No. 21A-_____

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.

APPLICATION FOR A STAY OF THE INJUNCTION ISSUED BY THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF MISSOURI PENDING APPEAL TO THE UNITED STATES COURT OF APPEALS FOR THE EIGHTH CIRCUIT AND FURTHER PROCEEDINGS IN THIS COURT

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PARTIES TO THE PROCEEDING

The applicants (defendants-appellants below) are Joseph R. Biden, Jr., in his official capacity as President of the United States; Xavier Becerra, in his official capacity as Secretary of the United States Department of Health and Human Services; Chiquita Brooks-LaSure, in her official capacity as Administrator for the Centers for Medicare & Medicaid Services; Meena Seshamani, in her official capacity as Deputy Administrator and Director of Center for Medicare; Daniel Tsai, in his official capacity as Deputy Administrator and Director of Center for Medicaid and CHIP Services; the United States; the United States Department of Health and Human Services; and the Centers for Medicare & Medicaid Services.

The respondents (plaintiffs-appellees below) are the States of Alaska, Arkansas, Kansas, Iowa, Missouri, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming.

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Pursuant to this Court's Rule 23 and the All Writs Act, 28 U.S.C. 1651, the Solicitor General, on behalf of applicants President Joseph R. Biden, Jr., et al., respectfully applies for a stay of the injunction issued by the United States District Court for the Eastern District of Missouri, pending the consideration and disposition of applicants' appeal from that injunction to the United States Court of Appeals for the Eighth Circuit and, if necessary, pending the filing and disposition of a petition for a writ of certiorari and any further proceedings in this Court.[1]

[1] As explained further below, the government is simultaneously filing an application for a stay of a similar injunction entered by the U.S. District Court for the Western District of Louisiana.

In response to an unprecedented pandemic that has killed 800,000 Americans, the Secretary of Health and Human Services exercised his express statutory authority to protect the health and safety of Medicare and Medicaid patients by requiring healthcare facilities that choose to participate in those programs to ensure that their staff are vaccinated (subject to medical and religious exemptions). That requirement will save hundreds or even thousands of lives each month, and the Eleventh Circuit has held that it is a valid exercise of the Secretary's authority. Yet the requirement has been blocked in ten States by the district court's preliminary injunction in this case, which a divided panel of the Eighth Circuit declined to stay in a one-sentence order. This application seeks a stay of that injunction to allow the Secretary's urgently needed health and safety measure to take effect before the winter spike in COVID-19 cases worsens further.

In establishing Medicare and Medicaid, Congress authorized the Secretary to condition healthcare facilities' participation in those programs on compliance with, inter alia, "requirements [that] the Secretary finds necessary in the interest of the health and safety" of patients. 42 U.S.C. 1395x(e)(9) (hospitals). For decades, the Secretary has exercised that authority to require participating healthcare providers to establish active programs for the "prevention" and "control" of "infectious diseases" within their facilities. 42 C.F.R. 482.42 (hospitals).

In November 2021, the Secretary amended those regulations to address the COVID-19 pandemic. 86 Fed. Reg. 61,555 (Nov. 5, 2021) (App., infra, 37a-109a). At the time, the country was averaging more than 70,000 new COVID-19 cases and more than 1000 COVID-19 deaths per day.[2] In response to that ongoing public health emergency, the Secretary required hospitals, nursing homes, and other healthcare facilities that participate in Medicare and Medicaid to ensure that their workers are vaccinated against COVID-19, subject to medical and religious exemptions. The Secretary explained that this vaccination condition was necessary to protect Medicare and Medicaid patients -- who are particularly vulnerable -- against infection with COVID-19 by staff members who could safely and conscientiously obtain vaccination. Id. at 61,557-61,569. And he stressed that adding the condition in light of the start of the winter season was critical to preventing outbreaks of the kind that had devastated Medicare- and Medicaid-participating facilities earlier in the pandemic. Id. at 61,584.

Although vaccination requirements have broad support in the healthcare industry, various States challenged the rule in federal district court. The first district court to address the rule denied a preliminary injunction, and the Eleventh Circuit then issued a precedential decision denying an injunction pending

[2] Unless otherwise noted, COVID-19 statistics in this application are drawn from the tracker maintained by the Centers for Disease Control and Prevention (CDC). See CDC, COVID Data Tracker, https://go.usa.gov/xeFyx.

appeal. Florida v. Department of Health & Human Servs., No. 21-14098, 2021 WL 5768796 (11th Cir. Dec. 6, 2021). The Eleventh Circuit held that the rule falls squarely within the Secretary's "express statutory authority to require facilities voluntarily participating in the Medicare or Medicaid programs to meet health and safety standards to protect patients." Id. at *11. The Eleventh Circuit also concluded that "[i]mposing an injunction to bar enforcement of the [requirement] would harm the public interest in slowing the spread of COVID-19 and protecting the safety of Medicare and Medicaid patients and staff." Id. at *17.

In this case, in contrast, the district court preliminarily enjoined enforcement of the rule in ten States, and a divided panel of the Eighth Circuit denied the government's motion for a stay pending appeal. App., infra, 1a. And in a third case brought by a different group of States, the Fifth Circuit narrowed a preliminary injunction to apply only within the plaintiff States, but otherwise denied a stay on the ground that the merits presented a "close call" under circuit precedent. Order at 3, Louisiana v. Becerra, No. 21-30734 (Dec. 15, 2021). The government is seeking a stay of that injunction from this Court contemporaneously with the filing of this application. See p. 1, n.1, supra.[3]

[3] In a fourth challenge to the vaccination rule at issue here, the Northern District of Texas last night issued a preliminary injunction against application of the rule to Medicare and Medicaid facilities within Texas. See D. Ct. Doc. 53, Texas v. Becerra, No. 21-cv-229 (Dec. 15, 2021).

This Court should stay the injunctions pending appeal. As the Eleventh Circuit recognized, the vaccine requirement falls squarely within the plain text of the Secretary's statutory authority and complies with all procedural requirements. Indeed, it is difficult to imagine a more paradigmatic health and safety condition than a requirement that workers at hospitals, nursing homes, and other medical facilities take the step that most effectively prevents transmission of a deadly virus to vulnerable patients. The conflicting positions of the courts of appeals make it highly likely that this Court will grant review if the district court's injunction is affirmed. And the exceptionally urgent need to reduce the risk of COVID-19 exposure for Medicare and Medicaid patients given the anticipated winter surge in infections tips the equities overwhelmingly in favor of a stay. Indeed, in the weeks since the Secretary issued the requirement, new COVID-19 cases have already increased by more than 60%, to nearly 120,000 per day. And the highly transmissible Omicron variant, which emerged after the issuance of the rule, threatens to drive up case rates and risks to Medicare and Medicaid patients even higher.

STATEMENT

A. Statutory and Regulatory Background

1. Congress spends hundreds of billions of dollars each year to pay for health care under the Medicare and Medicaid programs. See Azar v. Allina Health Servs., 139 S. Ct. 1804, 1808

(2019). Medicare, which is funded entirely by the federal government, covers individuals who are 65 or older or who have specified disabilities. See ibid. Medicaid, which is funded by the federal government and States, covers eligible low-income individuals, including those who are elderly, pregnant, or disabled. See Pharmaceutical Research & Mfrs. of Am. v. Walsh, 538 U.S. 644, 650-651 & n.5 (2003).

Medicare and Medicaid beneficiaries receive care at a variety of medical facilities, including hospitals, skilled nursing facilities (also known as nursing homes or long-term care facilities), and hospices. To participate in the Medicare or Medicaid program, each of those facilities must enter into a provider agreement and meet specified conditions of participation. E.g., 42 U.S.C. 1395cc, 1396a(a)(27).

Congress charged the Secretary with ensuring that facilities participating in Medicare and Medicaid adequately protect the health and safety of their patients. For example, the Medicare statute authorizes payments for "hospital services," 42 U.S.C. 1395d(a), and defines a "hospital" as an institution that meets such "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); see, e.g., 42 U.S.C. 1395i-3(d)(4)(B) (providing that a "skilled nursing facility must meet" such "requirements relating to the health, safety, and well-

being of residents or relating to the physical facilities thereof as the Secretary may find necessary"). The Medicaid statute also imposes health and safety requirements, see, e.g., 42 U.S.C. 1396r(d)(4)(B), or incorporates by cross-reference analogous Medicare standards for certain types of facilities, see, e.g., 42 U.S.C. 1396d(h) (psychiatric hospitals); 42 U.S.C. 1396d(l)(1) (rural health clinics); 42 U.S.C. 1396d(o) (hospices).

The Secretary has exercised those authorities to promulgate regulations establishing detailed conditions of participation in Medicare and Medicaid. The regulations address, for example, the qualifications of staff, the condition of the facilities, and other requirements that the Secretary deems necessary to protect patient health and safety. E.g., 42 C.F.R. Pt. 482 (conditions of participation for hospitals). The regulations also "focus a great deal on infection prevention and control standards, often incorporating guidelines as recommended by CDC and other expert groups." 86 Fed. Reg. at 61,568. For example, the regulations have long included a requirement that facilities maintain an "infection prevention and control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of communicable diseases and infections." 42 C.F.R. 483.80 (long-term care facilities); see, e.g., 42 C.F.R. 482.42(a) (hospitals); 42 C.F.R. 416.51(b) (ambulatory surgical centers).

2. On September 9, 2021, President Biden announced that the government would be undertaking "new steps to fight COVID-19," including a plan being developed by the Secretary to require vaccinations for workers "who treat patients on Medicare and Medicaid." Remarks on the COVID-19 Response and National Vaccination Efforts, Daily Comp. Pres. Docs., 2021 DCPD No. 00725, at 1-2. On November 5, 2021, the Secretary issued an interim final rule amending existing infection-control regulations and related conditions of participation in Medicare and Medicaid to require that participating facilities ensure that their covered staff are vaccinated against COVID-19. 86 Fed. Reg. at 61,561; see id. at 61,616-61,627 (text of amendments). The rule requires facilities to provide medical and religious exemptions. Id. at 61,572. It also contains exceptions for staff who telework full-time and others who perform infrequent, non-healthcare services. Id. at 61,571. Covered staff were originally required to receive the first dose of a vaccine by December 6, 2021, or to request an exemption by that date. Id. at 61,573. Non-exempt covered staff were to be fully vaccinated by January 4, 2022. Ibid.

a. The Secretary explained that he had determined that "vaccination of staff is necessary for the health and safety of individuals to whom care and services are furnished." 86 Fed. Reg. at 61,561. He observed that vaccination rates remain low in many healthcare facilities. Id. at 61,559. For example, as of

mid-September 2021, COVID-19 vaccination rates for hospital staff and long-term care facility staff averaged 64% and 67%, respectively. Ibid.

The Secretary found that unvaccinated staff at healthcare facilities pose a serious threat to the health and safety of patients because the virus that causes COVID-19 is highly transmissible and dangerous. 86 Fed. Reg. at 61,556-61,557. He explained that, unless appropriate protections are implemented, the virus can spread among healthcare workers and from workers to patients. See id. at 61,557 & n.16. He further explained that vaccination substantially diminishes the risk of such transmission by preventing infection and, according to "[e]merging evidence," by lowering the risk of transmission even in the event of "breakthrough infections." Id. at 61,558. By contrast, unvaccinated healthcare workers are at increased risk for infection and therefore at increased risk of exposing their patients and colleagues to the virus. See id. at 61,558 & nn.42-43 (discussing studies linking unvaccinated staff to increased risk of COVID-19 infection). And because eligibility for the Medicare and Medicaid programs turns on factors such as advanced age and disability, patients covered by those programs frequently face a higher risk of developing severe disease and of experiencing severe outcomes from COVID-19 if infected. Id. at 61,566, 61,609.

The Secretary also found that "[f]ear of exposure to and infection with COVID-19 from unvaccinated health care staff can lead patients to themselves forgo seeking medically necessary care," 86 Fed. Reg. at 61,558, which creates a further "risk[] to patient health and safety," ibid. The Secretary noted reports that individuals are "refusing care from unvaccinated staff," which limits "the extent to which providers and suppliers can effectively meet the health care needs of their patients and residents." Ibid. The Secretary also noted that absenteeism by healthcare staff as a result of "COVID-19-related exposures or illness" has created staffing shortages that have further disrupted patient access to care. Id. at 61,559.

The Secretary emphasized that a vaccination requirement for the facilities covered by the rule is consistent with the recommendation of "more than 50 health care professional societies and organizations," including the American Medical Association and the American Nurses Association (ANA), which had released a joint statement supporting vaccination requirements for healthcare workers. 86 Fed. Reg. at 61,565. Those various organizations "represent[] millions of workers throughout the U.S. health care industry," including "doctors, nurses, pharmacists, physician assistants, public health workers, and epidemiologists as well as long term care, home care, and hospice workers." Ibid. In the joint statement, the organizations urged that "all health care and

long-term care employers require their workers to receive the COVID-19 vaccine." App., infra, 110a-113a (Joint Statement). The organizations explained that this step fulfills "the ethical commitment of all health care workers to put patients as well as residents of long-term care facilities first and take all steps necessary to ensure their health and well-being." Ibid.

b. Notwithstanding that broad support, the Secretary acknowledged the risk that the rule could prompt some healthcare workers to leave their jobs rather than be vaccinated. 86 Fed. Reg. at 61,608. But he found that "many COVID-19 vaccination mandates have already been successfully initiated in a variety of health care settings," and that those examples showed that "very few workers quit their jobs rather than be vaccinated." Id. at 61,569. The Secretary explained, for example, that after the Houston Methodist Hospital system imposed a vaccine requirement, 99.5% of its staff received the vaccine. Ibid. Only 153 of its 26,000 workers resigned rather than receive the vaccine. See id. at 61,569 n.155 (citing article with the relevant figures). Similarly, a Detroit-based health system that imposed a vaccine requirement reported that 98% of its 33,000 workers were fully or partially vaccinated or in the process of obtaining a religious or medical exemption when the requirement went into effect, with exemptions comprising less than 1% of staff members. Id. at 61,569; see id. at 61,566, 61,569 (additional examples).

The Secretary also noted that any departures by staff to avoid vaccination ought to be "offset by reductions in current staffing disruptions caused by staff illness and quarantines once vaccination is more widespread." 86 Fed. Reg. at 61,608. And although the net effect could not be predicted with certainty given the "many variables and unknowns," the Secretary judged that any disruption from a vaccine requirement would likely be minor in comparison to normal patterns of worker turnover. Ibid.

c. The Secretary issued the rule as an interim final rule with a comment period, finding "good cause" to make the rule effective immediately, without prior notice and comment. 86 Fed. Reg. at 61,586; see 5 U.S.C. 553(b)(B). In doing so, he determined that "it would endanger the health and safety of patients, and be contrary to the public interest," to delay the vaccination requirement. 86 Fed. Reg. at 61,586. The Secretary noted that patients in facilities funded by the Medicare and Medicaid programs are more likely than the general population to suffer severe illness or death from COVID-19, id. at 61,609; that there had already been more than half a million COVID-19 cases among healthcare staff, id. at 61,585; that COVID-19 case rates among staff have grown since the Delta variant's emergence, ibid.; that COVID-19 cases are expected to spike during the winter, id. at 61,584; and that this spike will coincide with flu season, raising the additional danger of combined infections and increased

pressure on the healthcare system, ibid. The Secretary predicted that the rule will save "several hundred * * * or perhaps several thousand" lives every month. Id. at 61,612.

d. After issuance of the rule, the Omicron variant emerged. See CDC, Omicron Variant: What You Need to Know, https://go.usa.gov/xeFhz. That variant, which "likely will spread more easily than the original SARS-CoV-2 virus," ibid., increases the danger to Medicare and Medicaid patients and underscores the urgent need for the rule.

B. The Present Controversy

1. On November 10, 2021, respondents -- a group of ten States led by Missouri -- brought this action challenging the rule in the Eastern District of Missouri. App., infra, 6a. On November 29, 2021, the district court preliminarily enjoined enforcement of the rule within those States. Id. at 5a-36a. The court principally reasoned that respondents are "likely to succeed in their argument that Congress has not provided [the Centers for Medicare & Medicaid Services (CMS)] the authority to enact the regulation." Id. at 7a. The court did not identify any basis in the statutory language for that conclusion, and it relegated key portions of the statutory text to a footnote. See id. at 8a n.5. Instead, the court held that the Secretary could not adopt a vaccination requirement without "clear authorization from Congress," id. at 8a, which the court found to be lacking.

The district court also found that respondents were likely to succeed on two other grounds. First, notwithstanding the Secretary's finding that the rule will save hundreds or thousands of lives each month, the court held that the Secretary lacked good cause to issue the rule without prior notice and comment. The court faulted the Secretary for not acting sooner and declared that "COVID no longer poses the dire emergency it once did." App., infra, 15a; see id. at 14a-15a. Second, the court found that respondents are likely to show that the rule is arbitrary and capricious in several respects -- including because the Secretary purportedly failed to give adequate consideration to the "reliance interests" that would be unsettled if the rule caused staffing shortages at healthcare facilities, id. at 24a-27a.

Finally, the district court determined that the remaining factors supported a preliminary injunction. App., infra, 27a-35a. In particular, the court reasoned that respondents would suffer irreparable harm to their "sovereign interests" in enforcing state laws "surrounding vaccination mandates," id. at 28a; to their "quasi-sovereign interests" in the health of their residents, ibid., which the court viewed as threatened by the possibility of staffing shortages, see id. at 29a-31a; and to their "proprietary interests" in state-run facilities covered by the rule, id. at 32a. The court also reasoned that "the public would suffer little, if any, harm from maintaining the 'status quo'" during litigation,

observing that the pandemic "has continued for more than twenty months." Id. at 33a. The court later denied the government's motion for a stay pending appeal. Id. at 2a-4a.

2. The day after the district court issued its decision, on November 30, 2021, the government filed an emergency motion in the Eighth Circuit for a stay pending appeal. On December 13, a divided panel denied the stay motion in a one-sentence order. App., infra, 1a.

ARGUMENT

The government respectfully requests that this Court stay the district court's injunction pending appeal and, if necessary, pending further proceedings in this Court. Under this Court's Rule 23 and the All Writs Act, 28 U.S.C. 1651, a single Justice or the Court may stay a district court order pending appeal to a court of appeals. In deciding whether to issue a stay, the Court considers whether four Justices are likely to vote to grant certiorari if the court of appeals ultimately rules against the applicant; whether five Justices would then likely conclude that the case was erroneously decided below; and whether, on balancing the equities, the injury asserted by the applicant outweighs the harm to the other parties or the public. See San Diegans for the Mt. Soledad Nat'l War Mem'l v. Paulson, 548 U.S. 1301, 1302 (2006) (Kennedy, J., in chambers). Here, all of those factors powerfully support a stay.

I. This Court Would Likely Grant Review If The Eighth Circuit Affirmed The District Court's Injunction

The district court's injunction forbids the Secretary from enforcing in ten States a rule that the Secretary found will help to blunt the impact of "the deadliest disease in American history" and save "several hundred * * * or perhaps several thousand" lives every month. 86 Fed. Reg. at 61,556, 61,612. Whether the rule exceeds the Secretary's statutory authority is an issue of exceptional national importance that would warrant this Court's review if the Eighth Circuit allowed the injunction to stand. Sup. Ct. R. 10(c).

The likelihood of certiorari is especially clear because the district court's order (as well as the unexplained conclusion of the divided Eighth Circuit panel) contradicts a thorough published decision by the Eleventh Circuit rejecting a parallel challenge to the same rule. In that decision, the Eleventh Circuit specifically rejected many of the arguments that the district court accepted here, holding that "the Secretary was authorized to promulgate the interim rule" under his "express statutory authority to require facilities voluntarily participating in the Medicare or Medicaid programs to meet health and safety standards to protect patients." Florida v. Department of Health & Human Servs., No. 21-14098, 2021 WL 5768796, at *11 (Dec. 6, 2021).[4]

[4] Last night, Florida asked the en banc Eleventh Circuit to grant an injunction pending appeal in its challenge to the rule. That request is pending.

The Eleventh Circuit specifically rejected the argument that the rule violates what respondents call the "major questions" doctrine, which was a centerpiece of the district court's reasoning here. Florida, 2021 WL 5768796, at *12; see App, infra, 7a-11a. The Eleventh Circuit explained that the rule does not bring about any "enormous and transformative expansion" in federal regulatory authority, ibid. (quoting Utility Air Regulatory Grp. v. EPA, 573 U.S. 302, 324 (2014)), because Medicare and Medicaid are federal spending programs and the applicable statutes unambiguously give the Secretary a "broad grant of authority" to "make regulations for the 'health and safety' of Medicare and Medicaid recipients," ibid. The court found the rule to be a plainly permissible exercise of that authority, explaining that "it is the very opposite of efficient and effective administration for a facility that is supposed to make people well to make them sick with COVID-19." Ibid.

Especially when combined with the importance of the rule, the conflicting positions adopted by the federal courts of appeals that have addressed the issue make it likely that this Court would ultimately grant review if the Eighth Circuit affirmed. See, e.g., Department of Homeland Sec. v. New York, 140 S. Ct. 599 (2020) (staying lower-court injunction pending appeal where courts of appeals had adopted conflicting positions on a significant agency rule); Wolf v. Cook County, 140 S. Ct. 681 (2020) (same).

II. The Government Is Likely To Succeed On The Merits

If the Eighth Circuit affirmed the district court's injunction and this Court granted review, this Court would likely reverse. In holding that the Secretary lacked authority to issue the rule, the district court did not conduct any meaningful analysis of the relevant statutory text. Instead, it invoked an expansive and unsound conception of what it called the "major questions" doctrine that finds no support in this Court's precedents. The district court also erred in second-guessing the Secretary's expert judgments about the effectiveness and necessity of a vaccination requirement to protect Medicare and Medicaid patients. And this Court is unlikely to agree with the district court's apparent view that the COVID-19 pandemic no longer represents a public-health emergency sufficient to invoke the good-cause exception.

A. The Rule Is Authorized By Statute

The vaccination requirement falls within the Secretary's "express statutory authority to require facilities voluntarily participating in the Medicare or Medicaid programs to meet health and safety standards to protect patients." Florida, 2021 WL 5768796, at *11.

1. Like any other question of statutory interpretation, an analysis of an agency's statutory authority "begins with the statutory text" -- and, when the text is clear, it "ends there as

well." National Ass'n of Mfrs. v. Department of Defense, 138 S. Ct. 617, 631 (2018) (citation omitted); see, e.g., Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania, 140 S. Ct. 2367, 2380 (2020). Here, the Secretary's authority to adopt the rule flows directly from the unambiguous text of the statute.

Congress vested the Secretary with broad authority to make "rules and regulations * * * as may be necessary to the efficient administration of the functions with which he is charged under" the Medicare and Medicaid programs. 42 U.S.C. 1302(a); see 42 U.S.C. 1395hh(a)(1). And Congress specifically charged the Secretary with adopting requirements that he deems necessary to ensure patient health and safety. For example, in authorizing payments for "hospital services," 42 U.S.C. 1395d(a)(1), the Medicare statute defines a "hospital" as an institution that meets such "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). The statute similarly provides that a "skilled nursing facility must meet * * * requirements relating to the health, safety, and well-being of residents * * * as the Secretary may find necessary." 42 U.S.C. 1395i-3(d)(4)(B); see 42 U.S.C. 1395i-3(f)(1) (similar); see also 86 Fed. Reg. at 61,567 (listing statutory directions for each category of facilities covered by the rule).

The rule at issue here fits squarely within the Secretary's statutory authority to create health-and-safety-related conditions of participation. By "requiring healthcare workers to become vaccinated against a transmissible and highly deadly disease," the Secretary "was imposing a 'requirement' that was 'necessary in the interest of the health and safety' of the patients who obtained services at federally funded Medicare and Medicaid facilities." Florida, 2021 WL 5768796, at *12 (quoting 42 U.S.C. 1395x(e)(9)) (brackets omitted).

That straightforward reading of the statutory text accords with both science and common sense. Requiring healthcare workers at facilities participating in Medicare and Medicaid to be vaccinated protects the health and safety of patients at those facilities by reducing their risk of contracting the virus that causes COVID-19. As the Secretary explained, a recent study of heath care workers found that "full vaccination with COVID–19 vaccines was 80 percent effective in preventing * * * infection among frontline workers." 86 Fed. Reg. at 61,558. On top of that, "[e]merging evidence also suggests that vaccinated people who become infected with the * * * Delta variant have potential to be less infectious than infected unvaccinated people." Ibid. Together, "[f]ewer infected staff and lower transmissibility equates to fewer opportunities for transmission to patients." Ibid. Lowering such risks is particularly urgent for patients

covered by Medicare and Medicaid because they are disproportionately vulnerable to death or severe illness from COVID-19 -- as the devastating outbreaks at nursing homes have repeatedly demonstrated. See id. at 61,566, 61,568.

Reducing the risk that such patients will be infected by healthcare workers with COVID-19 also addresses a separate but significant health and safety problem: "[f]ear of exposure to and infection with COVID–19 from unvaccinated health care staff can lead patients to themselves forgo seeking medically necessary care." 86 Fed. Reg. at 61,558. At the most basic level, the purpose of the Medicare and Medicaid programs is to ensure that beneficiaries can access health care. Removing an obstacle to that access by assuring beneficiaries that a trip to the hospital or other participating facility will not entail exposure to unvaccinated staff directly advances that objective. See ibid.

The COVID-19 vaccination condition also fits with the history of the statute and the agency's practice. Congress directed the Secretary to create "health and safety" conditions on providers' participation in Medicare and Medicaid, 42 U.S.C. 1395x(e)(9), precisely "because it would be inappropriate and unnecessary to include in the legislation all the precautions against fire hazards, contagion, etc., which should be required of institutions to make them safe," H. R. Rep. No. 213, 89th Cong., 1st Sess. 25-26 (1965) (House Report) (emphasis added). As noted above, those

conditions have long included a requirement that facilities maintain "active * * * programs for" the "prevention" and "control" of "infectious diseases." 42 C.F.R. 482.42; see pp. 5-6, supra. The vaccine condition at issue here gives specific content to that requirement in the particular context of the COVID-19 pandemic. And although CMS had not itself directly required vaccination in the past, healthcare workers and Medicare and Medicaid facilities have long been subject to "employer or State * * * vaccination requirements," including for "influenza, and hepatitis B virus." 86 Fed. Reg. at 61,567; see id. at 61,568 (noting that many healthcare workers were also subject to childhood school vaccination requirements).

Indeed, "vaccination requirements, like other public-health measures, have been common in this nation." Klaassen v. Trustees of Ind. Univ., 7 F.4th 592, 593 (7th Cir. 2021) (Easterbrook, J.) (holding that a state university vaccination requirement was among the "normal and proper" conditions of enrollment), application for stay denied, No. 21A15 (Aug. 12, 2021). This Court upheld the constitutional validity of such requirements and traced their historical roots more than a century ago. See Jacobson v. Massachusetts, 197 U.S. 11, 25-35 (1905) (identifying vaccine requirements in the United States and other Western countries in the early 1800s). Consistent with that history, at least a dozen States have already established requirements for healthcare

workers to be vaccinated against COVID-19. See KFF, State COVID-19 Data and Policy Actions (Dec. 14, 2021), https://www.kff.org/report-section/state-covid-19-data-and-policy-actions-policy-actions/.

Courts have uniformly recognized that those requirements further "the State's interest in maintaining * * * safety within healthcare facilities." We The Patriots USA, Inc. v. Hochul, 17 F.4th 266, 295-296 (2d Cir. 2021) (per curiam) (upholding New York requirement in light of, inter alia, the devastating experience of "New York City nursing homes" during the pandemic), application for stay denied, No. 21A125 (Dec. 13, 2021); see Does 1-6 v. Mills, 16 F.4th 20, 27 (1st Cir. 2021) (upholding Maine requirement because, inter alia, "health care facilities are uniquely susceptible to outbreaks of infectious diseases like COVID-19"), application for stay denied, No. 21A90 (Oct. 29, 2021). And because the rule at issue here provides for religious exemptions, it does not raise the sort of free-exercise questions presented by some of those state requirements. 86 Fed. Reg. at 61,569; cf. Does 1-3 v. Mills, 142 S. Ct. 17, 19 (2021) (Gorsuch, J., dissenting from denial of application for injunctive relief).

The vaccination requirement thus falls squarely within the Secretary's statutory authority to set conditions on participation in Medicare and Medicaid to ensure the health and safety of patients. As the Eleventh Circuit summarized, "required

vaccination is a common-sense measure designed to prevent healthcare workers, whose job it is to improve patients' health, from making them sicker." Florida, 2021 WL 5768796, at *12. Indeed, it would be striking and anomalous if the Secretary's broad authority to adopt conditions protecting patient health and safety did not include a traditional, common, and highly effective mechanism like a vaccine requirement.

2. Respondents do not seriously dispute that the vaccination condition falls within the plain terms of CMS's statutory authority. But they nevertheless assert, and the district court held, that the condition is impermissible based on various extratextual arguments. App., infra, 7a-12a. That analysis is seriously flawed.

a. The district court principally reasoned that Congress must "speak clearly when authorizing an agency to exercise powers of 'vast economic and political significance.'" App., infra, 9a (quoting Alabama Ass'n of Realtors v. Department of Health & Human Servs., 141 S. Ct. 2485, 2489 (2021) (per curiam)). As explained above, however, Congress did speak clearly by authorizing the Secretary to impose, inter alia, "requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services" by facilities participating in Medicare and Medicaid. 42 U.S.C. 1395x(e)(9) (hospitals). "Congress could have limited [the Secretary's]

discretion in any number of ways, but it chose not to do so." Little Sisters of the Poor, 140 S. Ct. at 2380. And courts may not "impos[e] limits on an agency's discretion that are not supported by the text." Id. at 2381.

The district court erred in suggesting that this Court's decision in Alabama Association of Realtors held otherwise. There, the Court held that an eviction moratorium imposed by the CDC exceeded the agency's authority to "prevent the [interstate] introduction, transmission, or spread of communicable diseases." 42 U.S.C. 264(a). Reading that language in context, the Court held that its scope was informed by the next sentence "illustrating the kinds of measures that could be necessary," such as "fumigation" or "pest extermination." 141 S. Ct. at 2488. Those measures "directly relate to preventing the interstate spread of disease," whereas the eviction moratorium "relate[d] to interstate infection" only "indirectly," through the "downstream connection between eviction" and possible spread of COVID-19 by evicted individuals who move "from one State to another." Ibid.

Here, in contrast, there is no analogous language cabining the Secretary's broad authority. And even more to the point, the connection between the vaccine requirement and patient health and safety is clear and direct: By requiring healthcare workers to take the measure that most effectively reduces the risk that they contract and spread the virus that causes COVID-19, the Secretary

reduced the risk that vulnerable patients would contract the virus from those workers. See Florida, 2021 WL 5768796, at *12.

Respondents and the district court do not appear to dispute that the Secretary generally has authority to adopt measures preventing the spread of infectious diseases in Medicare- and Medicaid-funded facilities. Instead, the district court suggested that Congress had to expressly single out vaccination (or, even more specifically, COVID-19 vaccination) to authorize the condition at issue here. App., infra, 9a. That reasoning reflects a serious misreading of this Court's precedents.

The district court relied upon what it labeled the "political significance of a mandatory coronavirus vaccine," asserting that "it would be difficult to identify many other issues that currently have more political significance." App., infra, 9a. But this Court has never suggested that the emergence of political controversy about a particular agency action triggers a clear-statement requirement. See, e.g., Little Sisters, 140 S. Ct. at 2380 (analyzing whether HHS's contraceptive-mandate rule -- which generated considerable political controversy -- complied with the statutory text without any heightened-clarity requirement). The meaning of a statute does not change with the shifting winds of politics or public opinion, and opponents of an agency's policy cannot succeed in limiting the agency's authority merely by vocally opposing it.

Instead, the decisions on which the district court purported to rely have considered the enacting Congress's perspective, declining to interpret ambiguous statutes to grant agencies sweeping powers on the theory that Congress should "speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.'" Utility Air, 573 U.S. at 324 (quoting FDA v. Brown & Williamson Tobacco Corp., 529 U.S. 120, 160 (2000)). This case is entirely different for two reasons.

First, this Court's decisions in Utility Air, Brown & Williamson, and Alabama Association of Realtors all began with the statutory text and made clear that considerations of "'economic and political significance'" are relevant only "if the text [is] ambiguous." Alabama Ass'n, 141 S. Ct. at 2489. In both Utility Air and Brown & Williamson, for example, this Court reasoned that adopting the agency's position would have conflicted with other provisions of the very statute that the agency was interpreting. See, e.g., Utility Air, 573 U.S. at 321 (explaining that the agency's position was "inconsistent with -- in fact, would overthrow -- the Act's structure and design"); Brown & Williamson, 529 U.S. at 141, 156 (explaining that the agency's interpretation would be "incompatible" with other aspects of the statute). Here, no such ambiguity or incompatibility exists, and the district court did not even purport to conduct a traditional textual and structural analysis.

Second, and in any event, the Secretary does not claim any "unheralded power to regulate 'a significant portion of the American economy.'" Utility Air, 573 U.S. at 324 (quoting Brown & Williamson, 529 U.S. at 159). Instead, he is simply exercising long-recognized and common-sense power to adopt health and safety conditions for medical providers in federal spending programs that are already subject to extensive conditions of participation. And there is no reason to think that Congress -- which granted the Secretary broad authority to protect Medicare and Medicaid recipients precisely because it could not foresee all future threats to patient health and safety, see House Report 25-26 -- would have regarded a vaccine requirement as a matter requiring specific authorization. To the contrary, vaccine requirements have existed for centuries as a commonplace feature of American life. See, e.g., Klaassen, 7 F.4th at 593. Thus, "when it comes to vaccination mandates, there was no reason for Congress to be more specific than authorizing the Secretary to make regulations for the 'health and safety' of Medicare and Medicaid recipients." Florida, 2021 WL 5768796, at *12.

b. The district court also reasoned that "Congress must use 'exceedingly clear language if it wishes to significantly alter the balance between federal and state power.'" App., infra, 9a (quoting Alabama Ass'n, 141 S. Ct. at 2489). But that rationale ignores the nature of the requirement at issue: CMS's vaccine

requirement is a funding condition of facilities' participation in the federal Medicare and Medicaid programs. See 86 Fed. Reg. at 61,556. The requirement is not a "federal encroachment upon a traditional state power," App., infra, 10a (citation omitted), because States have traditionally not had any power to set conditions on the expenditure of federal funds.

To the contrary, this Court has long acknowledged -- and the Constitution expressly provides -- that "Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare" and "to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare." Sabri v. United States, 541 U.S. 600, 605 (2004). Congress's power to impose conditions on the acceptance of federal funds, moreover, applies regardless of whether Congress legislates "in an area historically of state concern." Id. at 608 n.*. Indeed, that principle holds even when (unlike here) States are the sole recipients of the federal funds. See, e.g., South Dakota v. Dole, 483 U.S. 203, 205-206 (1987). Because CMS's vaccine condition involves only "regulating a federal program," Florida, 2021 WL 5768796, at *12 (citation omitted), the district court's federalism concerns are misplaced.

c. Finally, the district court was similarly mistaken in reasoning that the vaccination requirement "invokes the outer limits of Congress' power." App., infra, 11a (citation omitted).

Contrary to the court's apparent understanding, the vaccination condition does not "dictate the private medical decisions of millions of Americans." Id. at 10a-11a. It instead imposes a health and safety requirement regarding vaccination of employees who choose to work at a facility that accepts federal funding through Medicare and Medicaid. Cf. We The Patriots, 17 F.4th at 293-294 ("Although individuals who object to receiving the vaccines * * * have a hard choice to make, they do have a choice. Vaccination is a condition of employment in the healthcare field; the State is not forcibly vaccinating healthcare workers."); Klaassen, 7 F.4th at 593 ("People who do not want to be vaccinated may go [to college] elsewhere."). Thus, whatever constitutional questions might arise about the contours of direct federal or state vaccination mandates, see App., infra, 11a, they are not presented by the funding condition here. Just as healthcare personnel who might prefer to operate on patients without surgical gloves or forgo vaccination "against * * * other infectious diseases," 86 Fed. Reg. at 61,569, must decide whether to subordinate those personal preferences to their work at particular medical facilities imposing those requirements, so too employees who prefer not to get the COVID-19 vaccine for reasons other than medical need or religious objection must decide whether to follow that preference or instead to receive a vaccine to work at

facilities that are funded by federal taxpayers through the Medicare and Medicaid programs.

B. The Rule Is Not Arbitrary And Capricious

There is no merit to the district court's view that the rule is arbitrary and capricious. The Secretary "examined 'the relevant data' and articulated 'a satisfactory explanation' for his decision, 'including a rational connection between the facts found and the choice made.'" Department of Commerce v. New York, 139 S. Ct. 2551, 2569 (2019) (quoting Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43 (1983)). The arbitrary-and-capricious standard does not require more. Nor does it license a court to "substitute its judgment for that of the agency." State Farm, 463 U.S. at 43. The Eleventh Circuit thus correctly rejected many of the same arguments, explaining that "ample evidence" supports the Secretary's determination that staff vaccination at facilities participating in Medicare and Medicaid "will provide important protections for patients." Florida, 2021 WL 5768796, at *15; see id. at *2-*3.

1. The district court identified several purported problems with the Secretary's reasoning, but respondents and the court focused on one in particular: that the Secretary failed to adequately consider the "reliance interests" that the rule would allegedly upset by causing staffing shortages, particularly in rural areas. App., infra, 25a; see id. at 25a-31a. But the

Secretary carefully considered "concerns about health care workers choosing to leave their jobs rather than be vaccinated" and how that dynamic might affect the availability of health care, and the Secretary determined that those concerns did not outweigh the need for a nationwide rule. 86 Fed. Reg. at 61,569; see id. at 61,608-61,609. The Secretary found that any adverse impact on the labor market is likely to be relatively small; at least partially offset by countervailing effects, such as reduced absenteeism due to COVID-19; and dwarfed by the regular staff turnover in the healthcare workforce, in which about 25% of the 10.4 million person workforce is newly hired in a typical year. See ibid.

For example, after the Houston Methodist Hospital system imposed a COVID-19 vaccine mandate, only 153 of its more than 26,000 workers -- that is, only 0.6% -- resigned rather than receive the vaccine. See p. 11, supra. Widespread compliance with vaccine mandates likewise occurred at a Detroit-based health system with more than 33,000 employees, a Delaware-based health system with more than 14,000 employees, and a long-term care corporation with more than 250 facilities. 86 Fed. Reg. at 61,566, 61,569. And at the North Carolina-based Novant Health system, only 375 of 35,000 employees across 15 hospitals, 800 clinics, and hundreds of outpatient facilities -- that is, only 1% of the workforce -- failed to comply. See id. at 61,566 n.132 (link to Novant press release containing those figures). In sum, the

Secretary found that "workers across the economy are responding to mandates by getting vaccinated," even if they previously expressed hesitation. Id. at 61,569.

The Secretary's decision to adopt the rule is also supported by a joint statement by more than 50 leading healthcare associations urging that "all health care and long-term care employers require their workers to receive the COVID-19 vaccine." Joint Statement. The signatories represent millions of workers throughout the Nation's healthcare industry. 86 Fed. Reg. at 61,565 & n.122. For example, the ANA -- which signed the joint statement and "represent[s] the interests of the nation's 4.2 million registered nurses" -- "supports health care employers mandating nurses and all health care personnel to get vaccinated against COVID-19." ANA, ANA Supports Mandated COVID-19 Vaccinations for Nurses and All Health Care Professionals (July 26, 2021), https://perma.cc/MS5A-4WTU.

The district court nevertheless dismissed that significant evidence and faulted the Secretary for purportedly not considering "all necessary reliance interests," including among workers who would resist a vaccine condition. App., infra, 25a. But the Secretary did consider this precise concern -- and reasonably concluded that the benefits of the rule outweighed this risk. Any suggestion that the Secretary "'entirely fail[ed] to consider'"

this "important aspect of the problem" is thus unfounded. App., infra, 26a (quoting State Farm, 463 U.S. at 43).

2. The other purported defects identified by the district court also cannot support the injunction. The court was wrong to suggest (App., infra, 20a-21a) that the Secretary failed to consider alternatives to vaccination, such as requiring testing of unvaccinated individuals or limiting the requirement to healthcare workers not previously infected with the virus that causes COVID-19. The Secretary specifically considered "daily or weekly testing of unvaccinated individuals," "[e]xempting previously infected individuals," and other alternatives, but concluded that those measures would not adequately protect patients. 86 Fed. Reg. at 61,614; see Florida, 2021 WL 5768796, at *3. Ultimately, the Secretary determined that the vaccination requirement was "the minimum regulatory action necessary" to protect the health and safety of Medicare and Medicaid patients in participating facilities. 86 Fed. Reg. at 61,613. Substantial evidence supported that determination, and the district court should not have "substitute[d] its views on epidemiology" for the Secretary's judgment. Florida, 2021 WL 5768796, at *15.

Nor was it arbitrary for the Secretary to "extrapolate" from data on the effects of COVID-19 in long-term care facilities when assessing the need for a vaccination requirement at other facilities. App., infra, 18a (citation omitted). The district

court found reliance on that data arbitrary because COVID-19 "disproportionally devastates [long-term care] facilities." Ibid. But the data from long-term care facilities was just one piece of the ample evidence supporting the Secretary's judgments about the risks of COVID-19 transmission and the benefits to patient safety of a vaccine condition.

Finally, neither the "broad scope" of the facilities covered by the rule (App., infra, 22a) nor the lack of prior vaccination requirements in the Secretary's condition-of-participation regulations (id. at 23a) provides any sound basis to enjoin the rule. The Medicare and Medicaid programs are themselves broad, and the conditions of participation that Congress expressly authorized the Secretary to adopt therefore may have comparable scope. The Secretary was not required to proceed in piecemeal fashion in adopting a measure he deemed urgently necessary to protect the lives and safety of patients in the many different types of facilities funded by Medicare and Medicaid. And as the Secretary explained, the vaccine requirement is a response to a "unique pandemic" in which Americans now have "unique access to effective vaccines." 86 Fed. Reg. at 61,568; see ibid. (explaining that it has not been necessary to require vaccination for other diseases "because other entities, including employers, states, and licensing organizations, already impose" such requirements).

C. The Secretary Had Good Cause To Issue The Rule Without Advance Notice And Comment

The district court further erred in rejecting the Secretary's determination that there was good cause to make the rule effective immediately. See 86 Fed. Reg. at 61,583-61,585. The Secretary determined that patients in facilities funded by the Medicare and Medicaid programs are more likely than the general population to suffer severe illness or death from COVID-19, id. at 61,609; that there have already been more than half a million COVID-19 cases among healthcare staff, id. at 61,585; that rates among staff have grown since the Delta variant's emergence, ibid.; that COVID-19 cases are expected to spike during the coming winter months, id. at 61,584, and that this spike will coincide with flu season, raising the additional danger of combined infections and added pressure on the healthcare system, ibid.

The Secretary determined that "a further delay in imposing a vaccine mandate would endanger the health and safety of additional patients and be contrary to the public interest." 86 Fed. Reg. at 61,584. And he predicted that the rule will save hundreds and potentially thousands of lives every month, id. at 61,612, which manifestly constitutes good cause to proceed immediately. See Sorenson Commc'ns Inc. v. FCC, 755 F.3d 702, 706 (D.C. Cir. 2014) ("[W]e have approved an agency's decision to bypass notice and comment where delay would imminently threaten life.").

The district court's suggestion that the Secretary should have acted "earlier," App., infra, 14a, would not, even if true, be reason to block a rule that will prevent many patient deaths in the coming weeks and months. And in any event, the Secretary acted in response to the rapidly evolving conditions of the pandemic, including low vaccination rates among healthcare workers, 86 Fed. Reg. at 61,559-61,560, and "the emergence and spread of the highly transmissible Delta variant," id. at 61,559; see also Florida, 2021 WL 5768796 at *14 n.2 (noting that the Secretary acted within a few months after the first vaccine received "final approval" from the Food and Drug Administration).

In addition, respondents have not identified any prejudice arising out of the lack of a prior comment period. 5 U.S.C. 706 ("[D]ue account shall be taken of the rule of prejudicial error."). They did not identify any significant issue that the Secretary failed to address, instead relying heavily on the staff-departure risk that the Secretary thoroughly addressed. Thus, respondents have failed to show any harm from the alleged procedural error. See Shinseki v. Sanders, 556 U.S. 396, 409-411 (2009) (explaining that the "burden of showing that an error is harmful normally falls upon the party attacking the agency's determination").

III. The Balance Of Equities Overwhelmingly Favors A Stay

The district court's injunction causes direct, irreparable injury to the interests of the United States and the public --

interests that "merge" here. Nken v. Holder, 556 U.S. 418, 435 (2009). Indeed, delaying the rule would cause serious, tangible harm to public health. If the rule remains stayed during this winter's anticipated COVID-19 surge, hundreds and potentially thousands of patients may die at hospitals, nursing homes, and other facilities participating in Medicare and Medicaid as the result of COVID-19 infections transmitted to them by staff. The Secretary reasonably determined that this direct threat to human life and health greatly outweighs the potential indirect effects if some workers quit rather than receive the vaccine. See App., infra, 28a-31a. There is no sound reason to reject the consensus of leading healthcare organizations and the judgment of the Secretary that the benefits of requiring healthcare workers to be vaccinated far outweigh any countervailing concerns.

Nor have respondents identified any other irreparable harm that could justify the broad preliminary injunction entered by the district court. As this Court has emphasized, the "role of courts" is limited to providing "relief to claimants, in individual or class actions, who have suffered, or will imminently suffer, actual harm." Lewis v. Casey, 518 U.S. 343, 349 (1996). The only claimants before the Court are the ten respondent States. They do not speak for healthcare workers, whose representatives strongly support COVID-19 vaccination requirements. See Joint Statement. Nor can the States bring suit on behalf of private providers or

other private parties, because "[a] State does not have standing as parens patriae to bring an action against the Federal Government." Alfred L. Snapp & Son, Inc. v. Puerto Rico, 458 U.S. 592, 610 n.16 (1982). And even with respect to their own state-run facilities, respondents cannot demonstrate irreparable harm, because any sanctions that might be imposed against such facilities for failing to comply with conditions of Medicare- or Medicaid-participation would be subject to judicial review. See Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1, 8-9 (2000) (describing the Medicare statute's special review system).

The balance of equities and public interest are unaltered by state laws purporting to restrict vaccine mandates. Cf. App., infra, 28a. Even assuming that a State's abstract interest in enforcing its law is a cognizable Article III interest, the federal government has a compelling interest in enforcing the vaccination condition in facilities it pays to care for Medicare and Medicaid patients. Thus, the balance of equities and public interest do not depend on abstract notions of sovereignty, but on the real-world impact of the vaccination rule. And as already explained, the protections that the rule provides for the health and safety of patients substantially outweigh any countervailing concerns.

At a minimum, a partial stay should be granted because the injunction is overbroad. See, e.g., Trump v. International Refugee Assistance Project, 137 S. Ct. 2080, 2088 (2017) (per curiam).

Article III demands that the remedy sought "be limited to the inadequacy that produced the injury in fact that the plaintiff has established." Gill v. Whitford, 138 S. Ct. 1916, 1931 (2018) (citation omitted). Bedrock principles of equity support the same requirement that injunctions be no broader than "necessary to provide complete relief to the plaintiff[]." Madsen v. Women's Health Ctr., Inc., 512 U.S. 753, 765 (1994) (citation omitted). Here, as already explained, respondents do not represent privately run facilities or their workers, whose leading professional associations strongly support vaccination requirements for staff. Thus, the Court should at a minimum stay the preliminary injunction except as to facilities operated by the respondent States.

CONCLUSION

The injunction should be stayed pending appeal and, if the Eighth Circuit affirms the injunction, pending the filing and disposition of a petition for a writ of certiorari and any further proceedings in this Court. At a minimum, it should be stayed as to all facilities other than those operated by respondents.

Respectfully submitted.

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