Nos. 21A240, 21A241

In the Supreme Court of the United States

XAVIER BECERRA, U.S. Department of Health and Human Services et al.,
Applicants,

v.

STATES OF LOUISIANA, MONTANA, ARIZONA, ALABAMA, GEORGIA, IDAHO, INDIANA, KENTUCKY, MISSISSIPPI, OHIO, OKLAHOMA, SOUTH CAROLINA, UTAH, AND WEST VIRGINIA ET AL.,
Respondents.

RESPONSE TO APPLICATION FOR A STAY PENDING APPEAL

To the Honorable Samuel A. Alito, Associate Justice and Circuit Justice for the Fifth Circuit

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INTRODUCTION

The Federal Government seeks a stay to permanently change the status quo, not to preserve it. If the Court grants this relief, millions of healthcare providers and workers will immediately fall into noncompliance with the new CMS Vaccine Mandate and be subject to termination. Across the country, healthcare workers are already far too scarce. This new Mandate worsens the problem, sidelining providers, professionals, and support staff who have led the fight against COVID-19. And, as is often the case, rural communities—already straining from threadbare resources—will bear the brunt of these consequences. Virtually every equitable consideration counsels against staying the injunctions entered below.

So do the merits. The Mandate is plainly unlawful. Most fundamentally, it exceeds CMS's statutory authority, which does not encompass such a sweeping mandate—especially in light of multiple clear-statement doctrines that apply here. CMS moreover eschewed notice and comment without good cause, even though it had sufficient time to take comments in the nearly two months from announcing the Mandate to promulgating it. And the Mandate is arbitrary and capricious for several reasons. Constitutionally, the Mandate also likely violates the Tenth Amendment and the Non-Delegation Doctrine. And it violates at least three statutory provisions within the Social Security Act, as the district court properly held. But the Applicants failed to address two of those grounds in their stay application, and addressed the third only in a footnote—omissions that shut down their likelihood of obtaining both a grant of certiorari (because their questions presented aren't dispositive) and a

reversal from this Court (because they do not answer all holdings supporting the injunction).

In sum, CMS, through the Vaccine Mandate, assumes sweeping new federal power over individuals even though Congress has never claimed such expansive authority for itself and even though the Executive Branch expressly disclaimed it only five months ago. To get there, the agency ignored and undermined the Social Security Act's driving purpose, repeatedly violated the APA, and rearranged the Constitution's structures of federalism and separation of powers.

HHS's application should also be denied because it effectively seeks ultimate relief, without either acknowledging that fact or attempting to satisfy the heightened—indeed extraordinary—burden that applies. *See, e.g.*, *Cousins v. Wigoda*, 409 U.S. 1201, 1206 (1972) (Rehnquist, J., in chambers). If the injunctions are lifted, healthcare workers are put to the choice immediately, with little or no time to comply before losing their jobs. And States, who were not consulted, face immediate destabilization of their Medicaid provider bases and must assume the task of enforcing the very Mandate that causes this disastrous result.

Lifting the injunctions puts patients across the country at risk of losing access to the healthcare they need now. Denying the stay merely prevents those harms from materializing at the cost of the President's vaccination agenda—an agenda formalized in ex post facto agency pronouncements the lower courts have already signaled are illegal.

The Court should deny the application for a stay.

STATEMENT

1. The Executive Branch's Expanding Views of Executive Power.

Just months ago, the Biden Administration disclaimed any legal authority over vaccine mandates, calling them "not the role of the federal government"—let alone of the Executive Branch acting alone. Press Briefing by Press Secretary Jen Psaki, July 23, 2021, https://bit.ly/3pWnJVr. Instead, the Administration thought it should ensure that "Americans' privacy and rights [were] protected" and that the vaccine rollout was "not used against people unfairly." *See* Press Briefing by Press Secretary Jen Psaki, April 6, 2021, https://bit.ly/3rBJVoL.

That position accords with the longstanding view that federal law does not authorize mandatory vaccination programs among the general population. *See, e.g.*, Cong. Research Serv., *Mandatory Vaccinations: Precedent and Current Laws* 9 (RS21414; May 21, 2014), https://bit.ly/3sEnEaf ("No mandatory vaccination programs are specifically authorized, nor do there appear to be any regulations regarding the implementation of a mandatory vaccination program at the federal level during a public health emergency."); *cf. In re MCP No. 165, Occupational Safety & Health Admin., Interim Final Rule: COVID-19 Vaccination & Testing*, __ F.4th __, 2021 WL 5914024, at *18-20 (6th Cir. 2021) (Bush, J., dissenting) ("For while Congress has long sought to *facilitate* safe and effective vaccines, it has never invoked the commerce power to *mandate* their administration upon the public at large.") (setting forth history of federal vaccination programs). And when Congress recently amended various CMS statutes in response to the COVID-19 pandemic, none of its

amendments authorized mandating vaccines. *See, e.g.*, Pub. L. No. 117-2, Title IX, §9402 (Mar. 11, 2021), 135 Stat. 127; 42 U.S.C. §§1395i-3, 1396r.

In early September, however, the Administration suddenly changed its collective mind after the President announced his plan to "use my power as President" to mandate vaccinations on "100 million Americans." The White House, *Remarks by President Biden on Fighting the COVID-19 Pandemic* (Sept. 9, 2021), https://bit.ly/3oI0pKr. He announced a series of federal vaccine mandates designed to compel most of the adult population of the United States to get a COVID-19 vaccine. *Id.* The Administration changed course not because Congress had authorized it to—in fact, Congress has done nothing to support vaccine mandates in the past year—but because the President's "patience" was "wearing thin" with those "who haven't gotten vaccinated." *Id.*

This case concerns the part of the President's mandatory vaccination agenda that targets healthcare workers and suppliers. In his early September remarks, the President announced that one of his vaccine mandates would apply to "a total of 17 million healthcare workers." Sept. 9, 2021 Remarks, *supra.* Specifically, his Executive Branch would "be requiring vaccinations" on all "those who work in hospitals, home healthcare facilities, or other medical facilities." *Id.* Notwithstanding his past remarks, he then declared, "I have that federal authority." *Id.*

Yet remarkably, on December 27 the President declared that "there is no federal solution. This gets solved at a state level."[1]

[1] *See Remarks by President Biden at COVID-19 Response Team's Regular Call With*

2. The CMS Mandate.

More than eight weeks after the President's September 9 remarks, the Centers for Medicare & Medicaid Services (CMS) published an interim final rule mandating vaccinations for healthcare workers. *Medicare and Medicaid Programs; Omnibus COVID-19 Heath Care Staff Vaccination*, 86 Fed. Reg. 61555 (Nov. 5, 2021). The Mandate governs 21 categories of Medicare or Medicaid providers and suppliers. *See id.* at 61556. It applies the same substantive standards to each. *See id.* at 61570, 61616-61627. As CMS explained, "we are issuing a common set of provisions for each applicable provider and supplier." *Id.* at 61570.

The Mandate requires that every covered entity "develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID–19." *See, e.g.*, 42 C.F.R. §416.51(c). The vaccination requirement applies to anyone "who provides any care, treatment, or other services for the [entity] and/or its patients"—including employees, contractors, trainees, students, and volunteers—even if they have no contact with patients. *Id.* §416.51(c)(1). To be exempt, a healthcare worker has to "exclusively provide" telehealth or support services "outside of the [entity's] setting" in permanent isolation. *Id.* §416.51(c)(2)(i).

The Mandate also originally required each covered entity to ensure that, by December 6, 2021, all healthcare workers submit to at least one vaccine dose. Any worker who did not submit cannot provide "any care, treatment, or other services for the [entity] and/or its patients." *Id.* §416.51(c)(3)(i); 86 Fed. Reg. at 61555. By January

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the National Governors Association (Dec. 27, 2021); https://bit.ly/34c27M9.

4, 2022, all such healthcare workers would have to be "fully vaccinated." 42 C.F.R. §416.51(c)(3)(ii); 86 Fed. Reg. at 61555. A covered entity is allowed to provide an exemption for those granted temporary delays when mandated by federal law or counseled to do so by the CDC's own guidance. 42 C.F.R. §416.51(c)(3).

But on December 28, 2021, CMS announced delayed enforcement of the Mandate in states in which it is not currently enjoined. *See* Guidance for the Interim Final Rule—Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination; https://go.cms.gov/3pxIOoE. For those 25 states, CMS establishes "enforcement action thresholds" of 80%, 90%, and 100% compliance after 30, 60, and 90 days, respectively. *See id.* (https://go.cms.gov/3eBm7K0). It then provides that after "90 days … following issuance of this memorandum [March 28, 2022], facilities failing to maintain compliance with the 100% standard may be subject to enforcement action." *Id.* Potential penalties include "civil monetary penalties, denial of payment, [and] termination." *Id.*

The Mandate also imposes heavy-handed surveillance obligations. It requires covered entities to "track[] and securely document[] information provided by those staff who have requested, and for whom the [entity] has granted, an exemption" or delay. 42 C.F.R. §416.51(c)(3)(vi)-(vii). It requires them to ensure that all documentation "support[ing] staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner." *Id.* §416.51(c)(3)(viii). And it requires that the covered entities implement a "process for tracking and securely documenting the COVID–19 vaccination status of all staff," including booster-shot

status. *Id.* §416.51(c)(3)(iv)-(v). And finally, because States implement Medicaid programs, the burden of surveying and terminating non-compliant providers falls upon the States. *See* D. Ct. Docs. 2-3, 2-14.

According to CMS, the Mandate captures 10.4 million healthcare workers—2.4 million of whom CMS contends are unvaccinated—and CMS anticipates the Mandate would apply to another 2.66 million new hires annually. 86 Fed. Reg. at 61608. The Mandate, by CMS's own calculation, would impose over $1 billion in compliance costs. *Id.* at 61609. Any entity that fails to fire its non-compliant workers faces penalties up to and including "termination of the Medicare/Medicaid provider agreement." 86 Fed. Reg. at 61574.

The Mandate provides no exception or alternative for healthcare workers with natural immunity. It likewise provides no exception or alternative for those who submit to routine testing. And though CMS issued the Mandate eight weeks after it was announced, and over six months after vaccines became widely available, it promulgated the Mandate without notice or comment.

CMS acknowledges that its Mandate is unprecedented. *See* 86 Fed. Reg. at 61567 ("We have not previously required *any* vaccinations.") (emphasis added); *id.* at 61568 ("We acknowledge that we have not previously imposed such requirements.").

3. CMS's Statutory Authority.

According to Applicants, the Executive Branch's newly discovered "authority to adopt the [Mandate] flows directly from the unambiguous text of the statute." Stay App. 20. The "statute" that Applicants refer to is presumably 42 U.S.C. §1302(a)

because, while CMS invoked a hodgepodge of authorities in issuing the Mandate, the only statute that it claimed could support the Mandate's application in full was §1302(a). *See* 86 Fed. Reg. at 61567; *see also* Stay App. 20.

Section 1302(a) delegates to the Secretary of Health and Human Services mere administrative responsibility in maintaining Medicare and Medicaid:

> The … Secretary of Health and Human Services … shall make and publish such rules and regulations, not inconsistent with this chapter, as may be necessary to the efficient administration of the functions with which [he] is charged under this chapter.

42 U.S.C. §1302(a).

Beyond §1302(a), CMS had originally listed other statutory provisions as authority for some aspects of the Mandate's application. For example, CMS applied the Mandate to "Ambulatory Surgery Centers," in part based on 42 U.S.C. §1395k(a)(2)(F)(i). *See* 86 Fed. Reg. at 61567. In their stay application before this Court, however, Applicants no longer mention many of those other statutory provisions.

4. Harm to Healthcare Workers, Patients, and States.

If the Mandate goes into effect, it will—and has already begun to—disrupt the lives and livelihoods of millions of Americans. CMS estimates it will force 2.4 million currently unvaccinated healthcare workers to either forfeit informed consent and bodily autonomy or their jobs. *See* 86 Fed. Reg. at 61607. It unabashedly admits that the Mandate is designed to exploit people's "fear of job loss" to coerce them into compliance. *Id.*

But many American healthcare workers will give up their jobs rather than violate their consciences or submit to a medical procedure they deem potentially harmful or unnecessary. CMS gives only a cursory nod to this reality: "there may be disruptions in cases where substantial numbers of health care staff refuse vaccination and are not granted exemptions and are terminated," which would lead to "consequences for employers, employees, and patients." 86 Fed. Reg. at 61608.

Those consequences will be more than painful—especially for the Americans that Medicare and Medicaid are designed to serve. All parties agree that currently "endemic staff shortages for all categories of employees at almost all kinds of health care providers and suppliers" exist. *Id*. at 61607. Indeed, in many of Plaintiff States, over 40% of nursing homes already faces staffing shortages. *See AARP Nursing Home COVID-19 Dashboard*, AARP Public Policy Institute (Dec. 16, 2021), bit.ly/30lrvgs. At the same time, in most Plaintiff States, over 30% of healthcare workers remain unvaccinated. *Id.* The Mandate is therefore likely to exacerbate these pre-existing labor shortages in the healthcare industry, which CMS does not dispute will cause sick and dying Americans to lose access to medical care.

5. The Injunction Against the Mandate.

Plaintiff States sued to enjoin the Mandate and have it vacated and declared unlawful before it could wreak its devastating toll. *See* D. Ct. Doc. 1. They administer Medicaid programs—Medicaid provider agreements are contracts with the States—and they operate regulated entities themselves. They will incur both enforcement and compliance costs. Additionally, they enforce laws that are purportedly preempted by

the Mandate. And they stand for their citizens who will lose access to or control over their medical care, or their jobs, as a result of the Mandate. To avoid those harms, Plaintiff States sought—and the district court granted—a preliminary injunction against the Mandate. *See* App.7a-8a.

The district court held that the Plaintiffs were likely to succeed on the merits of their claims on eight independent grounds and were not likely to succeed on the merits on two grounds due to a lack of evidence submitted with the preliminary-injunction motion. In particular, the district court held that Applicants:

- Exceeded their statutory authority in enacting the Mandate. App.27a-30a.
- Improperly bypassed notice and comment. App.22a-27a.
- Violated 42 U.S.C. §1395, which forbids Applicants from exercising "supervision or control over" the "selection, tenure, or compensation of any officer or employee of" healthcare providers. App.30a-31a.
- Did not comply with 42 U.S.C. §§1395z or 1302(b), which impose statutory procedural requirements that the Applicants flatly ignored. App.30a-31a.
- Violated the APA, as the Mandate was arbitrary and capricious for many reasons. App.31a-36a.
- Violated the Constitution by intruding into an area of traditional State police power and, if authorized by statute, exercising unconstitutionally delegated federal legislative power. App. 36a-39a.

The district court found that Plaintiff States would suffer at least four independent irreparable injuries if the Mandate went into effect. Specifically,

Plaintiff States' laws would be preempted, they would incur the increased cost of enforcing and complying with the Mandate, their procedural rights to their concrete interests would be denied, and their citizens' interests would be burdened. App.39a-40a. Carefully balancing those interests and the federal government's, it then held that the threatened harm outweighed any harm to the Applicants and that the injunction would advance the public interest. App.40a-41a.

6. The Fifth Circuit's Affirmance.

A Fifth Circuit panel of Judges Costa, Graves, and Southwick unanimously refused to stay the district court's preliminary injunction in all respects other than its geographic scope. App.6a. The panel held that the Applicants had not demonstrated a strong showing of likely success on the merits in defending the Mandate because it implicates a major question of the sort that would require clear congressional authorization. App.2a-3a. Echoing the district court's conclusion, the panel also held that because "the Secretary's vaccine rule has not gone into effect," it would not stay the injunction because "preserving the status quo 'is an important' equitable consideration in a stay decision." App.4a. It then narrowed the injunction's scope to the fourteen Plaintiff States. App.6a.

7. Parallel Litigation.

Meanwhile, two other district courts enjoined the Mandate—on similar bases—and one declined.[2] An Eighth Circuit panel upheld one of those injunctions,

[2] *See Missouri v. Biden*, No. 4:21-CV-01329, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021); *Texas v. Becerra*, No. 2:21-CV-229, 2021 WL 5964687 (N.D. Tex. Dec. 15, 2021); *Florida v. HHS*, No. 3:21-CV-2722, 2021 WL 5416122 (N.D. Fla. Nov. 20, 2021).

the other remains unappealed, and a split Eleventh Circuit panel upheld the denial of a preliminary injunction over Judge Lagoa's dissent.[3]

8. The Applicants' Emergency Stay Application.

After the Fifth Circuit denied a stay, Applicants filed this application for an emergency stay of the district court's injunction so that they could enforce the Mandate immediately. They contend that this Court would likely reverse the district court on the merits because the "unambiguous text of the statute" authorizes the Mandate as "necessary to the efficient administration" of the Secretary of Health and Human Service's operation of Medicaid and Medicare. App. 20. In support of their reading, Applicants invoke legislative history. *Id.* at 23. They reason that the Fifth Circuit "invoked an expansive and unsound conception of what [it] called the 'major questions' doctrine that finds no support in this Court's precedents." *Id.* at 19. And, remarkably, they claim they are not regulating "a significant portion of the American economy." *Id.* at 29.

Applicants also contend that the Mandate is not an exercise of unconstitutionally delegated federal legislative power or an intrusion into the States' traditional police power because healthcare employees "choose to work" at entities that accept Medicaid or Medicare funding. *Id.* at 31. They also claim that there is "no merit" to the district court's holding that the Mandate was arbitrary and capricious, *id.* at 32, and contend that they could bypass notice and comment (contrary to

[3] *See Missouri v. Biden*, No. 21-3725 (8th Cir. Dec. 13, 2021); *Florida v. HHS*, 19 F.4th 1271 (11th Cir. 2021).

Congress's express command) because they "acted in response to the rapidly evolving conditions of the pandemic," *id.* at 36-37. Finally, they reason that the public interest favors allowing them to enforce the Mandate immediately because of "the real-world impact" of enforcing it. *Id.* at 39. They do not, however, address the district court's independent holdings that the Mandate illegally violated 42 U.S.C. §§1395 and 1302(b), and they relegate to a footnote any discussion of its holding that the Mandate violated 42 U.S.C. §1395z.

ARGUMENT

The Court will stay a district court's order still pending before a court of appeals only in the rare circumstance when (1) four Justices are likely to vote to grant certiorari, (2) a majority of the Court is likely to reverse the district court's judgment, and (3) equitable factors—irreparable harm from granting or denying the stay, and (in close cases) the balance of harms to the applicant and respondent—favor granting a stay. *Hollingsworth v. Perry*, 558 U.S. 183, 190 (2010). Whatever might be said about the certworthiness of some issues here, *see infra* §V, Applicants fail to carry their burden of showing error in the district court's judgment and that the balance of equities favors a stay. The Court should deny the application.

I. Applicants Forfeited Challenges To The District Court's Holdings That The Mandate Independently Violates Three Specific Statutory Mandates And Prohibitions.

The Mandate is unlawful not just because HHS lacks general authority to promulgate it, *see* §II *infra*, but also because it violates three specific statutory requirements or prohibitions in 42 U.S.C. §§1395, 1302(b), and 1395z. The district

court held that HHS "did not comply with any of the[se] provisions, [and thus] the Plaintiff States are likely to succeed on the merits." App.30a-31a.

When Applicants sought a stay from the Fifth Circuit, they challenged only two of those holdings (ignoring §1302(b)). And in this Court, they challenge only one, §1395z—and then only in a footnote (at 37 n.6). Applicants' failure to address those district court holdings in any meaningful way effectively eliminates their chances of obtaining a grant of certiorari because the Court's decision on the few issues presented will not be dispositive. It also precludes their chances of securing a majority vote to reverse; they give no basis for this Court to conclude that every district court holding supporting the injunction is wrong.

Even setting aside those failures, their arguments would fail on the merits, making Applicants doubly unlikely to obtain a reversal of the injunction.

A. Section 1395 Prohibits The CMS Mandate Because It Seeks To "Control … the Selection [Or] Tenure" Of Healthcare Workers.

1. The district court held that Plaintiff States were likely to succeed in showing that the Mandate violates 42 U.S.C. §1395, which prohibits the federal government from exercising "any supervision or control" over the "selection, tenure, or compensation" of any person providing health services or the "administration or operation" of any health care institution. App.30a-31a. By failing to challenge this holding in its application, Applicants concede it for present purposes. *See Ohio Citizens for Responsible Energy, Inc. v. Nuclear Regul. Comm'n*, 479 U.S. 1312, 1312 (1986) (Scalia, J., in chambers) ("I will not consider counsel to have asked for such

extraordinary relief where, as here, he has neither specifically requested it nor addressed the peculiar requirements for its issuance.").

More generally, this Court "follow[s] the principle of party presentation." *United States v. Sineneng-Smith*, 140 S. Ct. 1575, 1579 (2020). The Court "rel[ies] on the parties to frame the issues for decision[.]'" *Id.* (citation omitted). Federal courts "'do not, or should not, sally forth each day looking for wrongs to right. They wait for cases to come to them, and when cases arise, courts normally decide only questions presented by the parties.'" *Id.* (cleaned up) (citation omitted). That's true in every case, but especially so when seeking a stay. For the party seeking that equitable relief "bears the burden of showing that the circumstances justify an exercise of that discretion." *Nken v. Holder*, 556 U.S. 418, 433–34 (2009). By failing to address the district court's holding on §1395, Applicants necessarily have failed to carry their burden. *Id.* Nor would belated presentation in their reply brief suffice. *See*, *e.g.*, *Republic of Argentina v. NML Cap., Ltd.*, 573 U.S. 134, 140 n.2 (2014).

2. Section 1395 plays a critical role in preserving the federal-state balance. This provision reflects the longstanding recognition that "the practice of medicine is, in general, a subject of state regulation." *Pennsylvania Med. Soc. v. Marconis*, 942 F.2d 842, 846 n.4 (3d Cir. 1991). Titled "Prohibition against any federal interference," §1395 provides, in broad language, that "*[n]othing in this subchapter* shall be construed to authorize *any Federal officer or employee* to exercise any supervision or control" over numerous matters, including the "*selection, tenure*, or compensation" of health care employees. 42 U.S.C. §1395 (emphasis added).

By (1) mandating that millions of health care employees either undergo vaccination or face termination, and (2) precluding the future hiring of unvaccinated healthcare workers—with an estimated 2.66 million hires each year—the Mandate plainly constitutes attempted "supervision or control" over "selection [and] tenure" of health care employees. In fact, that appears to be the Mandate's entire point.

Though Applicants ignore this issue in this Court, they attempted a cursory defense in the Fifth Circuit, arguing that the Mandate is nothing more than a "condition on federal funding for health care facilities." But that argument neither cited nor grappled with Congress's specific limitation on federal power over "selection [or] tenure" of employees. *Id.* No matter; Applicants' argument would render §1395 superfluous. Medicare is a spending program. Nearly everything that HHS can do under the subchapter could be characterized as a mere "condition on federal funding"—yet Congress nonetheless deemed it important to expressly limit federal authority in §1395. "As this Court has noted time and time again, the Court is obliged to give effect, if possible, to every word Congress used." *See National Ass'n of Mfrs. v. DOD*, 138 S. Ct. 617, 632 (2018) (cleaned up). But under HHS's interpretation, §1395 does nothing beyond occupy space in the U.S. Code.

B. HHS Violated §1302(b) In Promulgating the CMS Mandate.

1. By failing to challenge in their application the district court's holding that they violated 42 U.S.C. §1302(b)'s regulatory-impact-statement requirement, Applicants also waived this issue. *See Ohio Citizens*, 479 U.S. at 1312 (Scalia, J., in chambers). Applicants likewise did not raise this issue in their Fifth Circuit stay

briefs, which fail even to cite §1302(b). *See*, *e.g.*, *Sprietsma v. Mercury Marine*, 537 U.S. 51, 56 n.4 (2002) (failure to raise argument below waives it).

2. Had Applicants preserved a challenge to the district court's §1302(b) holding, their argument would again fail on the merits. Section 1302(b) requires the Secretary to prepare a regulatory impact analysis when publishing a rule that "may have a significant impact on the operations of a substantial number of small rural hospitals[.]" The Mandate itself identifies significant impacts on rural hospitals, stating that "early indications are that *rural hospitals are having greater problems* with employee vaccination refusals than urban hospitals, and [HHS] welcome[s] comments on ways to ameliorate this problem." 86 Fed. Reg. at 61613 (emphasis added). Plaintiff States submitted substantial uncontroverted evidence showing the Mandate "may have a significant impact on the operations of a substantial number of small rural hospitals." §1302(b)(1). *See* D. Ct. Docs. 2-2, 2-7, 2-12; *see also Rural COVID patients in ICUs at higher risk of dying than urban counterparts, according to WVU researcher,* WVU Today (Nov. 11, 2021), https://bit.ly/3HnFB1Q.

3. Applicants addressed this issue only in the district court. There, they did not dispute that §1302(b)'s "significant impact" threshold was met. D. Ct. Doc. 21 at 24. Instead, they made a novel statutory argument: that §1302(b) did not apply because "[t]he 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." *Id.*

That argument fails because §1302(b)(1) requires a final regulatory impact statement whenever "an initial regulatory impact analysis is required by paragraph (1)," §1302(b)(2)—that is, for any rule "that may have a significant impact on the operations of a substantial number of small rural hospitals," §1302(b)(1). Subsection (b)(2)'s requirement is thus triggered by what a rule *does*, not how it is promulgated.

In essence, HHS's arguments attempt to engraft the APA's "good cause" exception onto §1302(b). But Congress included no such exception in §1302(b), and that omission is presumptively intentional. *See United States v. Shabani*, 513 U.S. 10, 14 (1994) ("When a statutory term is absent in one statute, but is explicit in analogous statutes, Congress' silence speaks volumes." (cleaned up)); *cf. Brown v. Gardner*, 513 U.S. 115, 118 (1994) ("'[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.'" (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)).

Nor do Applicants' novel district court arguments comport with Congress's statutory design. Nothing in §1302(b) suggests that Congress would be *less* concerned about impacts to rural hospitals when those hospitals had been denied the opportunity to comment on a proposed rule. If anything, the need for a regulatory impact statement is heightened by lack of opportunity to comment.

C. HHS Violated §1395z's Consultation Requirement By Not Consulting With States Before Promulgating The Mandate.

1. The only specific statutory requirement Applicants address in this Court is §1395z's requirement of consulting with States—and even then only in passing by

footnote (at 37 n.6). The courts of appeals generally agree that raising an argument only in a footnote constitutes a waiver.[4] That rationale would support a holding by this Court that Applicants waived any challenge to the district court's conclusion that HHS "did not comply with" §1395z. App.31a.

2. Even if not waived, Applicants' footnote-only argument fails on the merits. For rules like the CMS Mandate, §1395z requires "the Secretary" to "consult with appropriate State agencies and recognized national listing or accrediting bodies," and permits him to "consult with appropriate local agencies." Applicants do not deny that HHS refused to engage in such consultation before promulgating the Mandate, and they identify no evidence that it has attempted to do so since then.

Applicants' only argument—yet another novel statutory claim—is that HHS's complete failure to consult with the States to date is lawful because §1395z "does not require that consultation occur in advance of a rulemaking." Stay App. 37 n.6 (citing 86 Fed. Reg. at 61567). Notwithstanding a clear statutory *command* to consult States, HHS posits that "[g]iven the urgent need to issue this rule, however, we do not believe that there exists an entity with which it would be appropriate to engage in these

[4] *See*, *e.g.*, *Healthbridge Mgmt., LLC v. Nat'l Lab. Rels. Bd.*, 672 F. App'x 1 (D.C. Cir. 2016) ("Petitioners' arguments … are forfeited because they were only briefly mentioned in a footnote."); *Carter v. Toyota Tsusho Am., Inc.*, 529 Fed. Appx. 601, 612 n.2 (6th Cir.2013) ("Generally, an argument raised in a footnote without further development is deemed waived."); *Arbuckle Mountain Ranch of Tex., Inc. v. Chesapeake Energy Corp.*, 810 F.3d 335, 339 n.4 (5th Cir. 2016) (same); *Unspam Techs., Inc. v. Chernuk*, 716 F.3d 322, 330 n* (4th Cir. 2013) (same); *John Wyeth & Bro. v. CIGNA Int'l Corp.*, 119 F.3d 1070, 1076 n.6 (3d Cir. 1997) (same);*City of Emeryville v. Robinson*, 621 F.3d 1251, 1262 n.10 (9th Cir. 2010) (same); *United States v. Hardman*, 297 F.3d 1116, 1131 (10th Cir. 2002) (same).

consultations in advance of issuing this IFC," and that it did not "understand the statute to impose a temporal requirement to do so in advance of the issuance of this rule." 86 Fed. Reg. at 61567. That argument fails for at least four reasons.

First, HHS's reasoning seemingly attempts (again) to graft a non-existent good-cause exception into §1395z's consultation requirement by claiming an "urgent need to issue this rule." *Id.* In other words, HHS attempts to rewrite the statute according to its own vision rather than what Congress enacted. But unlike the APA, §1395z contains no good-cause exception. And because CMS rules are generally subject to the APA, and because 42 U.S.C. §1302(a) provides general rulemaking authority under the APA's auspices, this omission is presumptively intentional. *See supra* at 18. HHS's attempt to invoke a good-cause exception that does not exist through rewriting statutes is not likely to succeed on appeal.

Second, even if an atextual good-cause exception could be read into §1302(b), Applicants could not satisfy it here. HHS had ample time between the September 9 announcement and the November 5 promulgation to engage in consultation. Indeed, OSHA managed to hold some 140 meetings during the same time window.[5]

Applicants never actually argue that those eight full weeks were insufficient time to consult with the States *if* HHS were so inclined. To the contrary, it appears HHS arbitrarily decided States weren't worthy of consulting. *See* 86 Fed. Reg. at 61567 ("[W]e do not believe that there exists an entity with which it would be

[5] *See* OIRA, EO 12866 Meetings Search Results, *available at* https://bit.ly/3FJBwUo.

appropriate to engage in these consultations in advance of issuing this IFC."). Congress mandated otherwise.

Third, Applicants' contention (at 37 n.6) that §1395z "does not require that consultation occur in advance of a rulemaking" is unavailing. By *mandating* consultation with the States, the statute requires a meaningful consultation rather than an *ex-post* rubber stamp. The suggestion that a post-promulgation consultation with States can satisfy that requirement is at best an empty formalism. Instead, the statute requires consultation with States *before* rules issue—just as the APA generally requires that notice and opportunity to comment *before* final rules issue. HHS's suggestion that it can simply relegate consultation to a perfunctory afterthought—a process occurring after federal regulators have picked, publicly committed to, and started enforcing a particular course—improperly renders the consultation requirement meaningless. *See*, *e.g.*, *Bloate v. United States*, 559 U.S. 196, 209 (2010) ("A statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.") (cleaned up). In any event, HHS's reliance on multiple novel revisions of the law are more reasons the injunction is appropriate now while it continues to litigate those claims below.

Fourth, even if HHS were correct that the consultation could occur after the IFR issues, HHS has not submitted *any* evidence that it has attempted to engage in such consultation with the States in the eight weeks since the CMS Mandate issued on November 5. That omission is particularly meaningful here as HHS has the

burden of proof in seeking a stay, and its failure to provide any supporting evidence undermines its claim that its putative *post hoc* efforts will be sufficient.

II. Applicants Are Unlikely To Prevail on the Merits of the Issues They Properly Raise.

A. No Statute Authorizes the Mandate.

Under this Court's precedent, agencies must show clear statements of congressional authority before enacting regulations with particularly important or sensitive implications. After all, "Congress does not casually authorize" major regulations. *Solid Waste Agency of N. Cook Cty. v. U.S. Army Corps of Engineers*, 531 U.S. 159, 172 (2001). So, for instance, an agency may not address issues of "deep economic and political significance" without showing that Congress has "expressly" given it the power to do so. *King v. Burwell*, 576 U.S. 473, 486 (2015).[6] Nor may an agency "significantly alter the balance between federal and state power" without showing that Congress has given it the power to do so through "exceedingly clear language." *U.S. Forest Serv. v. Cowpasture River Pres. Ass'n*, 140 S. Ct. 1837, 1849-50 (2020). And an agency may not "invoke[] the outer limits of Congress' power" without showing a "clear indication that Congress intended that result." *Solid Waste*,

[6] Applicants' contention (at 19) that the States' arguments based on this principle "find[] no support in this Court's precedents" is puzzling. *See, e.g.*, *Utility Air Regulatory Group v. EPA*, 573 U.S. 302, 324 (2014) ("We expect Congress to speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.'"); *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160 (2000) ("Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion."); *Alabama Realtors*, 141 S. Ct. at 2489 ("We expect Congress to speak clearly when authorizing an agency to exercise powers of vast economic and political significance.") (quotation marks omitted).

531 U.S. at 172. This Court recently reiterated these clear-statement requirements in emphatic terms. *See Alabama Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021).

The Mandate triggers all three clear-statement requirements. First, if the Mandate is not an issue of "deep economic and political significance," nothing is. The Mandate is controversial, heavy-handed, and unprecedented. 86 Fed. Reg. at 61567. It forces 2.4 million Americans to either submit to injections against their wills or lose their livelihoods. *Id.* at 61607. It commands States to enforce its terms upon threat of losing billions in Medicaid funding or valued and irreplaceable providers in an already-stressed employment market. 86 Fed. Reg. at 61574. It imposes over $1 billion in compliance costs. *Id.* at 61609.[7] And it will cause lost or reduced access to healthcare for the tens of millions of Americans who depend on Medicaid or Medicare—programs that "touch[] the lives of nearly all Americans." *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). Second, the Mandate "significantly alter[s] the balance between federal and state power." Vaccine-mandate policy falls within the "police power of a state." *Zucht v. King*, 260 U.S. 174, 176 (1922). More broadly, the "Constitution principally entrusts the safety and the health of the people

[7] The estimated compliance costs do not appear to take into account State enforcement costs and exposure to litigation for terminations. States, who administer the Medicaid program, are required by federal law to provide an administrative and judicial process for challenging terminations and deficiency reports. States have been sued over such terminations by providers and beneficiaries under the "free choice of provider" statute. *See, e.g., Gee v. Planned Parenthood of Gulf Coast, Inc.,* 139 S. Ct. 408 (2019) (Thomas, J., dissenting from denial of certiorari) (recognizing that Medicaid patients in some circuits can sue states under §1983 over termination of a provider based on some circuits' interpretation of 42 U.S.C. §1396(a)(23)).

to the politically accountable officials of the States." *South Bay United Pentecostal Church v. Newsom*, 141 S. Ct. 716, 717, 209 L. Ed. 2d 22 (2021) (Roberts, C.J., concurring). And third, the Mandate raises close constitutional questions and tests the "outer limits of Congress' power"—power that Congress, itself, has never acknowledged. *Supra* at 3-4.

Because the Mandate triggers those three rules, Applicants may not impose it unless Congress authorized them to do so "expressly," in "exceedingly clear language," and with the "clear indication that Congress intended that result." *Burwell*, 576 U.S. at 486; *Cowpasture River*, 140 S. Ct. at 1849-50, *Solid Waste*, 531 U.S. at 172. But Congress did not authorize them to impose the Mandate at all, let alone in express and clear terms.

Applicants rely upon only 42 U.S.C. §1302(a) to support the Mandate in full. But that housekeeping statute cannot bear the Mandate's freight.

To be sure, Applicants' initial publication listed other statutory provisions as authorizing some aspects of the Mandate. *See* 86 Fed. Reg. at 61567. Yet in their stay application before this Court, Applicants no longer mention many of those other statutes. Should Applicants try to reinvoke them, not one addresses—let alone authorizes—mandating employee vaccinations. *See* D. Ct. Doc. 1 at 11-17.

Applicants are left, then, with §1302(a), which merely delegates to the Secretary of HHS administrative responsibility for maintaining Medicare and Medicaid:

> The … Secretary of Health and Human Services … shall make and publish such rules and regulations, not inconsistent with this

> chapter, as may be necessary to the efficient administration of the functions with which [he] is charged under this chapter.

§1302(a). This authorization to make rules "necessary" to the "efficient administration" of his functions related to Medicaid and Medicare does not fairly suggest the sort of sweeping power that the Applicants assert here. Indeed, it is not even health-specific. Rather, the Act's structure demonstrates that §1302(a) confers the authority to make practical rules that help keep Medicaid and Medicare operating smoothly and economically, such as rules that update billing procedures or clarify discretionary grant-allocation criteria. *See, e.g.*, 42 C.F.R. §51a.5. Reading these grants of practical administrative authorities together with §1302(a) confirms that the terms "necessary" and "administration" do not grant the sweeping powers Applicants claim. *See Alabama Realtors*, 141 S. Ct. at 2488.

The plain meaning of the terms "administration" and "necessary" also preclude Applicants' expansive interpretation. The word "administration" refers to "the practical management and direction of the executive department and its agencies." *Administration*, Black's Law Dictionary (10th ed. 2014). The word "necessary" refers to that which "is needed for some purpose or reason" or which "must exist or happen and cannot be avoided." *Necessary*, Black's Law Dictionary (10th ed. 2014). And this Court has just recently rejected a federal assertion that the term "necessary" confers limitless power. *Alabama Realtors*, 141 S. Ct. at 2489 ("[T]he Government has identified no limit in [the statute] beyond the requirement that the [agency] deem a measure 'necessary'"). If Congress had wanted to authorize the Secretary to forcibly vaccinate or fire millions of healthcare workers, it would have needed to replace this

confining and mundane language with a precise and resounding grant of authority. It did not.

On Applicants' reading of §1302(a), there are no meaningful limits to the Secretary's power. Applicants contend that the Mandate is necessary because it "protects" and "ensure[s]" the "health and safety of patients." Stay App. 21, 25. But if that reading sufficed, the Secretary could also mandate—to take just one example—that all healthcare workers track and report their sleep schedules to their employers to ensure that they are alert enough to provide safe and competent care, with covered entities then firing those workers who rely on coffee to make up for late nights or early mornings. HHS could similarly require healthcare workers to satisfy maximum BMI or minimum exercise requirements, or mandate consumption of healthy foods like broccoli in the name of ensuring that can provide maximally effective and efficient care. *Cf. Nat'l Fed'n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 557-58 (2012).

Hypothetical directives that control health care workers' lives are endless but would all fall within the Secretary's view of his authority. Section 1302(a), however, "is a wafer-thin reed on which to rest such sweeping power." *Alabama Realtors*, 141 S. Ct. at 2489.

B. The Mandate Is Unconstitutional.

If Congress authorized the Mandate, it is unconstitutional under both the Spending Clause and the Non-Delegation Doctrine. Under the Spending Clause, Congress's power to legislate "rests on whether the State voluntarily and knowingly accepts the terms of the 'contract,'" which means that the federal government may not "impose a condition on the grant of federal money" unless it "do[es] so

unambiguously." *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17 (1981). Even if the federal government imposes a condition unambiguously, it may not use its power under the Spending Clause to "indirectly coerce[] a State" to adopt its policy. *Sebelius*, 567 U.S. at 577-78. Whether a condition on funding is impermissibly coercive turns on the consequences of opting out. *Id.* at 580-81. Here, when Plaintiff States accepted Medicaid funding, they had no notice of the Mandate. Quite the opposite: such matters have long been quintessential police powers reserved to States. And even if they had notice, the condition was impermissibly coercive because the consequence of opting out would be the loss of *all* Medicare and Medicaid funds. *See* 86 Fed. Reg. at 61574.

And under the Non-Delegation Doctrine, Congress may not delegate the federal legislative power to the Executive Branch. *Touby v. United States*, 500 U.S. 160, 165 (1991). While "power [may be] given to those who are to act under such general provisions to fill up the details" concerning certain legislation, "important subjects … must be entirely regulated by the legislature itself." *Wayman v. Southard*, 23 U.S. 1, 43 (1825); *see also Gundy v. United States*, 139 S. Ct. 2116, 2136 (2019) (Gorsuch, J., dissenting). Here, if §1302(a) or any other provision authorizes the Secretary to legislate the vaccination schedules of 10.4 million healthcare workers, it is an unconstitutional delegation of legislative authority.

At a minimum, those constitutional concerns warrant construing §1302(a) to avoid them. "[I]t is well established that statutes should be construed to avoid constitutional questions if such a construction is fairly possible." *Boos v. Barry*, 485

U.S. 312, 333 (1988). Here, it is not only "possible," but natural, to read §1302(a) as authorizing practical rules that help keep Medicaid and Medicare operating smoothly and economically, not sweeping and constitutionally questionable employee vaccination mandates.

Thus, the Secretary's arguments fail to meet the threshold requirement of showing a majority of this Court likely will vote to reverse.

C. The Mandate Is Arbitrary and Capricious.

The Mandate is arbitrary and capricious for several independently sufficient reasons. Most notably, as the district court found, the Mandate is at war with the central objective of the Social Security Act—patient wellbeing and access to care. *See Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 404 (1993). There is no dispute that the Mandate will adversely affect the healthcare labor market. The most Applicants can say (at 33) is that this impact will be "relatively small" and only "partially offset by countervailing effects." But their failure to consult with States renders this flawed assumption nothing more than self-serving. And in any event, overwhelming evidence shows that the Mandate will exacerbate already critical staff shortages.[8] Applicants' admission that the Mandate will adversely affect patient wellbeing—even

[8] There is already a critical shortage of healthcare workers. Montana, for example, already has a 39% nurse and aide shortage in nursing homes. AARP, *AARP Nursing Home COVID-19 Dashboard* (updated Dec. 16, 2021), https://bit.ly/3HhAWyy. Studies show that vaccine mandates will exacerbate those shortages. *See* Liz Hamel, et al., *KFF COVID-19 Vaccine Monitor: Oct, 2021*, Kaiser Family Foundation (Oct. 28, 2021), https://bit.ly/3wEiJWN; Chris Isidore & Virginia Langmaid, *72% of unvaccinated workers vow to quit if ordered to get vaccinated*, CNN.com (Oct. 28, 2021), https://cnn.it/3HdgDlw.

a little bit—is dispositive. The Social Security Act's goal of patient wellbeing and access to care must trump the Biden Administration's non-statutory vaccination goals. Applicants admit that the Mandate will reduce the number of healthcare workers and cannot dispute that fewer healthcare workers means greater harm to patients.

The isolated examples HHS pulls out of context do not rebut the overwhelming evidence that the Mandate will result in staff shortages and facility closures. HHS, which did not bother to take comments, *see infra*, ignored the Mandate's disparate impact on rural hospitals—a particularly egregious omission given the Act's special protections for rural healthcare populations. 42 U.S.C. §1302(b). Applicants' focus on large, primarily urban, hospital systems ignores a vital and statutorily-mandated aspect of the problem. Worse yet, Applicants try to elude the district court's factual findings demonstrating the Mandate's devastating impact on rural facilities and systems by simply ignoring them.[9] App.32a. But the APA denies Applicants the right

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[9] Had HHS taken comments, Respondents would have presented the evidence about rural facilities that HHS failed to consider—and upon which the district court found (at App.32a) that patient wellbeing at rural facilities will be devastated:

> This is backed up by a number of declarations of various individuals that verify healthcare worker shortages, a significant number of healthcare workers that remain unvaccinated, and the harm that will be caused to these facilities in the event that even a few of the unvaccinated healthcare workers quit or are fired as a result of the CMS Mandate. Some of the declarations also verify the huge percentage of money paid to these facilities through the Medicare and Medicaid Programs, showing these facilities would have to shut down or severely cut back on healthcare services if funding is cut off by the Government Defendants to these facilities. The Plaintiff States also provided a declaration which shows increased enforcement costs that would result if required to survey and enforce the CMS Mandate.

to be willfully blind to reality. Simply put, patient wellbeing is disserved by preventing the hiring and retention of qualified healthcare workers—a fact CMS would have known had it consulted the States and taken comments.

The district court also correctly concluded that HHS failed to consider alternatives to a mandate. Applicants contend (at 35) that "substantial evidence supported" the Secretary's determination that testing and natural immunity were not viable alternatives, but they fail to identify such evidence. That is because it does not exist. HHS both failed to identify its own evidence and contradicted evidence from the States demonstrating that testing requirements prevent employee reductions and preserve patient wellbeing. *See* App.33a ("The Declaration of Tracy Gruber declares that since July 2021, employees at the Utah State Hospital and Utah State Development Center have been required to be vaccinated or take a weekly COVID-19 test. That alternative has caused no apparent harm to patients or staff."). HHS's conclusory dismissal of obvious alternatives was not supported by any evidence whatsoever. *Cf. Texas v. Biden*, 10 F.4th 538, 556 (5th Cir. 2021) ("'Stating that a factor was considered ... is not a substitute for considering it.'").

Applicants also fail to address several other independent bases supporting the district court's judgment. The court held that "CMS failed to adequately explain its departure from its prior position of not requiring mandatory vaccines," App. 34a-35a; that the agency's rationale was likely pretextual, *id.* at 35a; that the agency ignored the States' reliance interests, *id.* at 35a-36a; and that the Mandate's scope is arbitrary, *id.* at 36a. Applicants fail to address any of those independently sufficient

reasons why the Mandate is arbitrary and capricious. Particularly given the burden they bear in this emergency posture, that failure is dispositive. *Cf. Danville Christian Acad., Inc. v. Beshear*, 141 S. Ct. 527, 528 (2020); *Ohio Citizens for Responsible Energy*, 479 U.S. at 1312 (Scalia, J., in chambers).

D. HHS Violated the APA's Notice-and-Comment Requirements Without Good Cause.

Applicants do not dispute that HHS failed to employ notice-and-comment procedures. Instead, they invoke the APA's "good cause" exception to notice and comment to excuse that failure. This Court owes HHS's good-cause determination no deference because "[t]o accord deference to an agency's invocation of good cause would be to run afoul of congressional intent." *Sorenson Commc'ns Inc. v. FCC*, 755 F.3d 702, 706 (D.C. Cir. 2014). The good cause exception to notice-and-comment should be read narrowly so that agencies do not get "an 'escape clause' from the requirements Congress prescribed" in the APA. *United States v. Johnson*, 632 F.3d 912, 928 (5th Cir. 2011); *see also Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012) (good-cause exception is not an "escape clause[]" to be "arbitrarily utilized at the agency's whim"). And "the good cause exception should not be used to circumvent the notice and comment requirements whenever an agency finds it inconvenient to follow them." *Johnson*, 632 F.3d at 929 (quotation marks omitted).

The district court faithfully applied those principles, yet Applicants dispute (at 36) the district court's conclusion that HHS's delay in issuing the Mandate undermines HHS's reliance on the exception. But delay usually precludes a good-cause finding not only because it undermines the agency's conclusion that the rule is

needed immediately, but also because an agency cannot avoid notice and comment through a crisis of its own creation. Applicants ignore this critical second rationale.

Applicants' good-cause arguments focus (at 35-36) on the health risks from COVID-19. But after almost two years, COVID-19 is a persistent feature of life and cannot itself constitute good cause; similarly, COVID-19 vaccinations have been approved under emergency authorizations for nearly a year. *See, e.g.*, *Florida v. HHS*, 19 F.4th at 1306 (Lagoa, J., dissenting) ("To allow COVID-19 to constitute good cause now would be to effectively repeal notice and comment requirements for the duration of the pandemic."). That is why courts have consistently rejected agency attempts to rely on COVID-19 to ignore notice and comment. *See Florida v. Becerra*, 2021 WL 2514138, at *45 (M.D. Fla. June 18, 2021); *Regeneron Pharms., Inc. v. HHS*, 510 F. Supp. 3d 29, 48 (S.D.N.Y. 2020); *Ass'n of Cmty. Cancer Centers v. Azar*, 509 F. Supp. 3d 482, 496 (D. Md. 2020). After so much time has passed, to deem the desire for universal vaccination against COVID-19 "good cause" for ignoring notice-and-comment requirements would effectively repeal those requirements indefinitely. *See also BST Holdings, L.L.C. v. OSHA*, 2021 WL 5279381, at *3 & n.10 (5th Cir. 2021) (OSHA vaccine mandate's "stated impetus—a purported 'emergency' that the entire globe has now endured for nearly two years … is unavailing[.]" (cleaned up)). That is particularly true here, where eight weeks passed between the September 9 announcement and the November 5 promulgation.

Applicants downplay the legal implication of their own delay by invoking (at 36) flu season. But this concern about winter and flu season—an annual and thus

eminently foreseeable occurrence—is a crisis of the agency's own making, which is not sufficient to establish good cause. *See, e.g.*, *United States Steel Corp. v. EPA*, 595 F.2d 207, 213-14 & n.15 (5th Cir.1979); *see also NRDC v. Abraham*, 355 F.3d 179, 205 (2d Cir. 2004) ("We cannot agree ... that an emergency of [an agency's] own making can constitute good cause."). HHS waited months to issue this supposedly emergency measure. But even if "flu season" might normally constitute good cause, it cannot here; "'[o]therwise, an agency unwilling to provide notice or an opportunity to comment could simply wait until the eve of a statutory, judicial, or administrative deadline, then raise up the 'good cause' banner and promulgate rules without following APA procedures.'" *NRDC v. NHTSA*, 894 F.3d 95, 114-15 (2d Cir. 2018) (collecting cases); *see also* App. 26a ("It took CMS longer to prepare the interim final rule without notice than it would have taken to comply with the notice and comment requirement."). In any event, if flu season is such a concern, it raises the question why CMS has never, even now, mandated the flu vaccine for health care workers and suppliers as a condition of participation in Medicare and Medicaid.

Delay aside, HHS failed to substantively establish good cause to forgo notice and comment. Applicants contend (at 22-24) that good cause excuses notice-and-comment requirements because a delay would harm the health and safety of patients. But CMS's good-cause analysis did not even consider how the Mandate will harm patients by exacerbating healthcare workforce shortages and, as explained, CMS elsewhere unreasonably dismissed that concern. And beyond that, the "more expansive the regulatory reach of" a rule, "the greater the necessity for public

comment" to allow those affected to be heard. *American Fed'n of Gov't Emp. v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981). There is no overlooking the Mandate's magnitude—never before has CMS conditioned participation in Medicare and Medicaid upon mandatory vaccination of the healthcare industry. 86 Fed. Reg. at 61,567. And the notice-and-comment process is even more vital in the Medicare and Medicaid context because those programs "touch[] the lives of nearly all Americans" and are two of the country's "largest federal program[s]." *Azar*, 139 S. Ct. at 1808. Even "minor changes" to the way those programs function "can impact millions of people and billions of dollars in ways that are not always easy for regulators to anticipate." *Id.* at 1816. The Mandate's importance only further confirms the need for notice and comment.

Applicants' attempt (at 37) to establish harmless error—an almost unattainable standard in the notice-and-comment context—easily fails. The harmless-error doctrine is to be used only "when a mistake of the administrative body is one that clearly had no bearing on the procedure used or the substance of decision reached." *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 215 (5th Cir. 1979) (citation omitted). Here, however, HHS's error altered its procedure for promulgating the Mandate, precluding a finding of harmless error. *See id.* What's more, in a comment period the States would have raised the issues described above for the agency's consideration. The States' inability to submit comments on the Mandate—which directly regulates them and their citizens and threatens billions of dollars in health care funding upon which States rely to provide services to the poor, elderly, disabled, and children—is

thus prejudicial. *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 96-97 (D.C. Cir. 2002) ("Here the government would have us virtually repeal section 553's requirements: if the government could skip those procedures, engage in informal consultation, and then be protected from judicial review unless a petitioner could show a new argument—not presented informally—section 553 obviously would be eviscerated.").

III. Applicants Seek Ultimate Relief Here But Cannot Establish Their Entitlement to It.

The stay application elides an extraordinary aspect of Applicants' request: granting the requested stay is tantamount to awarding ultimate relief. "[T]he fact that the entry of the stay would be tantamount to a decision on the merits in favor of the applicants" militates against granting it. *National Socialist Party of Am. v. Vill. of Skokie*, 434 U.S. 1327, 1328 (1977) (Stevens, J., in chambers); *accord Cousins*, 409 U.S. at 1206 (Rehnquist, J., in chambers). Similarly, the courts of appeals recognize that a "heightened standard applies" for requests for preliminary injunctions that "would provide the ultimate relief sought in the underlying action."[10] This Court has

[10] *Demirayak v. City of New York*, 746 F. App'x 49, 51 (2d Cir. 2018) ("A heightened standard applies when a movant seeks a preliminary injunction that either alters the status quo or would provide the ultimate relief sought in the underlying action."); *accord WarnerVision Ent. Inc. v. Empire of Carolina, Inc.*, 101 F.3d 259, 262 (2d Cir. 1996) ("As a general rule, therefore, a temporary injunction 'ought not to be used to give final relief before trial.'" (citation omitted)); *Tanner Motor Livery, Ltd. v. Avis, Inc.*, 316 F.2d 804, 808–09 (9th Cir. 1963) ("[I]t is not usually proper to grant the moving party the full relief to which he might be entitled if successful at the conclusion of a trial."); *Dunn v. Retail Clerks Int'l Ass'n, AFL-CIO, Loc. 1529*, 299 F.2d 873, 874 (6th Cir. 1962) ("We ought not to grant temporary relief which would finally dispose of the case on its merits.").

likewise cautioned that "it is generally inappropriate for a federal court at the preliminary-injunction stage to give a final judgment on the merits." *University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981).

Those equitable considerations strongly militate against granting a stay here because the stay's effect would be tantamount to awarding ultimate victory to HHS. CMS's most recent guidance makes clear that it expects rapid progress within 30 days (up to at least 80% compliance) and 100% compliance with 90 days. *Supra* at 6-7.

Because there is no masking alternative to vaccination, if the Court were to stay the injunctions after the January 7, 2022 oral argument, virtually all healthcare workers subject to the CMS Mandate would have little (or negative) time to become fully vaccinated or be fired from their jobs. With the CDC now recommending two-shot Pfizer or Moderna vaccines over the one-shot Johnson & Johnson regimen, *see* Lauran Neergaard & Mike Stobbe, *CDC Recommends Pfizer, Moderna COVID-19 shots over J&J's*, Assoc. Press (Dec. 16, 2021), https://bit.ly/32GzLIN, healthcare workers suddenly subject to the Mandate must get two shots in a truncated time—long before the Fifth Circuit could resolve Applicants' appeal from the injunction.

Or, worse yet, healthcare workers suddenly facing a past-due deadline to be fully vaccinated may rush to take the single-shot Johnson & Johnson vaccine—which the CDC affirmatively recommends they *not* take. *Id.* The Court should not deploy its equitable powers to coerce healthcare workers into accepting risks that the Executive Branch elsewhere recognizes are material, unwarranted, and affirmatively advised-against. And vaccination, of course, is irreversible—once individuals accede to HHS's

unlawful mandate, they will incur the resulting permanent infringement upon their liberties and whatever side effects are in store for them—and cannot be remedied by money damages (which are unavailable from HHS anyway).[11]

In short, the difference between Applicants winning a stay now and a merits judgment later is thus *de mininis*. Though Applicants' requested stay would not formally moot this case, the Mandate would become an irreversible *fait accompli* for nearly all healthcare workers. Applicants are not seeking a stay pending appeal so much as this Court's blessing in perpetuity.

IV. The Balance of Equities Disfavors a Stay.

Preventing Applicants from enforcing the unlawful Mandate pending appeal of the injunction will result in no cognizable injury—let alone irreparable harm—on them. Government officials simply "do[] not have an interest in the enforcement of" an unlawful statute or regulation. *N.Y. Progress & Prot. PAC v. Walsh*, 733 F.3d 483, 488 (2d Cir. 2013). In contrast, the district court held that Plaintiff States had shown a likelihood of "irreparable injury" in their sovereign, quasi-sovereign, and proprietary capacities without an injunction. App.39a-40a. Applicants do not meaningfully challenge those findings.

Instead, Applicants urge principally that "delaying the rule would cause serious, tangible harm to public health," Stay App. 37-38, contending that "hundreds and potentially thousands of patients may die at hospitals, nursing homes, and other

[11] The CDC's changing guidance about which vaccines to receive has a material impact on immunization and consent, decisions already being made under duress.

facilities participating in Medicare and Medicaid as the result of COVID-19 infections transmitted to them by staff," *id.* at 38. But in the Mandate itself, CMS acknowledged that "the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not currently known." 86 Fed. Reg. at 61615; *see also id.* at 61612 ("[P]redicting the full range of benefits … is all but impossible"). Applicants' public-interest argument is thus admittedly speculative. Moreover, "our system does not permit agencies to act unlawfully even in pursuit of desirable ends," thus precluding Applicants' reliance on the public interest. *Alabama Realtors*, 141 S. Ct. at 2490.

Plaintiff States' evidence further shows that the Mandate will drive out healthcare workers, reduce services, and close facilities—particularly in rural areas—thereby harming the very Medicare and Medicaid beneficiaries Applicants purport to serve. *See* D. Ct. Docs. 2-2 at 3 ("[O]ur rural nursing facility will soon face closing the doors permanently[.]"); 2-7 at 4 ("We are facing losing 67% of our radiology staff, 25% of surgical staff, 81% of nursing staff, and 50% of physical therapy staff."); 2-8 at 3-4 ("[T]he number of vacant staff positions has roughly doubled from September 2020 to September 2021," from 124 to 250.); 2-12 at 3 ("[L]osing even 10 or 20 employees, which is a likely outcome of the mandate, may have devastating results to our ability to provide the level of care we have provided in the past.").

The public interest thus weighs decidedly against Applicants' requested stay.

V. Applicants Overstate the Certworthiness of Their Claims.

Finally, Applicants overstate the certworthiness of the questions they presently advance. As an initial matter, Applicants have ignored case-dispositive grounds on which the challenged injunctions rest, thus rendering the questions they

do present unworthy of this Court's review. *Supra* §I. This Court does not typically grant review where the incomplete set of questions presented cannot alter the outcome below.

Moreover, Applicants mischaracterize the split by contenting (at 3-4) that it rests on a "precedential decision denying an injunction pending appeal." Eleventh Circuit stay decisions, however, are nonprecedential. *See*, *e.g.*, *Democratic Exec. Comm. v. Nat'l Repub. Sen. Comm.*, 950 F.3d 790, 795 (11th Cir. 2020) (noting that "the necessarily tentative and preliminary nature of a stay-panel opinion precludes the opinion from having an effect outside that case"). What's more, because Florida has sought initial en banc review of its *Florida v. HHS* appeal, the "conflicting positions adopted by the federal courts of appeals" upon which Applicants rely (at 19) could easily disappear before the dispute ever reaches this Court on the merits.

Applicants raise complex and novel antecedent procedural questions about the Secretary's authority to impose sweeping new changes and conditions for participation in the Medicaid and Medicare programs on States, providers, and employees without notice and comment or consultation. *Cf. Whole Woman's Health v. Jackson*, 141 S. Ct. 2494, 2495 (2021). No doubt this dispute is important and may easily warrant this Court's review—after the courts of appeals have passed on the merits of the underlying appeals. But Applicants' claim of a split based on non-precedential panel stay decisions badly misstates Applicants' principal current certworthiness argument.

CONCLUSION

For these reasons, the Court should deny the application for a stay pending appeal.

December 30, 2021

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