No. 21-14098

In the United States Court of Appeals for the Eleventh Circuit

STATE OF FLORIDA,

Plaintiff-Appellant.

v.

DEPARTMENT OF HEALTH & HUMAN SERVICES, ET AL.,

Defendants-Appellees.

ON APPEAL FROM THE
UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF FLORIDA
No. 3:21-cv-2722-MCR-HTC

REPLY IN SUPPORT OF TIME-SENSITIVE MOTION FOR INJUNCTION PENDING APPEAL

ASHLEY MOODY
Attorney General of Florida
HENRY C. WHITAKER
Solicitor General
DANIEL W. BELL
Chief Deputy Solicitor General
EVAN EZRAY
Deputy Solicitor General
DAVID M. COSTELLO
Assistant Solicitor General

JAMES H. PERCIVAL
Deputy Attorney General of Legal Policy
NATALIE CHRISTMAS
Assistant Attorney General of Legal Policy
Office of the Attorney General
PL-01, The Capitol
Tallahassee, FL 32399-1050
(850) 414-3300
david.costello@myfloridalegal.com
Counsel for Plaintiff-Appellant

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Plaintiff-Appellant certifies that, to the best of its knowledge, the following is a complete list of interested persons:

1. Becerra, Xavier, *Defendant-Appellee*
2. Bell, Daniel W., *Counsel for Plaintiff-Appellant*
3. Brooks-LaSure, Chiquita, *Defendant-Appellee*
4. Cannon, Hope T., *United States Magistrate Judge*
5. Christmas, Natalie, *Counsel for Plaintiff-Appellant*
6. Costello, David M., *Counsel for Plaintiff-Appellant*
7. Ezray, Evan, *Counsel for Plaintiff-Appellant*
8. Florida, State of, *Plaintiff-Appellant*
9. Guard, John, *Counsel for Plaintiff-Appellant*
10. Hilborn, Jason H., *Counsel for Plaintiff-Appellant*
11. Klein, Alisa, *Counsel for Defendants-Appellees*
12. McElvain, Joel L., *Counsel for Defendants-Appellees*
13. Moody, Ashley, *Attorney General of Florida*
14. Myron, Laura E., *Counsel for Defendants-Appellees*
15. Percival, James H., *Counsel for Plaintiff-Appellant*
16. Rodgers, Casey M., *United States District Judge*
17. U.S. Centers for Medicare & Medicaid Services, *Defendant-Appellee*

18. U.S. Department of Health & Human Services, *Defendant-Appellee*

19. United States of America, *Defendant-Appellee*

20. Whitaker, Henry C., *Counsel for Plaintiff-Appellant*

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

Statutes

Regulations

INTRODUCTION

CMS has ordered the forced vaccination of millions of healthcare workers, giving them until just December 6 to comply until their jobs are on the line. In imposing this unprecedented mandate, CMS hurtled statutory safeguards, disregarded its lack of clear authority, and cast aside evidence contradicting its preferred result. Nothing in the government's response begins to clean up the mess CMS has made.

The only two district courts that heard adversarial presentation on the matter enjoined the mandate. *Missouri v. Biden*, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021); *Louisiana v. Becerra*, 2021 WL 5609846 (W.D. La. Nov. 30, 2021). This Court should join those courts and enjoin the mandate pending appeal.

ARGUMENT

A. Florida is likely to succeed on the merits.

1. The mandate is contrary to law.

a) The mandate violates 42 U.S.C. § 1395.

The mandate violates § 1395: It arrogates to CMS the power to "supervise or control" the "selection, tenure, or compensation" of healthcare employees by requiring them to be vaccinated or be fired. Mot. 5–6. In response, CMS suggests that its mandate does not really exercise any "control" because it is merely a condition on federal funding. Resp. 16. But Medicare and Medicaid are Spending Clause programs. Section 1395 serves no purpose if "control" obtained by conditioning hundreds of

billions of dollars of federal funding, and the threat of heavy penalties on top of that, is not "control" under § 1395. Mot. 5–6; *accord Louisiana*, 2021 WL 5609846, at *12.

CMS also likens its mandate to requiring "providers to prevent the spread of infection within their facilities." Resp. 16–17 (citing select regulations). CMS, however, identifies not one regulation that does anything like requiring the unvaccinated to be fired.

b) CMS lacks statutory authority to issue the mandate.

CMS asserts that, to determine whether its statutes authorize the mandate, this Court need ask only whether the mandate is "reasonably related to the purposes" of those statutes. Resp. 15–16 (quoting *Mourning v. Family Publ'ns Serv., Inc.*, 411 U.S. 356 (1973)). CMS "overreads" this language. *Merck & Co. v. HHS*, 962 F.3d 531, 536 (D.C. Cir. 2020), and the district court made the same error in its unprompted Post-Appeal Order, DE 18.[1] The "reasonably related" standard is not a "canon of statutory interpretation for general rulemaking provisions." *Merck*, 962 F.3d at 536. To determine the authority granted by such a provision, courts must "employ" the typical "tools of statutory interpretation." *Id.* Not even CMS contends that its statutes clearly authorize it to mandate vaccination for millions of healthcare workers—as Congress must when

[1] The district court issued this order after Florida filed this motion for an injunction pending appeal, despite Florida's appeal having divested it of jurisdiction over the preliminary injunction, despite the district court having already issued two prior orders explaining its reasons for denying Florida relief, and despite the fact that the government had not filed a brief in either this Court or the district court.

authorizing an agency to exercise powers of "vast economic and political significance." *Ala. Ass'n of Realtors v. HHS*, 141 S. Ct. 2485, 2489 (2021) (cleaned up).

Remarkably, CMS denies that its rule has great significance, or that it alters "the constitutional balance between the National Government and the States," *Bond v. United States*, 572 U.S. 844, 862 (2014), again grounding its position on its attempt to condition federal funding. Resp. 16. That assertion overlooks that the "Spending Clause power, if wielded without concern for the federal balance, has the potential to obliterate distinctions between national and local spheres of interest and power by permitting the Federal Government to set policy in the most sensitive areas of traditional state concern, areas which otherwise would lie outside its reach." *NFIB v. Sebelius*, 567 U.S. 519, 675–76 (2012) (plurality op.). A first-of-its-kind vaccine mandate affecting "billions of dollars" and "millions of people," *King v. Burwell*, 576 U.S. 473, 485 (2015), no doubt requires a clear statement of statutory authority, *accord Missouri*, 2021 WL 5564501, at *2–4; *Louisiana*, 2021 WL 5609846, at *11. None exists here. Mot. 6–9.

c) The mandate violates 42 U.S.C. § 1395z.

Florida showed that CMS violated § 1395z in failing to consult "appropriate" state agencies before issuing its rule. Mot. 9–10. In response, CMS offers the conclusory assertion that nothing in the statute requires "that such consultations occur in advance." Resp. 22. The statute's use of the word "determination," meaning a decision that has already been made, shows quite the opposite. Mot. 9. Under CMS's reasoning, it could

delay the required "consultation" for even years after the requirements become effective.

2. CMS lacked good cause to bypass notice and comment.

CMS has no answer to Florida's arguments that its nearly two-month delay in publishing the mandate and its nearly year-long delay in mandating vaccines belies its good-cause finding. Mot. 11–12. It merely says these delays are "not . . . reason to block" the mandate, citing the Post-Appeal Order. Resp. 23. The district court, too, stated without analysis that CMS's delay "does little to diminish" its good-cause rationale. Post-Appeal Order 13. These conclusory statements misunderstand the basis for the rule that "[g]ood cause cannot arise as a result of the agency's own delay." *Nat. Res. Def. Council v. Nat'l Highway Traffic Safety Admin.*, 894 F.3d 95, 114 (2d Cir. 2018); *accord Missouri*, 2021 WL 5564501, at *5–6; *Louisiana*, 2021 WL 5609846, at *10. The point of this rule is that—if the agency had time to conduct notice and comment—it cannot let months pass and then claim "good cause" not to do so.

CMS also recites the mandate's statements about the need for swift action given the COVID-19 pandemic, the Delta variant, and the upcoming flu season. Resp. 23. But it cannot be that anything thought to stem COVID-19 warrants discarding basic administrative procedures, two years (and three vaccines) into the pandemic. Mot. 10–11; *accord Louisiana*, 2021 WL 5609846, at *10. CMS's excuses also ring hollow given its admissions that "the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not currently known," Omnibus COVID-19 Health Care Staff

Vaccination, 86 Fed. Reg. 61,555, 61,615 (Nov. 5, 2021), and that "the intensity of the upcoming 2021–2022 influenza season cannot be predicted," *id.* at 61,584; *accord Missouri*, 2021 WL 5564501, at *6–8.

3. The mandate is arbitrary and capricious.

CMS ignores Florida's assertions that it failed to rationally connect its evidence on the effect of vaccination to most facilities covered by its mandate, that it did not meaningfully consider testing as an alternative, and that it failed to explain its heel turn from a policy of vaccine education to a policy of vaccine coercion. Mot. 13–16. *Accord Missouri*, 2021 WL 5564501, at *7–10; *Louisiana*, 2021 WL 5609846, at *13–14.

Instead, CMS zeroes in on three points. *First*, CMS cherry-picks a statement from healthcare associations urging "all health care and long-term care employers to require their workers" to vaccinate. Resp. 18. But these associations urged "*employers*" to require vaccination, not the federal government. And CMS omits contradictory statements from other associations cited in the mandate's preamble, which recognized that individual "circumstances" should "shap[e] whether and how [vaccine mandates] are implemented," and that each "facility must make the best decision for their specific circumstances." 86 Fed. Reg. at 61,566 n.128 (providing link).

Second, CMS claims that it adequately considered and rejected the concern that a mandate would cause workers to flee the healthcare industry. Resp. 20–22. But CMS concluded that it had "insufficient evidence to quantify and compare adverse impacts on patient and resident care associated with temporary staffing losses" and "absences

due to . . . COVID-19." 86 Fed. Reg. at 61,569. In other words, it determined that its evidence was inconclusive, but barreled forward with the mandate anyway. That was arbitrary and capricious. Mot. 14–15.

CMS's evidence was indeed inadequate. For instance, to support its determination that vaccine mandates would cause only minor workforce disruptions, it cited anecdotal evidence from a handful of hospitals that have imposed mandates. 86 Fed. Reg. at 61,569. But locality-specific evidence provides little help—what triggers outrage in New Hampshire may take applause in Tennessee. *See Missouri*, 2021 WL 5564501, at *14 n.33. Worse yet, CMS ignored a nationwide survey—published a week before the mandate—finding that 72% of unvaccinated workers would quit rather than vaccinate. Mot. 14–15. And it disregarded contradictory statements from its own sources recognizing that "[v]accine mandates may further challenge providers trying to recruit and retain a qualified workforce." 86 Fed. Reg. at 61,566 n.128 (providing link).

CMS next claims it determined that any workers lost to the mandate will be offset by those that return because of the mandate. Resp. 21 (citing 86 Fed. Reg. at 61,608). CMS made no such finding. To the contrary, it determined that "since there are so many variables and unknowns . . . it is unclear how [resignation-related costs] might be offset by reductions in current staffing disruptions caused by staff illness and quarantine once vaccination is more widespread." 86 Fed. Reg. at 61,608.

Finally, CMS contends that it found that any worker losses will be offset by the natural turnover of the healthcare industry. Resp. 20. But it supported that premise with

mere speculation that mandate objectors "may" be replaced by those willing to accept a "vacant health care position requiring vaccination." 86 Fed. Reg. at 61,608. That is misguided, as many potential new hires likely would *avoid* the healthcare industry precisely because it has a vaccine mandate.

4. This Court has jurisdiction.

CMS claims 42 U.S.C. § 405(g) and (h) preclude a court from exercising jurisdiction over a pre-enforcement challenge to a condition of Medicare participation; "[s]uch challenges may proceed only through the special review system that the Medicare statute provides." Resp. 13–14. But CMS ignores that these channeling provisions permit only "dissatisfied institution[s] or agenc[ies]" to use the special review system, and they do not apply when they would effectively preclude any judicial "review at all." Mot. 16 (citing *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 24–25 (2000) (cleaned up)). Because Florida is an independent sovereign, not a "dissatisfied institution or agency," it cannot travel under the channeling provisions and would be unable to obtain judicial "review at all" if they applied. *Id.*; *accord Missouri*, 2021 WL 5564501, at *1; *Louisiana*, 2021 WL 5609846, at *3–4.

To this, CMS says Florida is no different from a trade association suing on behalf of its members and that such entities cannot "circumvent" the channeling provisions. Resp. 14. But Florida is not suing simply to vindicate injury to its citizens; it is suing to vindicate sovereign injury to itself. It is thus distinct from an association whose injury derives entirely from its members. Moreover, Florida's claims that CMS lacks authority

under the Medicaid Act are plainly outside the channeling provisions, which are applicable to Medicare. Mot. 17.

CMS also asserts that Florida lacks standing as parens patriae to sue the federal government. Resp. 13 (citing *Massachusetts v. Mellon*, 262 U.S. 447 (1923)). Again, Florida is asserting its own sovereign injury, not just parens patriae injury. Mot. 17. And *Mellon* does not apply when a State "assert[s] its rights under federal law," which Florida has here. Mot. 19 (quoting *Massachusetts v. EPA*, 549 U.S. 497, 520 n.17 (2007)).

B. Florida has suffered and will suffer irreparable harm.

As Florida has explained, Mot. 17, and as the district court acknowledged, Post-Appeal Order 7–8, the mandate's purportedly preemptive effect on Florida law constitutes irreparable sovereign harm. CMS does not try to rebut that premise.

Along with this, CMS does not refute Florida's claims that it will sustain heavy compliance costs under the mandate and will lose its surveying contract if it declines to comply. Mot. 18–19. These, too, are irreparable harms.

Ignoring these harms, CMS instead claims that Florida "cannot speak for *privately-run* facilities or their workers" since their representatives "have publicly supported vaccination requirements." Resp. 24. But statements from some healthcare associations are not the final word for the entire healthcare industry. And as Florida's evidence and two district courts have established, many facilities and employees have legitimate concerns that a mandate will cost employees their jobs and curtail the

provision of adequate medical care. *See* App. 98–130; *accord Missouri*, 2021 WL 5564501, at *12–13; *Louisiana*, 2021 WL 5609846, at *12–13.

Next, CMS argues that the threat of lost funding is not irreparable harm for two reasons, each insufficient. First, it claims (without citation) that any enforcement is not "imminent." Resp. 26. But Florida need show only that enforcement is "likely," *Benisek v. Lamone*, 138 S. Ct. 1942, 1944 (2018)—a hurdle it clears given the mandate's anticipated enforcement scheme and official statements promising enforcement. App. 69. Second, CMS claims (again without citation) that enforcement sanctions imposed on its facilities are not "irreparable because they are reviewable in court." Resp. 26. But it is "far from clear" whether these facilities could recover for withheld federal funding if the mandate is later struck down. Mot. 19. And even if withheld funding were recoverable, such recovery "would not compensate Florida for the services it would not bill in the interim, for the patients it would lose to other facilities, and for the employees it would be forced to cut loose in the process." *Id.*

C. The remaining factors favor Florida.

The equities favor an injunction. Mot. 20. CMS has not shown otherwise.

First, CMS claims that without its mandate "hundreds and potentially thousands of patients . . . may die as the result of COVID-19 infections transmitted to them by staff." Resp. 24. "But, in the very regulation at issue, CMS concluded that 'the effectiveness of the vaccine to prevent disease transmission by those vaccinated [is] not

currently known.'" *Missouri v. Biden*, 2021 WL 5631736, at *1 (E.D. Mo. Dec. 1, 2021). So, by CMS's own admission, this argument is speculative. *Id.*

Second, CMS disregards the harm to "an estimated 2.4 million" unvaccinated employees whom "would be required to either receive the vaccine or be terminated from their employment" without injunctive relief. *Louisiana v. Becerra*, 2021 WL 5711601, at *1 (W.D. La. Dec. 1, 2021).

Finally, CMS discounts the risk that healthcare workers will resign, claiming that this number is "very low." Resp. 25. But again, CMS has no reliable support for this conclusion and a nationwide study says otherwise. *Supra* 5–7.

D. Scope of injunctive relief.

CMS contends that injunctive relief should be limited to "those state-run facilities in Florida that demonstrated irreparable injury." Resp. 26. That argument overlooks that Florida is suing as a *sovereign*—not just on behalf of its facilities—and that Florida has suffered (and is threatened with) several irreparable sovereign harms divorced from those specific state-run facilities. Mot. 17–18. Injunctive relief should therefore extend throughout Florida. In addition, this is a suit under the APA, which authorizes courts to "set aside" unlawful agency action, 5 U.S.C. § 706(2), and "to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings," *id.* § 705. Nothing in that language restricts the Court's authority to extend relief beyond certain affected facilities. *See Lujan v. Nat'l*

Wildlife Fed'n, 497 U.S. 871, 890 n.2 (1990); *Nat'l Mining Ass'n v. U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409–10 (D.C. Cir. 1998).

CONCLUSION

For these reasons, the Court should enjoin the mandate pending this appeal.

Respectfully submitted,

Ashley Moody
Attorney General

Henry C. Whitaker
Solicitor General

Daniel W. Bell
Chief Deputy Solicitor General

Evan Ezray
Deputy Solicitor General

/s/ David M. Costello
David M. Costello
Assistant Solicitor General

James H. Percival
Deputy Attorney General of Legal Policy

Natalie Christmas
Assistant Attorney General of Legal Policy

Office of the Attorney General
The Capitol, Pl-01
Tallahassee, Florida 32399-1050
(850) 414-3300
david.costello@myfloridalegal.com

Counsel for Plaintiff-Appellant

CERTIFICATE OF COMPLIANCE

1. This document complies with the type-volume limits of Fed. R. App. P. 27 because, excluding the parts of the document exempted by Fed. R. App. P. 32(f), this document contains 2,598 words.

2. This document complies with the typeface and type-style requirements of Fed. R. App. P 27, Fed. R. App. P. 32(a)(5), and Fed. R. App. P. 32(a)(6) because this document has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Garamond font.

/s/ David M. Costello
Assistant Solicitor General

CERTIFICATE OF SERVICE

I certify that on December 3, 2021, I electronically filed this Reply in Support of Time-Sensitive Motion for Injunction Pending Appeal with the Clerk of Court using the Court's CM/ECF system, which will send a notice of docketing activity to all parties who are registered through CM/ECF.

/s/ David M. Costello
Assistant Solicitor General