No. 21-30734

IN THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

STATE OF LOUISIANA; STATE OF MONTANA; STATE OF ARIZONA; STATE OF ALABAMA; STATE OF GEORGIA; STATE OF IDAHO; STATE OF INDIANA; STATE OF MISSISSIPPI; STATE OF OKLAHOMA; STATE OF SOUTH CAROLINA; STATE OF UTAH; STATE OF WEST VIRGINIA; COMMONWEALTH OF KENTUCKY; STATE OF OHIO,

Plaintiffs-Appellees,

v.

XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; CHIQUITA BROOKS-LASURE; CENTERS FOR MEDICARE AND MEDICAID SERVICES,

Defendants-Appellants.

On Appeal from the United States District Court for the Western District of Louisiana

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CERTIFICATE OF INTERESTED PERSONS

No. 21-30734

STATE OF LOUISIANA, ET AL.,

Plaintiffs-Appellees,

V.

XAVIER BECERRA, SECRETARY, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL., Defendants-Appellants.

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

Plaintiffs-appellees:

States of Louisiana, Montana, Arizona, Alabama, Georgia, Idaho, Indiana, Mississippi, Ohio, Oklahoma, South Carolina, Utah, West Virginia, and the Commonwealth of Kentucky. A proposed amended complaint would add as plaintiffs the State of Tennessee and the Commonwealth of Virginia. Tennessee and Virginia have filed as amicus curiae in the Court of Appeals.

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TABLE OF CONTENTS

]	Page
INTF	RODU	CTION AND SUMMARY OF ARGUMENT	1
ARG	UMEI	NT	2
I.		Supreme Court's Decision Fully Resolved Plaintiffs' lenges To The IFR	2
	A.	The Supreme Court's Reasoning Was Not Tentative Or Preliminary	2
	В.	Plaintiffs Cannot Circumvent The Supreme Court's Ruling By Arguing That Changed Circumstances Make The IFR Unnecessary To Protect The Health And Safety Of Medicare And Medicaid Beneficiaries	5
	C.	Plaintiffs' Allegation That The IFR "Commandeered" State-Run Facilities Is Foreclosed By The Supreme Court's Decision	8
II.	For S	tiffs' Proposed Challenge To CMS Guidance Documents tate Survey Agencies Would Not Affect The Validity Of FR	10
CON	ICLUS	SION	15
CER	ΓΙFIC	ATE OF COMPLIANCE	
CFR	ΓΙΕΙ <i>C</i> /	ATE OF SERVICE	

TABLE OF AUTHORITIES

Cases: Page	(s)
Auer v. Robbins, 519 U.S. 452 (1997)	7
Bennett v. Spear, 520 U.S. 154 (1997)	13
Biden v. Missouri, 142 S. Ct. 647 (2022)	10
California v. Texas, 141 S. Ct. 2104 (2021)	.13
Camp v. Pitts, 411 U.S. 138 (1973)	5
FCC v. Prometheus Radio Project, 141 S. Ct. 1150 (2021)	8
Missouri v. Biden, No. 4:21-cv-1329, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021)	2
Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins., 463 U.S. 29 (1983)	6
Murphy v. NCAA, 138 S. Ct. 1461 (2018)	9
New York V. United States, 505 U.S. 144 (1992)	9
<i>Printz v. United States,</i> 521 U.S. 898 (1997)	9
Statutes:	
Administrative Procedure Act 5 U.S.C. § 553(e)	

5 U.S.C. § 702	7
5 U.S.C. § 706	
42 U.S.C. § 405	8
42 U.S.C. § 1395aa(a)	11
42 U.S.C. § 1396i(b)(2)	8
Regulations:	
42 C.F.R. § 488.10(a)	11
42 C.F.R. § 498.5(j)	8
Other Authorities:	
CMS, External FAQ: CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (last updated Jan. 20, 2022), https://perma.cc/PUW4-Y39E	3-4
CMS, State Obligations to Survey to the Entirety of Medicare and Medicaid Health and Safety Requirements under the 1864 Agreement (Feb. 9, 2022), https://go.cms.gov/34PVy24	13, 14
CMS, Vaccination Expectations for Surveyors Performing Federal Oversight (Jan. 25, 2022), https://go.cms.gov/34pQK3G	1 2, 1 3
86 Fed. Reg. 61,555 (Nov. 5, 2021)	2, 6, 11
Megan Messerly, Rural Hospitals Stave Off Mass Exodus of Workers to Vaccine Mandate, Politico (Feb. 22, 2022), https://perma.cc/BKS6-8T8W	7
President Biden, State of the Union Address (Mar. 1, 2022), https://www.whitehouse.gov/state-of-the-union-2022/	6

INTRODUCTION AND SUMMARY OF ARGUMENT

The parties agree that the Supreme Court's decision in this case, *Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam), requires that the preliminary injunction be vacated. However, the parties strongly disagree as to the reason for doing so and the terms of the remand to the district court. Because the Supreme Court rejected plaintiffs' challenges to the Interim Final Rule (IFR) on the merits, this Court should vacate the injunction and remand to the district court with instructions to enter judgment in the federal government's favor.

Plaintiffs instead urge this Court to "issu[e] the mandate with the utmost haste" to allow the district court to consider re-enjoining the same IFR that the Supreme Court found to be lawful in this very case. Pl. Br. 8. As explained below, a remand on those terms would thwart the will of the Supreme Court. The Supreme Court's decision—issued after the Court took the extraordinary measure of hearing oral argument on the stay applications—conclusively rejected plaintiffs' challenges to the IFR on the merits. Accordingly, this Court should vacate the preliminary injunction on the ground that the Supreme Court's decision fully resolved this case.

ARGUMENT

- I. The Supreme Court's Decision Fully Resolved Plaintiffs' Challenges To The IFR.
 - A. The Supreme Court's Reasoning Was Not Tentative Or Preliminary.

The IFR required healthcare facilities that accept federal funding under the Medicare or Medicaid programs to develop and implement policies to ensure that their covered staff were fully vaccinated against COVID-19, or had claimed an exemption, by January 4, 2022. See 86 Fed. Reg. 61,555, 61,573 (Nov. 5, 2021). The district court in *Missouri v. Biden*, No. 4:21-cv-1329, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021), issued a preliminary injunction that blocked the IFR's enforcement against facilities within the 10 States that were plaintiffs in that action, and the Eighth Circuit declined to stay that injunction. In this case, the district court issued a preliminary injunction that blocked the IFR's enforcement against facilities nationwide (carving out only the 10 States already covered by the Missouri injunction). This Court stayed the injunction as applied to facilities outside the 14 plaintiff States but denied a stay of the injunction as applied to facilities within the plaintiff States.

The government filed emergency applications asking the Supreme Court to stay the injunctions in their entirety. In opposing the applications, plaintiffs urged the Supreme Court that, in their view, "granting the requested stay [would be] tantamount to awarding ultimate relief" because the IFR would then go into effect in their States and would require covered facilities to ensure that their staff are vaccinated. Response To Application For A Stay Pending Appeal at 35, *Becerra v. Louisiana*, Nos. 21A240 & 21A241 (U.S. Dec. 30, 2021) ("Response to Stay Application"); see id. at 35-36 (similar).

After hearing oral argument, the Supreme Court issued a decision conclusively resolving the challenges to the IFR on the merits, rather than relying on other factors such as the balance of harms. Soon thereafter, the Centers for Medicare & Medicaid Services (CMS) indicated, as a matter of enforcement discretion, that it would monitor and enforce compliance with the IFR for facilities within the plaintiff States under a timeline in which covered employees would be expected to receive their first vaccine shot, or claim an exemption, by February 14, 2022, and non-exempt employees would receive a second shot by March 15, 2022. *See* CMS, *External FAQ*:

CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (last updated Jan. 20, 2022), https://perma.cc/PUW4-Y39E.

Plaintiffs are manifestly wrong to argue that the Supreme Court's decision leaves room for the district court to once again enjoin or invalidate the same IFR that the Supreme Court upheld in this very case. Plaintiffs invoke the general principle that "[a] preliminary injunction is not a final remedy but carries with it the specific intent that the parties will be able to continue to develop their cases going forward." Pl. Br. 2. That principle does not apply here, however, because the Supreme Court chose to resolve the merits of the dispute.

The Supreme Court's ruling was not tentative or preliminary. For the detailed reasons set forth in the opinion, the Supreme Court definitively held that "the Secretary's rule falls within the authorities that Congress has conferred upon him." *Biden v. Missouri*, 142 S. Ct. 647, 652 (2022) (per curiam). The Court did not merely conclude that the Secretary was "likely" to succeed on that issue. Likewise, the Supreme Court definitively held that "the interim rule is not arbitrary and capricious," *id.* at 653, and that plaintiffs' "[o]ther statutory objections to the rule fare no better," *id.* at

654. Accordingly, this Court should vacate the preliminary injunction and remand with instructions to enter judgment for the federal government.

B. Plaintiffs Cannot Circumvent The Supreme Court's Ruling By Arguing That Changed Circumstances Make The IFR Unnecessary To Protect The Health And Safety Of Medicare And Medicaid Beneficiaries.

Plaintiffs cannot circumvent the Supreme Court's decision by asserting that the IFR has become arbitrary and capricious due to ostensible changes in "the circumstances of and approach to the COVID-19 pandemic." Pl. Br. 2. The Supreme Court expressly concluded that "the interim rule is *not* arbitrary and capricious." *Missouri*, 142 S. Ct. at 653 (emphasis added). In so ruling, the Supreme Court applied the bedrock administrative-law principle that the validity of the rule is determined based on the record that was before the agency when the rule was issued, "not some new record made initially in the reviewing court." *Camp v. Pitts*, 411 U.S. 138, 142 (1973) (per curiam).

"Given the rulemaking record," the Supreme Court rejected plaintiffs' argument that "the Secretary failed to 'examine the relevant data and articulate a satisfactory explanation for' his decisions to (1) impose the vaccine mandate instead of a testing mandate; (2) require vaccination of

employees with 'natural immunity' from prior COVID-19 illness; and (3) depart from the agency's prior approach of merely encouraging vaccination." *Missouri*, 142 S. Ct. at 653-54 (first quoting *Motor Vehicle Mfrs. Ass'n of the U.S. v. State Farm Mut. Auto. Ins.*, 463 U.S. 29, 43 (1983); and then citing 86 Fed. Reg. at 61,583, 61,559-61, 61,614). The Supreme Court likewise rejected plaintiffs' contention that "the Secretary 'entirely failed to consider' that the rule might cause staffing shortages, including in rural areas." *Id.* at 654 (first quoting *State Farm*, 463 U.S. at 43; and then citing 86 Fed. Reg. at 61,566, 61,569, 61,607-09).

Plaintiffs cannot seriously suggest (Br. 1-2) that the President's remarks during the State of the Union Address—which underscored "how incredibly effective vaccines are"¹—called into question the Secretary's judgment that staff vaccination at medical facilities is necessary to protect the health and safety of Medicare and Medicaid patients. In any event, the forum for plaintiffs' "changed circumstances" argument is the agency, not the district court. The Supreme Court has long held that when a party

¹ President Biden, State of the Union Address (Mar. 1, 2022) (transcript available at https://www.whitehouse.gov/state-of-the-union-2022/).

affected by a rule believes that changed circumstances warrant a change, "[t]he proper procedure for pursuit of [that] grievance is set forth explicitly in the APA: a petition to the agency for rulemaking, § 553(e), denial of which must be justified by a statement of reasons, § 555(e), and can be appealed to the courts, §§ 702, 706." *Auer v. Robbins*, 519 U.S. 452, 459 (1997) (citing 5 U.S.C. §§ 553(e), 555(e), 702, 706).

A remand that would allow the district court to reassess pandemic conditions in the first instance would contravene the Supreme Court's admonition that the district court had erred by substituting its analysis of the data for the Secretary's expert judgment. Missouri, 142 S. Ct. at 654. The question whether evolving pandemic conditions warrant a change in policy is quintessentially a matter for the Secretary. Likewise, it is for the Secretary to evaluate the empirical evidence regarding the effects of the IFR's implementation on staffing. See, e.g., Megan Messerly, Rural Hospitals Stave Off Mass Exodus of Workers to Vaccine Mandate, Politico (Feb. 22, 2022), https://perma.cc/BKS6-8T8W (reporting, based on interviews with "[n]early two dozen rural hospital officials and state hospital association leaders," that predictions that "the mandate would lead to a workforce crisis and limit care, particularly in rural areas, have not been borne out").

Such questions could not properly be addressed by the district court in the first instance. A district court has authority to review—rather than to make—agency policy. As the Supreme Court emphasized in this case: "[T]he role of courts in reviewing arbitrary and capricious challenges is to 'simply ensur[e] that the agency has acted within a zone of reasonableness.'" *Missouri*, 142 S. Ct. at 654 (quoting *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021)).²

C. Plaintiffs' Allegation That The IFR "Commandeered" State-Run Facilities Is Foreclosed By The Supreme Court's Decision.

The Supreme Court's decision likewise forecloses plaintiffs' claim that the IFR amounts to "coercion" or "commandeering" of state-run

² Tennessee's amicus brief provides no basis for further proceedings in this case. As amicus, Tennessee notes that three of its state-operated facilities received notices of noncompliance with the IFR on February 11, 2022. *See* Tennessee Amicus Br. 4. The amicus brief further notes that surveyors would conduct site visits of these facilities on March 10. *See id.* It is our understanding that the facilities have already taken action to lift the immediate jeopardy and implement the IFR.

In any event, Tennessee is not a party to this case. If the affected facilities are aggrieved by final agency action, the forum for review is a district court in Tennessee or D.C. *See* 42 U.S.C. § 1396i(b)(2) (incorporating 42 U.S.C. § 405); 42 C.F.R. § 498.5(j). The district court in this case has no authority to review the agency's determinations regarding facilities that are located in Tennessee.

Government may not compel the States to enact or administer a federal regulatory program," *Printz v. United States*, 521 U.S. 898, 933 (1997) (quoting *New York v. United States*, 505 U.S. 144, 188 (1992)), valid conditions on federal funds are not commandeering. *See New York*, 505 U.S. at 167, 173 (contrasting funding conditions with commandeering); *Printz*, 521 U.S. at 936 (O'Connor, J., concurring). Furthermore, "[t]he anticommandeering doctrine does not apply when Congress evenhandedly regulates an activity in which both States and private actors engage." *Murphy v. NCAA*, 138 S. Ct. 1461, 1478 (2018).

Before the Supreme Court, plaintiffs argued that, as applied to state-run facilities, the IFR was "impermissibly coercive" because "the consequence of opting out would be the loss of *all* Medicare and Medicaid funds." Response to Stay Application 27. They further argued that, "[a]t a minimum, those constitutional concerns warrant construing [the statute] to avoid them." *Id*.

The Supreme Court was unpersuaded by those arguments and upheld the IFR as a condition of federal funding. The Supreme Court reasoned that the "vaccination requirement" was "a straightforward and

predictable example of the 'health and safety' regulations that Congress has authorized the Secretary to impose" on facilities that accept federal funds under Medicare or Medicaid. *Missouri*, 142 S. Ct. at 653. That reasoning forecloses plaintiffs' commandeering claim. As noted above, valid funding conditions do not implicate the anti-commandeering doctrine. Nor is the doctrine implicated when, as here, the condition applies evenhandedly to private and state-run facilities. And the anti-commandeering doctrine has no application whatsoever to the vast number of Medicare- and Medicaid-participating facilities that are run by private entities.

II. Plaintiffs' Proposed Challenge To CMS Guidance Documents For State Survey Agencies Would Not Affect The Validity Of The IFR.

Plaintiffs also seek a remand to amend their complaint in order to challenge two guidance documents that CMS provided to state survey agencies on January 25, 2022, and February 9, 2022. A challenge to those guidance documents would not affect the validity of the IFR, so it would not be foreclosed by the Supreme Court's ruling. However, a remand to amend the complaint to challenge these guidance documents would be futile. Plaintiffs' proposed challenge rests on a basic misunderstanding of

the guidance documents, which do not impose a vaccination requirement for employees of state survey agencies.

The January 25 and February 9 memoranda provide guidance for "state survey agencies," which are state agencies that enter into agreements with CMS to inspect facilities for compliance with the conditions of Medicare and Medicaid funds. As the government explained in the Supreme Court, a State's decision to enter into a survey agreement with CMS is voluntary. See Gov't Appl. Reply Br. at 17-18 n.5, Becerra v. Louisiana, Nos. 21A240 & 21A241 (U.S. Jan. 3, 2022) (quoting 42 U.S.C. § 1395aa(a)) (providing that "[t]he Secretary shall make an agreement with any State which is able and willing to do so") (emphasis added). A State that wishes to do so enters into an agreement (known as a "Section 1864 Agreement") with the federal government under which its survey agency is paid to conduct periodic surveys to determine whether providers meet conditions of Medicare and Medicaid participation. See 42 U.S.C. § 1395aa(a); see also 42 C.F.R. § 488.10(a).

State survey agencies are not "facilities" subject to the IFR. See 86
Fed. Reg. at 61,556 (explaining that the IFR applies to the specified categories of providers and suppliers, which do not include state survey

agencies). And, contrary to plaintiffs' understanding, neither the January 25 memorandum nor the February 9 memorandum imposes a "Vaccine Mandate on State surveyors." Pl. En Banc Pet. 4.

By its terms, the January 25 memorandum merely sets forth CMS's "expectations" for state surveyors. CMS, Vaccination Expectations for Surveyors Performing Federal Oversight (Jan. 25, 2022), https://go.cms.gov/34pQK3G. That memorandum makes no reference to the IFR and does not rest on the statutory authorities cited in the IFR. Instead, it is a general guidance document of the sort that CMS regularly provides to state survey agencies pursuant to a Section 1864 Agreement. The memorandum states that "[s]urveyors who are not fully vaccinated . . . should not participate as part of the onsite survey team performing federal oversight of certified providers and suppliers." *Id.* at 2. However, the memorandum does not reserve to CMS any role in enforcing the agency's "expectations" or threaten any consequence to state survey agencies that act contrary to this recommendation. Instead, the memorandum makes clear that "certified providers and suppliers are not permitted to ask surveyors for proof of their vaccination status as a precondition for entry"

and that "State Survey Agencies" alone "are ultimately responsible for compliance with this expectation." *Id.* at 3 (emphasis omitted).

A remand to allow plaintiffs to amend the complaint to challenge the January 25 memorandum would thus be futile. Under *California v. Texas*, 141 S. Ct. 2104, 2114 (2021), plaintiffs lack standing to challenge that memorandum because they "have not pointed to any way in which the defendants . . . will act to enforce" it. Likewise, the memorandum is not final agency action because it is not an action from which "legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997).

Nor does the February 9 memorandum impose a vaccination requirement on state survey agencies. Indeed, the February 9 memorandum makes no reference to vaccination of state surveyors. *See* CMS, *State Obligations to Survey to the Entirety of Medicare and Medicaid Health and Safety Requirements under the 1864 Agreement* (Feb. 9, 2022), https://go.cms.gov/34PVy24. That memorandum addresses a different topic. A state survey agency that enters into a Section 1864 Agreement with the federal government agrees to survey providers for compliance with all of the applicable standards of the Medicare and Medicaid conditions of participation, including (but not limited to) the IFR. The

February 9 memorandum simply indicates that, if a state agency does not fulfill this agreement, CMS would reduce the state agency's payments for survey activities by an amount "commensurate with the impact of the State actions and the federal resources needed to provide appropriate oversight of providers and suppliers." *Id.* at 2. That statement reflects the unremarkable fact that a state survey agreement is a contract, and CMS provides funds to the state survey agency in exchange for its performance of a contractual agreement to conduct surveys.

There is no basis for the district court to adjudicate at this juncture a hypothetical dispute arising out of state survey activities in the plaintiff States. Assuming that one or more state survey agencies refuse to conduct survey activities, and assuming that CMS reduces the payment to those state survey agencies as a result, the state survey agencies would be able to challenge the payment reduction at that time.

CONCLUSION

The Court should vacate the preliminary injunction and remand with instructions to enter judgment in the federal government's favor.

Respectfully submitted,

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March 2022

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit of Federal Rule of Appellate Procedure 32(a) (7) (B) because it contains 2,799 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)-(6) because it was prepared using Microsoft Word 2016 in Book Antiqua 14-point font, a proportionally spaced typeface.

s/ Laura E. Myron

LAURA E. MYRON

CERTIFICATE OF SERVICE

I hereby certify that on March 14, 2022, I electronically filed the foregoing reply brief with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/Laura E. Myron

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