

19 F.4th 1271
United States Court of Appeals, Eleventh Circuit.

STATE OF FLORIDA, Plaintiff-Appellant,
v.
DEPARTMENT OF HEALTH AND HUMAN
SERVICES, Secretary of the Department of Health
and Human Services, United States of America,
U.S. Centers for Medicare and Medicaid Services,
Administrator of the Centers for Medicare and
Medicaid, Defendants-Appellees.

No. 21-14098-JJ
|
Filed: 12/06/2021

Synopsis

Background: Florida brought action against Secretary of Health and Human Services (HHS), challenging interim rule requiring facilities that provided health care to Medicare and Medicaid beneficiaries to ensure that their staff, unless exempt for medical or religious reasons, were fully vaccinated against COVID-19. The United States District Court for the Northern District of Florida, No. 3:21-cv-02722-MCR-HTC, M. Casey Rodgers, J., 2021 WL 5416122, denied state's motion for preliminary injunction, and state appealed. State moved for injunction pending appeal.

Holdings: The Court of Appeals, Rosenbaum and Jill A. Pryor, Circuit Judges, held that:

out-of-circuit district court's subsequent issuance of nationwide preliminary injunction did not render appeal moot;

Florida failed to establish substantial likelihood that it would succeed on its claim that Secretary lacked statutory authority to issue interim rule;

Florida failed to establish substantial likelihood that it would succeed on its claim that district court abused its discretion when it rejected its argument that Secretary failed to follow proper procedures;

Florida failed to establish substantial likelihood that it would succeed on its claim that interim rule was arbitrary and capricious;

Florida failed to establish that it would face irreparable

injury absent stay; and

imposing injunction would harm public interest.

Motion denied.

Lagoa, Circuit Judge, dissented and filed opinion.

Procedural Posture(s): Interlocutory Appeal; Motion for Preliminary Injunction; Motion for Stay.

***1274** Appeal from the United States District Court for the Northern District of Florida, D.C. Docket No. 3:21-cv-02722-MCR-HTC

Attorneys and Law Firms

Henry Charles Whitaker, Florida Attorney General Service, Daniel William Bell, Natalie Christmas, David M. Costello, Jason H. Hilborn, James Hamilton Percival, II, Office of the Attorney General, Tallahassee, FL, David M. Costello, Attorney General's Office, Tampa, FL, for Plaintiff-Appellant.

Alisa Beth Klein, U.S. Attorney General's Office, Washington, DC, Joel L. McElvain, Laura Myron, U.S. Department of Justice, Civil Division, Washington, DC, for Defendants - Appellees Secretary, Department of Health and Human Services, Centers for Medicare and Medicaid Services, Administrator for the Centers for Medicare and Medicaid Services.

Alisa Beth Klein, U.S. Attorney General's Office, Washington, DC, Joel L. McElvain, Laura Myron, U.S. Department of Justice, Civil Division, Washington, DC, U.S. Attorney Service - Northern District of Florida, U.S. Attorney's Office, Northern District of Florida, Pensacola, FL, for Defendant - Appellee United States of America.

Before ROSENBAUM, JILL PRYOR, and LAGOA, Circuit Judges.

Opinion

ROSENBAUM and JILL PRYOR, Circuit Judges:

***1275** On November 5, 2021, the Secretary of Health and Human Services issued an interim rule that requires facilities that provide health care to Medicare and Medicaid beneficiaries to ensure that their staff, unless exempt for medical or religious reasons, are fully vaccinated against COVID-19. *See Omnibus COVID-19*

Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (Nov. 5, 2021) (the “interim rule”). Under the interim rule, covered staff must receive their first dose of a two-dose vaccine or a single-dose vaccine by December 6, 2021, or request an exemption by that date. Non-exempt covered staff must receive their second dose of a two-dose vaccine by January 4, 2021.

Florida brought this lawsuit challenging the interim rule. In the district court, Florida requested a preliminary injunction to bar the interim rule’s enforcement, which the district court denied. Florida has appealed the district court’s order denying its motion for a preliminary injunction. This case was presented to us on Florida’s Time-Sensitive Motion for Injunction Pending Appeal. After careful review, we denied the motion yesterday. Because of the time constraints involved, though we denied the motion yesterday, the attached opinion explains the reasons for our ruling as of the time that we denied the motion yesterday.

I. FACTUAL BACKGROUND

A. In Response to the Ongoing COVID-19 Public Health Crisis, the Secretary Issued the Interim Rule Mandating Vaccines for Healthcare Workers at Medicare and Medicaid Facilities.

The United States is currently facing a public health emergency as the result of a novel corona virus, which causes the disease COVID-19. *See* 86 Fed. Reg. at 65,519. In the United States, more than 44 million individuals have been infected with COVID-19 and over 720,000 have died. *See id.* COVID-19 is the “deadliest disease in American history.” *Id.*

The Secretary recently took steps in administering the Medicare and Medicaid programs to protect Americans from the risks associated with COVID-19. Tens of millions of Americans receive health care through these federally funded programs. *See Azar v. Allina Health Servs.*, — U.S. —, 139 S. Ct. 1804, 1808, 204 L.Ed.2d 139 (2019). Medicare, which is funded entirely by the federal government, covers individuals who are over age 65 or who have specified disabilities. *See id.* Medicaid, which is funded by the federal government and the States, covers eligible low-income individuals, including those who are elderly, pregnant, or disabled. *See Garrido v. Dudek*, 731 F.3d 1152, 1153–54 (11th Cir. 2013).

Medicare and Medicaid beneficiaries receive health care

services from a variety of entities including hospitals, skilled nursing facilities, home-health agencies, and hospices (collectively, “facilities”). To participate in the programs, a facility must enter into a provider agreement for the applicable program and demonstrate that it meets the conditions for participation. *See* 42 U.S.C. §§ 1395cc(a), 1396a(a)(27).

***1276** For both the Medicare and Medicaid programs, Congress charged the Secretary with ensuring that participating facilities protect the health and safety of their patients. For example, the Medicare statute authorizes payment for “hospital services,” *id.* § 1395d(a), defining a “hospital” as an institution that meets requirements “the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institution. *See id.* § 1395x(e)(9); *see also id.* § 1395i-3(d)(4)(B) (imposing a similar requirement for skilled nursing facilities). Likewise, the Medicaid statute requires that facilities meet health and safety standards “as the Secretary may find necessary.” *Id.* § 1396r(d)(4)(B), 1396d(l)(1). In addition, the Medicaid statute incorporates by cross reference analogous Medicare standards that grant the Secretary such authority. *See id.* § 1396d(h), (l)(1), (o).

Regulations establish detailed conditions of participation in the Medicare and Medicaid programs. Among other things, facilities must have effective “infection prevention and control program[s]” in place to “help prevent the development and transmission of communicable disease and infections.” 42 C.F.R. § 483.80. *See also id.* §§ 416.51, 482.42.

On November 5, the Secretary promulgated an interim rule to amend the infection-control regulations for facilities that participate in Medicare or Medicaid. As described above, this interim rule generally requires that facilities certified to participate in Medicare or Medicaid ensure their staff are fully vaccinated against COVID-19, unless an employee is exempt for medical or religious reasons. *See* 86 Fed. Reg. at 61,555, 61,561, 61,572. If a provider fails to comply with the vaccine-mandate requirement, it may be subjected to enforcement remedies, including civil monetary penalties, the denial of payment for new admissions, or termination of its Medicare or Medicaid provider agreement. *Id.* at 61,574.

The Secretary issued the interim rule because he found that requiring the vaccination of staff against COVID-19 was “necessary for the health and safety of individuals to whom care and services are furnished.” *Id.* at 61,561. Even though many health care workers have been vaccinated against COVID-19, the Secretary found that vaccination rates remain too low at many health care facilities. *Id.* at 61,559. Unvaccinated staff continue to

pose a significant threat to patients because the virus that causes COVID-19 is highly transmissible and dangerous. *Id.* at 61,557. The Secretary cited data reflecting that the virus spreads readily among health care workers and from health care workers to patients and that such spread is more likely when health care workers are unvaccinated. *Id.* In addition, the Secretary found that due to the same factors that qualified them for enrollment (age, disability, and/or poverty), patients covered by Medicare or Medicaid are “more susceptible” than the general population “to severe illness or death” if they contract COVID-19. *Id.* at 61,609.

The Secretary identified other ways that unvaccinated staff can jeopardize patients’ access to medical care and services. *Id.* at 61,558. Fearing exposure to the virus, some patients have refused care by unvaccinated staff, which limits the ability of providers to meet the health care needs of their patients. *Id.* Other individuals forgo medical care altogether to avoid the possibility of being exposed to COVID-19. *Id.* And when staff members are exposed to or infected with COVID-19, they are absent from work, which further disrupts patients’ access to medical care. *Id.* at 61,559.

In issuing the interim rule, the Secretary considered that requiring vaccinations *1277 could cause some health care workers to leave their jobs rather than be vaccinated. But after reviewing empirical evidence, the Secretary concluded that this concern was overstated and outweighed by countervailing considerations. *Id.* at 61,569. Among other things, the Secretary cited evidence showing that after a large hospital system in Texas imposed a vaccine mandate, 99.5% of its staff received the vaccine. *Id.* Only a very small number of workers—153 out of more than 26,000 (or 0.6%)—resigned rather than receive the vaccine. *Id.* Similarly, after a Detroit-based health system instituted a vaccine mandate, it reported that 98% of its 33,000 workers were fully or partially vaccinated or in the process of obtaining a religious or medical exemption, with less than one percent of staff receiving an exemption. *Id.*

Before issuing the interim rule, the Secretary also considered whether any alternatives to a vaccine mandate would adequately protect the health and safety of Medicare and Medicaid patients at the facilities. *See id.* at 61,613–14. One of these alternatives was to limit a vaccination requirement to health care workers who had not previously been infected with COVID-19. *Id.* at 61,614. But the Secretary rejected this alternative because uncertainties remained about “the strength and length” of immunity for individuals who had previously been infected. *Id.* A second alternative was to require daily or weekly testing of unvaccinated individuals. But the

Secretary rejected this alternative because the evidence showed that “vaccination was a much more effective infection control measure” than requiring testing alone. *Id.* Ultimately, the Secretary concluded that the vaccine mandate was “the minimum regulatory action necessary” to protect health and safety. *Id.* at 61,613.

The Secretary determined that the vaccine mandate requirement should go into effect immediately, even though the agency had not previously given the public notice or an opportunity to comment. The Secretary found good cause for bypassing the notice-and-comment procedure generally required by 5 U.S.C. § 553 because (1) patients in facilities funded by Medicare and Medicaid were more likely than the general population to suffer severe illness or death from COVID-19; (2) there had already been over half a million cases of COVID-19 among health care staff; (3) COVID-19 infection rates among health care staff increased when the Delta variant emerged; and (4) COVID-19 cases were expected to spike in the winter, which is also flu season, creating the risk of combined infections. *Id.* at 61,557–59, 61,583–84. Any “further delay in imposing a vaccine mandate,” the Secretary said, would endanger the health and safety of additional patients and be contrary to the public interest.” *Id.* at 61,584. Although the interim rule went into effect immediately, the Secretary afforded the public with notice and an opportunity to comment through January 4, 2022. *Id.* at 61,601.

B. Florida Filed This Lawsuit Challenging the Interim Rule.

About two weeks after the interim rule was issued, Florida filed this lawsuit along with a motion for a preliminary injunction, seeking to enjoin the Secretary from implementing and enforcing the interim rule. Florida challenged the rule under the Administrative Procedure Act, claiming that the interim rule exceeded the Secretary’s statutory authority, the Secretary failed to follow proper notice-and-comment procedures, and the interim rule was arbitrary and capricious.

The district court denied Florida’s motion for a preliminary injunction. It concluded that Florida failed to demonstrate the State faced an irreparable injury if the *1278 injunction was not granted. Florida asserted that it would be injured if the vaccine mandate went into effect because health care employees around the state would resign their positions rather than receive a vaccine. The court

determined these predictions were “speculative.” Doc. 6

at 9. Florida also asserted that it operated a large number of healthcare facilities and thus faced substantial economic harm if these facilities were unable to comply with the mandate and were cut off from federal funding as a result. The district court concluded, however, that the claimed economic injuries were not irreparable based on the “possibility that adequate compensatory or other corrective relief will be available at a later date, in the ordinary course of litigation.” *Id.* at 9–10 (internal quotation marks omitted). The court further found that Florida’s claim was speculative given the lack of evidence that healthcare workers would not take vaccines or receive exemptions from the vaccine requirement.

After the district court ruled, Florida notified the court that since the filing of its motion for a preliminary injunction the State had enacted a new statute regarding vaccine mandates. Under the new Florida statutory scheme, all employers, including the government, were barred from imposing COVID-19 vaccine requirements on their employees. Employers that violated the statute were subject to fines, ranging from \$5,000 to \$50,000 per violation. Fla. Stat. §§ 112.0441, 381.00317(4)(a).

Florida argued that it faced a further irreparable injury because under the interim rule, it would be unable enforce its new statutory scheme barring employers from imposing vaccine mandates. The district court was unpersuaded and in a second order on the motion for preliminary injunction concluded that Florida had failed to establish a substantial likelihood of success on the merits or a substantial risk of irreparable injury.

Florida appealed the district court’s order denying its motion for a preliminary injunction. It filed this motion for an injunction pending appeal.

C. Other States Filed Similar Lawsuits Challenging the Interim Rule.

Florida was not the only state to bring a lawsuit challenging the interim rule requiring COVID-19 vaccinations for healthcare workers. One group of ten states—Missouri, Alaska, Arkansas, Iowa, Kansas, Nebraska, New Hampshire, North Dakota, South Dakota, and Wyoming—challenged the interim rule in district court in the Eastern District of Missouri. *See Missouri v. Biden*, No. 4:21-cv-1329, — F.Supp.3d —, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021). A second group of ten states—Louisiana, Alabama, Arizona, Georgia, Idaho, Indiana, Kentucky, Mississippi, Montana, Ohio, Oklahoma, South Carolina, Utah, and West Virginia—brought a similar lawsuit in the Western

District of Louisiana. *Louisiana v. Becerra*, No. 3:21-cv-03970, — F.Supp.3d —, 2021 WL 5609846 (W.D. La. Nov. 30, 2021).

The district court in *Missouri* granted the motion for a preliminary injunction and enjoined the federal government from implementing or enforcing the interim rule in the ten plaintiff states. *See Missouri*, — F.Supp.3d at —, 2021 WL 5564501, at *15. The district court did not issue a nationwide preliminary injunction. *Id.*

After the district court in this case entered its order denying a preliminary injunction and the *Missouri* court entered its order granting one, the district court in *Louisiana* entered its own order granting the plaintiff states’ motion for a preliminary injunction. The *Louisiana* court entered a nationwide injunction (save for the *1279 states already covered by the *Missouri* injunction). *See* — F.Supp.3d at —, 2021 WL 5609846, at *17. The *Louisiana* nationwide injunction currently bars the federal government from implementing or enforcing the interim rule in Florida.

II. LEGAL STANDARD

An injunction pending appeal is an “extraordinary remedy.” *Touchston v. McDermott*, 234 F.3d 1130, 1132 (11th Cir. 2000) (en banc). Such an injunction “requires the exercise of our judicial discretion.” *Democratic Exec. Comm. of Fla. v. Lee*, 915 F.3d 1312, 1317 (11th Cir. 2019). For an injunction pending appeal, the movant must establish all the following: “(1) a substantial likelihood that [it] will prevail on the merits of the appeal; (2) a substantial risk of irreparable injury to the [movant] unless the injunction is granted; (3) no substantial harm to other interested persons; and (4) no harm to the public interest.” *Touchston*, 234 F.3d at 1132. Because such an injunction is an “extraordinary and drastic remedy,” we may not enter one “unless the movant clearly established the burden of persuasion as to each of the four prerequisites.” *Siegel v. LePore*, 234 F.3d 1163, 1176 (11th Cir. 2000) (en banc). The first two factors are “the most critical.” *Nken v. Holder*, 556 U.S. 418, 434, 129 S.Ct. 1749, 173 L.Ed.2d 550 (2009). Regarding the first prong, “[i]t is not enough that the chance of success on the merits be better than negligible.” *Id.* Similarly, as to the second prong, it is not enough simply to “show[] some possibility of irreparable injury.” *Id.* at 434–35, 129 S.Ct. 1749 (citation and internal quotation marks omitted).

In evaluating whether Florida can show a substantial

likelihood of success on the merits, we consider whether the State is likely to be able to show that the district court abused its discretion in denying a preliminary injunction. We thus apply “the usual standards of review governing our review of the merits of the preliminary injunction.” *Lee*, 915 F.3d at 1317. Accordingly, we examine the district court’s decision to deny a preliminary injunction for an abuse of discretion, reviewing *de novo* any underlying legal conclusions and for clear error any findings of fact. *Id.*

III. THIS CASE IS NOT MOOT DESPITE THE NATIONWIDE INJUNCTION ISSUED IN LOUISIANA, AND PRUDENTIAL CONCERNS FAVOR OUR DECIDING THE MOTION.

Of the three federal courts considering motions to enjoin enforcement of the interim rule, the district court here was the first to rule. It denied Florida’s motion because the State failed to demonstrate irreparable injury. While the motion for preliminary injunction was pending, Florida enacted a statute that barred public and private employers from enforcing vaccine mandates. The district court entered a second order considering the statute and concluded that Florida failed to establish a substantial risk of irreparable injury or a substantial likelihood of success on the merits.

The district court in the *Missouri* case reached a different conclusion concerning the facts before it. It granted the motion for a preliminary injunction and enjoined the federal government from implementing or enforcing the interim rule in the ten plaintiff states only. *See Missouri*, — F.Supp.3d at —, 2021 WL 5564501, at *15.

Then came *Louisiana*. Without even acknowledging the district court’s denial of a preliminary injunction in this case, the *Louisiana* district court entered a nationwide injunction that excluded only the ten *1280 states subject to the *Missouri* injunction. *See* — F.Supp.3d at —, 2021 WL 5609846, at *17.

The *Louisiana* nationwide injunction, which was in place when we denied Florida’s motion yesterday, purported to bar the federal government from implementing or enforcing the interim rule in Florida, effectively awarding Florida the relief it sought in the district court and it sought in its motion for injunction pending appeal, even though Florida was not a party to the *Louisiana* matter and even though the Northern District of Florida denied the State this relief.

Nevertheless, Florida urged us to decide its motion for

injunction anyway. It noted that the United States had moved to stay the *Missouri* order and indicated its expectation that the United States would seek the same relief in the Fifth Circuit. Based on these developments, Florida wrote, “Were the nationwide injunction stayed or narrowed, Florida and its citizens would be without protection beginning on December 6.” Mot. for Injunction Pending Appeal at 8. And it asked us “to consider Florida’s motion as time sensitive” and “issue a ruling before the December 6 deadline.” *Id.*

We therefore were required to determine whether we could do so. We concluded that we could. And so, yesterday, December 5, we issued our order denying Florida’s motion and indicated that our opinion would follow. We now explain why we had jurisdiction to proceed yesterday, despite the *Louisiana* preliminary injunction, and why prudential concerns militated in favor of our decision to rule. We address jurisdictional issues first and then prudential ones.

Article III limits the power of the federal courts to “[c]ases” and “[c]ontroversies.” U.S. Const. art. III, § 2; *see Lujan v. Defs. of Wildlife*, 504 U.S. 555, 559–60, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). The jurisdictional concern here implicates mootness. We have explained that a case becomes moot when events after its commencement “create a situation in which the court can no longer give the plaintiff meaningful relief.” *Nat’l Ass’n of Bds. of Pharmacy v. Bd. of Regents of the Univ. Sys. of Ga.*, 633 F.3d 1297, 1308 (11th Cir. 2011).

Here, we were required to consider whether the entry of the *Louisiana* injunction rendered this case moot. The *Louisiana* injunction purported to enjoin the interim rule throughout the nation—including, of course, in Florida. That fact, on its face, appeared, as practical matter, to moot the pending appeal: if the *Louisiana* injunction already enjoined the interim rule’s application in Florida, then Florida’s requested relief here—enjoining enforcement of the interim rule—could accomplish nothing more.

But Florida’s insistence that we decide this motion raised the capable-of-repetition-yet-evading-review exception to mootness. Under this exception, we may review a matter “if (1) the challenged action is in its duration too short to be fully litigated prior to its cessation or expiration, and (2) there is a reasonable expectation that the same complaining party will be subjected to the same action again.” *United States v. Sanchez-Gomez*, — U.S. —, 138 S. Ct. 1532, 1540, 200 L.Ed.2d 792 (2018) (internal quotation marks omitted).

Other courts have found this exception to the mootness doctrine applicable in similar situations. In *California v.*

U.S. Dep’t of Health & Hum. Servs., 941 F.3d 410 (9th Cir. 2019), judgment vacated on other grounds by *1281 *Little Sisters of the Poor Saints Peter & Paul Home v. Pennsylvania*, 591 U.S. —, 140 S. Ct. 2367, 207 L.Ed.2d 819 (2020), for example, the district court entered a preliminary injunction which was to be effective in only designated states. See *id.* at 420. After the district court issued that injunction, though, an out-of-circuit district court issued a similar preliminary injunction, but its reach was nationwide. See *id.* at 421. The Ninth Circuit considered whether, given the out-of-circuit nationwide injunction, the appeal of the in-circuit, more limited injunction had become moot. See *id.* at 421–22. The court concluded it had not because the matter was capable of repetition yet evading review. *Id.* at 423.

Noting the short period of time between when the in-circuit and out-of-circuit district courts had entered their injunctions, the Ninth Circuit reasoned that it was “clearly too short for the preliminary injunction to be fully litigated prior to its cessation or expiration.” *Id.* (cleaned up). This situation satisfied the first requirement of the capable-of-repetition-yet-evading-review exception. As for the second requirement of the exception, the court observed that the out-of-circuit court’s injunction was a preliminary injunction, so it would expire. *Id.* And when it did, the court continued, the defendants there would once again be subjected to the injunction in the in-circuit case. *Id.* Although the Ninth Circuit recognized that the district court could rule in favor of the plaintiffs on the permanent injunction and could choose to keep the nationwide aspect of it intact, it determined that “[t]hat mere possibility does not ... undermine our conclusion that, given the many other possible outcomes in the [out-of-circuit] case, there remains a ‘reasonable expectation’ that the federal defendants will be subjected to the injunction in this case.” *Id.* As the court explained, “[a] ‘reasonable expectation’ does not demand certainty.” *Id.*

Finally, observing that “[t]he Supreme Court has yet to address the effect of a nationwide preliminary injunction on an appeal involving a preliminary injunction of limited scope,” the court “acknowledge[d] that [it was] in uncharted waters.” *Id.* But it noted that its “approach to mootness” was “consistent with the Supreme Court’s interest in allowing the law to develop across multiple circuits,” *id.*—an interest that we discuss more below, in our analysis of the prudential aspects of reviewing the district court’s order here denying the preliminary injunction, given the *Louisiana* preliminary injunction.

We think the same reasoning required application of the exception here. Working backwards under the governing test, we start with the recognition that a reasonable expectation exists that Florida would be subjected to the

interim rule again. That was so because a reasonable expectation existed that during its review of the *Louisiana* injunction, the Fifth Circuit would, at the very least, do away with the nationwide aspect of that order.

Of course, we do not purport to review the propriety of the nationwide aspect of the *Louisiana* injunction; that’s the Fifth Circuit’s job. But to assess the applicability of the capable-of-repetition-yet-evading-review exception, we necessarily had to gauge the likelihood that the nationwide aspect of the *Louisiana* injunction would withstand scrutiny. And when we did that, we concluded that there was a reasonable expectation that, at the least, the Fifth Circuit would not uphold the nationwide aspect of the injunction.

Here’s why. To begin with, a federal district court may issue a nationwide, or “universal,” see *Trump v. Hawaii*, — U.S. —, 138 S. Ct. 2392, 2425 n.1, 201 L.Ed.2d 775 (2018) (Thomas, J., concurring) injunction “in appropriate circumstances.” *1282 *Texas v. United States*, 809 F.3d 134, 188 (5th Cir. 2015), as revised (Nov. 25, 2015). But notably, those appropriate circumstances are rare. See *City of Chicago v. Barr*, 961 F.3d 882, 916 (7th Cir. 2020). A nationwide injunction may be warranted where it is necessary to provide complete relief to the plaintiffs, to protect similarly situated nonparties, or to avoid the “chaos and confusion” of a patchwork of injunctions. *Id.* at 916–17 (citing Amanda Frost, *In Defense of Nationwide Injunctions*, 93 N.Y.U. L. Rev. 1065, 1101 (2018) (internal quotation marks omitted)). Or universal relief may be justified where the plaintiffs are dispersed throughout the United States, when immigration law is implicated, or when certain types of unconstitutionality are found. See *Int’l Refugee Assistance Project v. Trump*, 857 F.3d 554, 605 (4th Cir. 2017), as amended (June 15, 2017), vacated and remanded on other grounds sub nom. *Trump v. Int’l Refugee Assistance*, — U.S. —, 138 S. Ct. 353, 199 L.Ed.2d 203 (2017). None of these considerations supported the nationwide injunction imposed by the Western District of Louisiana. We review them in turn.

First, the court could have provided complete relief to the plaintiffs with an injunction limited in scope to the States that were plaintiffs there. Yet it nonetheless awarded relief to nonparties. Jurists and scholars have called into question both the wisdom and propriety of granting relief to nonparties. See, e.g., *Dep’t of Homeland Sec. v. New York*, — U.S. —, 140 S. Ct. 599, 600, 206 L.Ed.2d 115 (2020) (Gorsuch, J., concurring) (“The real problem here is the increasingly common practice of trial courts ordering relief that transcends the cases before them. ... [T]hese orders share the same basic flaw—they direct how the defendant must act toward persons who are not parties to the case.”); see also Samuel L. Bray, *Multiple*

Chancellors: Reforming the National Injunction, 131 Harv. L. Rev. 417, 421 (2017).

Second, this case raises no concerns that a non-nationwide preliminary injunction wouldn't provide the plaintiffs with complete relief because the plaintiffs were not dispersed among the United States or "myriad jurisdictions" like in a nationwide class action. See *Refugee*, 857 F.3d at 605. Rather, the plaintiffs were the fourteen states themselves. So the *Louisiana* court would have had no trouble fashioning a remedy that was certain to include all the plaintiffs. And as a practical matter, the *Louisiana* court had no need to worry about protecting similarly situated nonparties. Non-parties who wanted the same protection (ten states) had already achieved it through the *Missouri* injunction. See *Missouri*, — F.Supp.3d at —, 2021 WL 5564501, at *15. Given the relaxed joinder rules for plaintiffs, any remaining states that wanted protection from the interim rule could have obtained it by joining or intervening in either *Missouri* or *Louisiana*. Or, like Florida did here, they could have simply filed their own cases. So the *Louisiana* court could have provided the complete relief that its plaintiff states requested—an injunction against enforcement of the interim rule against them—without issuing a nationwide injunction. Indeed, that is exactly what the *Missouri* court did.

Third, courts have frequently found that a nationwide injunction can be warranted in the immigration law context or when certain unconstitutionality is found. Neither is implicated here.

Universal injunctions in the immigration context are based on the need for uniformity in the enforcement of immigration law and Congress's desire to create a comprehensive and unified system of immigration law. *Texas*, 809 F.3d at 187–88; see also *Refugee*, 857 F.3d at 605. The rule at *1283 issue here, though—the interim rule related to vaccination—has nothing to do with immigration.

Courts have also held that a nationwide injunction can be necessary when the challenged law suffers from constitutional infirmities implicating individual liberties. *Refugee*, 857 F.3d at 605 (holding that allowing executive action that violated the Establishment Clause should be enjoined universally because "[i]ts continued enforcement ... would only serve to reinforce the message that Plaintiffs are outsiders, not full members of the political community") (internal quotation marks omitted). Here, the plaintiff states in *Louisiana* did raise, and the court found a likelihood of success on the merits of, various constitutional challenges. But those challenges related to the Spending Clause, Tenth Amendment, Non-Delegation Doctrine, and Anti-Commandeering Doctrine. *Louisiana*,

— F.Supp.3d at — – —, 2021 WL 5609846, at *14–16. They did not implicate threats to constitutionally protected individual liberties such that nationwide relief would be warranted.

Fourth, any desire on the part of the *Louisiana* district court to avoid a patchwork of injunctions was outweighed by the need for "development in different factual contexts and in multiple decisions by the various courts of appeals." *California v. Azar*, 911 F.3d 558, 583 (9th Cir. 2018) (internal quotation marks omitted). When, as here, a regulatory challenge involves important and difficult questions of law, it is especially vital that various courts be allowed to weigh in so that the issues can percolate among the courts. See *Bray, Multiple Chancellors*, *supra*, at 461. As the Supreme Court has recognized, nationwide injunctions "may have a detrimental effect by foreclosing adjudication by a number of different courts and judges." *Califano v. Yamasaki*, 442 U.S. 682, 702, 99 S.Ct. 2545, 61 L.Ed.2d 176 (1979). The hasty imposition of a nationwide injunction undermines the judicial system's goals of allowing the "airing of competing views" and permitting multiple judges and circuits to weigh in on significant issues. *Dep't of Homeland Sec.*, 140 S. Ct. at 600 (Gorsuch, J., concurring).

The *Louisiana* court did not grapple with these factors when it entered the nationwide injunction. Instead, the entirety of the *Louisiana* court's reasoning for imposing a nationwide—as opposed to a more limited—injunction follows:

In addressing the geographic scope of the preliminary injunction, due to the nationwide scope of the CMS Mandate, a nationwide injunction is necessary due to the need for uniformity. *Texas*, 809 F.3d at 187–88. Although this Court considered limiting the injunction to the fourteen Plaintiff States, there are unvaccinated healthcare workers in other states who also need protection. Therefore, the scope of this injunction will be nationwide, except for the states of Alaska, Arkansas, Iowa, Kansas, Missouri, New Hampshire, Nebraska, Wyoming, North Dakota, South Dakota, since these ten states are already under a preliminary injunction order dated November 29, 2021, out of the Eastern District of Missouri.

Louisiana, — F.Supp.3d at —, 2021 WL 5609846, at *17.

As we have noted, we concluded that there was a reasonable expectation that this reasoning would not withstand scrutiny. For starters, it is conclusory. The *Louisiana* order never explains why there is a “need for uniformity” here, other than to cite *Texas*, 809 F.3d at 187–188, without explanation.

But that case has no applicability here. In *Texas*, the Fifth Circuit upheld a preliminary *1284 injunction that forbade implementation of the Deferred Action for Parents of Americans and Lawful Permanent Residents program. *See id.* In so doing, the court explained that “the Constitution requires ‘an *uniform* Rule of Naturalization’;[] Congress has instructed that ‘the immigration laws of the United States should be enforced vigorously and *uniformly*’:[] and the Supreme Court has described immigration policy as ‘a comprehensive and *unified* system.’[]” *Id.* at 187–88 (footnotes omitted). And of course, it is obvious why the United States—a single sovereign—must speak with one voice when it comes to matters of immigration.

But those considerations are not present with the subject matter of the *Louisiana* injunction. The *Louisiana* order offers no reason why, as a constitutional, statutory, or practical matter, the interim rule cannot be in effect in some states but not others. Nor could we think of any good reason.

Quite simply, this does not appear to be one of those “rare” situations where a nationwide injunction is warranted or even justifiable. For those reasons, it seemed to us an eminently “reasonable expectation” that, at the very least, the nationwide aspect of the *Louisiana* injunction would be eliminated, and Florida would be subject to the interim rule when upon its taking effect on December 6.

Having explained why there was a reasonable expectation that this situation would recur, we turn to the first requirement under the capable-of-repetition-yet-evading-review exception: the very short timeframe. When we denied Florida’s emergency motion, it was December 5, the day by which we had been asked to rule because the interim rule was supposed to become effective today, December 6. The government had asked the Fifth Circuit to decide the appeal in *Louisiana* by yesterday, December 5. For the reasons we have explained, at the time we denied Florida’s motion yesterday, we had a reasonable expectation that the Fifth Circuit would eliminate the nationwide aspect of the injunction. And if it did, very little time would remain between then and when Florida

would again be subjected to the interim rule. Because the interim rule requires immediate vaccination for covered employees for whom a valid exception does not apply, if we did not decide the case yesterday, the case would have again become moot—but this time because the subject employees will have been vaccinated.

A recent Supreme Court opinion involving a similar situation perhaps suggests that a court outside the jurisdiction that entered a purported nationwide injunction does not lack jurisdiction to address the same challenge as it arises in that court’s jurisdiction. In *Department of Homeland Security v. Regents of the University of California*, — U.S. —, 140 S. Ct. 1891, 207 L.Ed.2d 353 (2020), the Supreme Court reviewed three cases out of three courts in different circuits that raised the same issue, including two cases where the district courts had each entered nationwide preliminary injunctions against the government. *See id.* at 1904. The government appealed all three rulings. *See id.* at 1905. While those appeals to the three circuit courts were pending, the government simultaneously sought certiorari before judgment. *Id.* After one circuit court affirmed the nationwide injunction, but before rulings issued from the other two circuits, the Supreme Court granted certiorari and consolidated the cases. *Id.* Given the overlapping nationwide injunctions, amici had urged the Court to address the propriety of nationwide injunctions. *See, e.g.,* Brief *Amicus Curiae* of Citizens United, *et al., Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, Nos. 18-587 & 18-589. But the Supreme Court chose not *1285 to do so. And in its opinion, though it acknowledged the overlapping nationwide injunctions, *see* 140 S. Ct. at 1904, it did not comment further on them.

We are, of course, aware that the Supreme Court’s “decision to grant cert on one question doesn’t implicitly answer any others presented.” *Babb v. Sec’y, Dep’t of Veterans Affs.*, 992 F.3d 1193, 1201 (11th Cir. 2021). But considering that courts lack Article III jurisdiction when a case is moot, we think it likely that, had the Supreme Court thought one or more of the courts that rendered the decisions it was reviewing lacked subject matter jurisdiction, it would have commented on that. This, then, further supports the proposition that the issue facing this Court fell into the capable-of-repeating-yet-evading-review exception to mootness, and that this Court did not lack jurisdiction.

Not only did we have jurisdiction here, but also prudential concerns militated in favor of ruling on the pending motion, despite the *Louisiana* nationwide injunction. Those concerns implicate comity and what has been described as “percolation.”

First, comity: “The federal courts long have recognized that the principle of comity requires federal district courts—courts of coordinate jurisdiction and equal rank—to exercise care to avoid interference with each other’s affairs.” *W. Gulf Mar. Ass’n v. ILA Deep Sea Local 24*, 751 F.2d 721, 728 (5th Cir. 1985). Comity dictates that courts should “avoid rulings which may trench upon the authority of sister courts.” *Id.* Principles of comity generally guide federal courts to “exercise ... restraint” when an injunction in one federal proceeding would interfere with another federal proceeding. *Brittingham v. U.S. Comm’r*, 451 F.2d 315, 318 (5th Cir. 1971). In particular, as some of our sister circuits have recognized, the issuance of a nationwide injunction may create comity problems when similar, parallel lawsuits involving different plaintiffs are pending in other district courts. *See L.A. Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644, 664 –65 (9th Cir. 2011) (vacating nationwide injunction in case involving review in several courts of appeals of challenges to regulation); *United States v. AMC Ent., Inc.*, 549 F.3d 760, 773 (9th Cir. 2008) (vacating portion of nationwide injunction based on “comity” concerns when Fifth Circuit had “judicially repudiated” the challenge in a separate, parallel case); *Va. Soc’y for Human Life, Inc. v. FEC*, 263 F.3d 379, 393 (4th Cir. 2001) (same), *overruled on other grounds by Real Truth About Abortion, Inc. v. FEC*, 681 F.3d 544, 550 n.2 (4th Cir. 2012). Here, the *Louisiana* district court never acknowledged that the district court in this case had already denied Florida’s motion for a preliminary injunction. It likewise did not consider the comity problems that arose from effectively awarding relief to Florida that the district court in this case had already denied.

As to percolation, as we have discussed, when a case raises a novel and important issue, allowing multiple federal appellate courts the opportunity to express their views on the issue adds value. Indeed, the Supreme Court has recognized that the ultimate resolution of such issues benefits from litigation in multiple cases because various circuit courts may effectively debate one another over the proper outcome. *See Califano*, 442 U.S. at 702, 99 S.Ct. 2545 (warning that nationwide injunctions “may have a detrimental effect by foreclosing adjudication by a number of different courts and judges”); *United States v. Mendoza*, 464 U.S. 154, 160, 104 S.Ct. 568, 78 L.Ed.2d 379 (1984) (criticizing approach that would interfere with “the development of important questions of law” by barring multiple courts of appeals from exploring a difficult question); *see also Dep’t of Homeland Sec.*, 140 S. Ct. at 600 (Gorsuch, J., *1286 concurring) (criticizing the practice of issuing nationwide injunctions because it interferes with the traditional system of case-by-case review that allows “multiple judges and multiple circuits to weigh in only after careful deliberation,” which

“permits the airing of competing views that aids this Court’s own decisionmaking process”); *Hawaii*, 138 S. Ct. at 2425 (Thomas, J., concurring) (stating that nationwide injunctions “are beginning to take a toll on the federal court system ... [by] preventing legal questions from percolating through the federal courts”). Here, by evaluating the interim-rule issue anew, we add to that percolation.

In short, the *Louisiana* nationwide preliminary injunction did not deprive us of jurisdiction over this motion for injunction. Nor did any prudential concerns dictate that we should abstain. In fact, the opposite is true. So we will turn to the merits of the motion.

IV. FLORIDA FAILED TO CARRY ITS BURDEN TO ESTABLISH IT IS ENTITLED TO THE EXTRAORDINARY REMEDY OF AN INJUNCTION PENDING APPEAL.

Florida has failed to meet its extremely high burden and clearly establish its entitlement to a preliminary injunction pending appeal. Having carefully considered the relevant factors, we conclude that Florida failed to demonstrate (1) a substantial likelihood that it will prevail on the merits of its appeal from the denial of a preliminary injunction; (2) it will suffer irreparable injury absent an injunction; or (3) the balance of the equities favor an injunction.

A. Florida Failed to Carry Its Burden to Establish a Substantial Likelihood That It Will Succeed on the Merits of Its Appeal.

We begin with the first of the two most critical factors: whether Florida established a substantial likelihood that it will succeed on the merits of its appeal challenging the district court’s denial of a preliminary injunction. Florida carries a heavy burden. The grant of a preliminary injunction is “the exception rather than the rule.” *United States v. Lambert*, 695 F.2d 536, 539 (11th Cir. 1983). “It is not enough that the chance of success on the merits be better than negligible.” *Nken*, 556 U.S. at 434, 129 S.Ct. 1749. Here, we cannot say that it is substantially likely that Florida can demonstrate the district court abused its discretion when it denied the motion for a preliminary injunction.

In this lawsuit, Florida challenged the validity of the interim rule under the Administrative Procedure Act (“APA”). Under the APA, a court must “hold unlawful and set aside agency action” that is “arbitrary, capricious,

an abuse of discretion, or otherwise not in accordance with law;” that is in excess of statutory authority; or that is “without observance of procedure required by law.” 5 U.S.C. § 706(2) (A), (C)–(D). The procedures required by law under the APA generally include that an agency must afford interested persons notice of proposed rulemaking and an opportunity to comment before a substantive rule is promulgated. *See Chrysler Corp. v. Brown*, 441 U.S. 281, 313, 99 S.Ct. 1705, 60 L.Ed.2d 208 (1979) (citing 5 U.S.C. § 553).

Florida argues that it is likely to succeed on the merits on appeal of the district court’s orders denying a preliminary injunction because the Secretary failed to show that he had the statutory authority to impose a vaccine mandate on healthcare workers, acted contrary to law by promulgating the interim rule without following notice-and-comment procedures, and acted arbitrarily and capriciously by imposing the vaccine mandate. We are not persuaded *1287 that Florida has shown that it is substantially likely that it will succeed on any of these arguments.

1. Florida Failed to Demonstrate It Is Likely to Succeed in Showing That the Secretary Lacked the Statutory Authority to Issue the Interim Rule.

After reviewing the relevant statutory scheme, we conclude that Florida failed to carry its burden to show a substantial likelihood that it will prevail on the merits of its claim that the Secretary lacked the statutory authority to enact the interim rule. The Secretary has express statutory authority to require facilities voluntarily participating in the Medicare or Medicaid programs to meet health and safety standards to protect patients. Based on this statutory authority, the Secretary was authorized to promulgate the interim rule.

In both the Medicare and Medicaid statutes, Congress authorized the Secretary to set standards to protect the health and safety of patients. For example, the Medicare statute authorizes payments to be made for “hospital services.” 42 U.S.C. § 1395d(a). Congress baked into the statutory definition of “hospital” that the institution must meet any “requirements that the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the institutions.” *Id.* § 1395x(e)(9). The Secretary was acting pursuant to this statutory authority in promulgating the interim rule: by requiring healthcare workers to become vaccinated against a transmissible and highly deadly disease, he 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. *Id.*; *see, e.g., id.* §§ 1395x(e)(9), (f)(2), (aa)(2)(k), (dd)(2)(G); 1396d(h), (l)(1), (o); 1396r(d)(4)(B).

Florida argues that the Secretary’s decision to impose a vaccine mandate for all covered health care workers is foreclosed by a separate federal statute that prohibits a federal officer from exercising supervision or control over the practice of medicine, the manner in which medical services are provided, or the operation of an institution. *See* 42 U.S.C. § 1395. We agree with the district court that “[t]his argument misconstrues the nature of the vaccination mandate.” Doc. 18 at 15. With the interim rule, the Secretary is not regulating the practice of medicine, the manner in which medical services are provided, or the operation an institution. As the district court explained, the Secretary is simply “regulating a federal program by requiring facilities that receive federal funding to develop and implement policies and procedures to ensure the vaccination of covered healthcare workers and staff for the health and safety of patients within those facilities.” *Id.* The interim rule is akin to longstanding, unchallenged regulations that require facilities to prevent the spread of infection. *See, e.g.,* 42 C.F.R. §§ 416.51(b), 482.42(a).

The dissent argues that the interim rule violates the major questions doctrine. Its premise is flawed. As a matter of fact, the interim rule does not “bring about an enormous and transformative expansion in ... regulatory authority without clear congressional authorization.” Dissent at 1303 (quoting *Util. Air Regal. Grp. v. EPA*, 573 U.S. 302, 324, 134 S.Ct. 2427, 189 L.Ed.2d 372 (2014)). First, as the dissent acknowledges, the Medicare and Medicaid statutes give the Secretary the authority to issue regulations for the “administration” of Medicare and Medicaid and the “health and safety” of recipients. *Id.* at 1302–03. The Secretary has explained how the vaccine *1288 mandate furthers both aspects of his authority. As to administration of Medicare and Medicaid, 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. If that happens, more patients will have to be treated by Medicare and Medicaid. It is also highly inefficient for facility employees to be out sick with COVID-19. As to health and safety, COVID-19 is a deadly disease that has killed more than three quarters of a million Americans in less than two years. It is also highly transmissible. The regulation reasonably, perhaps necessarily, covers all employees who work at these facilities as a health and safety measure because if any one of them has COVID-19 and is present at the facility, she can spread it to the patients, whether directly or indirectly through other employees.

Second, the dissent argues that “CMS has never before enforced a vaccination mandate” and “nothing” in the statutes “indicates” that the agency has such authority. *Id.* at 1303. But by its very nature, a broad grant of authority such as Congress has given the Secretary here—which plainly encompasses the Secretary’s actions—does not require an indication that specific activities are permitted. And it’s no surprise that CMS has never enforced a vaccine mandate because vaccinations for healthcare employees have never been an issue of economic and political significance before now. Indeed, healthcare workers have long been required to obtain inoculations for infectious diseases, such as measles, rubella, mumps, and others, *see* 86 Fed. Reg. at 61567–68, because required vaccination is a common-sense measure designed to prevent healthcare workers, whose job it is to improve patients’ health, from making them sicker. Indeed, mandatory vaccinations for the public at large have long been held valid. *See Jacobson v. Massachusetts*, 197 U.S. 11, 35, 25 S.Ct. 358, 49 L.Ed. 643 (1905). So, 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. To suggest otherwise would mean that Congress had to have anticipated both the unprecedented COVID-19 pandemic and the unprecedented politicization of the disease to regulate vaccination against it.¹

To support their argument that that federal statutes do not authorize the Secretary to impose a vaccine-mandate requirement for health care workers, Florida and the dissent also cite to the Supreme Court’s recent order in *Alabama Association of Realtors v. Department of Health and Human Services*, — U.S. —, 141 S. Ct. 2485, 210 L.Ed.2d 856 (2021). We are not persuaded that the Supreme Court’s order in *Alabama Association of Realtors* establishes that the Secretary lacked the statutory authority to issue the interim rule.

In *Alabama Association of Realtors*, the Court stayed a lower court order that permitted *1289 the Centers for Disease Control (“CDC”) to extend a nationwide moratorium on evictions due to the COVID-19 pandemic. *Id.* at 2486. The CDC claimed the authority to impose the eviction moratorium under the Public Health Services Act, 42 U.S.C. § 264(a). This statute authorized the CDC to make and enforce regulations necessary “to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.” *Id.* at 2487 (quoting 42 U.S.C. § 264(a)). It specified that the types of measures that could be necessary included inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of contaminated animals and articles. The

Court rejected the CDC’s argument, concluding that the plain language of that statute, which permitted the CDC to take measures that “directly relate to preventing the interstate spread of disease by identifying, isolating, and destroying the disease itself” did not authorize the CDC to impose the eviction moratorium. *Id.* at 2488. It explained that the “downstream connection between eviction and the interstate spread of disease is markedly different from the direct targeting of disease that characterizes the measures identified in the statute.” *Id.*

We are not persuaded that the Court’s order in *Alabama Association of Realtors* sheds any light here. As an initial matter, in that case the Court was considering whether a different statutory scheme authorized the CDC to impose a nationwide eviction moratorium. Nothing in that case bore on whether the Secretary was authorized to require health care workers at covered facilities to be vaccinated to protect patient health and safety. Even more importantly, here, both the interim rule and the authorizing statutes are similar. They both directly relate to efforts to prevent the spread of disease at facilities treating Medicare or Medicaid patients to protect the health and safety of those patients.

2. Florida Failed to Demonstrate That It Is Likely to Succeed in Showing That the Secretary Was Not Permitted to Bypass the Notice-and-Comment Requirement.

The APA also requires a reviewing court to “hold unlawful and set aside agency action ... found to be ... without observance of procedure required by law.” 5 U.S.C. § 706(2)(D). Florida argues that the interim rule should be set aside because the Secretary failed to comply with the notice-and-comment requirement. But the notice-and-comment requirement does not apply “when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.” 5 U.S.C. § 553(b). We conclude that Florida has not established a substantial likelihood that it will succeed on appeal in demonstrating that the district court abused its discretion when it rejected Florida’s argument that the Secretary failed to follow proper procedures.

In the interim rule, the Secretary provided a detailed explanation for why there was good cause for dispensing with the notice-and-comment requirement. The Secretary discussed the urgency presented by the ongoing pandemic, the outbreaks associated with the Delta variant, and the oncoming influenza season. 86 Fed. Reg. at

61,556–59, 61,583–84. Given these circumstances, the Secretary determined, a further delay “would endanger the health and safety of additional patients and be contrary to the public interest.” *Id.* at 61,584; *see id.* at 61,612 (estimating that “total *1290 lives saved under this rule may well reach several hundred a month”). We agree with the district court that the Secretary set forth a sufficient basis to dispense with the notice-and-comment requirement. *See Sorenson Commc’ns Inc. v. F.C.C.*, 755 F.3d 702, 706 (D.C. Cir. 2014) (“In the past we have approved an agency’s decision to by-pass notice and comment where delay would imminently threaten life or physical property”).

Florida says that the district court erred because “after almost two years, COVID-19 is a persistent feature of life and cannot itself constitute good cause” and that to conclude otherwise would “effectively repeal notice-and-comment requirements for the duration of the pandemic.” Mot. for Injunction Pending Appeal at 11.² But recognizing that good cause existed in this case does not mean that the COVID-19 pandemic *always* will justify an agency’s bypassing the notice-and-comment process. In this case, the Secretary identified specific reasons why in the environment of healthcare facilities that provide care to patients covered by Medicare or Medicaid the ongoing pandemic constituted good cause for dispensing with the usual notice-and-comment requirements.³

3. Florida Failed to Demonstrate That Is Likely to Succeed in Showing that the Interim Rule is Arbitrary and Capricious.

Florida argues that the interim rule is arbitrary and capricious. The arbitrary and capricious standard is “exceedingly deferential.” *Miccosukee Tribe of Indians of Fla. v. United States*, 566 F.3d 1257, 1264 (11th Cir. 2009). A court is not permitted to substitute its judgment for the agency’s “as long as [the agency’s] conclusions are rational.” *Id.* A decision is arbitrary and capricious only if the factors the agency relied on are not what Congress would intend, if the agency “entirely failed to consider an important aspect of the problem,” if the agency offered an explanation counter to the evidence before the agency, or if the agency action “is so implausible that it could not be ascribed to a difference in view or the product of *1291 agency expertise.” *Id.* (internal quotation marks omitted).

Because, as shown above, ample evidence supports the Secretary’s determination that facility staff vaccination will provide important protection for patients, we cannot

say that the district court erred in concluding that the interim rule was not arbitrary or capricious.

Florida raises a variety of arguments about why the agency should have reached the opposite conclusion and determined that the Secretary’s decision to impose a vaccine-mandate requirement for health care workers was irrational. Florida argues that it was arbitrary and capricious for the United States to impose a vaccine mandate instead of requiring that unvaccinated employees routinely be tested or exempting from vaccination individuals who have natural immunity from a previous COVID-19 infection. Florida essentially seeks to substitute its views on epidemiology for the Secretary’s judgment about the best way to protect the public from infection. But “[w]e are not authorized to substitute our judgment for the agency’s as long as its conclusions are rational.” *Miccosukee Tribe*, 566 F.3d at 1264. Even if we were to agree with Florida that these other options were preferable to the vaccine mandate the Secretary imposed, this would not come close to showing that the district court erred in concluding that the Secretary’s decision was not arbitrary or capricious.

Florida also argues that the Secretary failed to adequately consider the risk that the interim rule will cause unvaccinated workers to flee the industry rather than submit to vaccination. We disagree that the Secretary failed to consider this risk. Rather, the Secretary addressed it when he discussed evidence showing that when large hospital systems and other health care employers imposed vaccine mandates, workers responded to the mandates by getting vaccinated, not leaving their jobs. *See* 86 Fed. Reg. at 61,569.

After considering all of Florida’s arguments, we see no substantial likelihood that it will succeed in establishing that the district court abused its discretion when it denied the States’ motion for a preliminary injunction.

B. Florida Failed to Establish That It Will Face Irreparable Injury Absent an Injunction.

Florida also failed to establish the second “most critical” factor, *Nken*, 556 U.S. at 434, 129 S.Ct. 1749, that it will face an irreparable injury if we do not enter an injunction pending appeal. Importantly, the possibility of an irreparable injury is not enough. *See Winter v. NRDC*, 555 U.S. 7, 22, 129 S.Ct. 365, 172 L.Ed.2d 249 (2008) (explaining that issuing a preliminary injunction “based only on a possibility of irreparable harm” would be “inconsistent” with treating a preliminary injunction as an “extraordinary remedy”).

Florida argues that it faces irreparable injury from the interim rule because by preempting contradictory state law, the rule intrudes on Florida's sovereign authority to enforce its own law barring public and private employers from imposing vaccine mandates. But it is black-letter law that the federal government does not "invade[]" areas of state sovereignty "simply because it exercises its authority" in a way that preempts conflicting state laws. *Hodel v. Va. Surface Mining & Reclamation Ass'n*, 452 U.S. 264, 291, 101 S.Ct. 2352, 69 L.Ed.2d 1 (1981) (rejecting argument that Congress invaded state sovereignty simply because it exercised its authority in a manner that "displaces the States' exercise of their police powers").⁴ *1292 Here, because the Secretary had the authority to issue the interim rule and federal law preempts conflicting state law, we cannot say that Florida faces an irreparable injury. Indeed, to conclude otherwise would mean that a state would suffer irreparable injury from all law federal laws with preemptive effect. Florida cites no cases establishing such a broad standard.⁵

Florida also argues that it established irreparable injury because the interim rule's mandate threatens "to deprive Florida of vital medical staff, exacerbating an already critical healthcare-staffing shortage." Mot. for Injunction Pending Appeal at 18. Florida predicts that the mandate will cause workers in Florida to quit their jobs rather than be vaccinated. But the district court found Florida's affidavits predicting such new staffing shortages as a result of the vaccine mandate as "speculative" and "conclusory." Doc. 6 at 8. Notably, Florida does not explain why the district court's findings were erroneous.

Despite Florida's failure to address the district court's findings, the dissent, relying on these declarations, concludes that Florida faces irreparable harm because State agencies would lose so many employees at state-operated facilities that the agencies would experience severe staffing shortages and a disruption in, and reductions to, the quality of care that patients received at facilities. [See Dissent at 1313.] But we are not persuaded that Florida came close to carrying its burden of establishing that such resignations would occur. Some of Florida's declarations state that "up to" certain numbers of employees "may" resign if required to be vaccinated. Doc. 2-3 at 5 (affidavit from Department of Health employees); see Doc. 2-6 at 5 (similar affidavit saying "it is possible" that employees for the Agency for Persons with Disabilities would resign). Other declarations say nothing more than that "some employees" may resign rather than be vaccinated. See also Doc. 2-2 at 4 (predicting that "some employees" of the Department of Children and Families would resign); Doc. 2-4 at 5 (same for employees of Florida Department of Correction); 2-5 at 4 (same for employees of the

Department of Veterans' Affairs). This testimony is, as the district court found, entirely speculative; none of it indicates with any degree of certainty whatsoever that these employees will resign. In crediting this evidence, the dissent never grapples with the evidence showing that when health care workers were faced with a vaccine mandate going into effect, "very few workers" actually quit their jobs rather than be vaccinated, as found by the Secretary. See 86 Fed. Reg. at 61,569. Florida has thus failed to carry its burden of showing an irreparable injury is likely.⁶

Finally, Florida claims that it will suffer an irreparable harm "as *parens patriae* for the many Floridians who work in healthcare and do not wish to receive a vaccine." Mot. for Injunction Pending Appeal at 19. *1293 But we agree with the district court that Florida does not face an irreparable injury if employees who choose to work in a federally funded healthcare facility are forced to abide by the rules that govern the administration of that federal program. See *Commonwealth of Mass. v. Mellon*, 262 U.S. 447, 485–86, 43 S.Ct. 597, 67 L.Ed. 1078 (1923) ("It cannot be conceded that a state, as *parens patriae*, may institute judicial proceedings to protect citizens of the United States from the operation of the statutes thereof.")

C. Florida Failed to Establish that the Remaining Factors Support an Injunction.

The last two requirements for a preliminary injunction involve a balancing of the equities between the parties and the public. Where the government is the party opposing the preliminary injunction, its interest and harm—the third and fourth elements—merge with the public interest. *Swain v. Junior*, 958 F.3d 1081, 1091 (11th Cir. 2020).

Imposing an injunction to bar enforcement of the interim rule would harm the public interest in slowing the spread of COVID-19 and protecting the safety of Medicare and Medicaid patients and staff. And this interest is particularly compelling within the setting of the healthcare facilities at issue, where the population of patients covered by Medicare and Medicaid is more likely than the general population to experience severe complications if they contract COVID-19. Indeed, the last thing patients seeking medical help (and their families and friends who love them) should have to endure is the infliction of a potentially deadly virus on them by those who are supposed to be taking care of them, when it could have been prevented by their caretakers' obtaining of an FDA-approved vaccination.⁷

V. CONCLUSION

For the reasons set forth above, we DENY Florida's motion for an injunction pending appeal.

Lagoa, Circuit Judge, dissenting:

I dissent from the panel's decision to deny the State of Florida's motion for an injunction pending its appeal of the district court's order denying the State's motion for preliminary injunction. The State seeks to enjoin an interim final rule of the Centers for Medicare and Medicaid Services ("CMS") mandating COVID-19 vaccinations for covered staff in most facilities receiving Medicare and Medicaid funding (the "mandate"). See Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555 (Nov. 5, 2021).

The majority devotes a substantial amount of space to the issue of nationwide injunctions but does not provide much *1294 analysis of the issues actually presented to us by the State of Florida's motion for an injunction pending appeal. For the reasons explained below, I would grant the State of Florida's motion.

I. BACKGROUND

A. November 5, 2021, CMS Mandate

CMS primarily administers Medicare, see *Cape Cod Hosp. v. Sebelius*, 630 F.3d 203, 205 (D.C. Cir. 2011), and partners with states to administer Medicaid, see *Douglas v. Indep. Living Ctr. of S. Cal., Inc.*, 565 U.S. 606, 610, 132 S.Ct. 1204, 182 L.Ed.2d 101 (2012). On September 9, 2021, the President announced his intention to promulgate federal vaccine mandates. Nearly two months later, on November 5, 2021, CMS issued an interim final rule entitled "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff

Vaccination," which "revises the requirements that most Medicare- and Medicaid-certified providers and suppliers must meet to participate in the Medicare and Medicaid programs" and "establish[es] COVID-19 vaccination requirements for staff at the included Medicare- and Medicaid-certified providers and suppliers." 86 Fed. Reg. at 61,555; see also *id.* at 61,556 (listing the types of "providers and suppliers" covered by the mandate). The category of individuals who are considered covered staff under the interim final rule is extremely broad—the mandate applies to a wide range of people including employees, trainees, students, volunteers, and contractors who provide any care, treatment, or other services for the facility. *Id.* at 61,570.

The following fifteen categories of Medicare and Medicaid certified providers and suppliers are covered under the mandate: (1) Ambulatory Surgical Centers; (2) Hospices; (3) Psychiatric residential treatment facilities; (4) Programs of All-Inclusive Care for the Elderly; (5) Hospitals (acute care hospitals, psychiatric hospitals, long term care hospitals, children's hospitals, hospital swing beds, transplant centers, cancer hospitals, and rehabilitation hospitals); (6) Long Term Care Facilities (i.e., nursing homes); (7) Intermediate Care Facilities for Individuals with Intellectual Disabilities; (8) Home Health Agencies; (9) Comprehensive Outpatient Rehabilitation Facilities; (10) Critical Access Hospitals; (11) Clinics, rehabilitation agencies, and public health agencies as providers of out-patient physical therapy and speech language pathology services; (12) Community Mental Health Centers; (13) Home Infusion Therapy suppliers; (14) Rural Health Clinics and Federally Qualified Health Centers; and (15) End Stage Renal Disease Facilities. *Id.* at 61,556.

The mandate requires all covered staff to receive the initial dose of a COVID-19 vaccine by December 6, 2021, and to complete their "primary vaccination series" by January 4, 2022. *Id.* at 61,555, 61,573. Covered providers and suppliers that fail to comply with the mandate "may be subject to enforcement remedies," including "civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid provider agreement." *Id.* at 61,574. The mandate also provides for "appropriate accommodations, to the extent required by Federal law, for employees who request and receive exemption from vaccination because of a disability, medical condition, or sincerely held religious belief, practice, or observance." *Id.* at 61,569.

CMS stated that it was issuing the mandate based on its "broad statutory authority to establish health and safety regulations." *Id.* at 61,560. Specifically, CMA claimed its authority was primarily based on

***1295** sections 1102 and 1871 of the Social Security Act (the Act)[, which] grant[ed] the Secretary of Health and Human Services authority to make and publish such rules and regulations, not inconsistent with the Act, as may be necessary to the efficient administration of the functions with which the Secretary is charged under this Act and as may be necessary to carry out the administration of the insurance programs under the Act.

Id.; accord *id.* at 61,567; see 42 U.S.C. §§ 1302, 1395hh (codifying sections 1102 and 1871 of the Social Security Act). CMS also explained that, in its “discussions of the provider- and supplier-specific provisions” in the mandate, it “set out the specific authorities for each provider or supplier type.” See 86 Fed. Reg. at 61,560, 61,616–27. CMS noted there were “concerns about health care workers choosing to leave their jobs rather than be vaccinated,” but concluded there was “insufficient evidence to quantify and compare adverse impacts on patient and resident care associated with temporary staffing losses due to mandates and absences due to quarantine for known COVID-19 exposures and illness.” *Id.* at 61,569. The mandate goes into effect on December 6, 2021—one month after its issuance.

In issuing the mandate, CMS waived the notice-and-comment period under the Administrative Procedures Act (“APA”) on the basis of “good cause.” See *id.* at 61,583–86; 5 U.S.C. § 553(b)(B). CMS found the APA’s normal notice-and-comment procedures to be “impracticable and contrary to the public interest” based on “a combination of factors, including but not limited to failure to achieve sufficiently high levels of vaccination based on voluntary efforts and patchwork requirements, potential harm to patients from unvaccinated healthcare workers, and continuing strain on the health care system and known efficacy and safety of available vaccines.” 86 Fed. Reg. at 61,586. CMS also stated the mandate preempted state and local laws as applied to Medicare- and Medicaid-certified providers and suppliers. *Id.* at 61,568.

B. The Proceedings Before the District Court

On November 17, 2021, the State filed a complaint and a motion for a temporary restraining order (“TRO”) or preliminary injunction as to the Mandate. In support of its motion, the State attached six sworn affidavits from the following state agency representatives: (1) Kimberly Smoak, the Deputy Secretary for Health Quality Assurance (“HQA”) at the Florida Agency for Health Care Administration (“AHCA”); (2) Erica Thomas, the Assistant Secretary for Substance Abuse and Mental Health at the Florida Department of Children and Families (“DCF”); (3) Mark Lander, the Interim Deputy Secretary for County Health Systems at the Florida Department of Health (“DOH”); (4) Carl Kirkland Jr., the Deputy Director of Institutional Operations for the Florida Department of Corrections (“FDC”); (5) Robert Asztalos, the Deputy Executive Director of the Florida Department of Veterans’ Affairs (“FDVA”); and (6) Tom Rice, the Deputy Executive Director for Programs at the Florida Agency for Persons with Disabilities (“APD”). The following un rebutted evidence was presented to the district court:

1. Kimberly Smoak, Deputy Secretary for HQA at AHCA

Smoak attested to the following in her affidavit. AHCA, “a department of the Executive Branch of the government of the State of Florida,” is “the chief health policy and planning entity for the state” and “charged with health facility licensure, inspection and regulatory enforcement and the administration of the Medicaid program.” ***1296** Doc. 2-1 at 2. On behalf of CMS, AHCA’s division of HQA conducts surveys of healthcare facilities to determine whether they are in compliance with federal law governing Medicare providers. *Id.* at 3. When serious violations are found or remain uncorrected, AHCA sends that information to CMS, which “utilizes a range of federal enforcement mechanisms from fines to termination of facilities’ Medicare provider agreements” against the noncompliant facilities. *Id.* at 3–4. If CMS terminates a facility’s Medicare agreement, then AHCA must terminate the facility’s Medicaid provider agreement as well. *Id.* at 4. The mandate requires state surveyors, such as AHCA, to determine if providers and suppliers are compliant with the mandate’s requirements. *Id.* AHCA’s HQA receives federal funding from CMS to conduct federal survey activity, and “[i]f AHCA were to refuse to enforce the mandate and withdraw from participation in its agreement with [CMS],” HQA would likely lose all federal funds relating to surveying and certification. *Id.* Additionally, the federal government could terminate the agreement in whole or in part or limit

the scope of the parties' agreement, which "would result in a commensurate loss of federal funding." *Id.*

Health Systems at DOH

2. Erica Thomas, Assistant Secretary for Substance Abuse and Mental Health at DCF

Thomas attested to the following. "DCF is the designated mental health authority for the State," exercising "executive and administrative supervision over all psychiatric residential treatment facilities in collaboration with [AHCA]." Doc. 2-2 at 2. "Failure on the part of a psychiatric residential treatment facility to comply with the mandate can subject the facility to enforcement remedies imposed by CMS and other remedies available under Federal law," e.g., "civil money penalties, denial of payment for new admissions, or termination of the Medicare/Medicaid provider agreement." *Id.* at 3. DCF operates six psychiatric residential treatment facilities and employs approximately 3,013 employees in those facilities. *Id.* "DCF currently maintains staffing shortages at all of [its] facilities" based on "wage pressure from an improving job market and larger trends in healthcare," including "statewide shortages of nurses and psychiatric providers." *Id.* This was especially true for rural areas, where "there is limited workforce and it is difficult to find qualified employees." *Id.* Overall, DCF is "experiencing difficulty recruiting and retaining nursing staff due to competing wage and benefit pressure in the private market," with a turnover rate exceeding 20%, and DCF's facilities are "currently experiencing a staffing crisis." *Id.* at 3-4. Because some of DCF's unvaccinated employees would refuse vaccination, the mandate "will further amplify the staffing shortage and the facilities will not be able to provide effective treatment for the patients or a safe environment for both patients and staff." *Id.* at 4. Additionally, the reduction in staff at Florida's state mental health treatment facilities would result in longer waiting periods in jail for forensic patients seeking treatment who are charged with felony offenses and determined to be not guilty by reason of insanity or incompetency. *Id.* DCF would lose approximately \$6.7 million in funding, which is "critical to support patient services and treatment," if it does not comply with the mandate. *Id.*

Lander attested as to the following. DOH is "responsible for the state's public health system, providing public health services through its County Health Departments." *1297 Doc. 2-3 at 2. DOH operates "Federally Qualified Health Centers" ("FQHC"), including FQHCs in Bradford, Union, and Walton Counties, in conjunction with its County Health Departments. *Id.* at 3. As to the FQHCs in Bradford and Union Counties, "up to 12 employees may be lost to employment" as a result of the mandate. *Id.* Most of those employees "provide services that impact direct patient care," and "[i]t would take at least 90 days to hire employees to replace them in the current labor market." *Id.* "The anticipated vacancy time could extend several months creating a domino effect that would increase clinical wait times and loss of services," "dental and prenatal services may be delayed," and the delay in services would result in "a negative impact for clients served by" those two FQHCs. *Id.* at 3-4. Noncompliance with the mandate would result in a projected loss of Medicare and Medicaid revenue to the Bradford and Union FQHCs, and the lack of funding would result in a "workforce reduction/separation," "an approximate 50% reduction in services and access," and a negative impact to patient access. *Id.* at 4.

As to the FQHC in Walton County, that facility would lose "up to 57 employees" upon implementation of the mandate, which "could cause a serious disruption in services" as most of those employees provide direct patient care and hiring replacements "would take at least 90 days" given the current labor market. *Id.* at 5. "Approximately 70% of the clinical licensed practical nurses are unvaccinated" in the FQHC in Walton County, and the FQHC could lose "frontline employees, including clerical and medical records support as well as medical providers." *Id.* This would result in clinicians being "required to work up their own clients," slowing down the process and reducing availability of appointments. *Id.* Additionally, "with the loss of 57 employees, services will be disrupted (cancelled or significantly delayed)," which would result in "a negative impact for clients." *Id.* Registered nurses and licensed practical nurses positions were "difficult" to fill based on the demand in Florida, and "[t]he months taken to hire and train these positions would expend valuable time that is needed to treat patients who have left critical chronic illnesses go unchecked during the pandemic." *Id.* And noncompliance with the mandate by the FQHC in Walton County would result in the loss of Medicare and Medicaid revenue, which in turn would lead to a reduction of staff and patient services. *Id.* at 6.

3. Mark Lander, Interim Deputy Secretary for County

result in delay of care, or worse.” *Id.*

4. *Carl Kirkland Jr., Deputy Director of Institutional Operations for FDC*

Kirkland attested to the following. FDC is “responsible for the supervisory and protective care, custody, and control of the inmates, buildings, grounds, property, and all other matters pertaining to the correctional and other facilities and programs for the imprisonment, correction, and rehabilitation of adult offenders.” Doc. 2-4 at 2. FDC’s responsibilities include transporting inmates who require medical care that cannot be provided within FDC’s prison “to outside hospitals where they received medical treatment and are thereafter transported back to prison.” *Id.* at 3. FDC has agreements with two hospitals—Jacksonville Memorial Hospital and North Shore Hospital in Miami—“that have a dedicated, secure unit within the hospital for care of inmates,” and “FDC provides a sufficient number of correctional officers to supervise [those] inmates.” *Id.* FDC also has a medical vendor, Centurion, which contracts “with at least 57 hospitals throughout the state to provide medical services to inmates.” *Id.* FDC has experienced a staff shortage over the past few years, as shortages “have greatly increased since the outbreak of COVID-19,” and “[t]he mandate *1298 would undoubtedly exacerbate this staff shortage issue.” *Id.* at 4.

As to Jacksonville Memorial Hospital, the Reception and Medical Center, which was FDC’s institution responsible for security staffing at that hospital, “had 31 vacancies” on the roster—equivalent to an “absence of 35.63% of FDC’s required uniformed staff.” *Id.* Given these vacancies, “FDC’s ability to provide care in line with the Eighth Amendment” was threatened, and the mandate would “further exacerbate[]” the issue, as some of its staff at Jacksonville Memorial Hospital would quit or request to work at other facilities to avoid the mandate. *Id.* at 5. “This, in turn, would limit the pool of available replacements/supplemental staff to staff the hospital,” resulting “in a delay of care, or worse,” and hindering “FDC’s constitutional obligations to ensure minimally adequate medical care.” *Id.* As to North Shore Hospital in Miami, it would experience negative impacts similar to those affecting Jacksonville Memorial Hospital. *Id.* And as to Centurion, FDC’s medical vendor which contracts with “at least 57 hospitals throughout [Florida] to provide medical services to inmates,” “[m]andating vaccines for FDC staff across [the State of Florida] who would potentially be responsible for transport of inmates to hospitals or who would remain with inmates at the hospital, would pose a significant challenge to an already understaffed FDC.” *Id.* The requirement would “likely

5. *Robert Asztalos, the Deputy Executive Director of the FDVA*

Asztalos attested to the following. FDVA “advocate[s] for Florida veterans and link[s] them to services, benefits, and support.” Doc. 2-5 at 2. FDVA operates six “State Veterans’ Nursing Homes” (“SVNH”) throughout Florida. *Id.* Each of the SVNHs “have struggled with staffing shortages, especially direct care staff,” and the pandemic had exacerbated the shortage. *Id.* at 4. FDVA may lose federal funding from CMS if it does not comply with the mandate. *Id.* If FDVA did comply with the mandate, “some employees may leave FDVA employment,” and, consequently, “FDVA would need to increase [its] use of nursing staffing agencies to cover any staff shortages,” increasing its operating costs. *Id.* If a substantial number of employees leave FDVA, it would consider reducing occupancy rates in its SNVHs, thereby decreasing the number of veterans admitted to its facilities. *Id.*

6. *Tom Rice, the Deputy Executive Director for Programs at APD*

Rice attested to the following. APD is “responsible for coordinating and providing services to Floridians with intellectual and developmental disabilities, including the operation of state-operated institutional programs and the programmatic management of Medicaid waivers established to provide home and community based services” to those individuals. Doc. 2-6 at 2. APD operates two “Intermediate Care Facilities for Individuals with Intellectual Disabilities” and “employs 1,092 direct care staff, registered nurses, food service, maintenance, administrative and management staff,” who would be subject to the mandate, at those facilities. *Id.* at 3–4.

The pandemic “exacerbated existing staffing challenges” at APD’s intermediate care facilities, with “approximately 32.34% of positions” being vacant despite ongoing recruiting and retention efforts. *Id.* at 5. And the mandate would “compound these existing recruiting and retention efforts.” Some of APD’s employees have “chosen not to

be vaccinated,” and “[b]ased on the responses to a survey conducted ... and *1299 the indications of staff,” APD would “lose about 10% of [its] total filled positions on average at both facilities, due to the mandate.” *Id.* For example, at one of its facilities, “194 out of 599 filled positions are not vaccinated,” and “close to 95% of the 194 could resign.” *Id.* “Widespread resignations of existing staff, coupled with the inability to replace such employees, would most importantly place the health and safety of residents at risk, as well as risk coming out of compliance with [required] staffing ratios.” *Id.* Staffing reassignments to ameliorate the resulting staffing shortage would “further increas[e] the risk of burn out and resignations [of those staff members] due to more favorable employment or low morale.” *Id.* at 6. These staffing issues would also “severely impact[]” the routines of the residents at the intermediate care facilities, “likely leading to distress and negative health outcomes.” *Id.* Additionally, failure to comply with the mandate could result in loss of federal funding via the Medicare and Medicaid programs. *Id.* at 5–6.

APD also operates two “forensic facilities,” and its employees at those facilities will likely be subject to the mandate as the facilities are located “on the grounds of other licensed facilities directly subject to the [mandate].” *Id.* at 6–7. APD’s forensic facilities suffer from the same personnel issues as its intermediate care facilities. *Id.* at 7.

* * * *

The district court denied the State’s motion on November 20, 2021, concluding that the State failed to make an adequate showing that the State would suffer irreparable injury harm without a TRO or preliminary injunction prior to December 6, 2021. The district court found that the agency representatives’ statements in their affidavits were merely “opinions” without “supporting factual evidence” such that they were “speculative and may be disregarded as conclusory.” It further found that statements regarding employees’ intent to resign if required to be vaccinated were “hearsay.” As to the agencies losing federal funding, which the State asserted would result in loss of services and patient care as well as longer waits and drives for patients, the district court concluded that any economic loss of funding was not irreparable, as the funding could be remedied and restored in the ordinary course of litigation. The district court also found that there was no evidence suggesting that the anticipated loss of federal funding from noncompliance would immediately occur on December 6, 2021, “because the asserted loss of staff is speculative, the affidavits fail take into account any impact from the availability of the exemption process provided in the [mandate], and even if noncompliance occurs, any potential termination of funding would not occur on December 6.” Finally,

addressing the State’s argument that there was irreparable harm to its own sovereignty if its state laws and policies were disregarded, the court noted that Florida had referenced no law or policy, as the Florida Legislature was only contemplating legislation to prohibit vaccine mandates.

On November 24, 2021, the State filed a notice of appeal with this Court, as well as a motion for an injunction pending appeal in the district court. On November 27, 2021, the district court denied the motion for an injunction pending appeal but *sua sponte* reinstated the State’s request for preliminary injunction, explaining that its November 20 order was only intended to address the State’s request for a TRO. The district court noted the State’s new argument, i.e., that Florida had enacted a law on November 18, 2021, which prohibited private and public employer COVID-19 vaccination mandates, and that the mandate’s *1300 preemption of the state law demonstrated an irreparable sovereign injury because the mandate precludes the State from enforcing its own law and forces state agencies to choose between which law to follow and which to violate. *See* Fla. Stat. §§ 308.00317, 112.0441 (2021). The district court stated that it would consider the effect of the newly enacted law and scheduled an evidentiary hearing on the matter. The parties, however, filed a joint motion in the district court to waive briefing and the hearing, which the district court granted. The State then filed the instant motion for an injunction pending appeal with this Court.

On December 1, 2021, the district court denied the State’s request for a preliminary injunction to prevent implementation of the mandate and specifically addressed the State’s new law “in aid of the appeal.”¹ The district court noted that the State had exercised its sovereign lawmaking powers to broadly prohibit employers from imposing COVID-19 vaccination mandates on their employees, but that the mandate, by its terms, preempted Florida’s law with regard to covered healthcare staff in Medicare- or Medicaid-participating facilities. Relying on *Jacobson v. Massachusetts*, 197 U.S. 11, 25 S.Ct. 358, 49 L.Ed. 643 (1905),² the district court explained that, while the mandate had far-reaching impacts because many facilities accepted federal funding under the Medicare and Medicaid programs, vaccination mandates generally had not been found to be unlawful or unconstitutional. It also explained that the mandate provided medical- and religious-related exemptions. As such, the district court found that the State did not have a *parens patriae* interest in shielding employees who choose to work in federally-funded healthcare facilities from rules governing the administration of the federal program.

The district court then turned to the State’s argument that the conflict between federal and state law would force

state agencies to decide, by December 6, which law to follow. The district court explained that if there was no likelihood that the mandate would be found unlawful on the merits, the conflict of choice faced by the state agencies was eliminated. Turning to the success on the merits factor, the district court rejected all of the State's arguments. As to the State's consultation argument, the district court concluded that CMS's interpretation of 42 U.S.C. § 1395z to have no temporal requirement for consulting with state agencies would be given *Chevron*³ deference. The district court also rejected the State's notice-and-comment argument, stating that CMS's "detailed" explanation in the mandate "based on the urgency presented by the ongoing pandemic, the 2021 outbreaks associated with the Delta variant, and the oncoming influenza season" established "good cause" under § 553(b)(B) of the APA to waive the notice-and-comment procedures normally required.

The district court also rejected the State's argument that the mandate was arbitrary and capricious due to CMS's failure to consider less intrusive alternatives because CMS explained its reasoning, discussed the considered alternatives, ***1301** and explained why they were unworkable and because CMS's policy choice between those alternatives was likely to be accorded deference. It found that the State, at this early stage, had failed to present evidence to show CMS's decision ran counter to, or lacked a rational connection to, the factual evidence before the agency. The district court similarly rejected the State's argument that CMS was unable to issue the mandate under 42 U.S.C. § 1395 because CMS was not regulating the practice of medicine, the healthcare that may be provided in facilities that accept federal funds, the manner in which medical services are provided, or the operation of the institution or its employees. Rather, the district court explained that CMS is regulating "a federal program by requiring facilities that receive federal funding to develop and implement policies and procedures to ensure the vaccination of covered healthcare workers and staff for the health and safety of patients within those facilities" and these requirements were not expressly foreclosed by the statute.

The district court also found the State's Spending Clause argument was without merit. While the State asserted that any conditions on Medicare and Medicaid funding must have been disclosed to it from the beginning, the district court stated it was "inconceivable that every facet of [those] program[s] would have been known and agreed to from the beginning" and that the mandate was unambiguous and did not "present an immediate all or nothing penalty." Thus, because the mandate was related to the safe and efficient administration of federal programs, did not alter or expand existing programs, and provided an array of penalties for noncompliance, the

district court concluded there was little likelihood of success on the Spending Clause claim.

As to the final two factors for an injunction, the district court found there was a public safety interest—"the safety of Medicare and Medicaid patients and staff administering the program throughout this pandemic, ... and the need to slow the spread of the virus, are greatly enhanced by virtue of the COVID-19 vaccine"—that was "especially compelling within the context of healthcare facilities" and weighed heavily on the side of denying injunctive relief. The district court noted that the State had not denied the benefits of the vaccine nor any public health benefit to its citizens from enforcement of its new law prohibiting COVID-19 vaccine mandates by employers. Thus, the district court concluded the balance of equities weighed against granting the injunction. Accordingly, while the State's enactment of its law added a sovereign interest to its analysis, the district court determined a preliminary injunction was not warranted on the record before it.

II. ANALYSIS

Pursuant to Federal Rule of Appellate Procedure 8(a)(2), a party may file a motion with the court of appeals seeking an injunction pending appeal. Here, the State of Florida has appealed the district court's decision denying its motion for a preliminary injunction and now seeks to enjoin the CMS vaccine mandate during the pendency of its appeal. "[T]he traditional stay factors ... govern a request for a stay pending judicial review." *Nken v. Holder*, 556 U.S. 418, 426, 129 S.Ct. 1749, 173 L.Ed.2d 550 (2009). Thus, the party seeking an emergency stay or injunction pending appeal "must show: (1) a substantial likelihood that they will prevail on the merits of the appeal; (2) a substantial risk of irreparable injury to the intervenors unless the injunction is granted; (3) no substantial harm to other interested persons; ***1302** and (4) no harm to the public interest." *Touchston v. McDermott*, 234 F.3d 1130, 1132 (11th Cir. 2000); accord *Nken*, 556 U.S. at 426, 129 S.Ct. 1749. While no single factor is determinative, "[o]rordinarily the first factor is the most important." *Garcia-Mir v. Meese*, 781 F.2d 1450, 1453 (11th Cir. 1986). However, under our precedent, the movant need not always show that he probably will succeed on the merits of his appeal. *Id.* Instead, where the "balance of the equities weighs heavily in favor of granting the [injunction]," the movant need only show a "substantial case on the merits." *Ruiz v. Estelle*, 650 F.2d 555, 565 (5th Cir. Unit A 1981).⁴

In its motion for an injunction pending appeal, the State contends that it has made a sufficient showing as to each of the factors for the entry of an injunction pending appeal. I agree that the State of Florida has satisfied its burden as to each factor and that each of these factors favors granting the injunction pending judicial review. I begin with the first factor: whether the State of Florida's challenges to CMS's vaccine mandate are substantially likely to succeed on the merits of the appeal.

A. Substantial Likelihood of Success on the Merits

1. CMS's statutory authority to issue the mandate.

In challenging CMS's vaccine mandate, the State of Florida contends that Congress has not provided CMS the statutory authority to enact the mandate at issue here. Under the Administrative Procedure Act, we must "hold unlawful and set aside agency action ... found to be ... in excess of statutory ... authority." 5 U.S.C. § 706(2)(C). It is well established that "an agency literally has no power to act, let alone pre-empt the validly enacted legislation of a sovereign State, unless and until Congress confers power upon it." *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 357, 106 S.Ct. 1890, 90 L.Ed.2d 369 (1986). CMS is part of the Executive Branch—specifically, the Department of Health and Human Services ("HHS")—and CMS therefore must derive its regulatory powers from Congress. CMS claims it derived its purported authority to issue the mandate via the Social Security Act and CMS's general authorization to administer Medicare and Medicaid, primarily invoking 42 U.S.C. §§ 1302 and 1395hh as the statutory authority. See 86 Fed. Reg. at 61,560, 61,567.

Congress gave the HHS Secretary the authority to "make and publish such rules and regulations ... as may be necessary to the efficient administration of the functions" of Medicare and Medicaid. See 42 U.S.C. § 1302(a); see also 42 U.S.C. § 1395hh(a). Below, the district court determined that:

This broad rulemaking authority is entitled to substantial deference, and "considerable weight" is given to the agency's "construction of a statute it is

entrusted to administer." *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–44, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984) (stating where Congress has not spoken directly on an issue but given an administrative agency the power to administer a program, this power necessarily includes the formation of policy and the making of rules to fill any gap left by Congress).

But this determination is untenable. While Congress has authorized the Secretary *1303 of Health and Human Services general authority to issue regulations for the "administration" of Medicare and Medicaid and the "health and safety" of recipients, there is no dispute that there is no specific congressional authorization for the mandate. See *Ala. Ass'n of Realtors v. Dep't of Health & Hum. Servs.*, — U.S. —, 141 S. Ct. 2485, 2486, 210 L.Ed.2d 856 (2021) ("It would be one thing if Congress had specifically authorized the action that the CDC has taken. But that has not happened.").

Contrary to the district court's assertion, a federal agency cannot "bring about an enormous and transformative expansion in ... regulatory authority without clear congressional authorization." *Util. Air Regul. Grp. v. EPA*, 573 U.S. 302, 324, 134 S.Ct. 2427, 189 L.Ed.2d 372 (2014). Indeed, the major questions doctrine instructs that courts "expect Congress to speak clearly if it wishes to assign to an agency decisions of vast 'economic and political significance.'" *Util. Air*, 573 U.S. at 324, 134 S.Ct. 2427 (quoting *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 160, 120 S.Ct. 1291, 146 L.Ed.2d 121 (2000)); accord *Ala. Ass'n of Realtors*, 141 S. Ct. at 2489 (relying on *Utility Air*); see also *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 468, 121 S.Ct. 903, 149 L.Ed.2d 1 (2001) ("Congress ... does not, one might say, hide elephants in mouseholes."); *Brown & Williamson*, 529 U.S. at 160, 120 S.Ct. 1291 ("[W]e are confident that Congress could not have intended to delegate a decision of such economic and political significance to an agency in so cryptic a fashion."). It is hard to imagine how a decision mandating vaccines for much of this nation's healthcare workforce—regardless of whether they have contact with a patient—does not constitute an agency decision of vast economic and political significance.

The Fifth Circuit's recent decision in *BST Holdings, LLC v. OSHA*, 17 F.4th 604 (5th Cir. 2021), is instructive. In *BST Holdings*, the Fifth Circuit addressed OSHA's mandatory vaccination requirement, which was issued on the same day as the CMS mandate. *Id.* at 609. The Fifth Circuit concluded that a vaccination mandate clearly implicated the type of significant economic and political considerations subject to the major questions doctrine. *Id.* at 617 ("The [m]andate derives its authority from an old

statute employed in a novel manner, imposes nearly \$3 billion in compliance costs, involves broad medical considerations that lie outside of OSHA's core competencies, and purports to definitively resolve one of today's most hotly debated political issues." (footnote omitted)).

CMS has never before enforced a vaccination mandate, and CMS cannot point to clear statutory authorization from Congress for the mandate. Simply put, nothing in 42 U.S.C. §§ 1302 and 1395hh indicates that Congress intended to assign CMS sweeping authority to impose a nationwide vaccine mandate—not only on healthcare workers providing direct patient care, but on all facility administrators and employees, trainees, students, volunteers, and third-party contractors who provide any care, treatment, or other services for the facilities falling under the mandate. Based on the major questions doctrine, the State of Florida has shown a substantial likelihood of success on the merits of its claim that Congress has not provided clear statutory authorization for the CMS mandate.

2. CMS's Bypass of Notice and Comment Rulemaking

The APA requires a reviewing court to "hold unlawful and set aside agency action ... found to be ... without observance of procedure required by law." 5 U.S.C. § 706(2)(D). Such procedures include the ***1304** notice and comment provisions of 5 U.S.C. § 553, which require agencies to provide notice of proposed rulemaking and an opportunity for interested parties to provide comments before promulgation of any rule. § 553(b)–(c). The State of Florida challenges CMS's vaccine mandate based on CMS's failure to follow the notice and comment procedures.

The APA's notice and comment requirements are not mere procedural niceties, but instead play an important role in our system of government. Providing notice and the opportunity for comment "reintroduce[s] public participation and fairness to affected parties after governmental authority has been delegated to unrepresentative agencies." *Batterton v. Marshall*, 648 F.2d 694, 703 (D.C. Cir. 1980); *Dep't of Homeland Sec. v. Regents of the Univ. of Cal.*, — U.S. —, 140 S. Ct. 1891, 1929 n.13, 207 L.Ed.2d 353 (2020) (Thomas, J., concurring in the judgment in part and dissenting in part) ("[T]he notice and comment process at least attempts to provide a 'surrogate political process' that takes some of the sting out of the inherently undemocratic and

unaccountable rulemaking process." (quoting Asimow, *Interim-Final Rules: Making Haste Slowly*, 51 Admin. L. Rev. 703, 708 (1999))).

Instead of following the notice and comment procedures, however, CMS attempts to invoke the "good cause" exception of 5 U.S.C. § 553(b)(B). This exception excuses compliance with the notice and comment rulemaking requirements "when the agency for good cause finds ... that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest." *Id.*

The good cause exception should be read narrowly and applied reluctantly. *United States v. Dean*, 604 F.3d 1275, 1279 (11th Cir. 2010); *U.S. Steel Corp. v. EPA*, 595 F.2d 207, 214 (5th Cir. 1979); *Mack Trucks, Inc. v. U.S. EPA*, 682 F.3d 87, 93 (D.C. Cir. 2012) ("We have repeatedly made clear that the good cause exception 'is to be narrowly construed and only reluctantly countenanced.' " (quoting *Util. Solid Waste Activities Grp. v. EPA*, 236 F.3d 749, 754 (D.C. Cir. 2001))). The majority accepts at face value CMS's justifications for dispensing with notice and comment, which the district court summarized as including "the urgency presented by the ongoing pandemic, the outbreaks associated with the Delta variant, and the oncoming influenza season," as well as CMS's determination that further delay "would endanger the health and safety of additional patients and be contrary to the public interest." 86 Fed. Reg. at 61,584. An examination of the regulation leads me to conclude, however, that the State of Florida has a strong likelihood of success on the issue that CMS violated the APA by bypassing the notice-and-comment requirements. *See In re Gateway Radiology Consultants, P.A.*, 983 F.3d 1239, 1263 (11th Cir. 2020) ("[W]e are not a rubber stamp [on agency action]—'courts retain a role, and an important one, in ensuring that agencies have engaged in reasoned decisionmaking.' " (quoting *Judulang v. Holder*, 565 U.S. 42, 53, 132 S.Ct. 476, 181 L.Ed.2d 449 (2011))).

While the good cause exception is not exclusively confined to emergency situations, CMS must "show that there is good cause to believe that delay would do real harm." *Dean*, 604 F.3d at 1281. In the mandate, CMS explained that "[t]he data showing the vital importance of vaccination indicate[s] ... that we cannot delay taking this action in order to protect the health and safety of millions of people receiving critical health care services, the workers providing care, and our fellow citizens living and working in communities across the nation." 86 Fed. Reg. at 61583. But an ***1305** agency cannot create urgency by its own delay; indeed, such delay demonstrates a lack of urgency. *See Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 114–15 (2d Cir. 2018) ("Good cause cannot arise as a result of the agency's own

delay, because ‘[o]therwise, an agency unwilling to provide notice or an opportunity to comment could simply wait ..., then raise up the “good cause” banner and promulgate rules without following APA procedures.’ ” (quoting *Council of S. Mountains, Inc. v. Donovan*, 653 F.2d 573, 581 (D.C. Cir. 1981)); *United States v. Brewer*, 766 F.3d 884, 890 (8th Cir. 2014) (“[T]he Attorney General’s stated concern for public safety further is undermined by his own seven-month delay in promulgating the Interim Rule.”).

The mandate was announced two months before it was issued by CMS, and the mandate itself does not take effect until one month after the issuance date. Moreover, vaccines have been available to healthcare workers for nearly a year before the issuance of the mandate,⁵ and the Delta variant has been spreading in the United States for months, yet CMS took no action. Additionally, in the explanation of the mandate, CMS itself concedes that it could have acted earlier—almost a year earlier—but chose not to. See 86 Fed. Reg. at 61,583 (noting CMS could have mandated vaccines approved for Emergency Use Authorization, but that “CMS initially chose, among other actions, to encourage rather than mandate vaccination”). And what’s more, CMS has previously issued five interim final rules “to help contain the spread of [COVID-19]” since its onset—none of which included a vaccine mandate. *Id.* at 61,561. These facts alone cast significant doubt on the agency’s claim of an increased urgency justifying abandoning the notice and comment requirement. Indeed, CMS gave itself more time to issue the mandate after the President announced it was coming than it gave participating facilities to meet its terms. CMS’s own regulation establishes a lack of urgency on its part, either demonstrating that the situation is not so dire as it claims, or that it created the urgency by its own delay. Finally, as the agency concedes, “newly reported COVID-19 cases, hospitalizations, and deaths have begun to trend downward at a national level.” *Id.* at 61,584. This is encouraging news and, of course, it may change, but there is no way to reconcile this reported decrease in cases, hospitalizations, and deaths with what CMS suggests is an increased urgency that would satisfy the “good cause” necessary to dispense with notice and opportunity for comment.

I turn now to the agency’s other asserted justifications for good cause. Although CMS notes that “the intensity of the upcoming 2021-2022 influenza season cannot be predicted,” CMS nonetheless cites the possibility of a more severe flu season as justification for good cause. *Id.* The idea is that COVID-19 vaccinations will help “decreas[e] stress on the U.S. health care system during ongoing circulation of influenza.” *Id.* We have yet to hold that future harm can justify good cause, but surely meeting the exception would require a showing of more

than the mere possibility of such harm. *Cf. Brewer*, 766 F.3d at 890 (“Although the risk of future harm may, under some circumstances, justify a finding of good cause, that risk must ***1306** be more substantial than a mere possibility.”).

CMS also claims that proceeding through notice and comment is contrary to the public interest. 86 Fed. Reg. at 61,584 (claiming “a further delay in imposing a vaccine mandate would endanger the health and safety of additional patients and be contrary to the public interest”). But that misunderstands the statutory criterion. The question is not whether delaying the rule to provide notice and comment would be contrary to the public interest, “but whether *providing* notice and comment would be contrary to the public interest.” *Mack Trucks*, 682 F.3d at 95. In other words, notice and comment is contrary to the public interest if its use would actually harm the public interest. See *id.* at 94–95. “It is appropriately invoked when the timing and disclosure requirements of the usual procedures would defeat the purpose of the proposal—if, for example, ‘announcement of a proposed rule would enable the sort of financial manipulation the rule sought to prevent.’ ” *Id.* at 95 (quoting *Util. Solid Waste Activities Grp.*, 236 F.3d at 755).

The burden is on the agency to establish that notice and comment need not be provided. See *Action on Smoking & Health v. Civil Aeronautics Bd.*, 713 F.2d 795, 801 n.6 (D.C. Cir. 1983). Not only does CMS fail to argue that providing notice and comment on this matter would be contrary to the public interest, but the fact that the mandate is unprecedented, controversial, and health-related weighs strongly in favor of providing notice and comment. “The more expansive the regulatory reach of [agency] rules, of course, the greater the necessity for public comment.” *Am. Fed’n of Gov’t Emps., AFL-CIO v. Block*, 655 F.2d 1153, 1156 (D.C. Cir. 1981). And “[e]specially in the context of health risks, notice and comment procedures assure the dialogue necessary to the creation of reasonable rules.” *Nat’l Ass’n of Farmworkers Orgs. v. Marshall*, 628 F.2d 604, 621 (D.C. Cir. 1980). In a recent order enjoining CMS’s vaccine mandate, the Eastern District of Missouri aptly pointed out that requiring hesitant individuals to get vaccinated—without giving them an opportunity to be heard—undermines the purpose of the APA’s procedural safeguards and exacerbates vaccine hesitancy. *Missouri v. Biden*, No. 4:21-cv-01329-MTS, — F.Supp.3d at —, — — —, 2021 WL 5564501, at *6–7 (E.D. Mo. Nov. 29, 2021).

Perhaps the overarching issue is that we are two years into a global pandemic, with multiple, widely available vaccines and treatments that are only getting better. 86 Fed. Reg. at 61,612. At this point, and under these

circumstances, COVID-19, in and of itself, cannot constitute good cause to avoid notice and comment required by the APA. See *BST Holdings*, 17 F.4th at 611–12 (“The Mandate’s stated impetus—a purported ‘emergency’ that the entire globe has now endured for nearly two years, and which [the agency] itself spent nearly two months responding to—is unavailing” (footnotes omitted)); see also *Does 1-3 v. Mills*, No. 21A90, — U.S. —, 142 S.Ct. 17, — L.Ed.2d —, 2021 WL 5027177, at *3 (U.S. Oct. 29, 2021) (Gorsuch, J., dissenting) (noting that COVID-19 “cannot qualify as [a compelling interest] forever” and that “civil liberties face grave risks when governments proclaim indefinite states of emergency”). To allow COVID-19 to constitute good cause now would be to effectively repeal notice and comment requirements for the duration of the pandemic.

For the foregoing reasons, the State of Florida has shown a substantial likelihood of success on the merits as to its claim that CMS improperly invoked the good cause *1307 exception of 5 U.S.C. § 553(b)(B) to waive notice and comment procedures.

3. The Vaccination Mandate is Arbitrary and Capricious

Agencies are required to engage in reasoned decisionmaking. *Allentown Mack Sales & Serv., Inc. v. NLRB*, 522 U.S. 359, 374, 118 S.Ct. 818, 139 L.Ed.2d 797 (1998). The APA directs reviewing courts to “hold unlawful and set aside agency action, findings, and conclusions found to be ... arbitrary [and] capricious.” 5 U.S.C. § 706(2)(A). Judicial review under this standard is “exceedingly deferential,” but we must “ensure that the agency came to a rational conclusion.” *Sierra Club v. Van Antwerp*, 526 F.3d 1353, 1360 (11th Cir. 2008) (quoting *Fund for Animals, Inc. v. Rice*, 85 F.3d 535, 541 (11th Cir. 1996)). And while the majority claims the State “essentially seeks to substitute its views on epidemiology for the Secretary’s judgment about the best way to protect the public from infection,” Maj. Op. at 1291, the majority fails to analyze whether CMS’s conclusions rationally follow from the evidence the agency purports to rely on. What the State of Florida actually argues is that the mandate is arbitrary and capricious because, among other reasons, CMS failed to rationally connect its evidence to its decision and CMS did not meaningfully consider alternatives to the vaccination mandate. As discussed below, the State of Florida has shown a substantial likelihood of success on the merits as to its claim that the mandate is arbitrary and capricious and therefore unlawful.

i. Rational Connection Between Evidence and CMS’s Decision to Issue the Mandate.

To survive arbitrary and capricious review, “the 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, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983) (quoting *Burlington Truck Lines v. United States*, 371 U.S. 156, 168, 83 S.Ct. 239, 9 L.Ed.2d 207 (1962)). A court will find a rule arbitrary and capricious if the agency’s explanation “runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise.” *Id.*

Noting its lack of comprehensive data on how vaccination status impacts the spread of COVID-19 in most covered healthcare facilities, CMS “extrapolated” the data from its long-term care facilities. 86 Fed. Reg. at 61,585. The only justification offered by the agency for extrapolation, instead of gathering data, is that “[a]cute and [long-term care] facilities engage many, if not all, of the same health care professionals and support services of other provider and supplier types.” *Id.* But residents of long-term care facilities, i.e., nursing homes, are among the most vulnerable to COVID-19. As noted by CMS, they “make up less than 1 percent of the U.S. population” yet “accounted for 35 percent of all COVID-19 deaths” during the first year of the pandemic, and of the total COVID-19 deaths through September 10, 2021, 30 percent are estimated to have died during or after staying at such facilities. *Id.* at 61,566, 61,601. While such evidence may support a vaccine mandate in long term care facilities, data from these facilities with their concededly unique status cannot reasonably be “extrapolated” to others. And CMS presents no similar evidence for imposing the vaccine mandate on either the other fourteen kinds of covered facilities or the broad category of covered staff at these facilities. *1308 *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221, 136 S.Ct. 2117, 195 L.Ed.2d 382 (2016) (“[A]n agency must give adequate reasons for its decisions.”).

CMS also suffers a lack of data regarding vaccination status and transmissibility. The mandate was enacted, in part, to minimize “[t]he threats that unvaccinated staff pose to patients” by transmission. 86 Fed. Reg. at 61,558. The mandate, however, conflates data regarding disease

severity with disease transmission. CMS notes that the vaccines are “safe and highly effective at protecting vaccinated people against symptomatic and severe COVID-19,” *id.* at 61,560, but concedes that “the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not currently known,” *id.* at 61,615. Because CMS admits it does not have data demonstrating the vaccine is effective in preventing transmission, the mandate cannot be justified on this basis.

“We may not supply a reasoned basis for the agency’s action that the agency itself has not given.” *State Farm*, 463 U.S. at 43, 103 S.Ct. 2856 (quoting *SEC v. Chenery Corp.*, 332 U.S. 194, 196, 67 S.Ct. 1760, 91 L.Ed. 1995, (1947)). For these reasons, I believe that the State of Florida is substantially likely to succeed on the merits of its argument on appeal that CMS did not make a “rational connection between the facts found and the choice made” and that, thus, the mandate is unlawful as it is arbitrary and capricious. *Id.*; see also *Camp v. Pitts*, 411 U.S. 138, 143, 93 S.Ct. 1241, 36 L.Ed.2d 106 (1973) (“If [a] finding is not sustainable on the administrative record made, then the [agency’s] decision must be vacated and the matter remanded ... for further consideration.”).

ii. CMS’s Consideration of Alternatives to Vaccination Mandates.

CMS considered and rejected two alternatives to a vaccine mandate: (1) regular COVID-19 testing, and (2) natural immunity resulting from a previous COVID-19 infection. Regarding testing as an alternative, CMS dismissed this less restrictive alternative in a single sentence: “We have reviewed scientific evidence on testing and found that vaccination is a more effective infection control measure.” 86 Fed. Reg. at 61,614. But the “scientific evidence” relied on by the agency, however, was not provided. Although we do not require an agency to consider all policy alternatives in reaching a decision, without knowing what data the agency relied on, we cannot say the agency has provided “a satisfactory explanation for its action” or that “the decision was based on a consideration of the relevant factors [or] whether there has been a clear error of judgment.” *State Farm*, 463 U.S. at 43, 51, 103 S.Ct. 2856 (quoting *Bowman Transp. Inc. v. Ark.-Best Freight Sys.*, 419 U.S. 281, 285, 95 S.Ct. 438, 42 L.Ed.2d 447 (1974)).

Turning to natural immunity, CMS justifies rejecting this as an alternative to the vaccine mandate because “[t]here

remain many uncertainties about as to [sic] the strength and length of this immunity compared to people who are vaccinated.” 86 Fed. Reg. at 61,614. But the agency contradicts itself on this point twice. As to the strength of natural immunity, CMS notes that both people who receive a vaccine and those that recover from infection “reduce the risk to both health care staff and patients substantially, likely by about 20 million persons a month *who are no longer sources of future infections.*” *Id.* at 61,604 (emphasis added). As to longevity of protection, the agency concedes that the data regarding the vaccines is equally uncertain. *Id.* at 61,614 (“[T]he duration of vaccine effectiveness in preventing COVID-19, reducing disease severity, [and] reducing the risk of death ... are not currently *1309 known.”). These contradictions are strong indications that the agency’s decision was arbitrary and capricious. *State Farm*, 463 U.S. at 43, 103 S.Ct. 2856 (stating agency action arbitrary and capricious if the agency’s explanation “runs counter to the evidence”). Therefore, the State of Florida is substantially likely to succeed on the merits of this claim on appeal.

4. The Constitutionality of CMS’s Vaccine Mandate

In addition to the issues arising under the major questions doctrine and the APA, there are significant and serious questions regarding the constitutionality of CMS’s vaccine mandate that make it substantially likely that the State of Florida will prevail on the merits of its appeal, or at least counsels against adopting CMS’s broad reading of 42 U.S.C. §§ 1302 and 1395hh and against denying the State an injunction pending appeal.

“Our precedents require Congress to enact exceedingly clear language if it wishes to significantly alter the balance between federal and state power.” *U.S. Forest Serv. v. Cowpasture River Pres. Ass’n*, — U.S. —, 140 S. Ct. 1837, 1849–50, 207 L.Ed.2d 186 (2020). “Absent a clear statement of th[ose] purpose[s], we will not presume Congress to have authorized such a stark intrusion into traditional state authority.” *Bond v. United States*, 572 U.S. 844, 866, 134 S.Ct. 2077, 189 L.Ed.2d 1 (2014).

The Tenth Amendment to the United States Constitution provides: “The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people.” U.S. Const. amend. X. One such power is the States’ police power, which “is defined as the authority to provide for the public health, safety, and morals” of the States’

populaces. *Barnes v. Glen Theatre, Inc.*, 501 U.S. 560, 569, 111 S.Ct. 2456, 115 L.Ed.2d 504 (1991); *see also* *Gibbons v. Ogden*, 22 U.S. 1, 203, 9 Wheat. 1, 6 L.Ed. 23 (1824) (noting that “health laws of every description” constitute “a portion of that immense mass of legislation, which embraces every thing within the territory of a State, not surrendered to the general government: all which can be most advantageously exercised by the States themselves”). Compulsory vaccination mandates have long been understood to be part of the States’ police power. *See Zucht v. King*, 260 U.S. 174, 176, 43 S.Ct. 24, 67 L.Ed. 194 (1922) (“Long before this suit was instituted, *Jacobson v. Massachusetts* ... had settled that it is within the police power of a state to provide for compulsory vaccination.”); *Jacobson*, 197 U.S. at 35, 25 S.Ct. 358 (upholding a smallpox vaccination requirement adopted by the city of Cambridge, Massachusetts, based on Massachusetts’s police power). The mandate, thus, is a federal foray into an area historically understood as a core power of the States and significantly alters the balance of power between them and the federal government. I find no such clear statement from Congress in any of the statutory sections relied on by CMS to justify this intrusion by a federal agency into the police power traditionally reserved to the States.

Moreover, there is a significant question regarding Congress’s power to mandate vaccinations in the first place. Currently, “no existing federal law expressly imposes vaccination requirements on the general population.” Wen W. Shen, Cong. Rsch. Serv., R46745, *State and Federal Authority to Mandate COVID-19 Vaccination* 5 (Apr. 2, 2021). And “sometimes ‘the most telling indication of [a] severe constitutional problem ... is the lack of historical precedent’ for Congress’s action.” *1310 *Nat’l Fed’n of Indep. Bus. v. Sebelius*, 567 U.S. 519, 549, 132 S.Ct. 2566, 183 L.Ed.2d 450 (2012) (quoting *Free Enter. Fund v. Pub. Co. Acct. Oversight Bd.*, 561 U.S. 477, 505, 130 S.Ct. 3138, 177 L.Ed.2d 706 (2010)).

The two likeliest sources of congressional power here would be the Commerce and the Spending Clauses. U.S. Const. art. I, § 8, cl. 3 (Commerce Clause); U.S. Const. art. § 8, cl. 1 (Spending Clause). It seems unlikely that the Commerce Clause provides the answer for CMS. *See BST Holdings*, 17 F.4th at 617 (“A person’s choice to remain unvaccinated and forgo regular testing is noneconomic inactivity. ... The Commerce Clause power may be expansive, but it does not grant Congress the power to regulate noneconomic inactivity traditionally within the States’ police power.”); *see also* *United States v. Lopez*, 514 U.S. 549, 584, 115 S.Ct. 1624, 131 L.Ed.2d 626 (Thomas, J., concurring) (“[W]e always have rejected readings of the Commerce Clause and the scope of federal power that would permit Congress to exercise a police

power; our cases are quite clear that there are real limits to federal power.”); *United States v. Morrison*, 529 U.S. 598, 618 n.8, 120 S.Ct. 1740, 146 L.Ed.2d 658 (2000) (“With its careful enumeration of federal powers and explicit statement that all powers not granted to the Federal Government are reserved, the Constitution cannot realistically be interpreted as granting the Federal Government an unlimited license to regulate.”). As Chief Justice Roberts noted in *Sebelius*:

People, for reasons of their own, often fail to do things that would be good for them or good for society. Those failures—joined with the similar failures of others—can readily have a substantial effect on interstate commerce. Under the Government’s logic, that authorizes Congress to use its commerce power to compel citizens to act as the Government would have them act.

That is not the country the Framers of our Constitution envisioned. James Madison explained that the Commerce Clause was “an addition which few oppose and from which no apprehensions are entertained.” The Federalist No. 45, at 293. While Congress’s authority under the Commerce Clause has of course expanded with the growth of the national economy, our cases have “always recognized that the power to regulate commerce, though broad indeed, has limits.” *Maryland v. Wirtz*, 392 U.S. 183, 196 [88 S.Ct. 2017, 20 L.Ed.2d 1020] (1968).

567 U.S. at 554, 132 S.Ct. 2566.

But whether or not Congress, in the abstract, has the power to mandate vaccinations under the Commerce Clause, CMS lacks such power on its own. As noted by the Supreme Court, “[w]here an administrative interpretation of a statute invokes the outer limits of Congress’ power, we expect a clear indication that Congress intended that result.” *Solid Waste Agency of N. Cook Cnty. v. U.S. Army Corps of Eng’rs*, 531 U.S. 159, 172, 121 S.Ct. 675, 148 L.Ed.2d 576 (2001). The need for such an indication is “heightened where the administrative interpretation alters the federal-state framework by permitting federal encroachment upon a traditional state power.” *Id.* at 172, 121 S.Ct. 675; *see also* *United States v. Bass*, 404 U.S. 336, 349, 92 S.Ct. 515, 30 L.Ed.2d 488 (1971) (“[U]nless Congress conveys its purpose clearly, it will not be deemed to have significantly changed the federal-state balance.”) Congress has not given such an indication here, which is enough in this case for me to conclude that the State of Florida is substantially likely to succeed on the merits of its claims on appeal.

And while Congress *may* have the ability to condition

federal funds on a vaccination requirement under the Spending Clause, there, too, Congress must give a ***1311** clear indication of its intent. Indeed, “if Congress intends to impose a condition on the grant of federal moneys [under its Spending Clause power], it must do so unambiguously.” *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1, 17, 101 S.Ct. 1531, 67 L.Ed.2d 694 (1981). When looking at the statutes in question, I cannot conclude that Congress unambiguously conditioned Medicare and Medicaid funding on the requirement that all healthcare workers, employees, trainees, students, volunteers, and third-party contractors at covered facilities are vaccinated.

To be sure, the Medicare and Medicaid statutes discuss, in general and generic language, the health and safety of individuals who use the services of certain healthcare institutions. *See, e.g.*, 42 U.S.C. § 1395d(a); *id.* § 1396r(d)(4)(B)). And, in looking for some statutory authority for the mandate, CMS and the majority necessarily relies on that language. But, as the State of Florida notes, the statutes also contain other provisions like 42 U.S.C. § 1395, which states:

Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

Imposing a vaccination requirement with its concomitant penalties that include withholding funding from facilities that choose to employ or contract with nonvaccinated individuals certainly seems to fall within the plain meaning of the words “supervision or control” “over the selection [or] tenure ... of any officer or employee,” or “over the administration or operation” of a covered facility. As with the Commerce Clause, the lack of any clear indication by Congress conditioning receipt of Medicare and Medicaid funding on vaccination is sufficient for me to conclude that the State of Florida is substantially likely to succeed on the merits of its claims on appeal.

* * * *

Accordingly, for the reasons discussed above, the State of Florida has shown a substantial likelihood that it will prevail on the merits of its appeal. This fact weighs heavily in favor of granting the State’s motion to enjoin the mandate pending judicial review. I now turn to the remaining factors.

B. Irreparable Injury

To establish entitlement to an injunction pending appeal, the State must also demonstrate that there is a substantial likelihood it will suffer irreparable harm unless the injunction is granted. *See Touchston*, 234 F.3d at 1132; *Nken*, 556 U.S. at 426, 129 S.Ct. 1749. “An injury is ‘irreparable’ only if it cannot be undone through monetary remedies.” *Barrett v. Walker Cnty. Sch. Dist.*, 872 F.3d 1209, 1229 (11th Cir. 2017) (quoting *Deerfield Med. Ctr. v. City of Deerfield Beach*, 661 F.2d 328, 338 (5th Cir. Unit B 1981)).

The State advances several arguments that it has and will suffer several irreparable harms without an injunction pending appeal to prevent the mandate’s implementation. First, the State contends that it will be unable to enforce the laws passed by the Florida Legislature prohibiting employers from implementing vaccine mandates on their workforces. *See Fla. Stat. §§ 308.00317, 112.0441* (2021). As the Supreme Court has noted, a state’s “inability to enforce its duly enacted plans clearly inflicts irreparable harm on the State.” ***1312** *Abbott v. Perez*, — U.S. —, 138 S. Ct. 2305, 2324 n.17, 201 L.Ed.2d 714 (2018); *see also Maryland v. King*, 567 U.S. 1301, 1303, 133 S.Ct. 1, 183 L.Ed.2d 667 (2012) (Roberts, C.J., in chambers) (explaining that when a state is enjoined “from effectuating statutes enacted by representatives of its people, it suffers a form of irreparable injury” (quoting *New Motor Vehicle Bd. of Cal. v. Orrin W. Fox Co.*, 434 U.S. 1345, 1351, 98 S.Ct. 359, 54 L.Ed.2d 439 (1977))); *Hand v. Scott*, 888 F.3d 1206, 1214 (11th Cir. 2018) (“[T]he State Executive Clemency Board would be harmed if it could not apply its own laws to grant clemency to eligible applicants now”).

Here, the State of Florida has demonstrated a substantial likelihood that its sovereign interests are likely to suffer irreparable harm without an injunction pending appeal. The Florida Legislature enacted laws prohibiting employers from imposing COVID-19 vaccine mandates

on their workforces, see Fla. Stat. §§ 308.00317, 112.0441 (2021), and those state laws apply to all facilities covered by the mandate that are located in Florida. The mandate “preempts inconsistent State ... laws as applied to Medicare-and Medicaid-certified providers and suppliers,” 81 Fed. Reg. at 61,568, i.e., the mandate would preempt the Florida statutes prohibiting the vaccine mandate that CMS seeks to impose.

While the majority concludes that this is not an irreparable injury because it is “black-letter law that the federal government does not ‘invade[]’ areas of state sovereignty ‘simply because it exercises its authority,’ ” Maj. Op. at 1291 (quoting *Hodel v. Va. Surface Mining & Reclamation Ass’n*, 452 U.S. 264, 291, 101 S.Ct. 2352, 69 L.Ed.2d 1 (1981)), that argument relies on the majority’s conclusion that the mandate was lawfully enacted. But as discussed above, the State of Florida has a substantial likelihood of success on the merits of its claims that the mandate is unlawful, including its preemption of state laws like the one enacted by Florida. Thus, absent an injunction pending appeal, the State has demonstrated a substantial risk it will suffer irreparable harm because (1) it is unable to enforce its duly enacted laws, and (2) its state agencies will be forced to choose between complying with Florida law or complying with a federal rule that is likely unlawful. See *BST Holdings*, 17 F.4th at 618 (“The States, too, have an interest in seeing their constitutionally reserved police power over public health policy defended from federal overreach.”).

Second, the State contends that it will suffer irreparable harm because the mandate will deprive the State and its agencies of vital medical staff, exacerbating an already critical staffing shortage for healthcare workers. In turn, the State asserts that exacerbating the healthcare staffing shortages in its state agencies will result in serious disruptions in patient services in the form of cancellations and delays as well as an overall reduction in the quality of patient care provided by the agencies.

“[A] State has a quasi-sovereign interest in the health and well-being—both physical and economic—of its residents in general” as well as an interest in “ensuring that the State and its residents are not excluded from the benefits that are to flow from participation in the federal system.” *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 607–08, 102 S.Ct. 3260, 73 L.Ed.2d 995 (1982).

Here, the State has provided affidavits, outlined above, from several officials representing its state agencies. These officials attested that the agencies they represent are already suffering from healthcare staffing shortages, especially in Florida’s *1313 rural areas.⁶ These officials further attested that implementation of the mandate would

result in further staffing shortages because employees would end their employment instead of complying with the vaccination requirement. Most of the affiants provided estimates as to the number of employees the agencies expected to lose.

The district court found that these affidavits were speculative and conclusory, and the majority concludes that Florida failed to demonstrate that the district court’s holding was erroneous. Contrary to the conclusion of the district court and the majority, see Maj. Op. at 1291–93, the affidavits provided by the State are not merely “speculative” or phrased in “conclusory” terms. Rather, in these affidavits, which were submitted by officials from various state agencies based on their professional knowledge and experience, several of the agency officials concretely explain: (1) the existing healthcare staffing shortages in their respective agencies; (2) how the mandate will exacerbate the staffing shortages those agencies face, as a number of employees have indicated they will leave employment rather than comply with the vaccination requirement in the mandate; and (3) how that exacerbated staffing shortage will result in disruptions in, and reductions to, the quality of patient care. For example, several affidavits provided estimates as to the number of employees the agencies expect to lose. And several of the agency officials attested that it would take at least ninety days to hire replacement staff, given the current labor market, and that the interim vacancies would cause patient care cancellation and delays and would reduce the overall quality of care the agencies’ patients received.

“At the preliminary injunction stage, a district court may rely on affidavits and hearsay materials which would not be admissible evidence for a permanent injunction, if the evidence is ‘appropriate given the character and objectives of the injunctive proceeding.’ ” *Levi Strauss & Co. v. Sunrise Int’l Trading Inc.*, 51 F.3d 982, 985 (11th Cir. 1995) (quoting *Asseo v. Pan Am. Grain Co.*, 805 F.2d 23, 26 (1st Cir. 1986)). Simply put, the State has provided evidence in the form of affidavits showing that its state agencies will be adversely impacted by exacerbated staffing shortages if the mandate is implemented and how those shortages will likely affect the amount, timing, and quality of patient care provided by the agencies. Cf. *BST Holdings*, 17 F.4th at 618 (“[T]he companies seeking a stay in this case will also be irreparably harmed in the absence of a stay, whether by the business and financial effects of a lost or suspended employee.”). Based on this record, the State has shown a substantial risk that it will suffer irreparable harm in the form of an exacerbated staffing shortage leading to delays in and a reduction in the quality of patient care that its agencies provide.

Finally, the State asserts that it will suffer irreparable harm in the form of heavy compliance costs if its

agencies—in particular, AHCA—were to implement the mandate and that these costs would likely be nonrecoverable even if the mandate was ultimately held to be invalid. Indeed, as the Fifth Circuit recently noted in *BST Holdings*, “complying with a regulation later *1314 held invalid almost *always* produces the irreparable harm of nonrecoverable compliance costs.” *Id.* at 618 (emphasis in original) (quoting *Texas v. EPA*, 829 F.3d 405, 433 (5th Cir. 2016)); see also *Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 220–21, 114 S.Ct. 771, 127 L.Ed.2d 29 (1994) (Scalia, J., concurring in part and in the judgment). And the Fifth Circuit thus concluded that “compliance and monitoring costs associated with” a vaccine mandate constituted irreparable harm to the companies seeking a stay of the mandate. See *BST Holdings*, 17 F.4th at 618. Similarly here, the State has demonstrated a substantial risk of irreparable harm in the form of compliance costs associated with the mandate incurred by its agencies.

And the State also contends that the mandate threatens Florida with the loss of critical federal funding from the Medicare and Medicaid programs to its state-run facilities. While, as the majority summarily notes, economic or monetary injuries are generally reparable at law and weigh against a claim of irreparable harm, see *Ne. Fla. Chapter of Ass’n of Gen. Contractors of Am. v. City of Jacksonville*, 896 F.2d 1283, 1285 (11th Cir. 1990), several of the agency officials attested in their affidavits that if their agencies did not comply with the mandate, the resulting loss of federal funding would lead to a reduction in patient care, i.e., services the agencies would be unable to provide and receive revenue from, or a reduction in staff the agencies were able to employ. As the State explains, these ripple effects from the lack of Medicare and Medicaid funding to its agencies would directly impact that care its agencies’ facilities provide on a daily basis and that impact would not be recoverable, even if the mandate was held invalid and the State was able to claw back the withheld funding. Here again, the State of Florida has shown a substantial risk that it will suffer irreparable harm in the form of reduction in patient care at its agencies’ facilities due to a loss of federal funding.

* * * *

Accordingly, for the reasons discussed above, the balance of equities weighs heavily in favor of granting the State of Florida’s motion and enjoining the mandate pending appeal.

C. Remaining Factors

The final two factors for a preliminary injunction require an assessment of the harm to the opposing party and the weighing of the public interest. *Nken*, 556 U.S. at 435, 129 S.Ct. 1749. In doing so, “courts ‘must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief.’ ” *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 24, 129 S.Ct. 365, 172 L.Ed.2d 249 (2008) (quoting *Amoco Prod. Co. v. Gambell*, 480 U.S. 531, 542, 107 S.Ct. 1396, 94 L.Ed.2d 542 (1987)). Where the government opposes the preliminary injunction, “its interest and harm merge with the public interest.” *Swain v. Junior*, 958 F.3d 1081, 1091 (11th Cir. 2020); accord *Nken*, 556 U.S. at 435, 129 S.Ct. 1749.

The balance of the equities in this case weighs in favor of granting an injunction. There is no question that the public has an interest in stopping the spread of COVID-19. See *Ala. Ass’n of Realtors*, 141 S. Ct. at 2490. But, as even CMS recognizes, there are “major uncertainties” as to “the future course of the pandemic, including but not limited to vaccine effectiveness in preventing ‘breakthrough’ disease transmission from those vaccinated, the long-term effectiveness of vaccination, the emergence of treatment options, and the potential for some new disease variant even more dangerous *1315 than Delta.” 86 Fed. Reg. at 61,612.

Moreover, “our system does not permit agencies to act unlawfully even in pursuit of desirable ends.” *Ala. Ass’n of Realtors*, 141 S. Ct. at 2490. Indeed, there is “no public interest in the perpetuation of unlawful agency action.” *League of Women Voters of U.S. v. Newby*, 838 F.3d 1, 12 (D.C. Cir. 2016). “To the contrary, there is substantial public interest in having governmental agencies abide by the federal laws that govern their existence and operations.” *Id.* Because there is a substantial likelihood that the State of Florida will prevail on the merits on appeal, an injunction pending appeal is in the public interest in order to preserve the status quo. See *BST Holdings*, 17 F.4th at 618; see also *Am. Med. Ass’n v. Weinberger*, 522 F.2d 921, 927 (7th Cir. 1975) (explaining that the public interest requires that courts “be permitted to utilize interim injunction relief in a manner which enables those courts to scrutinize administrative action in an orderly and lawful manner”). Furthermore, maintaining the status quo would avoid exacerbating the healthcare staff shortages at the State’s agencies and a resulting decrease in the quality of patient care. Cf. *Missouri*, — F.Supp.3d at —, 2021 WL 5564501, at *14 (“[W]hile, according to CMS, the effectiveness of the vaccine to prevent disease transmission by those vaccinated is not currently known, what is known based

on the evidence ... is that the mandate will have a crippling effect on a significant number of healthcare facilities in Plaintiffs' states, ... create a critical shortage of services ... , and jeopardize the lives of numerous vulnerable citizens." (footnote omitted)). Thus, the balance of the harms and the public interest favor granting the State of Florida's motion for an injunction pending appeal.

III. CONCLUSION

For the foregoing reasons, I would grant the State's motion for injunction pending appeal and therefore dissent from the majority's denial of the motion.

All Citations

19 F.4th 1271, Med & Med GD (CCH) P 307,184, 29 Fla. L. Weekly Fed. C 607

Footnotes

- ¹ The dissent also questions the constitutionality of the federal government's imposing a vaccine mandate on healthcare workers, saying that the requirement "significantly alter[s] the balance between federal and state power." Dissent at 1309. We disagree. The federal government's authority to impose the interim rule's vaccine requirement derives from the Spending Clause. See U.S. Const. art. I, § 8, cl. 1. When a facility, even one operated by a State, voluntarily chooses to participate in the Medicare and Medicaid programs and receives federal funding for services provided to beneficiaries, the facility must comply with the federal law. And, as we explained above, Congress unambiguously conditioned the payment of funds under the Medicare and Medicaid programs to facilities that comply with "health and safety standards" set by the Secretary. See Section I-A, *supra*.
- ² The dissent, like Florida, argues that the district court erred in concluding that good cause existed because the Secretary waited until vaccines had been available to healthcare workers for over a year before adopting the interim rule. We are not convinced that this is a case where the Secretary waited so long to issue the interim rule that he cannot rely on the good-cause exception. This argument ignores that when the vaccines were originally made available, the Food and Drug Administration ("FDA") approved them under only an emergency use authorization. The FDA gave final approval to the first vaccine late August. It was within the Secretary's discretion to wait for approval, indicating that the vaccines were safe and effective before requiring health care employees to receive them. Rather than show a lack of good cause, this fact demonstrates appropriate caution and thought on the part of the Secretary. See 86 Fed. Reg. at 61,584 (noting that "[h]ealthcare workers whose hesitancy was related to [the emergency use authorization] status now have a fully licensed COVID-19 vaccination option").
- ³ Florida also argues that the district court erred because a separate federal statute required the Secretary to consult with States before issuing the interim rule. In addition to the APA's notice-and-comment requirement, federal law imposes another requirement before the Secretary may issue a new rule: "the Secretary must consult with appropriate State agencies" when carrying out functions "relating to determination of conditions of participation by providers of services." 42 U.S.C. § 1395z. Florida has not shown that the district court erred when it concluded that the Secretary satisfied the consultation requirement because States will have the opportunity to consult during the ongoing notice-and-comment period, reasoning that the statute imposed "no temporal requirement for the necessary consultation to occur *before* an interim rule is issued." Doc. 18 at 10.
- ⁴ If the Secretary lacked the authority to issue the interim rule, then Florida might be able to establish irreparable injury.
- ⁵ The district court also correctly pointed out that Florida enacted its statute after the Secretary issued the interim rule. The district court found that this timing "suggest[ed] an attempt to alter the status quo by creating a self-inflicted irreparable sovereign injury after the fact." Doc. 18 at 7 (internal quotation marks omitted).
- ⁶ Likewise, we are not persuaded that Florida has carried its burden of showing that, absent an injunction, it will

suffer an economic injury that could not be redressed if the interim rule turns out to be invalid. *See Ne. Fla. Chapter of Ass'n of Gen. Contractors v. City of Jacksonville*, 896 F.2d 1283, 1285 (11th Cir. 1990) (recognizing the “possibility that adequate compensatory or other corrective relief will be available at a later date” weighs “heavily against a claim of irreparable harm”).

⁷ Although the dissent does not dispute that the “public has an interest in stopping the spread of COVID-19,” our dissenting colleague concludes that the equities weigh in favor of a stay because of “uncertainties” related to the ongoing pandemic. Dissent at 1314–15 (internal quotation marks omitted). The dissent points to the recent emergence of the Omicron variant and speculates that currently available vaccines may “offer diminished protection” against this variant. *Id.* at 1315 n.7. As an initial matter, this is speculation; the dissent cites nothing to support its assertion about the effectiveness of vaccines against the Omicron variant. More fundamentally, though, the dissent’s position is flawed because taken to its logical end, it would mean that there would never be a public interest in the federal government’s taking proactive steps to protect the public from the COVID-19 virus—or any other deadly virus—because of the possibility, however remote, that the virus would mutate in the future.

¹ *See United States v. Diveroli*, 729 F.3d 1339, 1341 (11th Cir. 2013) (“When an appeal is filed, ‘the district court is divested of jurisdiction to take *any* action with regard to the matter except in aid of the appeal.’ ” (quoting *Shewchun v. United States*, 797 F.2d 941, 942 (11th Cir. 1986))).

² As discussed below, *Jacobson* addresses a state’s power to mandate vaccination, not the federal government’s power to do so.

³ *See Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–44, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984).

⁴ In *Bonner v. City of Prichard*, 661 F.2d 1206, 1209 (11th Cir.1981) (en banc), this Court adopted as binding precedent all decisions of the former Fifth Circuit handed down prior to October 1, 1981.

⁵ The Food and Drug Administration authorized two vaccines under Emergency Use Authorization in December 2020. 86 Fed. Reg. at 61,584. According to CMS, the agency could have imposed a vaccine mandate for vaccines authorized for Emergency Use Authorization. *Id.* at 61,583.

⁶ Indeed, the healthcare staffing shortages in Florida over the last several months have been widely publicized. *See Florida Healthcare Groups Warn of Growing Workforce Crisis*, Orlando Sentinel (Nov. 1, 2021, 1:47 PM), <https://www.orlandosentinel.com/politics/os-ne-health-care-staffing-crisis-florida-20211101-iluz3jbbt5ffbp7s3juqe2soe-story.html>; Kirby Wilson, *Florida Will Be Short Nearly 60,000 Nurses by 2035, Report Says*, Tampa Bay Times (Sept. 30, 2021), <https://www.tampabay.com/news/florida-politics/2021/09/30/florida-will-be-short-nearly-60000-nurses-by-2035-report-says/>

⁷ As to CMS’s last point, early evidence as to the Omicron variant of COVID-19, discovered in the weeks following the issuance of the mandate, suggests that it is much more transmissible than the Delta variant and potentially able to avoid the protection provided by the currently available COVID-19 vaccines. *See Michaela Doucleff, New Evidence Shows Omicron Likely Spreads Twice as Fast as Delta in South Africa*, NPR (Dec. 3, 2021, 5:30 PM), <https://www.npr.org/sections/goatsandsoda/2021/11/30/1059859253/why-omicron-variant-spreads-so-quickly-infectious-mutations>. While the relative severity of the Omicron variant remains to be seen, the possibility that current vaccines offer diminished protection against it raises further questions as to whether the mandate can be currently viewed as in the public interest.