No. 21A240

In the Supreme Court of the United States

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

v.

STATE OF MISSOURI, ET AL.,
Respondents.

On Application for Stay of the Injunction Issued by the
United States District Court for the Eastern District of Missouri

RESPONSE TO APPLICATION FOR A STAY

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INTRODUCTION

This Court "typically greet[s]" with skepticism an administrative agency's sudden discovery "in a long-extant statute" of "an unheralded power" to regulate matters of "vast 'economic and political significance.' " *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324 (2014) (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 159–60 (2000)). That's because the "lack of historical precedent" is often "the most telling indication" that an agency lacked the power to regulate. *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 505 (2010) (quoting *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 537 F.3d 667, 699 (D.C. Cir. 2008) (Kavanaugh, J., dissenting)). Applying these principles recently, the Court rejected the CDC's "unprecedented" "claim of expansive authority" to impose a nationwide eviction moratorium as a "necessary" measure to prevent the spread of COVID–19. *Alabama Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2487, 2489 (2021) (per curiam).

The Court should do the same here. The Secretary of Health and Human Services' sweeping and unprecedented vaccine mandate for healthcare workers threatens to create a crisis in healthcare facilities in rural America. The mandate would force millions of workers to choose between losing their jobs or complying with an unlawful federal mandate. But for the district court's preliminary injunction, last year's healthcare heroes would have become this year's unemployed. Preserving the status quo, as the district court did here, was

critical to avoid irreparable injury to the States and a catastrophe in rural health care.

The Secretary seeks an extraordinary stay to undo that necessary remedy and immediately reimpose the mandate, creating confusion, causing a logistical nightmare, and unleashing the "prevalent, tangible, and irremediable" harm that the injunction forestalls. App.34a. All this despite the district court's meticulous, 32-page opinion issued after full briefing, where the Secretary was entitled to introduce whatever evidence he chose. The district court carefully surveyed thirty declarations submitted by the States describing the devastating impact the mandate will have on healthcare access in rural parts of the States—reliance interests the Secretary simply failed to consider. The court also reached sound legal conclusions showing the mandate exceeded the Secretary's statutory authority, bypassed notice-and-comment requirements, and was arbitrary and capricious, in violation of the Administrative Procedure Act (APA). The Court of Appeals found the district court's opinion so persuasive—and the Government's stay request so meritless—that it denied the same relief requested here in a one-line order. App.1a; *see also id.* at 2a-4a (district court denying stay pending appeal after finding four factors under *Nken v. Holder*, 556 U.S. 418 (2009), did "not … weigh in favor" of one).

At bottom, the lower courts got it right, and the Secretary is not entitled to a stay of the preliminary injunction pending appeal. This Court should thus deny his request for a stay here.

STATEMENT OF THE CASE

I. The Ongoing Healthcare Worker Crisis.

The Secretary admits that "currently there are endemic staff shortages for almost all categories of employees at almost all kinds of health care providers and supplier[s]." App.89a. One in five hospitals, he notes, "report that they are currently experiencing a critical staffing shortage." *Id.* at 41a. In addition, "approximately 23 percent of LTC [long-term-care] facilities report[] a shortage in nursing aides," and "21 percent report[] a shortage of nurses." *Id.*

The States' experience confirms this. App. 29a (citing declarations). The situation is so dire that over the last few months, many of those States have issued emergency orders aiming to alleviate the endemic staffing shortages. ECF No. 9, at 3, 12 (discussing emergency measures in Missouri, Nebraska, and Wyoming).[1]

II. The President's Shifting Position on Vaccine Mandates.

Initially, President Biden's Administration correctly affirmed that mandating vaccines is "not the role of the federal government."[2] Yet on September 9, 2021, amid flagging poll numbers, the Administration exhibited a dramatic about-face. That day, the President announced a six-point plan on COVID-19, and to further his first goal of "requir[ing] more Americans to be vaccinated,"

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[1] Documents cited using "ECF No." refer to district court filings not in the Government's Appendix. And "R.App." refers to citations to Respondents' Appendix.

[2] Press Briefing (July 23, 2021), The White House, https://bit.ly/3Dh3hl8.

the President called for several vaccine mandates, including the mandate challenged here.[3] This week the President's position shifted again; on a call with state governors to discuss the COVID–19 pandemic (specifically the Omicron variant), he stated that "there is no federal solution. This gets solved at the state level."[4]

III. The CMS Vaccine Mandate.

Nearly two months after the President's announcement, the Secretary published the challenged vaccine mandate on November 5, 2021. App.37a-109a. The Secretary recognizes that this mandate is unprecedented because CMS had "not previously required any vaccinations." *Id.* at 49a. Even so, he did not comply with statutory obligations to provide notice and comment or to consult with the States. *See* 5 U.S.C. § 553(b)-(c); 42 U.S.C. § 1395z.

The mandate broadly commandeers 15 categories of Medicare- and Medicaid-certified providers and suppliers that are "diverse in nature," App.84a, ranging from LTC facilities serving elderly patients, to Psychiatric Residential Treatment Facilities (PRTFs) for individuals under age 21, *id.* at 38a. The Secretary invoked different statutory authority for his attempt to regulate each of these facility types. *Id.* at 49a. In addition to two general rulemaking provisions, *see* 42 U.S.C. §§ 1302(a) & 1395hh(a)(1), the Secretary cited statutes

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[3] Joseph Biden, Remarks (Sept. 9, 2021), https://bit.ly/31jHiww.

[4] Dan Diamond et al., *U.S. hospitals brace for continuing surge in covid cases fueled by the omicron variant*, Washington Post (Dec. 27, 2021), https://wapo.st/3zg8xoL.

that mention regulatory "requirements" addressing "health and safety" for some facilities, *see, e.g.*, 42 U.S.C. § 1395x(e)(9) (hospitals); but many statutes addressing other facilities do not reference "health" or "safety" at all, *see, e.g.*, 42 U.S.C. § 1396d(h)(1)(B)(i) (PRTFs). Likewise, while some of the regulations amended by the rule already addressed "infection prevention and control," 42 C.F.R. § 482.42(a) (hospitals), many of them did not, *see, e.g.*, 42 C.F.R. § 441.151 (PRTFs); 42 C.F.R. § 485.58 (Comprehensive Outpatient Rehabilitation Facilities (CORFs)).

The Secretary's rule demands vaccines for practically every full-time employee, part-time worker, trainee, student, volunteer, and third-party contractor entering those facilities, including all staff "regardless of … patient contact," App.52a, and third parties working on a "project" who "use shared facilities" such as restrooms, *id.* at 53a. Given the scope of facilities and individuals covered, the Secretary notes that "virtually all health care staff in the U.S.," *id.* at 55a—an estimate of 10.3 million individuals, *id.* at 85a—will fall under the mandate.

The Secretary rejected the option of allowing workers to undergo "daily or weekly [COVID-19] testing" instead of mandatory vaccination for only one unexplained reason: because he believes that "vaccination is a more effective infection control measure" than testing. *Id.* at 96a. The Secretary also rejected the alternative of affording different options to healthcare workers who have

developed infection-induced (or natural) immunity because of perceived "uncertainties … as to the strength and length of [natural] immunity." *Id.*

The Secretary was "aware of concerns about health care workers choosing to leave their jobs rather than be vaccinated" and knew that "there might be a certain number of health care workers who choose to do so." *Id.* at 51a. But without seeking public comment or consulting with States, he dismissed these concerns because "there is insufficient evidence to quantify" that risk and balance it against others. *Id.*

The Secretary intends for the mandate to "preempt[] inconsistent State and local laws." *Id.* at 50a. He also demands that "State-run facilities that receive Medicare and Medicaid funding" administer the vaccine mandate by "imposing [it] on their employees," *id.* at 95a, and by complying with overbearing record-keeping obligations (including tracking booster vaccination status even though the mandate does not (yet) require boosters), *id.* at 53a. And the Secretary forces "State surveyors … to assess compliance with" the mandate. *Id.* at 56a.

IV. The Mandate's Disastrous Consequences.

The mandate will have disastrous consequences on healthcare, particularly in rural communities. The States submitted thirty declarations detailing the coming catastrophe, and the district court carefully reviewed them. App.28a-32a (summarizing those declarations). These declarations, many of which indicate how many healthcare workers are likely to "leave employment"

under the mandate, explain that the workforce reduction "will decrease the quality of care provided at facilities, compromise the safety of patients, and place even more stress on the remaining staff." *Id.* at 29a. In addition, the loss of staffing "will diminish entire areas of care" within certain facilities and "in many instances will result in *no care at all*, as some facilities will be forced to close altogether." *Id.* at 30a-31a. These threats face both private healthcare facilities and state-run institutions. *E.g.*, R.App.39a-40a.

Cherry County Hospital in rural Valentine, Nebraska projects that the mandate will force 50 of its 159 employees to leave their positions, which will require the hospital to close its dialysis and chemotherapy departments, dramatically reduce the surgeries it provides, and perhaps even shut down entirely. R.App.87a-90a. Likewise, 20 of 65 employees at Scotland County Care Center—a nursing home in rural Memphis, Missouri—have indicated that "if the mandate is imposed, … they will quit," which will cause the facility to " 'close its doors' and displace residents." App.31a (quoting R.App.63a-64a). Similar examples abound throughout the States' declarations.

None of this should have been a surprise to the Secretary. He admits that vaccination rates "are disproportionately low among nurses and health care aides" in rural locations, App.48a, and that "rural hospitals are having greater problems with employee vaccination … than urban hospitals," *id.* at 95a. A recent survey predating the mandate also shows that a substantial portion of "unvaccinated workers"—a whopping 72%—"say they will quit" rather than

submit to a vaccine mandate.[5] Here, the district court found—and the Secretary did not dispute—that some workers have already followed through and resigned. App.29a.[6]

ARGUMENT

"Stays pending appeal to this Court are granted only in extraordinary circumstances." *Graves v. Barnes*, 405 U.S. 1201, 1203 (1972) (Powell, J., in chambers). "A lower court judgment, entered by a tribunal that was closer to the facts ... is entitled to a presumption of validity." *Id.* This Court will grant a stay pending appeal only where the applicant demonstrates (1) "a reasonable probability that four Justices will consider the issue sufficiently meritorious to grant certiorari"; (2) "a fair prospect that a majority of the Court will conclude that the decision below was erroneous"; and (3) "a likelihood that irreparable harm will result from the denial of a stay." *Conkright v. Frommert*, 556 U.S. 1401, 1402 (2009) (Ginsburg, J., in chambers). Yet "[a] stay is not a matter of right, even if irreparable injury might otherwise result." *Ind. State Police Pension Tr. v. Chrysler LLC*, 556 U.S. 960, 961 (2009) (per curiam). Additionally, "in a close case it may be appropriate to balance the equities, to assess the relative harms to the parties, as well as the interests of the public at

[5] *72% of unvaccinated workers vow to quit*, CNN.COM (Oct. 28, 2021), https://cnn.it/3G7JarE.

[6] The Secretary simply refuses to engage with—much less refute—the district court's extensive factual findings, which "are subject to review only for clear error." *Cooper v. Harris*, 137 S. Ct. 1455, 1465 (2017) (citing Fed. R. Civ. P. 52(a)(6)).

large." *Id.* at 960 (quotation marks omitted). The Secretary fails to meet this daunting standard at every turn.

I. The Secretary Cannot Show a Reasonable Probability that Four Justices will Consider the Issues Sufficiently Meritorious to Grant Certiorari Now.

The Secretary has not shown "a reasonable probability that four Justices will consider the issue[s here] sufficiently meritorious to grant certiorari" now. *Conkright*, 556 U.S. at 1402. Because the Eighth Circuit's denial of a stay is not a determination on the merits, it has not yet "decided an important question of federal law that has not been, but should be, settled by this Court[.]" Sup. Ct. R. 10(c). Thus, certiorari is not warranted at this time.[7]

The Secretary relies heavily on the Eleventh Circuit motions panel's opinion in *Florida v. HHS*, 19 F.4th 1271 (11th Cir. 2021), to argue (at 3 and 16) that a split in "precedential decision[s]" justifies certiorari. But that 2-to-1 denial of the State of Florida's stay application is not precedential, *see Dem. Exec. Comm. v. Nat'l Repub. Sen. Comm.*, 950 F.3d 790, 795 (11th Cir. 2020) ("a stay-panel opinion" does not have "effect outside" a particular case), and as shown below, the majority's analysis is thoroughly unpersuasive. Thus, at present, this Court would be unlikely to grant certiorari.

[7] Alternatively, if this case raises issues of "exceptional national importance that would warrant this Court's review"—as the Solicitor General states (at 16)—then Respondents have no objection to the Court treating the Secretary's Application as requesting certiorari before judgment. *Cf. Whole Woman's Health v. Jackson*, 142 S.Ct. 522, 531–32 (2021).

II. The Secretary Cannot Show a Fair Prospect that Five Justices will Conclude that the District Court's Decision is Erroneous on the Merits.

The Secretary has also failed to show that there is "a fair prospect that a majority of the Court will conclude that the decision below was erroneous," *Conkright*, 556 U.S. at 1402, for a simple reason: he is wrong on the merits.

A. The mandate exceeds the Secretary's statutory authority.

The Secretary offers several arguments why the Court should issue a stay, each of which has been soundly rejected by both the district court and the Court of Appeals. These twice-rejected arguments are no more meritorious for their repetition.

1. The text, structure, and context of the statutes the Secretary invokes here do not support his interpretation that he had authority to promulgate the vaccine mandate. *See FDA*, 529 U.S. at 132–33 (in analyzing "whether Congress has directly spoken to the precise question at issue," the Court "should not confine itself to examining a particular statutory provision in isolation" because "the meaning—or ambiguity—of certain words or phrases may only become evident when placed in context" and "with a view to their place in the overall statutory scheme") (cleaned up).

a. Start with the text of the statutes the Secretary invokes. First, the Secretary argues (at 19) that he is vested with "broad authority" under 42 U.S.C. §§ 1302(a) & 1395hh(a)(1) and such authority allowed him to impose the challenged nationwide vaccine mandate.

Not so. To be sure, the Secretary's "administrative authority is undoubtedly broad." *Merck & Co. v. United States Dep't of Health & Hum. Servs.*, 962 F.3d 531, 537 (D.C. Cir. 2020) (citing *Thorpe v. Hous. Auth. of City of Durham*, 393 U.S. 268, 277 n.28 (1969)). "But it is not boundless." *Id.* And here neither § 1302(a) nor § 1395hh(a)(1) gives the Secretary the power to impose a nationwide vaccine mandate.

Section 1302(a) directs the Secretary to "make and publish such rules and regulations, not inconsistent with [the Social Security Act], as may be *necessary to the efficient administration of the functions* with which [the Secretary] is charged under" the Medicare and Medicaid programs. (Emphasis added). Similarly, Section 1395hh(a)(1) directs the Secretary to "prescribe such regulations as may be *necessary to carry out the administration of the insurance programs* under" the Medicare Act. (Emphasis added).

The word "administration" is the "central focus" of these statutes, and its original meaning in 1935 was "the practical management and direction of its various programs (including eventually Medicare and Medicaid), as well as their management and conduct." *Merck*, 962 F.3d at 537 (quotations omitted). In other words, a regulation must be "necessary" to the programs' "administration," and "the further a regulation strays from truly facilitating the 'administration' of the Secretary's duties, the less likely it is to fall within the statutory grant of authority." *Id.* at 537–38.

The Secretary doesn't dispute this textual analysis or even attempt to defend the vaccine mandate as "necessary" to Medicare's and Medicaid's "administration"; instead, he claims (at 24) that "it would be striking and anomalous if [his] broad authority to adopt conditions protecting patient health and safety did not include a … mechanism like a vaccine requirement."

But the Secretary's invocation of results-oriented purposivism—*i.e.*, the Secretary has always had regulatory authority to promote the health and safety of Medicare and Medicaid recipients—is a poor substitute for any *text* in §§ 1302(a) and 1395hh(a)(1) that supports his authority. Indeed, neither statute even mentions "health and safety" (and the Secretary does not argue otherwise). The cruel irony here—one the district court found based on facts that the Secretary does not dispute—is that the mandate will actually result in patients *not* having access to essential healthcare services. *See, e.g.*, App.30a-31a. That's quite the opposite of promoting patients' "health and safety."

Further supporting the States' interpretation of §§ 1302(a) and 1395hh(a)(1) is that even though the Secretary invoked these statutes as authorizing the mandate, he openly recognized that the mandate was unprecedented—never before had the agency mandated *any* vaccination. App.49a. Indeed, the Secretary recognized that vaccination requirements on healthcare workers in Medicare- and Medicaid-certified facilities had traditionally been left to the States and private employers—not the federal government. *See*

id.; *accord Jacobson v. Massachusetts*, 197 U.S. 11, 38 (1905) (vaccine requirements "do not ordinarily concern the national government"); *Valdez v. Grisham*, No. 21A253 (U.S. Dec. 21, 2021) (Gorsuch, J.) (denying stay of New Mexico's healthcare worker vaccine mandate); App'l, at 23 (collecting stay denials of Maine's and New York's healthcare worker vaccine mandates).

Thus, the Secretary's characterization of this sweeping mandate as a mere routine exercise of his broad regulatory authority is simply wrong.

b. The Secretary next argues (at 19) that Congress vested him with specific statutory authority to adopt "requirements that he deems necessary to ensure patient health and safety." Again, this argument is meritless.

For starters, many of the statutes the Secretary invokes *do* reference "health and safety" requirements, but only for *some* covered facilities, such as hospitals. The Secretary ignores that the statutes mentioning "standards," "criteria," or "requirements" for many other facilities—such as Psychiatric Residential Treatment Facilities (PRTFs) for individuals under age 21 and Home Infusion Therapy (HIT) suppliers—do *not* reference "health and safety" at all.[8] Such nondescript statutes do not come close to authorizing a vaccine mandate

[8] *See, e.g.*, 42 U.S.C. § 1396d(h)(1)(B)(i) (governing PRTFs and mentioning "standards as may be prescribed"); 42 U.S.C. § 1396d(d)(1) (governing Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICFs-IID) and mentioning "standards as may be prescribed"); 42 U.S.C. § 1395rr(b)(1)(A) (governing End-Stage Renal Disease (ESRD) facilities and mentioning "requirements as the Secretary shall by regulation prescribe"); 42 U.S.C. § 1395x(iii)(3)(D)(i)(IV) (governing HIT suppliers and mentioning "requirements as the Secretary determines appropriate").

for those facilities. Because CMS applied its mandate to those facilities anyway, the agency vastly exceeded its statutory authority.

Moreover, the specific statutes that the Secretary cites in his brief (at 19) fail to clearly authorize this mandate. The Secretary points to 42 U.S.C. 1395d(a)(1), which authorizes payments for "hospital services." But nothing in the text of this provision even mentions "health" or "safety" or vaccinations and, when read in context—not in isolation—the primary audience is Medicare beneficiaries, not Medicare-certified providers.

The Secretary argues, however, that this provision uses the term "hospital" and that term is defined, in a different statutory provision, 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." 42 U.S.C. § 1395x(e)(9). Thus, the Secretary contends that, through the vaccine mandate, he was merely imposing a "requirement[]" that was "necessary in the interest of the health and safety" of patients.

Reading the entirety of § 1395x(e)(1)-(9), rather than § 1395x(e)(9) in isolation, "it is a stretch to maintain that" this statute gives the Secretary the authority to impose this vaccine mandate. *Alabama Ass'n of Realtors*, 141 S. Ct. at 2488. Under § 1395x(e), a "hospital" is defined as an institution that:

> (1) is primarily engaged in providing, by or under the supervision of physicians, to inpatients (A) diagnostic services and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, or sick persons, or (B) rehabilitation services for the rehabilitation of injured, disabled, or sick persons;

(2) maintains clinical records on all patients;

(3) has bylaws in effect with respect to its staff of physicians;

(4) has a requirement that every patient with respect to whom payment may be made under this subchapter must be under the care of a physician, except that a patient receiving qualified psychologist services (as defined in subsection (ii)) may be under the care of a clinical psychologist with respect to such services to the extent permitted under State law;

(5) provides 24-hour nursing service rendered or supervised by a registered professional nurse, and has a licensed practical nurse or registered professional nurse on duty at all times; except that until January 1, 1979, the Secretary is authorized to waive the requirement of this paragraph for any one-year period with respect to any institution, insofar as such requirement relates to the provision of twenty-four-hour nursing service rendered or supervised by a registered professional nurse (except that in any event a registered professional nurse must be present on the premises to render or supervise the nursing service provided, during at least the regular daytime shift), where immediately preceding such one-year period he finds that—

(A) such institution is located in a rural area and the supply of hospital services in such area is not sufficient to meet the needs of individuals residing therein,

(B) the failure of such institution to qualify as a hospital would seriously reduce the availability of such services to such individuals, and

(C) such institution has made and continues to make a good faith effort to comply with this paragraph, but such compliance is impeded by the lack of qualified nursing personnel in such area;

(6)(A) has in effect a hospital utilization review plan which meets the requirements of subsection (k) and (B) has in place a discharge planning process that meets the requirements of subsection (ee);

(7) in the case of an institution in any State in which State or applicable local law provides for the licensing of hospitals, (A) is licensed pursuant to such law or (B) is approved, by the agency of

> such State or locality responsible for licensing hospitals, as meeting the standards established for such licensing;
>
> (8) has in effect an overall plan and budget that meets the requirements of subsection (z); and
>
> (9) 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.

42 U.S.C. § 1395x(e).

While the Secretary contends that the last provision in § 1395x(e) gives him authority to establish requirements he deems necessary to health and safety—including issuing the vaccine mandate—the phrase "such other requirements" informs the agency's "grant of authority," *Alabama Ass'n of Realtors*, 141 S. Ct. at 2488, because it ties the provision back to the kinds of requirements listed in § 1395x(e)(1)-(8). *Accord FDA*, 529 U.S. at 132–33; *AT&T Corp. v. Iowa Utilities Bd.*, 525 U.S. 366, 408 (1999) (Thomas, J., concurring in part & dissenting in part) (statutory provision "best interpreted by reference to that which precedes and follows it") (quoting *Neal v. Clark*, 95 U.S. 704, 708 (1877) (Harlan, J.)); *see also King v. Burwell*, 576 U.S. 473, 487 (2015) (defining "such" as "that or those; having just been mentioned") (cleaned up); 17 Oxford English Dictionary 101 (2d ed.1989) (defining "such" as "of the character, degree, or extent described ... in what has been said") (cleaned up); Webster's Third New International Dictionary 2283 (2002) (defining "such" as something "previously characterized or specified"). Indeed, phrases must be construed by

the surrounding text to avoid ascribing a meaning so broad that it gives "unintended breadth to the Acts of Congress." *Gustafson v. Alloyd Co.*, 513 U.S. 561, 575 (1995).

The vaccine mandate is not authorized under this statute because the mandate is materially unlike the requirements listed in the preceding eight provisions. For starters, the prior provisions impose structural requirements on hospitals themselves: medical services rendered, administration, management, recordkeeping, licensing, and location. They do not authorize requirements on hospital *staff*—much less immunization requirements.

In addition, compulsory COVID–19 vaccines require staff to submit to a permanent medical procedure that, according to CMS, entails some risk of "[s]erious adverse reactions" even though "they are rare." App.47a; *cf. In re MCP No. 165, Occupational Safety & Health Admin., Interim Final Rule: COVID-19 Vaccination & Testing*, --- F.4th ----, 2021 WL 5914024, at *12 (6th Cir. Dec. 15, 2021) (en banc) (Sutton, C.J., dissenting from the denial of initial hearing en banc) (contrasting wearing a mask during work with undergoing a vaccination "medical procedure that cannot be removed at the end of the shift"). None of the explicit statutory conditions remotely implies the authority to force healthcare workers to submit to a permanent medical procedure.

The same analysis applies to the Secretary's cited statute governing long-term-care (LTC) facilities. *See* 42 U.S.C. § 1395i-3(d)(4)(B). That statute contains the same "such other requirements" language. *Id.* While the explicit

conditions in that statute include the generic mandate for each facility to have "an infection control program" on the premises, 42 U.S.C. § 1395i-3(d)(3), in addition to administrative and licensing requirements, 42 U.S.C. § 1395i-3(d)(1)-(2), none of those requirements is akin to forcing staff to undergo a medical procedure that lasts long after work hours end.

Moreover, the breadth of authority that the Secretary claims counsels against his reading of these statutes. The mandate operates indirectly in its attempt to protect patients: it aims to keep workers from getting sick, which, in turn, may prevent transmission to patients. But holding that the Secretary may require healthcare workers to take steps to bolster their own health in hopes of indirectly protecting patients "would facilitate a breathtaking expansion of the [Secretary's] power." *MCP No. 165*, 2021 WL 5914024, at *7 (Sutton, C.J., dissenting). It would allow CMS to regulate countless off-duty details of healthcare workers' lives, including the places they go, the people they visit, the supplements they ingest, and the foods they eat.

42 U.S.C. § 1395 confirms the States' reasonable reading of the Secretary's authority. That statute forbids CMS from "exercise[ing] any supervision or control … over the selection [or] tenure … of any officer or employee of any institution, agency, or person providing health services." 42 U.S.C. § 1395. Yet the Secretary understands his power to afford precisely that authority—by permitting him, through the mandate, to tell covered facilities that they cannot

hire or retain unvaccinated workers. It is unreasonable to construe the Secretary's power to allow what 42 U.S.C. § 1395 forbids. *Texas v. Becerra*, --- F. Supp. 3d ----, 2021 WL 5964687, at *5 (N.D. Tex. Dec. 15, 2021).

Without clear support in the statutory text, the Secretary argues (at 21) that "the agency's practice" illustrates its power to issue this vaccine mandate. In fact, the opposite is true. As CMS admits, this mandate is unprecedented: the agency has "not previously required any vaccinations." App.49a. A "lack of historical" precedent is often "the most telling indication" that an agency lacks the power to promulgate a regulation. *Free Enter. Fund*, 561 U.S. at 505 (cleaned up); *see also Util. Air Regul. Grp.*, 573 U.S. at 324.

The Secretary nevertheless argues (at 22) that the mandate fits squarely within CMS's past practices because healthcare facilities "have long been subject to 'employer or State … vaccination requirements.' " This does not help the Secretary. That the States or employers might have the power to mandate vaccines does nothing to prove that a federal agency has that authority. *See Jacobson*, 197 U.S. at 38 (noting that vaccine requirements "do not ordinarily concern the national government").

The Secretary also mentions (at 22) that some of the covered facilities have already been subject to regulations addressing the " 'prevention' and 'control' of 'infection diseases.' " This, too, is unavailing. While some of the covered

facilities have been subject to such regulations, many have not.[9] This confirms that CMS never thought it had the power to impose infection-control measures on those facilities. And even for the facilities previously subject to infection-control regulations, that CMS never mandated vaccines through those regulations shows that it has not considered its authority to reach that far.

2. "Even if the text were ambiguous, the sheer scope" of the Secretary's "claimed authority" under the foregoing statutes "would counsel against the Government's interpretation." *Alabama Ass'n of Realtors*, 141 S. Ct. at 2489.

This Court "expect[s] Congress to speak clearly" in at least three situations relevant here: (1) "when authorizing an agency to exercise powers of vast economic and political significance," *id.*; (2) when "federal law overrides the usual constitutional balance of federal and state powers," *Bond v. United States*, 572 U.S. 844, 858 (2014) (cleaned up); and (3) when "an administrative interpretation of a statute invokes the outer limits of Congress' power," *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng'rs*, 531 U.S. 159, 172 (2001).

These are often referred to as clear-statement rules. They "eliminate any power-enhancing uncertainty in the meaning of the statute." *In re MCP No. 165*, 2021 WL 5914024, at *12 (Sutton, C.J., dissenting). And where,

[9] *See, e.g.*, 42 C.F.R. § 441.151 (PRTFs); 42 C.F.R. § 483.430 (ICFs-IID); 42 C.F.R. § 485.58 (CORFs); 42 C.F.R. § 485.904 (Community Mental Health Centers (CMHCs)); 42 C.F.R. § 486.525 (HIT suppliers); 42 C.F.R. § 491.8 (Rural Health Clinics).

as here, there are " 'significant … federalism questions raised' " and a "federalism-protecting interpretation of the statute [is] not clearly ruled out," courts "must accept that interpretation[.]" *Id.* (quoting *Solid Waste Agency*, 531 U.S. at 174). At bottom, agencies seeking to take major regulatory action must do so with clear authorization from Congress; "an *ambiguous* grant of statutory authority is not enough." *United States Telecom Ass'n v. FCC*, 855 F.3d 381, 421 (D.C. Cir. 2017) (en banc) (Kavanaugh, J., dissenting from the denial of rehearing en banc).

All three of these rules apply here. First, this first-of-its-kind national vaccine mandate covers "virtually all health care staff in the U.S.," App.55a—an estimate of 10.3 million individuals, *id.* at 85a—alters massive government programs involving "billions of dollars," *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1816 (2019), and threatens economic ruin and patient harm throughout the healthcare industry. Such a sweeping mandate affecting "billions of dollars" and "millions of people" requires a clear statement of congressional authorization. *King*, 576 U.S. at 485–86. Attempting to cobble together congressional intent through vague sections scattered throughout the Social Security Act does not provide the clear authorization needed. Second, the mandate seeks to usurp the States' traditional police power to "protect the public health" by addressing mandatory vaccination—a topic that "do[es] not ordinarily concern the national government." *Jacobson*, 197 U.S. at 24–25, 38. Third, in attempting to mandate vaccines without clear congressional notice to the

States, the mandate reaches beyond the outer limits of Congress's power. The district court correctly found that all these "fundamental principles" apply and that "clear congressional authorization" is needed. App.8a.

The Secretary disputes (at 24-31) that any of the clear-statement rules applies here. He is wrong.

Starting with the major-questions doctrine, the Secretary's efforts to distinguish *Alabama Association of Realtors* (at 25) fail. Here, as explained above, the explicit conditions in the statutes that CMS cites, much like the specific statutory examples in *Alabama Association of Realtors*, do in fact cabin CMS's authority to create "such other requirements" addressing health and safety. 42 U.S.C. § 1395x(e)(9) (hospitals).

Moreover, *Alabama Association of Realtors* applied the major-questions doctrine because the eviction moratorium covered "[a]t least 80% of the country, including between 6 and 17 million tenants at risk of eviction," and impacted billions of dollars. 141 S. Ct. at 2489. Similarly, here, the CMS mandate applies throughout the entire country, covers "virtually all health care staff," App.55a—about 10.3 million workers, *id.* at 85a—and modifies large government programs in which even "minor changes" affect "billions of dollars." *Azar*, 139 S. Ct. at 1816; *see also* App.95a (estimating that compliance for only the first year will cost $1.38 billion). The major-questions doctrine thus applies here, just as it did in *Alabama Association of Realtors*.

The Secretary then (at 27) dismisses *Utility Air Regulatory Group* and *Brown & Williamson Tobacco* because the Court in those cases "reasoned that adopting the agency's position would have conflicted with other provisions." Yet the same is true here, as the prior discussion of 42 U.S.C. § 1395 shows.

The Secretary also argues (at 27) that the major-questions doctrine does not apply because the statutes at issue are not "ambiguous." But the prior analysis demonstrates that the statutes CMS cites, *see* App.49a—many of which do not even reference "health" or "safety"—fail to unambiguously authorize this sweeping mandate. The Secretary thus cannot avoid the major-questions doctrine on this basis.

The Eleventh Circuit motions panel's rejection of the major-questions doctrine is unconvincing. While conceding that *this* vaccine mandate is "an issue of economic and political significance," the panel said that "a broad grant of authority" to an agency "does not require an indication that specific activities are permitted." *Florida*, 19 F.4th at 1288. But this flawed logic essentially rejects the premise of the major-questions doctrine, which by its nature cabins seemingly broad grants of regulatory authority.

The Secretary next discards (at 28-29) the federalism clear-statement rule because this mandate is an exercise of Spending Clause power. But this Court—including in the Secretary's only cited case, *Sabri v. United States*, 541 U.S. 600 (2004)—has not dismissed this clear-statement rule in the Spending Clause context. *Sabri* decided a constitutional challenge to a federal criminal

statute, and the Court neither construed a statute nor mentioned this clear-statement rule. That opinion is thus irrelevant to the issues raised here.

In any event, it would be improper to assess the "Spending Clause power" "without concern for the federal balance" because that would allow the federal government "to set policy in the most sensitive areas of traditional state concern." *NFIB v. Sebelius*, 567 U.S. 519, 675–76 (2012) (plurality op.) (noting that an unchecked spending power "would present a grave threat to the system of federalism created by our Constitution"). And because Spending Clause statutes must give "clear notice" to "recipients of federal funds" of "federally imposed conditions," *Arlington Cent. Sch. Dist. Bd. of Educ. v. Murphy*, 548 U.S. 291, 296 (2006), the federalism clear-statement rule is fully consistent with Spending Clause analysis, which likewise requires the statute to provide "clear notice" to the States. No such clear statement is provided here.

B. The mandate is arbitrary and capricious.

"The APA's arbitrary-and-capricious standard requires" the agency to "reasonably consider[] the relevant issues and reasonably explain[] the decision." *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021). "[T]he agency must examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.' " *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (citation omitted). It must also "assess

whether there were reliance interests, determine whether they were significant, and weigh any such interests against competing policy concerns." *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, 140 S. Ct. 1891, 1915 (2020).

The district court identified five reasons why the mandate is arbitrary and capricious: (1) CMS's lack of evidence regarding most of the covered healthcare facilities; (2) CMS's improper rejection of alternatives; (3) the mandate's irrationally broad scope; (4) CMS's pretextual change in course; and (5) CMS's failure to consider or properly weigh reliance interests and the risk that this failure will impose devastating consequences on healthcare services. App.18a-27a. To prevail on appeal, the Secretary must refute all five reasons. But he cannot rebut even one.

1. *Lack of Evidence on Most Facilities.* The district court held that it is unreasonable for CMS to "extrapolate" its data on long-term-care (LTC) facilities that house the elderly "to justify" applying its mandate to the 14 other diverse types of covered facilities, which include places like Psychiatric Residential Treatment Facilities (PRTFs) for individuals under age 21. App.18a-20a. Illustrating the irrationality of this explanation is CMS's recognition that the "risk of death from infection from an unvaccinated 75- to 84-year-old person is 320 times more likely than the risk for an 18- to 29-years old person." App.92a.

The Secretary defends his heavy reliance on LTC facility data (at 34-35) because that data "was just one piece of the ample evidence." But the Secretary

does not cite anything indicating what "ample evidence" he is referencing and does not highlight evidence derived from other covered facilities.

2. *Improperly Rejected Alternatives.* The district court identified two alternatives that CMS improperly rejected: "daily or weekly testing" for all workers; and different treatment for workers with "natural immunity." App.20a-21a. The Secretary argues (at 34) that the district court "substitute[d] its views on epidemiology" for CMS's judgment. But the court did no such thing. Rather, it pointed out CMS's own inconsistencies on these issues.

Concerning the testing option, the district court noted that CMS announced an unexplained one-sentence conclusion, cited no evidence, and contradicted itself through "its admission that it lacks solid evidence regarding transmissibility of COVID by the vaccinated." App.20a-21a (footnote omitted). And regarding natural immunity, the court observed that CMS "contradict[ed] itself regarding the value of natural immunity" when it acknowledged that individuals who "have recovered from infection … *are no longer sources of future infections*." App.21a (quoting App.86a). Furthermore, while CMS questioned the supposed "uncertainties" about "the strength and length" of natural immunity "compared to people who are vaccinated," App.96a, it simultaneously conceded that "the duration of vaccine effectiveness" is "not currently known," *id.* at 97a. "Such contradictions," the district court aptly observed, "are telltale signs of unlawful agency actions." App.21a.

3. *The Mandate's Irrationally Broad Scope and CMS's Pretextual Change.* The Secretary seeks to excuse the mandate's irrational scope and the agency's pretextual change in position (at 35) by arguing that this is a "unique pandemic." But pretext, regardless of whether it arises in unique circumstances, necessarily renders agency action arbitrary and capricious. *Dep't of Com. v. New York*, 139 S. Ct. 2551, 2575–76 (2019). Here, the mandate is pretextual because the Administration originally (and correctly) declared that vaccine mandates are "not the role of the federal government," *supra*, at n.2; the President then announced that the goal of this and other mandates is to increase societal vaccination rates, *supra*, at n.3; and CMS now justifies this mandate as necessary to protect patient health. Because "the evidence tells a story that does not match the explanation [CMS] gave," this mandate cannot stand. *Dep't of Com.*, 139 S. Ct. at 2575.

4. *Reliance Interests and Devastating Consequences on Healthcare.* The district court also held that "CMS did not properly consider *all* necessary reliance interests of facilities, healthcare workers, and patients" in "concluding that the mandate's benefits outweigh the risks to the healthcare industry." App.25a. "CMS looked only at evidence from interested parties in favor of the mandate," and by dispensing with procedural rulemaking requirements, the agency "ignored evidence showing that the mandate threatens devastating consequences" by exacerbating already severe workforce shortages in healthcare. *Id.* at 25a-26a.

Despite CMS's recognition that "compliance with [the mandate] may create some short-term disruption of current staffing levels for some providers or suppliers in some places," App.91a, if "[e]ven a small fraction" of unvaccinated healthcare workers leave their jobs, *id.* at 94a, the agency dismissed those concerns because it thought "there is insufficient evidence to quantify" and balance those against other risks. *Id.* at 51a. But this Court *requires* the agency to "assess … reliance interests … and weigh [them] against competing policy concerns." *Regents*, 140 S. Ct. at 1915. And as the district court held, it was irrational to foreclose interested "parties' ability to provide information regarding the mandate's effects on the healthcare industry, while simultaneously dismissing those concerns based on 'insufficient evidence.' " App.25a.

Trying to justify himself, the Secretary places great weight (at 33) on a joint statement of professional associations supporting vaccine mandates for healthcare workers. But this simply proves the district court's point that CMS acted arbitrarily in "look[ing] only at evidence from interested parties in favor of the mandate, while completely ignoring evidence from interested parties in opposition." App.25a. The thirty declarations filed in this case show that there is a different perspective widely held in the healthcare industry that CMS unreasonably ignored. *See* R.App.35a-139a.

The Secretary also cites (at 32) experiences of a few private healthcare systems that implemented vaccine mandates in mostly urban areas to justify

CMS's dismissal of workforce concerns. But those cherry-picked examples cannot bear the weight CMS puts on them. Privately imposed mandates are poor proxies for a nationwide government-imposed mandate. And the experiences of healthcare providers in mainly urban areas, which have larger labor pools and higher community vaccination rates than rural areas, are not representative of the impact on rural providers. As the district court found, "whatever might make sense in Chicago, St. Louis, or New York City, could be actually counterproductive and harmful in rural communities like Memphis (MO) or McCook (NE)." App.34a.

In its stay application, the Government replicates the Secretary's error by repeatedly citing vaccine mandates in Detroit and Houston to justify imposing a mandate in rural Missouri, Nebraska, Alaska, and similar areas. Thus, the Government studiously overlooks "obvious distinctions" between the problems and challenges facing rural healthcare providers in tiny communities, as opposed to those in major urban centers. *Dry Color Mfrs. Ass'n, Inc. v. Dep't of Labor*, 486 F.2d 98, 105 (3d Cir. 1973). The mandate is quintessentially arbitrary and capricious because the Secretary " 'failed to consider ... important aspect[s] of the problem' before [him]." *Regents*, 140 S. Ct. at 1910 (quoting *State Farm*, 463 U.S. at 43). In its rule, CMS also relied on New York's experience imposing a statewide vaccine mandate on healthcare workers. App.51a. But the *New York Times* article that CMS cited raises cause for se-

rious concern. *Id.* (citing *Thousands of N.Y. Health Care Workers Get Vaccinated Ahead of Deadline*, N.Y. Times (Sept. 28, 2021)). It reported that when the mandate took effect, only 92% of "the state's more than 650,000 hospital and nursing home workers had received at least one vaccine dose." That means 8% of those healthcare workers—a total of 52,000 people—had not even begun the vaccination process. This directly undercuts CMS's assertion, which immediately followed its *Times* citation, that the mandate "will result in *nearly all* health care workers being vaccinated." *Id.* (emphasis added).[10]

Beyond this, the *Times* article noted that New York "hospitals and nursing homes continue[d] to brace for potential staffing shortages," and that "even minor staff losses … could put some patients at risk." The article also observed that the "governor declared a state of emergency" just days before the mandate's deadline "allow[ing] her to use the National Guard to fill staffing shortages." And it reported that a hospital-affiliated nursing home in Buffalo placed 20% of its staff "on unpaid leave … for refusing to get vaccinated," causing the facility to "transfer[] staff in from other facilities, reduc[e] beds at the nursing home[,] and suspend[] some elective surgeries at the hospital." Facing these

[10] Recent media coverage has reported that since New York's mandate on healthcare workers took effect, "31,858 health care workers at nursing homes, hospitals and other health providers have been terminated, furloughed or forced to resign because they would not comply with the mandate." *Termination of unvaccinated health care workers backfires*, Fox News (Dec. 28, 2021), https://fxn.ws/3qxu5cz.

disturbing facts, it was unreasonable for CMS to fail to mention them, let alone to rely on this article to *dismiss* the workforce shortage concerns.[11]

The Secretary additionally speculates (at 32) that the mandate's "adverse impact on the labor market" will be offset by "reduced absenteeism due to COVID-19." But this conjecture unreasonably ignores that maintaining a larger pool of employees, even if some might have a bout with COVID–19, is better than excluding an entire group of current workers.

The Secretary lastly insists (at 32) that any workforce losses will be "dwarfed by the regular staff turnover in the healthcare workforce." Not so. CMS admits that the mandate covers "virtually all health care staff" and that it disqualifies all unvaccinated workers from those positions. App.55a. Excluding an entire category of workers from most healthcare jobs is not the ordinary "turnover" of the labor market. The notion that "business as usual" measures can counteract the impending doom is unreasonable. And the extensive credible evidence from the States' thirty declarants belies CMS's rose-tinted views on this point.

[11] Later developments continue to demonstrate the fallout from New York's mandate. *See Long Island hospital temporarily closing ER*, ABC 7 New York (Nov. 22, 2021), https://bit.ly/3G6rzA2 ("The emergency department at a Nassau County hospital has temporarily closed due to nursing staff shortages as a result of New York's vaccine mandate.").

The Eleventh Circuit motions panel's decision does not refute these points. *Florida*, 19 F.4th at 1290–91. The panel addressed only two of the five arbitrary-and-capricious arguments that the district court accepted here. Even for those two arguments (CMS's improper rejection of alternatives and the risk of exacerbating workforce shortages), the panel's perfunctory discussion is unpersuasive because, among other things, it ignores the many CMS contradictions discussed above.

C. The Mandate Violates Multiple Procedural Requirements.

The district court determined that CMS did not establish good cause to excuse compliance with notice-and-comment procedural requirements. App.12a-17a. The good-cause standard is particularly stringent here, the court concluded, given "the unprecedented, controversial, and health-related nature of the mandate," and "CMS's own delay" in implementing its mandate. *Id.*[12] Also, "[t]he 'more expansive' a rule's reach, 'the greater the necessity for public comment.' " *MCP No. 165*, 2021 WL 5914024, at *10 (Sutton, C.J., dissenting) (quoting *Am. Fed'n of Gov't Emps. v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981)).

[12] The district court found that the "mandate was announced nearly two months before" its official release. App.14a. The Secretary could have received comments within that sixty-day period just as he is receiving comments during the current sixty-day comment period. *See id.* at 37a (rule published November 5, 2021, with comments due January 4, 2022).

In arguing that the district court erred, the Secretary raises (at 36) five justifications for skipping notice and comment: (1) some patients' vulnerability to COVID-19; (2) the number of total COVID-19 cases among healthcare workers; (3) the Delta variant's emergence in June; (4) an anticipated winter spike in cases; and (5) the coming flu season.

The first two reasons are generalized to healthcare during the pandemic; they do not address why undertaking notice and comment *now* will cause harm, and they do not explain why the Secretary could not have accepted comments in the two months between the President's announcement and the mandate's promulgation. If these excuses suffice, that will effectively "sideline the notice-and-comment process" for the remainder of the pandemic. *MCP No. 165*, 2021 WL 5914024, at *11 (Sutton, C.J., dissenting). Reliance on Delta is also unavailing because, as CMS recognizes, Delta's June uptick had "begun to trend downward" when the mandate issued. App.65a. Finally, speculation about a coming winter "spike" and the "flu season" fails because CMS admits that flu season's "intensity" "cannot be predicted." App.15a (quoting App.66a). This "mere possibility" of "future harm" cannot establish good cause. *United States v. Brewer*, 766 F.3d 884, 890 (8th Cir. 2014).

The Secretary then claims (at 37) that the States "have not identified any prejudice arising out of the lack of a prior comment period." But all the information in the hundreds of pages of declarations filed below could have been

communicated to CMS during the comment period, thus showing the impending healthcare disaster. Cutting off that information shaded the rulemaking process and prejudiced everyone opposing the mandate. In any event, to assert this procedural claim, the States need only show "some possibility" that their comments might have persuaded or affected the agency's decision—a very low bar. *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007).

III. The Remaining Factors Do Not Favor a Stay.

For the reasons stated above, this is not "a close case," *Ind. State Police*, 556 U.S. at 960, so the Court need not reach the balancing of equities, the relative harms, and the public interest. But if it does, these additional factors weigh overwhelmingly against granting a stay.

A. *Balancing Irreparable Harm.* Where, as here, "the lower court has already performed th[e] task" of determining the parties' respective harms "in ruling on a stay application, its decision is entitled to weight and should not lightly be disturbed." *Williams v. Zbaraz*, 442 U.S. 1309, 1312 (1979) (Stevens, J., in chambers). Before the district court, it was the States—not the Secretary—that demonstrated irreparable harm. Thus, this part of the district court's "thorough analysis" "warrant[s] respect." *Barr v. E. Bay Sanctuary Covenant*, 140 S. Ct. 3, 5 (2019) (Sotomayor, J., dissenting from grant of stay).

Preventing the Secretary from enforcing his unlawful mandate will inflict no cognizable injury—let alone irreparable harm—on him because "[a]ny interest [he] may claim in enforcing an unlawful … [regulation] is illegitimate." *BST Holdings, LLC v. OSHA*, 17 F.4th 604, 618 (5th Cir. 2021). On the flip

side, granting the stay would irreparably harm the States in several ways. App.27a-32a.

First, a stay would inflict sovereign harm by overriding the States' "duly enacted laws surrounding vaccination mandates." *Id.* at 28a (citing preempted state laws). This Court has repeatedly affirmed that this kind of injury is irreparable. *See, e.g.*, *Abbott v. Perez*, 138 S. Ct. 2305, 2324 n.17 (2018) ("[T]he inability to enforce its duly enacted plan clearly inflicts irreparable harm on the State."); *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (Roberts, C.J., in chambers) ("Any time" a State is blocked "from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury").

Second, a stay would harm the States' quasi-sovereign interest in the health and wellbeing of their citizens because the loss of healthcare staff, reduction of services, and closure of facilities caused by the mandate will "imped[e] access to care for the elderly and for persons who cannot afford it." App.28a-31a. The Secretary says (at 39) that the States lack standing to raise this interest, but that is not true. Though a State may not file suit solely "to protect her citizens from the operation of federal statutes," it may "assert its rights under federal law," including procedural administrative rights like those at issue here, and when doing so, the State may "litigate as *parens patriae* to protect quasi-sovereign interests—*i.e.*, public … interests that concern

the state as a whole." *Massachusetts*, 549 U.S. at 520 n.17 (cleaned up). Because the States are raising their own rights here, they also have standing to assert quasi-sovereign interests in the health and wellbeing of their citizens.

Third, the States, as operators of state-run healthcare facilities, will also experience irreparable proprietary harms. App.32a.[13] These include the "business and financial effects of a lost or suspended employee, compliance and monitoring costs associated with the Mandate, [and] the diversion of resources necessitated by the Mandate." *Id.* (quoting *BST Holdings*, 17 F.4th at 618); *see also Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220–21 (1994) (Scalia, J., concurring) ("[A] regulation later held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs.").

B. *Public Interest.* Finally, even if this were a "close case," the Court should consider "the interests of the public at large." *Ind. State Police*, 556 U.S.

[13] The Secretary argues (at 39) that state-run facilities sanctioned for failing to comply with conditions of participation may seek judicial review under 42 U.S.C. § 1395cc(h)(1). But the Secretary has already conceded that States cannot use § 1395cc(h)(1)'s procedural mechanism because they are plainly neither "institution[s]" nor "agenc[ies]" "dissatisfied" with the Secretary's determination regarding eligibility or receipt of benefits under that statute. App.6a-7a; *see also Massachusetts*, 549 U.S. at 518 (States are "not normal litigants for the purposes of invoking federal jurisdiction"). Thus, consistent with *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 16 (2000), the district court correctly concluded that 42 U.S.C. § 405(h), as incorporated by 42 U.S.C. § 1395ii, has no application here. App.6a-7a. And the States' claims that arise under the Medicaid Act—as opposed to the Medicare Act—"are not subject to the § 405(h)'s jurisdictional bar"—a conclusion the Secretary doesn't challenge here. *Id.* (citing *Avon Nursing & Rehab. v. Becerra*, 995 F.3d 305, 311 (2d Cir. 2021)).

at 960. The public interest favors continuing to "enjoin[] the mandate[] and thus preserving the 'status quo.' " App.34a. If the mandate were to take effect, it "will have a crippling effect on a significant number of healthcare facilities in Plaintiffs' states, especially in rural areas, create a critical shortage of services (resulting in *no medical care at all* in some instances), and jeopardize the lives of numerous vulnerable citizens." *Id.* at 33a-34a.

The Secretary argues (at 38) that the public interest nonetheless favors a stay because "patients may die" from "COVID-19 infections transmitted to them by staff." Despite the public's interest in preventing the spread of COVID-19, agencies cannot act unlawfully—even in the pursuit of desirable ends. *Ala. Ass'n of Realtors*, 141 S. Ct. at 2490. And according to CMS, "the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] *not currently known*." App.97a (emphasis added); *see also id.* at 33a. The Secretary's public-interest argument—and the principal justification for the mandate itself—is thus admittedly speculative. In contrast, the States' undisputed evidence concretely shows that the mandate will drive out healthcare workers, reduce services, and close facilities—all of which will harm people seeking healthcare. The harm this poses to the public is even more pressing now, as evidenced by the President's announcement earlier this week

that existing staff shortages are so great he is mobilizing "1,000 military doctors and nurses and medics to help staff hospitals." *Supra*, at n.10. Given this, the public interest weighs decidedly against the Secretary.[14]

The Court should also reject the Secretary's last-ditch plea (at 40) to limit the injunction "to facilities operated by the … States." As discussed above, the States have a cognizable quasi-sovereign interest in the health and wellbeing of their citizens, and thus the injunction must reach private facilities within their States. In addition, the State's irreparable sovereign injuries, which include the preemption of their laws, are alone sufficient to justify applying the injunction throughout their borders.

[14] The Secretary (at 5 and 13) repeatedly references the Omicron variant to bolster the purported need for the mandate, but this is purely "impermissible *post hoc* rationalization[]" and thus is "not properly before" the Court. *Regents*, 140 S. Ct. at 1909.

CONCLUSION

The Court should deny the motion for a stay pending appeal.

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