2021). The rule is comprehensive and detailed, discussing in 72 pages its new requirements for Medicare and Medicaid suppliers and providers. It requires various categories of providers and suppliers that participate in the Medicare and Medicaid programs, including hospitals, long-term care facilities, and end-stage renal dialysis facilities, 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." *Id.* at 61,561. Specifically, vaccination and accompanying documentation are required for any non-exempt staff that "interact with other staff, patients, residents, clients, or [elderly care] program participants in any location[.]" *Id.* at 61,568, 61,570; *see also id.* at 61,570 (listing the types of facility staff subject to the vaccination requirement). At the same time, facilities must develop policies to permit their staff to request exemptions from the vaccination requirement, given that staff "who cannot be vaccinated or tested because of an ADA disability, medical condition, or sincerely held religious belief, practice, or observance may in some circumstances be granted an exemption from their employer." *Id.* at 61,572.

The rule establishes two implementation phases. Phase 1 is effective 30 days after publication, i.e., December 6, 2021, and requires all relevant staff to have received the first dose of a two-dose COVID-19 vaccine or a single-dose COVID-19 vaccine, or to have requested or have been granted an exemption under the health care facility's exemption policies. *Id.* at 61,573. In addition, Phase 1 requires that facilities subject to the rule have developed and implemented policies and procedures to vaccinate staff by that date. *Id.* Phase 2 is effective 60 days after publication, i.e., January 4, 2022, and requires that all non-exempt staff who are covered by the rule be vaccinated by that date. *Id.* The rule states that CMS will issue interpretive guidelines regarding assessment of compliance with these requirements, and provider and suppliers cited for noncompliance may be subject to certain enforcement remedies depending "on the level of noncompliance and the remedies available under Federal law." *Id.* at 61,574.

The Secretary also concluded in the rule that there was good cause to waive the notice and comment process in rulemaking. He explained in detail how "current levels of COVID-19 vaccination

coverage up until now have been inadequate to protect health care consumers and staff," and demonstrated a "pressing need for a consistent Federal policy mandating staff vaccination in health care settings that receive Medicare and Medicaid funds." *Id.* at 61,583-84. In particular, the Secretary reasoned that there was a pressing need for action in light of the coming winter influenza season, which he noted could be particularly intense and could lead to a dramatic increase in both influenza and COVID-19 cases among vulnerable populations, including Medicare and Medicaid beneficiaries. *Id.* at 61,584. These findings demonstrated to the Secretary that "a vaccine mandate for healthcare workers is an essential component of the nation's COVID-19 response, the delay of which would contribute to additional negative health outcomes for patients *including loss of life*." *Id.* (emphasis added). Thus, CMS concluded "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.

VI. This litigation is brought.

The Plaintiff States challenge the rule, asserting claims purportedly arising under the Administrative Procedure Act ("APA"), the Social Security Act, and Article I and the Tenth Amendment to the United States Constitution. Compl. ¶¶ 166-257. The Plaintiffs filed their Complaint on November 10, 2021. *See* Compl. On November 12, 2021, the Plaintiffs moved for a preliminary injunction. *See* Pl. States' Mem. in Supp. of Mot. for Prelim. Inj., ECF No. 9 ("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 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). To establish such entitlement, a plaintiff must demonstrate that (1) it is likely to succeed on the merits; (2) it is likely to suffer irreparable harm in the absence of preliminary relief; (3) the balance of equities tips in its favor; and (4) an injunction is in the public interest. *Id.* at 20. "No single factor is dispositive," but the "likelihood of success on the merits is the most significant." *Turtle Island Foods, SPC v. Thompson*, 992 F.3d 694,

699 (8th Cir. 2021) (citation omitted). When the government is the opposing party, the last two factors merge. *Nken v. Holder*, 556 U.S. 418, 435 (2009).

ARGUMENT

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

The Plaintiffs dispute the validity of the vaccination rule, and argue that health care facilities in their States should not be subject to any sanction, in the form of loss of Medicare funding or eligibility for participation in the Medicare program, for a violation of the rule. This Court lacks jurisdiction over these claims. Any claim arising under the Medicare statute must be channeled through that statute's exclusive channeling provisions, no matter whether the Plaintiffs attempt to bring their claim as a pre-enforcement challenge, or whether they bring a constitutional challenge.

The Medicare statute "channels most, if not all, Medicare claims through [a] special review system." *Illinois Council*, 529 U.S. at 8; *see also Degnan v. Burwell*, 765 F.3d 805, 808 (8th Cir. 2014). Under 42 U.S.C. § 1395cc(h)(1), for example, a provider dissatisfied with the agency's decision to terminate its Medicare agreement is entitled to "a hearing thereon by the Secretary" and to "judicial review of the Secretary's final decision" as is provided in 42 U.S.C. § 405(g). Congress made this avenue of judicial review exclusive. The statute provides that "[n]o findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as herein provided." 42 U.S.C. § 405(h) (made applicable to the Medicare statute by 42 U.S.C. § 1395ii). And the same provision also forecloses any alternative bases for jurisdiction, such as federal-question jurisdiction, over any claim "arising under" the Medicare statute. *Id.*; *see also Illinois Council*, 529 U.S. at 10; *Smith v. Berryhill*, 139 S. Ct. 1765, 1772 (2019) ("Congress made clear that review would be available only 'as herein provided'—that is, only under the terms of § 405(g).").[3]

[3] In addition to asserting federal-question jurisdiction under 28 U.S.C. § 1331, the Plaintiffs also invoke the Declaratory Judgment Act, 28 U.S.C. § 2201, and the Mandamus Act, 28 U.S.C. § 1361. But "the federal Declaratory Judgment Act . . . is a procedural statute, not a jurisdictional statute." *McGowen, Hurst, Clark & Smith, P.C. v. Com. Bank*, 11 F.4th 702, 708 n.2 (8th Cir. 2021). And mandamus is only available to order "a precise, definite act about which an official ha[s] no discretion

In *Illinois Council*, the Supreme Court concluded that the federal courts lacked jurisdiction over constitutional, statutory, and procedural claims brought by an association of nursing home operators, which had asserted that pre-enforcement review was needed of the facial validity of a Medicare regulation governing termination procedures for nursing homes found to be in violation of their conditions of participation. The Court made inescapably clear that claims involving the Medicare program may not be brought in federal court before a party first presents its claim to the agency. The Court held that "the bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies,'" which are subject to well-established exceptions, and instead "demands the 'channeling' of virtually all legal attacks through the agency." 529 U.S. at 12–13. As the Court explained, this stringent requirement "assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts applying 'ripeness' and 'exhaustion' exceptions case by case." *Id.* at 13.

The Supreme Court recognized that "this assurance comes at a price, namely, occasional individual, delay-related hardship." *Illinois Council*, 529 U.S. 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 broad reach of the channeling requirement. The Supreme 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

---

whatever." *Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 63 (2004) (cleaned up); *see also Family Rehab., Inc. v. Azar*, 886 F.3d 496, 505–06 (5th Cir. 2018). "The duty owed to the plaintiff must be ministerial and a positive command so plainly prescribed as to be free from doubt." *Mitchael v. Colvin*, 809 F.3d 1050, 1054 (8th Cir. 2016) (internal quotation omitted). The Plaintiffs here seek to invalidate a federal regulation, not to compel the performance of a ministerial duty.

the relief sought." 529 U.S. at 13–14. The Court 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 In re Bayou Shores SNF, LLC*, 828 F.3d 1297, 1329 (11th Cir. 2016) (dismissing claim by skilled nursing facility for pre-enforcement review of termination of provider agreement).

The Plaintiffs' claims are subject to the jurisdiction-channeling provision of § 405(h), and federal-question jurisdiction is barred, if they arise under the Medicare statute, even if they may also rise under the Constitution or under other statutes such as the Administrative Procedure Act. A claim "arises under" the Medicare statute if "both the standing and the substantive basis for the presentation" of 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 Clarinda Home Health v. Shalala*, 100 F.3d 526, 529 (8th Cir. 1996). The "arising under" inquiry looks to the claim's "essence," and "not whether [the claim] lends itself to a 'substantive' rather than a 'procedural' label." *Ringer*, 466 U.S. at 614-15, 624. Accordingly, the Supreme Court has stated that this rule applies not only to "a claim for future benefits," but also to "all aspects" of any such present or future claim, including requests for injunctive and declaratory relief. *See Illinois Council*, 529 U.S. at 12-14 (quoting *Ringer*, 466 U.S. at 614-15).

Under this standard, all the claims at issue here plainly "arise under" the Medicare statute. The Plaintiffs, acting purportedly on behalf of several state-run health care facilities and as *parens patriae* for privately-run health care facilities within their borders, challenge the Secretary's statutory authority under the Medicare statute to issue the rule governing standards for COVID-19 vaccinations. They seek pre-enforcement review to challenge the Secretary's authority to impose the Medicare statute's remedies of civil monetary penalties, withholding of payments, or termination on facilities that violate the rule. The standing and substantive basis for these claims arise 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).[4]

It does not matter that the Plaintiffs also allege various constitutional violations; the Medicare statute's channeling requirement applies equally to constitutional as well as nonconstitutional claims. *See Illinois Council*, 529 U.S. at 10 ("The statute plainly bars § 1331 review … irrespective of whether the individual challenges the agency's denial [of a benefit] on evidentiary, rule-related, statutory, constitutional, or other legal grounds."); *id.* at 12 (stressing that "'all aspects' of any such present or future claim must be 'channeled' through the administrative process"). *See also Weinberger v. Salfi*, 422 U.S. 749, 760–62 (1975).

The Supreme Court has recognized a narrow exception to § 405(h)'s jurisdictional bar; the Court presumes that Congress did not intend to preclude review when the application of the channeling requirement "would not simply channel review through the agency, but would mean no review at all." *Illinois Council*, 529 U.S. at 19.[5] 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., Inc. v. CMS*, 718 F.3d 436, 441 (5th Cir. 2013) ("The fact that a plaintiff would suffer great hardship if forced to proceed through administrative channels before obtaining judicial review is insufficient to warrant application of the *Illinois Council* exception."). "[T]he 'channeling' of virtually all legal attacks through the agency . . . comes at a price, namely, occasionally individual, delay-related hardship," but Congress

[4] The conditions of participation regulations are common Medicare and Medicaid regulations, which are enforced through a unitary enforcement scheme that determines eligibility and penalties under both programs. Because this system requires review of these determinations "through the Medicare administrative appeals procedure," the channeling requirement of § 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).

[5] A second narrow exception applies where a plaintiff has presented its claim to the agency, and either the agency or the court finds adequate grounds to excuse further exhaustion of that claim. *See Degnan*, 765 F.3d at 808-09. But even where exhaustion might be excused, the presentment of a claim to the agency is a non-waivable jurisdictional requirement under § 405(h). *See Illinois Council*, 529 U.S. at 15. No party has yet presented a claim to the agency to contest an enforcement action, and so this exception cannot apply here.

nonetheless deemed that price "justified" when it enacted the Medicare statute. *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 judicial review." *Id.* at 22-23 (emphasis added); *see also Sensory Neurostimulation, Inc. v. Azar*, 977 F.3d 969, 983–84 (9th Cir. 2020); *Blue Valley Hosp.*, 919 F.3d at 1287–88.

The application of § 405(h) here would not result in the "complete preclusion" of judicial review of the Secretary's vaccination rule. Any provider or supplier that violates the rule and 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). Alternatively, such a facility, upon receiving notice of a potential sanction and after filing 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). Far from a "complete preclusion" of review, the Medicare statute sets forth an orderly procedure for parties to contest the legality of sanctions that the Secretary would seek to impose 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]" within the meaning of 42 U.S.C. § 1395cc(h)(1), and thus the States themselves could not use that statute's vehicle for judicial review, although individual state-operated facilities could do so if they faced a sanction. But the same point was true of the association that was the plaintiff in *Illinois Council*, and the Supreme Court held that that was immaterial. It is the "rights to review" of health care facilities subject to the vaccination rule "that are at stake," and "the statutes that create the special review channel adequately protect those rights." 529 U.S. at 24. Health care facilities that are aggrieved by the enforcement of the vaccination rule 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.[6]

[6] At all events, the Plaintiffs' claims against President Biden must be dismissed for lack of jurisdiction, because the courts have "no jurisdiction of a bill to enjoin the President in the performance of his official duties." *Franklin v. Massachusetts*, 505 U.S. 788, 803 (1992).

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

A. CMS has statutory authority for the rule.

As noted above, the Secretary has broad authority under the Social Security Act to issue such 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). The Medicare statute further confirms this authority by directing the Secretary to "prescribe such regulations as may be necessary to carry out the administration of the insurance programs under" that statute. *Id.* § 1395hh(a)(1). Binding Supreme Court and Eighth Circuit case law confirms the extent of the Secretary's authority under these statutes. Addressing similar enabling language in other statutes, the Supreme Court has concluded that this language grants the agency "broad authority." *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356, 365 (1973) (quotation marks omitted). More specifically, "[w]here the empowering provision of a statute states simply that the agency may 'make . . . such rules and regulations as may be necessary to carry out the provisions of this Act,'" the Court held that "the validity of a regulation promulgated thereunder 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)).

Applying this standard, the Supreme Court has recognized that § 1302(a) confers "broad rule-making powers . . . in substantially the same language" as the rulemaking provision in the cases cited above. *Thorpe*, 393 U.S. at 277 n.28; *see also Blum v. Bacon*, 457 U.S. 132, 140 n.8 (1982) (same). Because the rulemaking provision of the Social Security Act, § 1302(a), contains essentially the same terms as were at issue in *Mourning* and *Thorpe*, the Eighth Circuit applies the same "reasonably related" standard in reviewing an attack on the Secretary's authority to promulgate regulations under § 1302(a). *See Ark. Pharmacists Ass'n v. Harris*, 627 F.2d 867, 870 (8th Cir. 1980); *Leimbach v. Califano*, 596 F.2d 300, 304 (8th Cir. 1979); *see also Ark. State Bank Comm'r v. Resol. Tr. Corp.*, 911 F.2d 161, 170 (8th Cir. 1990).

The vaccination rule is comfortably within the Secretary's statutory authority under this standard. As noted above, Congress created both the Medicare and Medicaid programs as a means 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 services to these populations, of course, is to advance and maintain patients' health, not to harm them. It is therefore unsurprising that Congress has taken care to instruct the Secretary to administer these programs in a way that ensures that the health and safety of patients are protected. Throughout the Medicare statute, Congress has charged the Secretary to use the various tools at his disposal to ensure that health care providers do not cause harm to their patients. *See, e.g.*, 42 U.S.C. § 1395aa(a) (instructing the Secretary to impose any conditions on facilities found to be noncompliant that he "finds necessary in the interest of health and safety of individuals who are furnished care or services" at the facility); *id.* § 1396a(a)(36) (same); *id.* § 1395bb(c) (instructing the Secretary to deem facilities ineligible for participation if they are found to be in violation of health and safety regulations); *id.* § 1395bbb(b) (imposing duty on the Secretary to assure "the enforcement of such conditions and requirements are adequate to protect the health and safety of individuals under the care of a home health agency").

Of particular relevance here, numerous provisions throughout the Medicare and Medicaid statutes charge the Secretary with the responsibility to issue regulations, as he deems necessary, that condition health care facilities' eligibility for the Medicare and Medicaid programs on those facilities' 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) (defining a "hospital" as an institution which, among other things, "meets 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) ("A skilled nursing facility must meet such other requirements relating to the health, safety, and well-being of residents or relating to the physical facilities thereof as the Secretary may find necessary."); *id.* § 1395i-3(f)(1) (instructing the Secretary to ensure that regulatory requirements for skilled nursing facilities "are adequate to protect the health, safety, welfare, and rights of residents").[7]

[7] *See also* 42 U.S.C. § 1395k(a)(2)(F)(i) (requiring ambulatory surgical centers to meet "health, safety, and other standards specified by the Secretary in regulations"); *id.* §§ 1395x(dd)(2)(G) (requiring hospice programs to meet "such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by such agency or organization"); 1395x(o)(6) (requiring home health agencies to meet "such other conditions of

As the Eighth Circuit held last month, these provisions of the Medicare and Medicaid statutes operate "capaciously," and "are broadly worded to give HHS significant leeway in deciding how best to safeguard [patients'] health and safety and protect their dignity and rights." *Northport Health Servs. of Arkansas, LLC v. U.S. Dep't of Health & Hum. Servs.*, 14 F.4th 856, 870 (8th Cir. 2021) (discussing § 1395i-3(f)(1)). The statutes thus accord the Secretary the authority, and the responsibility, 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 since the onset of the COVID-19 pandemic. The Secretary, at least, reasonably understood his authority to encompass this responsibility, and that understanding is entitled to deference from this Court. *See id.*

The Plaintiffs do not dispute that a rule requiring the vaccination of health care facility employees protects the "health and safety" of those facilities' patients, as those words are ordinarily understood. Instead, they invoke the doctrine of *noscitur a sociis* to contend that, given the detail with which Congress addressed other standards in these statutes, the statutes' failure to expressly address vaccinations means that Congress intended to deny the Secretary the authority to find vaccination requirements to be necessary to protect the health and safety of patients. Br. at 26-27. But that canon "may only be used where words are of obscure or doubtful meaning." *Iverson v. United States*, 973 F.3d

---

participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such agency or organization[.]"); 1395x(p)(4)(A)(v), (B) (providers of outpatient physical therapy services must meet "such other conditions relating to the health and safety of individuals who are furnished services by such clinic or agency on an outpatient basis, as the Secretary may find necessary"); 1395x(aa)(2)(K) (rural health clinics must meet "such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are furnished services by the clinic"); 1395x(cc)(2)(J) (requiring comprehensive outpatient rehabilitation facilities to meet "such other conditions of participation as the Secretary may find necessary in the interest of the health and safety of individuals who are furnished services by such facility"); 1395x(ff)(3)(B)(iv) (community mental health center must meet "such additional conditions as the Secretary shall specify to ensure the health and safety of individuals being furnished such services"); 1395x(iii)(3)(D)(i)(IV) (qualified home infusion therapy supplier must meet "such other requirements as the Secretary determines appropriate"); 1395rr(b)(1)(A) (providers of services for individuals with end-stage renal disease must meet "such requirements as the Secretary shall by regulation prescribe"); 1395eee(f)(4) (authorizing regulations "to ensure the health and safety of individuals enrolled in a PACE program"); 1395i-4(e)(3) (requiring critical access hospitals to meet "such other criteria as the Secretary may require"); 1396d(d)(1) (requiring intermediate care facilities for individuals with intellectual disabilities to meet "such standards as may be prescribed by the Secretary"); 1396d(h)(1) (incorporating for psychiatric residential treatment facilities, through cross-referenced statutes, the health and safety requirements for hospitals under § 1395x(f)).

843, 853 (8th Cir. 2020) (citing *Russell Motor Car Co. v. United States*, 261 U.S. 514, 520 (1923)). Here, where the words "health" and "safety" have "a character of [their] own" that plainly encompasses the avoidance of a deadly disease, the canon has no application. *Russell Motor Car Co.*, 261 U.S. at 519. And, in any event, this canon "is a feeble helper in an administrative setting, particularly when, as here, [the Plaintiffs] point[] to no evidence suggesting that Congress considered the unnamed possibility and meant to say no to it." *Northport Health,* 14 F.4th at 871 (citations and internal quotations omitted).

For this reason, the Plaintiffs' reliance on *Alabama Association of Realtors v. Department of Health & Human Services*, 141 S. Ct. 2485 (2021), is misplaced. The Supreme Court in that case rejected the issuance of a national eviction moratorium by the Centers for Disease Control and Prevention under a far different provision of the Public Health Service Act, 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 seeking to regulate the "downstream" effects of the pandemic. Rather, the statutes directly instruct him to protect the health and safety of beneficiaries of the Medicare and Medicaid programs, while those individuals are receiving care that is paid for by either program. Because the Secretary determined that the virulence of SARS-CoV-2 poses a unique threat to patients' health and safety in these settings, he discharged his statutory responsibility 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, for purposes of Sections 1302 and 1395hh, between an invalid rule with only "a hoped-for trickle-down effect on the regulated programs" and a valid rule that has "an actual and discernible nexus between the rule and the conduct or management of Medicare and Medicaid programs").[8]

Finally, the Plaintiffs contend that the rule violates 42 U.S.C. § 1395, in that the Secretary has

[8] The 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. at 27. As the Plaintiffs themselves acknowledge, a "statutory delegation is constitutional as long as Congress lays down by legislative act an intelligible principle to which the person or body authorized to exercise the delegated authority is directed to conform." *Bhatti v. Fed. Hous. Fin. Agency*, 15 F.4th 848, 854 (8th Cir. 2021) (internal quotations and alterations omitted). The Secretary's statutory authority to protect the health and safety of Medicare and Medicaid patients easily meets this minimal standard.

purportedly asserted control over the selection of health care facility employees or the administration of health care institutions. This assertion misconstrues the nature of the Medicare and Medicaid programs, and of the vaccination rule. Health care facilities "voluntarily participate in the Medicare and Medicaid programs," and if they choose to do so, they "must comply with the [Secretary's health and safety regulations] as the price of admission to obtain federal funding." *Northport Health*, 14 F.4th at 869 n.5. Those conditions on federal funding have long included detailed rules addressing the qualifications of employees at health care facilities. *See, e.g.*, 42 C.FR. § 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) ("The regulation does not actually direct or prohibit any kind of treatment or diagnosis. It only refuses subsequent Medicare reimbursement for certain kinds of services."); *see also Am. Acad. of Ophthalmology, Inc. v. Sullivan*, 998 F.2d 377, 387 (6th Cir. 1993).

B. The rule is the product of reasoned decisionmaking.

The Plaintiffs contend that the Secretary acted arbitrarily by issuing a rule to protect the health and safety of Medicare and Medicaid patients. This Court reviews this claim under 42 U.S.C. § 405(g), which provides that the Secretary's findings, "if supported by substantial evidence, shall be conclusive." Even if this statute incorporates the Administrative Procedure Act'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.

The APA's arbitrary-and-capricious standard "is a highly deferential standard of review." *Adventist Health Sys./SunBelt, Inc. v. U.S. Dep't of Health & Hum. Servs.*, — F.4th —, No. 21-1589, 2021 WL 5170810, at *7 (8th Cir. Nov. 8, 2021). The courts "defer to agency action so long as an agency examined the relevant data and articulated a satisfactory explanation for its action." *Id.* (citation and alterations omitted). "A court cannot substitute its judgment for that of the agency." *Id.* (citation and alterations omitted). "This is particularly true when the resolution of the dispute involves primarily

issues of fact and analysis of the relevant information requires a high level of technical expertise by an agency acting within its sphere of expertise." *Id.* (citation and alterations omitted). In short, the arbitrary-and-capricious standard simply "requires that agency action be reasonable and reasonably explained." *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. As explained above, the Social Security Act assigns to the Secretary the primary responsibility to protect the health and safety of Medicare and Medicaid beneficiaries while those individuals are receiving care from facilities that are funded by either program. The Secretary reasonably considered the available evidence to conclude that his vaccination rule would protect these patients' health and safety; indeed, the record overwhelmingly points to this conclusion.

The virus that causes COVID-19 is highly transmissible, and extremely dangerous. 86 Fed. Reg. at 61,556-57. By the time this rule was promulgated, it had caused the deaths of at least 720,000 people in the United States, including at least 1,900 health care workers. *Id.* at 61,556, 61,569. It has hospitalized at least 3 million people. *Id.* at 61,556. In short, it is "the deadliest disease in American history." *Id.*

Given the virulence of this virus, it is easily transmitted among health care workers, and from health care workers to patients, in health care facilities. 86 Fed. Reg at 61,557 n.16. Unvaccinated health care workers are highly susceptible to transmitting the virus to their colleagues and to their patients. *Id.* at 61,558 n.42. Patients in facilities funded by the Medicare and Medicaid programs are more likely than the general population to suffer severe illness or death from COVID-19. *Id.* at 61,609. For these reasons, the Secretary concluded, "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 the medical care that they need is jeopardized

by low rates of vaccination among health care workers at facilities funded by these programs. *Id.* Patients in these programs have refused care from unvaccinated staff, or have forgone care altogether, to avoid contracting SARS-CoV-2 from health care workers. *Id.* Absenteeism from health care staff as a result of SARS-CoV-2 infection and COVID-19 illness has also contributed to staffing shortages that disrupt patient access to recommended care. *Id.* at 61,559.

The effects have been compounded by the emergence this summer of the Delta variant. *Id.* In particular, cases among long-term care facility and end-stage renal disease facility staff have increased by over 1400 percent and 850 percent, respectively, since the Delta variant emerged. *Id.* Between June and September 2021, daily cases of COVID-19 increased over 1200 percent, new hospital admissions for patients with COVID-19 increased over 600 percent, and daily deaths from COVID-19 increased over 800 percent. *Id.* at 61,583. The vast majority of cases during this time period were among the unvaccinated population. *Id.*

What is more, the evidence points to a resurgence in COVID-19 cases over the next several weeks. *Id.* at 61,584. There was a large spike in cases during the winter of 2020, demonstrating that COVID-19 follows seasonal patterns that are common for other respiratory virus infections. *Id.* There is strong reason to fear that SARS-CoV-2 will be exceptionally virulent during this period, as a severe 2021-2022 winter influenza season is anticipated, and the interaction between SARS-CoV-2 and the influenza virus may lead to worse outcomes over the next several months. *Id.* at 61,584 n.190. The Secretary accordingly reasoned that "it is imperative that the risk for healthcare-associated COVID-19 transmission be minimized during the influenza season." *Id.* at 61,584.

Fortunately, the COVID-19 vaccines that have been approved or authorized for use in the United States are safe, 86 Fed. Reg. at 61,562, and are highly effective in preventing serious outcomes of COVID-19, including hospitalization and death, *id.* at 61,565 n.115. These vaccines continue to 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 also show that the vaccines are highly effective in preventing SARS-CoV-2 infection among frontline workers. *Id.* at 61,585 n.205. Studies have 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.

In short, as the Secretary recognized, the available scientific evidence overwhelmingly points to the conclusion that the virus that causes COVID-19 is extremely dangerous for Medicare and Medicaid patients, and that vaccinations of health care staff are highly effective in preventing transmission among health care workers, and from health care workers to their patients. The Secretary, at minimum, reasonably reached this conclusion, and took action on that basis to fulfill his statutory responsibility to protect the health and safety of program beneficiaries while they are receiving 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 concluded that high rates of transmission of SARS-CoV-2 among health care staff have contributed to a shortage of health care workers, and that his vaccination rule would alleviate this problem. As noted above, many health care workers have missed work due to SARS-CoV-2 infection, and these absences have disrupted patient access to care. 86 Fed. Reg. at 61,559. There have been at least 500,000 reported COVID-19 cases, and at least 1,900 reported COVID-19 deaths, among health care staff; and the true figures are likely much higher. *Id.* And the rate of infection among health care staff has increased dramatically with the rise of the Delta variant. *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 reasonably concluded and fully explained that the rule would serve to alleviate personnel shortages at health care facilities. *Id.* at 61,569-70.

The Plaintiffs protest that they predict that a substantial portion of health care workers will choose to leave their jobs rather than be vaccinated, thereby threatening the operation of health care facilities. Br. at 16. The Secretary considered this possibility and rejected it, after reviewing the empirical evidence that has developed in recent months with regard to the effect of government-imposed or privately-imposed vaccination requirements.

Numerous health systems and individual health care employers throughout the country have

implemented COVID-vaccine requirements. 86 Fed Reg. at 61,566. These policies have been overwhelmingly successful, even among health care workers who were previously hesitant to obtain vaccination. *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 (citing Todd Ackerman, *Houston Methodist Requires COVID-19 Vaccine for Credentialed Doctors* (June 8, 2021), https://www.houstonmethodist.org/leading-medicine-blog/articles/2021/jun/houston-methodist-requires-covid-19-vaccine-for-credentialed-doctors/). Novant Health, similarly, achieved 98.6% compliance with its mandatory vaccination requirement for its staff. *Id.* at 61,566 n.132 (citing *Novant Health Update on Mandatory COVID-19 Vaccination Program for Employees* (Sept. 21, 2021), https://www.novanthealth.org/home/about-us/newsroom/press-releases/newsid33987/2576/novant-health-update-on-mandatory-covid-19-vaccination-program-for-employees.aspx). Contrary to Plaintiffs' claim that "CMS did not reference data on any past efforts to mandate COVID-19 vaccines in rural areas," Br. at 18, Novant Health in fact operates numerous hospitals, physician clinics, and urgent care centers, including several in rural North Carolina. *See, e.g.,* Novant Health, *Urgent Care Locations*, https://www.novanthealth.org/home/patients--visitors/locations/urgent-care-locations.aspx (last visited Nov. 20, 2021).

The State of New York also reported a 92% compliance rate with its vaccine requirement, for all 650,000 hospital and nursing home workers in that state, a figure which plainly accounts for the rural areas of New York as well. 86 Fed. Reg. at 61,569 n.159 (citing New York Times, *Thousands of N.Y. Healthcare Workers Get Vaccinated Ahead of Deadline* (Sept. 28, 2021)). 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 (citing Ezekiel J. Emanuel and David J. Skorton, *Mandating COVID-19 Vaccination for Health Care Workers*, Annals of Internal Medicine (Sept. 2021), http://doi.org/10.7326/M21-3150).

On the basis of this evidence, 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 memberships, of patients, and of health care facilities. 86 Fed. Reg. at 61,565. A leading national association of long-term care providers also concluded that acceptance of the vaccine would be high among the staff of its members' facilities and urged the issuance of a rule that would require vaccination. *Id.*

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 absenteeism 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. These effects would be dwarfed, however, by the ordinary degree of churn in the market of labor in the health care industry. In any given year, it is typical for about 2.66 million employees in health care settings to be new hires, in comparison to a total workforce of 10.4 million employees. *Id.* Health care providers are accustomed to regularly finding and replacing employees, and there is no reason to believe that the need to find staffing will be noticeably more onerous as a result of the vaccination rule, even if some unvaccinated health care workers leave for other employment and some vaccinated workers seek jobs in health care facilities. *Id.*

In sum, after reviewing the real-world evidence of the success 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. The Eighth Circuit has long held that "[j]udicial deference to agency action is 'especially important' when [an] agency's judgments are 'predictive.'" *Citizens Telecomms. Co. of Minn., LLC v. FCC*, 901 F.3d 991, 1010 (8th Cir. 2018) (quoting *Sw. Bell Tel. Co. v. FCC*, 153 F.3d 523, 547 (8th Cir. 1998)); *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) ("When, as here, an agency is making 'predictive judgments about the likely economic effects of a rule,' we are particularly loath to second-guess its analysis.") (citation omitted).

Asserted Reliance Interests. The Plaintiffs also argue that the Secretary failed to take into account the reliance interests of health care facilities and their workers. Br. at 16. To the contrary, as discussed above, the Secretary directly took into account the costs that employers and some employees would

incur under the rule. *See* 86 Fed. Reg. at 61,607-10. He concluded, however, that the benefits far outweighed the costs. He calculated that any combination of 120 lives saved, or 600 hospitalizations prevented, would result in the benefits of the rule outweighing its costs. *Id.* at 61,612. The lives saved under the rule will probably be "many times higher" than that threshold. *Id.* Although these estimates are subject to some uncertainty, "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 any costs under the rule more heavily in this analysis. The Plaintiffs claim that they relied on the Secretary's May 2021 rule, which had not yet required vaccinations in health care facilities, in their hiring of "workforces without concern for vaccination." Br. at 20. But that rule expressly required education on COVID-19 vaccines and the provision of vaccines in nursing homes, so it strains credulity to conclude that the rule encouraged employers or employees to forgo vaccination. That rule, moreover, was plainly described as just "*one step* in the broad effort to support those individuals at higher risk," 86 Fed. Reg. at 26,308 (emphasis added), and the Secretary explained that comments submitted in response to that rule "will help inform future CMS actions." *Id.* The Secretary did not, in his rule issued six months earlier, in any way disclaim the possibility of additional regulation to protect the health and safety of Medicare and Medicaid patients from SARS-CoV-2 and COVID-19, as circumstances developed. And, when he issued the rule at issue in this case, he reasonably explained that, although he had previously encouraged but did not require vaccinations, the continued low rates of vaccination uptake among health care workers and the concerns of the coming danger to Medicare and Medicaid patients in the winter months had cause him to reconsider that policy. 86 Fed. Reg. at 61,583-84.

But even assuming any reliance interests were at issue here, the Secretary "reasonably explained the departure from CMS's prior policy in spite of those reliance interests." *Northport Health*, 14 F.4th at 876. "[A]n agency need only provide a reasoned explanation for disregarding facts and circumstances that underlay or were engendered by the prior policy," *id.* (citation and alterations omitted), a standard that was easily met here.

Federalism Concerns. The Plaintiffs also incorrectly contend that the Secretary did not consider

the rule's impact on state sovereignty. Br. at 20-21. In fact, he specifically acknowledged that he needed to consider federalism concerns under Executive Order 13132, 86 Fed. Reg. at 61,613, recognized that his rule "would pre-empt some State laws that prohibit employers from requiring their employees to be vaccinated for COVID-19," *id.*, and determined that it was still necessary to establish the rule as the "minimum regulatory action necessary to achieve the objectives of the statute." *Id.* He determined that the "contagion rates of the existing strains of coronavirus and their disproportionate impacts on Medicare and Medicaid beneficiaries," necessitated that a vaccine mandate be imposed so as "to promote and protect patient health and safety." *Id.* That was more than sufficient consideration of the federalism concerns. The Plaintiffs' position that protecting the public health and mandatory vaccinations "'do not ordinarily concern the national government,'" Br. at 20 (quoting *Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905)), ignores the Secretary's responsibility to ensure the health and safety of Medicare and Medicaid patients while they are receiving care at facilities funded by those programs.

The Risk of Reinfection in Previously Infected Individuals. The Plaintiffs next fault the Secretary for his purported failure to consider whether to exempt individuals who were previously infected with the COVID-19 virus from the scope of his rule. Br. at 21. They cite a study of patients in Israel, which reported a finding of high levels of immunity for previously-infected individuals. *Id.* Contrary to their claims, the Secretary directly considered the issue of "natural immunity" in general, and their cited study in particular, but he concluded that the weight of the scientific evidence pointed against exempting individuals with prior infections.

The Secretary concluded that infection-induced immunity is not equivalent to receiving vaccination for COVID-19, 86 Fed. Reg. at 61,559, and that, even among those persons with prior SARS-CoV-2 infections, vaccination provides strong protection against reinfection. *Id.* at 61,585 n.205. Among persons previously infected with the virus, people who remain unvaccinated after that infection are more than twice as likely to be reinfected, as compared to fully vaccinated people. *See* Cavanaugh, et al., 70 Morbidity and Mortality Weekly Report at 1081. The Secretary accordingly followed the recommendations of CDC, which has found that the best academic evidence supports

the benefits of vaccination for all people, regardless of their infection history. 86 Fed. Reg. at 61,560.

In particular, CDC found on the basis of a comprehensive review of the academic literature that, among previously infected individuals, "[n]umerous immunologic studies have consistently shown that vaccination of individuals who were previously infected enhances their immune response, and growing epidemiologic evidence indicates that vaccination following infection further reduces the risk of subsequent infection, including in the setting of increased circulation of more infectious variants." *Id.* at 61,560 n.70 (citing CDC, *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States*, https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#CoV-19-vaccination).

In reaching this conclusion, CDC engaged in a comprehensive review of studies on the subject, including the Israeli study cited by the Plaintiffs as well as a more recent analysis that critiqued the methodology of that study; the later analysis found that the Israeli study had only considered short-term effects of infection, and that over a longer period, "there was a 5.5 times higher odds of laboratory-confirmed COVID-19 among previously infected patients than among fully vaccinated patients." *Science Brief: SARS-CoV-2 Infection-induced and Vaccine-induced Immunity* (citing Catherine H. Bozio, et al., *Laboratory-Confirmed COVID-19 Among Adults Hospitalized with COVID-19–Like Illness with Infection-Induced or mRNA Vaccine-Induced SARS-CoV-2 Immunity — Nine States, January–September 2021*, 70 Morbidity and Mortality Weekly Report 1539 (Oct. 29, 2021), https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/vaccine-induced-immunity.html) (linked to in *Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States*, cited at 86 Fed. Reg. 61,560 n.70, and accessible by clicking hyperlinked "studies" under "COVID-19 vaccination and SARS-CoV-2 infection: People with prior or current SARS-CoV-2 infection").

Because the overall weight of the scientific evidence pointed in favor of increased benefits of vaccinations of previously infected individuals, the Secretary reasonably chose not to create an exemption for these persons. 86 Fed. Reg. at 61,614. That easily satisfies the standards of APA review. 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). Moreover, the Secretary reasoned, an exemption would have raised complex issues of administrability, including, but not limited to, developing a methodology to evaluate the declining levels of antibodies over time in previously infected persons. 86 Fed. Reg. at 61,614. The Secretary reasonably declined that undertaking.

Allegedly Post-Hoc Reasoning. Nor can the Plaintiffs succeed on their claim that the vaccination rule amounts to a "*post hoc* rationalization." Br. at 22. In reviewing agency action, "a court is ordinarily limited to evaluating the agency's contemporaneous explanation in light of the existing administrative record." *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2573 (2019). The Secretary provided a comprehensive statement of the reasons supporting his issuance of the rule, at the time that he did so. This statement provides the "contemporaneous explanation" for the issuance of the rule. *Camp v. Pitts*, 411 U.S. 138, 143 (1973). This case is entirely unlike the agency's justification in *Department of Homeland Security v. Regents of the Univ. of California*, 140 S. Ct. 1891, 1909 (2020)—the only case cited by the Plaintiffs—which involved an agency memorandum created far after the predicate action took place.

The Scope of the Rule. Finally, the Plaintiffs contend that the rule is overly broad, either because it should have applied only to facilities that care for the elderly and infirm, or because the rule should have exempted personnel without direct contact with patients. Br. at 22. The Secretary reasonably explained his policy choices on both scores.

The Plaintiffs assert that the rule "reaches categories of healthcare facilities, such as Psychiatric Residential Treatment Facilities ("PRTFs") for individuals under age 21, that are not related to CMS's asserted interest in protecting elderly and infirm patients from COVID-19." *Id.* But that misstates the Secretary's interest; nowhere in the rule did he claim that his statutory responsibilities extended *only* to the elderly or infirm. Instead, his statutory responsibility—and his asserted interest—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) (incorporating for psychiatric residential treatment facilities,

through cross-referenced statutes, the health and safety requirements for hospitals under § 1395x(e)(9)). And he reasonably concluded that individuals in congregate care settings, such as psychiatric residential treatment facilities, are at greater risk of acquiring infections, including infection with the virus that causes COVID-19. 86 Fed. Reg. at 61,575. He also noted the danger of cross-transmission of the virus, since staff at certain facilities may work across facility types. *Id.* Residents of these facilities also may have difficulty adhering to alternative protocols used to limit the transmission of the virus. *Id.* In addition to this discussion of the risks posed in these particular facilities, the Secretary explained his rationale for extending the rule to each of the types of providers that are subject to its requirements. *See id.* at 61,575-83.

The Plaintiffs also contend that the rule is overbroad because it requires the vaccination of all staff that may come into contact with others at the site of care. Br. at 22. But far from being "inexplicable," *id.*, the Secretary explained at length why these personnel should be covered by the vaccination requirements. *See, e.g.,* 86 Fed. Reg. at 61,570-71. He concluded that these persons may "encounter fellow employees, such as in an administrative office or at an off-site staff meeting, who will themselves enter a health care facility or site of care for their job responsibilities[.]" *Id.* at 61,568. Given the high transmissibility of the virus and demonstrated rates of transmission of the virus among health care workers, this conclusion was eminently reasonable. *See id.* at 61,557. The Secretary elected to exempt persons who perform only infrequent tasks at health care facilities, and directed providers to consider "frequency of presence, services provided, and proximity to patients and staff" in evaluating which of their employees would be covered under the rule. *Id.* at 61,571. He considered a broader exemption to "exclud[e] individual staff members who are present at the site of care less frequently than once per week from these vaccination requirements, but [was] concerned that this might lead to confusion or fragmented care." *Id.* at 61570-71. Accordingly, the rule provides strong protection to patients by requiring the vaccinations of health care providers and personnel who interact with patients directly, along with staff who pose a danger of indirect transmission of the virus.[9]

[9] At the same time, the rule exempts from the vaccine requirements those staff who "telework

Ultimately, the Plaintiffs' argument boils down to a dispute over where to draw the line with a vaccination requirement. 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); *see also ExxonMobil Gas Mktg. Co. v. FERC*, 297 F.3d 1071, 1085 (D.C. Cir. 2002) ("We are generally 'unwilling to review line-drawing performed by the Commission unless a petitioner can demonstrate that lines drawn . . . are patently unreasonable, having no relationship to the underlying regulatory problem.'") (quoting *Cassell v. FCC*, 154 F.3d 478, 485 (D.C. Cir. 1998)). Although the Plaintiffs would prefer for the rule to cover fewer health care staff, the APA does not permit them to "substitute [their] policy judgment for that of the agency." *Prometheus Radio Project*, 141 S. Ct. at 1158. It was plainly reasonable for the Secretary to pursue robust protection for patients by requiring vaccination of the categories of staff set forth above, and reasonableness is all the APA requires. *See id.* ("A court simply ensures that the agency has acted within a zone of reasonableness and . . . has reasonably considered the relevant issues and reasonably explained the decision.").

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

The Plaintiffs are unlikely to succeed on their claim that the Secretary was required to follow notice-and-comment procedures before issuing the rule. Notice-and-comment rulemaking is not required "when the agency for good cause finds (and 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) (incorporating 5 U.S.C. § 553(b)(B)) into the Medicare statute). 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.

As the Secretary explained, "a further delay in imposing a vaccine mandate would endanger

---

full-time," and vendors and other professionals who perform infrequent, non-healthcare services. 86 Fed. Reg. at 61,571. CMS 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.*

the health and safety of additional patients and be contrary to the public interest." 86 Fed. Reg. at 61,584; *see id.* at 61,583, 61,586 (similar). The Secretary found that any delay for a comment period would be contrary to the public interest, given the "life-saving importance" of the rule, *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981), just as the APA permits. *See also, e.g.*, *Nw. Airlines, Inc. v. Goldschmidt*, 645 F.2d 1309, 1321 (8th Cir. 1981) (holding that the "urgent necessity for rapid administrative action under the circumstances of the present case would justify the Secretary's finding of 'good cause'"). If, as the Eighth Circuit held, the desire for smooth air travel "on the eve of the winter holiday season," constitutes "good cause" to implement an air traffic rule with a seven-day comment period, *id.*, then the urgent need to protect the health and safety of Medicare and Medicaid patients from a virus that has claimed more than 720,000 lives plainly suffices to waive the notice-and-comment requirement as well.

The Secretary reasonably determined 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." 86 Fed. Reg. at 61,567. In fact, he projected that the "total lives saved under this rule may well reach several hundred a month or perhaps several thousand a month." *Id.* at 61,612; *accord United States v. Brewer*, 766 F.3d 884, 890 (8th Cir. 2014) (recognizing that "the risk of future harm may, under some circumstances, justify a finding of good cause" where the risk is "more substantial than a mere possibility"). *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").

Unable to dispute these findings, the Plaintiffs simply ignore them. This omission is of a piece with the Plaintiffs' failure to acknowledge the now more than 760,000 total lives lost to COVID-19 in the United States, or that COVID-19 continues to claim over 1,000 lives in this country *every day*.[10]

[10] *See* New York Times, Coronavirus in the US: Latest Map and Case Count (updated Nov. 17, 2021), https://www.nytimes.com/interactive/2021/us/covid-cases.html (stating a daily average of 1,158 deaths, 48,276 hospitalizations, and 94,669 cases).

But the Eighth Circuit has long recognized that "considerations of public health and safety" may constitute good cause to waive notice and comment. *United States v. Gavrilovic*, 551 F.2d 1099, 1105 (8th Cir. 1977). The court recognized that "[a]s the degree of risk and the potential for harm increase the need to provide immediate controls increases accordingly. The issue is whether the need is so great and the emergency so defined that it justifies administrative rule making without according the public the ordinary notice required by law." *Id.* The COVID-19 pandemic is indeed a precisely defined emergency. Moreover, with COVID-19 being "the deadliest disease in American history," 86 Fed. Reg. at 61,556, "the degree of risk and potential for harm" yield a "need to provide immediate controls" of unparalleled and (at the least) sufficient "greatness" to clear the good cause hurdle. *Gavrilovic*, 551 F.2d at 1105; *accord Hedge v. Lyng*, 689 F. Supp. 884, 892–93 (D. Minn. 1987) (explaining that "legitimate grounds" for invoking the good cause exception include "an urgency of conditions coupled with a demonstrated and unavoidable limitations of time") (citation omitted).

Beyond reasonably concluding and explaining that the need to prevent loss of additional human life justifies the immediate action here, the Secretary also detailed the nature of the emergency over the most recent several months and reached reasonable predictions about the nature of the emergency over the coming few months. He explained that he initially chose a policy of "encourag[ing] rather than mandat[ing] vaccination," believing that a combination of other efforts and actions would be "adequate." 86 Fed. Reg. at 61,583. However, despite all of these other efforts, *id.* "vaccine uptake among health care staff" remains "insufficient to protect the health and safety of individuals receiving health care services from Medicare- and Medicaid-certified providers and suppliers." *Id.*; *see also id.* at 61,559 (detailing average vaccination rates below 70% among health care staff across different types of facilities). This conclusion is supported by data "demonstrat[ing] SARS–CoV–2 transmissions between health-care workers and patients in hospitals, despite universal masking and other protocols." *Id.* at 61,585. As a result, any delay of the rule "would contribute to additional negative health outcomes for patients including loss of life." *Id.* at 61,584.

The Secretary also explained why the advent of the Delta variant requires addressing the currently inadequate vaccination levels without delay. *Id.* at 61,583. As the Secretary explained, the

emergence of Delta in summer 2021 reversed the declines in cases, hospitalizations, and deaths in the first half of the year, with daily cases increasing over 1200 percent, hospitalizations, over 600 percent, and deaths, by nearly 800 percent, with the overwhelming majority occurring among individuals who were not fully vaccinated. *Id.* These persistently high hospitalization rates, which are concentrated among the unvaccinated, are, together with "persistent staffing shortages due, at least in part, to COVID-19 infection or quarantine following exposure," placing "tremendous strain" on the health care system. *Id.* As of mid-October 2021, CDC had reported an estimated more than 500,000 cases and 1,900 deaths among health care staff, a likely underestimate. *Id.* at 61,585. Moreover, data shows that cases among health care workers have "grown in tandem with broader national incidence trends since the Delta variant's emergence," *id.*; among those healthcare staff for whom data was reported to the CDC, cases "increased by nearly 600 percent between June and August 2021." *Id.* As the Secretary explained, "[b]ecause they are at greater risk for developing COVID-19 infection and severe disease, unvaccinated staff present a risk of exacerbating ongoing staffing shortages—particularly during periods of community surges in SARS–CoV–2 infection, when demand for health care services is most acute." *Id.*

Further, and based on available data, the Secretary reasonably predicted that a renewed surge, the coming flu season, or a combination of the two will further exacerbate the strain on the health care system. *See, e.g.*, *Citizens Telecoms. Co. of Minn., LLC*, 901 F.3d at 1010 (judicial deference is particularly important to an agency's predictive judgments). First, the Secretary identified "emerging indications of potential increases" in cases, "particularly [in] northern states where the weather has begun to turn colder," indications which are consistent with evidence that "[r]espiratory virus infections typically circulate more frequently during the winter months." *Id.* at 61,584.[11]

Second, the Secretary explained that the coming flu season "presents an additional threat to patient health and safety," given that the interaction of the flu virus with the COVID-19 virus could

[11] Although Plaintiffs assert that CMS's claims of "emerging indications of potential increases" are "uncited" and "undocumented," those indications were evident in the CDC COVID Data Tracker cited numerous times throughout the rule, including in this discussion. *See, e.g.*, 86 Fed. Reg. at 61,583-84 n.185.

lead to particularly severe outcomes for health care facility patients. *Id.* While he acknowledged that the "intensity" of the coming flu season "cannot be predicted," he identified "[s]everal factors" that "could make this flu season more severe." *Id.* ("return to school by children with no prior exposure to flu . . . , waning protection over time from previous seasonal influenza vaccination, and the fact that adult immunity . . . will now partly depend on exposure to viruses two or more seasons earlier"). The number of factors cited by the agency, and the likelihood of each occurring, raises the risk of a severe flu season above "a mere possibility." *Brewer*, 766 F.3d at 890 (cited in Br. at 34).

Moreover, the Secretary cited "[p]reliminary evidence suggest[ing] that a combination of infections with influenza and SARS–CoV–2 would result in more severe health outcomes for patients than either infection alone." *Id.* He determined that the strain on the health care system produced by the coincidence of persistently high (or rising) COVID-19 cases together with an imminent and potentially severe flu season would "adversely impact patient access to care and care quality" and, therefore, "it is imperative that the risk for healthcare-associated COVID-19 transmission be minimized during the influenza season." *Id.* Because flu incidence is highest "between December through March" and "COVID-19 vaccines require time after administration for the body to build an immune response," he reasonably determined that "a staff COVID-19 vaccination requirement for the providers and suppliers identified in this rule cannot be further delayed." *Id.* In this regard, and contrary to the Plaintiffs' suggestion, Br. at 33, the Secretary has "point[ed] to something specific that illustrates a particular harm that will be caused by the delay required for notice and comment." *Brewer*, 766 F.3dat 890 (citation omitted). Moreover, his invocation of a renewed COVID-19 surge, the coming flu season, or a combination of the two, are not merely recitations of the reasons for the rule, *contra* Br. at 33; they are, rather, considered, supported reasons that the rule is necessary *right now*.

Based on all of these reasons, and considering all of the available data, the Secretary determined that "a further delay in imposing a vaccine mandate would endanger the health and safety of additional patients and be contrary to the public interest," *id* at 61,584; *see also id.* at 61,586 (same), and, accordingly, carried its burden of demonstrating that delay occasioned by the notice and comment procedures "would in fact harm that interest." *Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 95 (D.C. Cir.

2012); *see also Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 113–14 (2d Cir. 2018). The fact that the Secretary issued the rule several weeks after President Biden's announcement does not "weaken[]" this determination. Br. at 34. Any rule—whether or not accompanied by notice and comment procedures—must be the result of considered judgment and a reasoned decisionmaking process, a process that takes time to complete. To the extent the President's announcement is relevant here, the fact that the Secretary issued the rule less than two months after that announcement demonstrates that he acted with appropriate dispatch.

Because the Secretary had good cause to dispense with notice-and-comment rulemaking, the Plaintiffs' two additional procedural arguments are unavailing. First, the Plaintiffs contend that the Secretary violated 42 U.S.C. § 1395z. Br. at 35. That statute directs 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 and recognized national listing or accrediting bodies[.]" 42 U.S.C. § 1395z. 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." 86 Fed. Reg. at 61,567. Based on that finding of the existence of an emergency, he determined that there are no entities with which it would be "appropriate to engage in these consultations in advance of issuing" the interim rule, but noted that he would engage in consultations following the rule's issuance "in carrying out [his] functions." *Id.*

This determination is entitled to deference from this Court, 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) (statutory language authorizing agency to take "appropriate" action "is a hallmark of vast discretion"). *See also 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, the Plaintiffs contend that the Secretary's issuance of his rule on an emergency basis violated 42 U.S.C. § 1302(b), which requires the preparation of a regulatory impact analysis upon the

publication of a "notice of proposed rulemaking," *id.* § 1302(b)(1), or upon the 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, such as this one, 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 are not free to impose additional procedural requirements on rulemakings beyond those expressed in statute).

D. The rule is constitutional.

The vaccination rule does not, as the Plaintiffs contend, upset any federal-state "balance" or exceed Congress's power to regulate interstate commerce. The Supreme Court "long ago rejected the suggestion that Congress invades areas reserved to the States by the Tenth Amendment simply because it exercises its authority under the Commerce Clause [or, as here, the Spending Clause] in a manner that displaces the States' exercise of their police powers." *Hodel v. Va. Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 291 (1981). In fact, "[a] Tenth Amendment challenge to a statute necessarily fails if the statute is a valid exercise of a power relegated to Congress." *United States v. Louper-Morris*, 672 F.3d 539, 563 (8th Cir. 2012) (citation omitted). Even though "public health" is an "area[] of traditional state concern," "Congress' authority under the Spending Clause to choose how to fund the Medicare program is not in doubt." *Minnesota ex rel. Hatch v. United States*, 102 F. Supp. 2d 1115, 1123 (D. Minn. 2000), *aff'd sub nom. Minnesota Senior Fed'n, Metro. Region v. United States*, 273 F.3d 805 (8th Cir. 2001). And it stands to reason that if a statute constitutes a valid exercise of congressional power, any regulation validly promulgated pursuant to statutory authority must also be immune from a Tenth Amendment challenge. Accordingly, because, for the reasons articulated above, *see supra*

Section II.A., the vaccination rule is a valid exercise of the agency's statutory authority, the Plaintiffs are unlikely to succeed on the merits of their Tenth Amendment challenge.

The Plaintiffs next contend briefly that the vaccination rule was not a valid exercise of the Commerce Clause. Br. at 31. But the statutes upon which the Secretary relied are exercises of the Congressional spending power, rather than the commerce power, so the Plaintiffs' discussion of the Commerce Clause is irrelevant here. *See Coll. Sav. Bank v. Fla. Prepaid Postsecondary Educ. Expense Bd.*, 527 U.S. 666, 686 (1999) ("Congress may, in the exercise of its spending power, condition its grant of funds to the States upon their taking certain actions that Congress could not require them to take, and that acceptance of the funds entails an agreement to the actions."). And, in any event, the States miss the mark in arguing that the vaccination rule "does not regulate ongoing commercial activity," Br. at 31, or in likening it to the provision of the Affordable Care Act at issue in *National Federation of Independent Business v. Sebelius*, 567 U.S. 519, 520 (2012) ("*NFIB*"). The vaccination rule does not compel any parties to become active in commerce; instead, it is a condition on payment of funds to entities that make the voluntary choice to participate in the Medicare and Medicaid programs. *See Northport Health Servs.*, 14 F.4th at 869 n.5.

The Plaintiffs likewise err when they reach the constitutional provision that does apply here, the Spending Clause. They argue that the vaccination rule violates the Spending Clause by allegedly commandeering the States' administrative apparatus for federal purposes without clear notice to the States. Br. at 29-30. But the conditions on federal spending of which the Plaintiffs complain are imposed on public or private entities that choose to participate in the Medicare and Medicaid programs, not on States in their capacity as States. *See Northport Health Servs.*, 14 F.4th at 869 n.5.

In any event, "under Congress['s] spending power, [it] may attach conditions on the receipt of federal funds," as long as '[s]uch conditions . . . bear some relationship to the purpose of the federal spending." *New York v. United States*, 505 U.S. 144, 167 (1992) (citation omitted). "Congress has broad power to set the terms on which it disburses federal money to the States." *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006). "[L]egislation enacted pursuant to the spending power

is much in the nature of a contract: in return for federal funds, the States agree to comply with federally imposed conditions." *Pennhurst States Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981).

Medicare and Medicaid are massive federal programs that impose all sorts of conditions with which participants must comply in order to receive funds. Even where, unlike here, the Medicaid program has conditioned federal funding for State governments on the States' agreement to certain conditions, courts have upheld those conditions under Congress's spending authority, absent, in certain circumstances not present here, a conclusion that the offer of federal funding is coercive. *See, e.g.*, *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 502 (1990) ("Although participation in the [Medicaid] program is voluntary, participating [s]tates must comply with certain requirements imposed by the Act and regulations promulgated by the Secretary."). And Congress acts on even stronger footing when it offers federal funding to private entities in exchange for their agreement to abide by certain conditions on that funding, such as an agreement to protect the health and safety of their patients. *See Minn. Ass'n of Health Care Facilities, Inc. v. Minn. Dep't of Pub. Welfare*, 742 F.2d 442, 446 (8th Cir. 1984) ("Despite the strong financial inducement to participate in Medicaid, a nursing home's decision to do so is nonetheless voluntary."); *see also Northport Health*, 14 F.4th at 869 n.5; *Se. Ark. Hospice, Inc. v. Burwell,* 815 F.3d 448, 450 (8th Cir. 2016) (holding that hospice provider's voluntary participation in Medicare "forecloses the possibility that the statute could result in an imposed taking of private property which would give rise to the constitutional right of just compensation" (quoting *Minn. Ass'n*, 742 F.2d at 446)).

The Plaintiffs nevertheless argue—again, on the basis of *NFIB*—that "[f]orcing States to administer the mandate or jeopardize *all Medicare and Medicaid funds flowing into their States* (even to private healthcare providers) is 'a gun to the head' that compels states to participate against their will." Br. at 30 (Plaintiffs' emphasis) (quoting *NFIB*, 567 U.S. at 581). The *NFIB* plurality reasoned that Congress had coerced the States by conditioning all funding for one program, the traditional Medicaid program, on the States' agreement to participate in a new, second program, the expansion of the program to new populations. But here, the Secretary is not "enlisting the States in a new health care program," *NFIB*, 567 U.S. at 584. *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.

The Plaintiffs also contend that they did not have "clear notice" of the obligations imposed by the rule. Br. at 30 (quoting *Arlington Cent. Sch. Dist.*, 548 U.S. at 296). But health care facilities that choose to receive federal funding do so with the awareness that they are subject to the Secretary's health and safety standards. *See* 42 U.S.C. § 1395cc(a). Likewise, if States choose to operate as state surveyors, they enter into a voluntary agreement, that is terminable by either party, to receive funding for their survey activities. If they enter into such an agreement, they simply commit themselves to review health care facilities' compliance with federal standards and to report their findings to the Secretary for further action, *see* 42 U.S.C. § 1395aa(a); 42 C.F.R. § 488.10(a), 42 C.F.R. § 488.26(c)(1), using "the survey methods, procedures, and forms that are prescribed by CMS," *id.* § 488.26(d).

Despite making that commitment, the Plaintiffs now protest that the Secretary's health and safety standards are not expressly spelled out by statute. 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) ("[T]he Federal Government simply could not prospectively resolve every possible ambiguity concerning particular applications of [a grant program's] requirements . . . ."). "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). At bottom, the choice of health care facilities to participate in the Medicare and Medicaid programs is a voluntary one, and facilities that make that choice do so with the knowledge that the Secretary may impose requirements on them that he finds necessary to further the Congressional purposes of protecting the health and safety of program beneficiaries. *See Northport Health*, 14 F.4th at 869 n.5.

III. THE REMAINING INJUNCTION FACTORS REQUIRE DENIAL OF PLAINTIFFS' MOTION.

A. Plaintiffs fail to establish irreparable harm.

The Plaintiffs also cannot demonstrate likely irreparable harm. *See Florida v. Dep't of Health &*

Human Servs., No. 3:21-cv-02722-MCR-HTC (N.D. Fla. Nov. 20, 2021), Order, ECF No. 6 (denying preliminary injunction in a nearly identical suit for the State's failure to show irreparable harm). Such a showing is indispensable for a preliminary injunction. *Planned Parenthood Minn., N.D., S.D. v. Rounds*, 530 F.3d 724, 732–33 & n.5 (8th Cir. 2008) (en banc). "In order to demonstrate irreparable harm, a party must show that the harm is certain and great and of such imminence that there is a clear and present need for equitable relief." *Iowa Utils. Bd. v. FCC*, 109 F.3d 418, 425 (8th Cir. 1996). "Speculative harm" or a mere "possibility of irreparable harm" is not enough. *S.J.W. ex rel. Wilson v. Lee's Summit R-7 Sch. Dist.*, 696 F.3d 771, 779 (8th Cir. 2012); *Winte*, 555 U.S. at 22. Economic loss alone is not irreparable harm unless the injuries cannot be recovered. *See Chlorine Inst., Inc. v. Soo Line R.R.*, 792 F.3d 903, 915 (8th Cir. 2015).

1. The Plaintiffs suffer no cognizable harm to their "sovereign, quasi-sovereign, or proprietary" interests at all, let alone a harm of the type required for equitable relief. The Plaintiffs do not have a cognizable interest for Article III purposes in the abstract question whether state law is preempted. *See Va. ex rel. Cuccinelli v. Sebelius*, 656 F.3d 253, 270 (4th Cir. 2011); *see also Florida*, Order at 10 (rejecting this same argument as "lack[ing] merit"). And, as for the Plaintiffs' quasi-sovereign interests or *parens patriae* interests, the Plaintiffs have no standing to sue the federal government in that capacity and therefore cannot assert that they have been irreparably harmed on the basis of such interests. *See Iowa ex rel. Miller v. Block*, 771 F.2d 347, 355 (8th Cir. 1985) ("[W]e cannot allow the State to proceed as *parens patriae* in this case. To do so would intrude on the sovereignty of the federal government and ignore important considerations of our federalist system."); *see also 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").

Finally, regarding the Plaintiffs' proprietary interests, they assert they will suffer "irreparable pocketbook harm" and "a diversion of state resources," Br. at 40, but neither constitutes irreparable harm. *See Florida,* Order at 9 ("[E]conomic loss such as the loss of funding is not irreparable."). In fact, as explained previously, the Supreme Court recognized § 405's channeling provision "comes at a price, namely, occasional individual, delay-related hardship," but concluded that Congress judged this

price to be justified "[i]n the context of a massive, complex health and safety program such as Medicare." *Illinois Council*, 529 U.S. at 13.

2. The Plaintiffs' claims of irreparable harm are also speculative, as the *Florida* court recognized. That court "disregarded as conclusory" and as "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*, Order at 8. 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.* at 10.

The Plaintiffs' evidence here is equally lacking. They rely on conjecture that the rule will "exacerbate an alarming shortage of healthcare workers." Br. at 1. "'Bare allegations of what is likely to occur are of no value since the court must decide whether the harm will *in fact* occur.'" *Packard Elevator v. Interstate Com. Comm'n*, 782 F.2d 112, 115 (8th Cir. 1986) (quoting *Wis. Gas Co. v. FERC*, 758 F.2d 669, 674 (D.C. Cir. 1985) (per curiam)). As stated in the rule, "many health care workers already comply with employer or State government vaccination requirements (for example, influenza, and hepatitis B virus (HBV))," 86 Fed. Reg. at 61,567, and "most of these individuals met State and local vaccination requirements in order to attend school." *Id.* at 61,567-68. The Secretary recognized concerns that health care workers would choose to leave their jobs rather than be vaccinated, but found "insufficient evidence to quantify and compare adverse impacts on patient and resident care associated with temporary staffing losses due to mandates and absences due to quarantine for known COVID-19 exposures and illness." *Id.* at 61,569. Further, the Secretary identified real-world evidence showing that, when COVID-19 vaccination requirements have been initiated, workers have responded by getting vaccinated. "99.5 percent of . . . staff" at a large hospital system in Texas responded to the system's mandate by getting vaccinated, *id.*; 98 percent of a 33,000 employee health system in Detroit did the same, *id.*; 95 percent of workers at more than 250 long-term care facilities did so, *id.*; and New York's state-wide health care worker mandate also saw a "jump in vaccine compliance in the final days

before the requirements took effect," *id.* *See also* 86 Fed. Reg. 63,418, 63,422 (Nov. 16, 2021) (Office of Management and Budget analysis noting that "Tyson Foods reported more than 96 percent of its workforce is now vaccinated" after the company imposed a vaccination requirement).

The Plaintiffs identify no evidence demonstrating that health care workers will actually leave their jobs in large numbers if the vaccination rule remains in effect. They cite declarations from health care facilities that "project" losses, "fear[]" that they will not survive, and "expect[]" to lose employees, Br. at 9, but they have not identified any facilities that actually issued or were subject to vaccination requirements and lost significant numbers of employees. In the absence of such evidence, the Plaintiffs cannot show that the harm they fear will *in fact* occur.

Moreover, the Plaintiffs fail to set forth any evidence that the labor loss they fear will certainly outstrip staffing losses and absences due to quarantine for known COVID-19 exposures or the normal churn in the health care labor market. The Plaintiffs set forth statistics about staffing shortages, but they do not evaluate why those shortages exist. The Secretary explored this issue, and found that "some hospitals and health care systems are currently experiencing tremendous strain due to high case volume, coupled with persistent staffing shortages due, at least in part, to COVID-19 infection or quarantine following exposure." 86 Fed. Reg. at 61,583. Nor do the Plaintiffs provide any evidence that in the absence of the vaccination rule, they will be able to stave off additional staffing problems. In fact, the opposite appears to be the case. The Plaintiffs admit that during the pandemic, "there has been a boom in demand for travel nurses" and that "small rural hospitals . . . cannot afford to pay their nurses more to stay." Br. at 2. The longer the pandemic rages, the more the demand for travel nurses will stay high and the more employees will be lured away for higher pay. The Plaintiffs cannot carry their burden to show irreparable harm when they cannot show that in the absence of the rule they will be able to retain all of their current employees.

Accordingly, they cannot show that the harm they fear is "certain and great and of such imminence that there is a clear and present need for equitable relief." *Novus Franchising, Inc. v. Dawson*, 725 F.3d 885, 895 (8th Cir. 2013) (citation omitted). Because the Plaintiffs cannot show irreparable harm, they are not entitled to injunctive relief. *Mgmt. Registry, Inc. v. A.W. Companies, Inc.*, 920 F.3d

1181, 1184 (8th Cir. 2019).

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

The third and fourth requirements for issuance of a preliminary injunction—the balance of harms and whether the requested injunction will disserve the public interest—"merge when the Government is the opposing party." *Nken*, 556 U.S. at 435. Here, these considerations tilt decisively in the Defendants' favor.

First, enjoining the rule would harm the public interest in slowing the spread of COVID-19 among millions of health care workers and Medicare and Medicaid patients. As the Supreme Court has recognized, "[s]temming the spread of COVID-19 is unquestionably a compelling interest." *Roman Catholic Diocese of Brooklyn v. Cuomo,* 141 S. Ct. 63, 67 (2020). Accordingly, numerous courts reviewing "executive action designed to slow the spread of COVID-19" have concluded that, "[t]he public interest in protecting human life—particularly in the face of a global and unpredictable pandemic—would not be served by" an injunction. *Tigges v. Northam*, 473 F. Supp. 3d 559, 573–74 (E.D. Va. 2020); *see also, e.g.*, *Am.'s Frontline Drs. v. Wilcox*, No. EDCV 21-1243, 2021 WL 4546923, at *8 (C.D. Cal. July 30, 2021); *Valdez v. Grisham*, ---F. Supp. 3d---, 2021 WL 4145746, at *13 (D.N.M. Sept. 13, 2021), appeal filed, No. 21-2105 (10th Cir. Sept. 15, 2021); *Harris v. Univ. of Mass., Lowell*, ---F. Supp. 3d---, 2021 WL 3848012, at *8 (D. Mass. Aug. 27, 2021), appeal filed, No. 21-1770 (1st Cir. Sept. 28, 2021); *Williams v. Brown*, ---F. Supp. 3d---, 2021 WL 4894264, at *10-11 (D. Or. Oct. 19, 2021); *Wise v. Inslee*, No. 2:21-cv-0288, 2021 WL 4951571, at *6 (E.D. Wash. Oct. 25, 2021); *Mass Corr. Officers Federated Union v. Baker*, ---F. Supp. 3d---, 2021 WL 4822154, at *7-8 (D. Mass. Oct. 15, 2021); *Johnson v. Brown*, ---F. Supp. 3d---, 2021 WL 4846060, at *26-27 (D.Or. Oct. 18, 2021); *TJM 64, Inc. v. Harris*, 475 F. Supp. 3d 828, 840–41 (W.D. Tenn. 2020); *Talleywhacker, Inc. v. Cooper*, 465 F. Supp. 3d 523, 543 (E.D.N.C. 2020).

Second, enjoining the rule would harm the public interest by further exposing Medicare and Medicaid patients and staff—and the Medicare and Medicaid programs—to unvaccinated health care workers. For patients and staff, this means numerous additional lives affected by disease,

hospitalization, or even death. *See supra* at 31. For providers, this means a further contribution to staffing shortages owing to both time off for illness and quarantine, as well as staff deaths. The Secretary cited concrete evidence that an increase in vaccinated health care staff improves patient safety and access to care. As the Secretary detailed in the rule, "evidence has shown that influenza vaccination of health care staff is associated with declines in nosocomial [meaning, health-care-associated or hospital-acquired] influenza in hospitalized patients, and among nursing home residents." 86 Fed. Reg. at 61,558. Additionally, "[f]ewer infected staff and lower transmissibility equates to fewer opportunities for transmission to patients." *Id.* at 61,558. And further, "case rates among [long-term care] facility residents are higher in facilities with lower vaccination coverage among staff," and "nursing home outbreaks have [been] linked . . . to unvaccinated health care workers." *Id.* Finally, the Secretary demonstrated that "illnesses and deaths associated with COVID-19 are exacerbating staffing shortages across the health care system." *Id.* at 61,559. In particular, "[o]ver half a million COVID-19 cases and 1,900 deaths among health care staff have been reported to CDC since the start of the [public health emergency]," numbers that are likely undercounts. *Id.*

Not only has the Secretary identified concrete, data-driven harms, but he reasonably determined, based on the available evidence, that a tool exists to counter those harms. "FDA-approved and FDA-authorized vaccines in use in the U.S. are both safe and highly effective at protecting vaccinated people against symptomatic and severe COVID-19." *Id.* at 61,560. Moreover, "[e]merging evidence also suggests that vaccinated people who become infected with the SARS–CoV–2 Delta variant have potential to be less infectious than infected unvaccinated people, thus decreasing transmission risk." *Id.* at 61,558. Reducing COVID-19 cases, hospitalizations, and deaths, as well as the transmissibility of COVID-19 among health care workers will both prevent some staffing shortages and protect patient health. *Id.*

By comparison, any theoretical harm that the Plaintiffs might experience absent a preliminary injunction is, as explained *supra* at Part III.A, both speculative and purely economic. Nowhere do the Plaintiffs dispute this evidence of positive effects of vaccination on patient care and health, including the saving of lives. In fact, in discussing the public interest prong, the Plaintiffs fail to even

acknowledge the unparalleled American casualties from COVID-19. Rather, the Plaintiffs argue that the rule will cause health care staff to leave their jobs, with cascading effects on patient access to care. But they have set forth no evidence to demonstrate 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 near 100 percent. 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) (hospitals); 1395i–3(d)(4)(B) (Medicare long-term care facilities). The public interest favors allowing the Secretary to fulfill these responsibilities.

At bottom, the balance of harms and the public interest factors of the injunctive relief analysis weigh heavily in favor of allowing the federal government to take reasonable steps to protect the health of patients and staff in health care facilities that participate in the Medicare and Medicaid programs. Granting the Plaintiffs' motion would do far more certain harm to the public interest than denying the motion might (potentially) harm the Plaintiffs.

IV. ANY INJUNCTIVE RELIEF SHOULD BE LIMITED TO FACILITIES OPERATED BY THE PLAINTIFFS AND ONLY TO ANY UNLAWFUL ASPECTS, IF ANY, OF THE RULE.

If the Court disagrees with the Defendants' arguments, any relief should be no broader than necessary to remedy the demonstrated irreparable harms of the specific Plaintiffs in this case. "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 the 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 the 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, the Plaintiffs have no serious interest in whether 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 in the Plaintiffs States that Plaintiffs do not operate, and the Plaintiffs' claims would be fully redressed through a preliminary injunction prohibiting the Secretary from "implementing" or "enforcing" the rule against facilities Plaintiffs operate alone.

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 the Plaintiffs' claims against the rule's operation in other jurisdictions. Moreover, more than half of the States are not challenging the vaccination rule. There is no reason why the 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 challenge under the APA).

CONCLUSION

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

Dated: November 22, 2021

Respectfully submitted,

BRIAN M. BOYNTON
Acting Assistant Attorney General

MICHELLE R. BENNETT
Assistant Branch Director
Federal Programs Branch

/s/ Joel McElvain
JOEL McELVAIN
Bar No. 448431(DC)
Senior Trial Counsel

JULIE STRAUS HARRIS
Bar No. 1021298(DC)
Senior Trial Counsel

JONATHAN D. KOSSAK
Bar No. 991478(DC)
Trial Attorney

MICHAEL L. DREZNER
Bar No. 83836(VA)
Trial Attorney

U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street NW
Washington, DC 20530
Tel: (202) 616-8298
Fax: (202) 616-8470
Email: Joel.L.McElvain@usdoj.gov

Attorneys for Defendants