

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF LOUISIANA
MONROE DIVISION

STATE OF LOUISIANA, <i>et al.</i> ,)	
)	
Plaintiffs,)	
)	
v.)	Civil Action No. 3:21-CV-03970
)	
XAVIER BECERRA, in his official capacity)	
as Secretary of the United States Department)	
of Health and Human Services, <i>et al.</i> ,)	
)	
Defendants.)	

**DEFENDANTS' MEMORANDUM IN OPPOSITION TO
PLAINTIFFS' MOTION FOR LEAVE TO FILE SECOND AMENDED,
SUPPLEMENTAL, AND RESTATED COMPLAINT**

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INTRODUCTION

The Supreme Court has effectively resolved this case. In *Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam), the Supreme Court granted the federal government's application for a stay of the preliminary injunction that this Court had entered. After briefing and oral argument, the Supreme Court explicitly concluded that the vaccination rule at issue here is within the Secretary's statutory authority. The Supreme Court also explicitly rejected Plaintiffs' claims that the vaccination rule is arbitrary and capricious, procedurally invalid, and contrary to law. Plaintiffs' constitutional challenges were fully briefed and argued to the Supreme Court, and the Supreme Court implicitly rejected those claims as well.

The implications of the Supreme Court's ruling in this case are the subject of the appeal that is now pending before the Fifth Circuit. The court of appeals will decide if any claims in this case remain viable following the Supreme Court's decision. While that appeal is pending, this Court is divested of jurisdiction to consider Plaintiffs' claims, unless the Fifth Circuit grants this Court permission to proceed. Plaintiffs' motion for leave to file a second amended complaint should therefore be denied. If this Court is nonetheless inclined to address Plaintiffs' challenge to the vaccination rule, the proper procedure would be for Plaintiffs to ask this Court to issue an indicative ruling, and then, after the indicative ruling has been issued, Plaintiffs could ask the Fifth Circuit to remand to allow this Court to act.

However, there is no good reason to issue such an indicative ruling, because the Supreme Court's reasoning forecloses Plaintiffs' ostensibly new claims. Plaintiffs now argue that the emergence of the Omicron variant renders the vaccination rule arbitrary and capricious. But the Supreme Court was well aware of the Omicron variant when it ruled that the vaccination rule should be allowed to take effect in the plaintiff States. Moreover, in accordance with settled principles of administrative law, the Supreme Court reviewed the rule based on the record that was before the Secretary at the time the rule was issued. In any event, Plaintiffs are also wrong to assert that the Omicron variant calls into question the Supreme Court's holding, rendered less than a month ago, that the vaccination rule is a reasonable exercise of the Secretary's authority to protect the health of patients.

There is likewise no good reason to allow Plaintiffs to amend the complaint to challenge a memorandum that the Centers for Medicare & Medicaid Services (CMS) issued on January 25, 2022. That document states the federal agency’s desire that state survey agencies use vaccinated staff for on-site tours of health care facilities, when these state agencies perform federal surveys. By its terms, that memorandum merely set out CMS’s “expectations” and has no enforcement mechanism. Thus, under the reasoning of the Supreme Court’s decision in *California v. Texas*, 141 S. Ct. 2104, 2114 (2021), Plaintiffs lack standing to challenge this memorandum, and for similar reasons, the memorandum is not final agency action.

For all of these reasons, the Plaintiffs’ motion for leave to file an amended and supplemental complaint should be denied.

BACKGROUND

I. PRIOR PROCEEDINGS OF THIS LITIGATION.

On November 5, 2021, CMS published the interim final rule (“IFR”) at issue here, which requires various categories of Medicare and Medicaid providers and suppliers to develop and implement plans and policies to “ensure staff are fully vaccinated for COVID-19, unless exempt, because vaccination of staff is necessary for the health and safety of individuals to whom care and services are furnished.” Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,561 (Nov. 5, 2021). The Secretary concluded that “it would endanger the health and safety of patients, and be contrary to the public interest to delay” issuance of a vaccine requirement for staff in health care settings, *id.* at 61,586, and that, accordingly, there was good cause to waive notice and comment procedures, *id.* at 61,583-86. Under the rule, all relevant staff were to receive the first dose of a two-dose COVID-19 vaccine or a single-dose COVID-19 vaccine, or request or have been granted an exemption under the health care facility’s exemption policies, by December 6, 2021. *Id.* at 61,573. By January 4, 2022, all non-exempt staff who are covered by the rule were to be fully vaccinated. *Id.*

But on November 15, 2021, Plaintiffs—an initial group of 12 States led by Louisiana—brought this action in the Western District of Louisiana. ECF No. 1. Plaintiffs filed their motion for preliminary

injunction the same day, ECF No. 2, and a week later amended their original complaint to add Kentucky and Ohio as plaintiffs. ECF No. 11 (re-alleging the same allegations, but adding Paragraphs 15(a)-(b) and 86(a)-(b), related to the two new parties). On November 30, 2021, this Court preliminarily enjoined enforcement of the rule nationwide, except in ten States already covered by a materially identical injunction entered by the U.S. District Court for the Eastern District of Missouri. ECF Nos. 28-29 (Mem. Op. and Order); *see also Missouri v. Biden*, -- F. Supp. 3d --, No. 4:21-CV-01329, 2021 WL 5564501 (E.D. Mo. Nov. 29, 2021). The Court ruled that Plaintiffs were likely to succeed on the merits of their claims that the Secretary lacked statutory authority to issue the rule, Mem. Op. at 18-22; that the Secretary lacked good cause to issue the rule without advance notice and comment, *id.* at 14-19; that the rule violated the requirements of 42 U.S.C. § 1395z, 42 U.S.C. § 1395, and 42 U.S.C. § 1302(b)(1), *id.* at 22-23; that the rule was arbitrary and capricious, *id.* at 23-28; and that the statute would raise constitutional problems if it was construed to authorize the rule, *id.* at 28-31. The Court also concluded that the remaining factors supported a preliminary injunction. *Id.* at 31-34.

Defendants filed a notice of appeal on December 1, 2021. ECF No. 31. They also filed a motion to stay the preliminary injunction pending appeal, *see* ECF No. 32, which the Court denied. ECF No. 35. Defendants filed their opening brief on appeal on January 31, 2022. *Louisiana v. Becerra*, No. 21-30734 (5th Cir. Jan. 31, 2022), Dkt. No. 00516186586 (“Appellants’ Br.”).

Defendants also filed an emergency motion before the Fifth Circuit seeking a stay of the preliminary injunction pending appeal. On December 15, 2021, the Court of Appeals granted in part and denied in part that motion, maintaining this Court’s preliminary injunction but narrowing its scope to the 14 Plaintiff States. *Louisiana v. Becerra*, 20 F.4th 260, 262-64 (5th Cir. 2021) (per curiam).

Defendants then filed applications in the Supreme Court for stays pending further review of both the preliminary injunction in this case and the preliminary injunction issued by the district court in *Missouri v. Biden*, 2021 WL 5564501. The Supreme Court granted the stay applications and, as explained in detail below, effectively resolved the merits of the challenges in Defendants’ favor. *See Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam).

Following the Supreme Court’s decision, the plaintiffs in parallel litigation voluntarily dismissed

their challenges to the interim final rule. The State of Texas moved for voluntary dismissal of its complaint, “in light of the Supreme Court’s ruling in *Biden v. Missouri*.” Pls.’ Mot. for Dismissal, *Texas v. Becerra*, No. 21-cv-00229-Z, ECF No. 63 (N.D. Tex. Jan. 18, 2022). The district court granted the motion, similarly reciting that “[c]onsidering the U.S. Supreme Court’s ruling in *Biden v. Missouri*, . . . this Court finds that Plaintiffs’ Motion to Dismiss should be and hereby is **GRANTED**.” Order, *Texas v. Becerra*, No. 21-cv-00229-Z, ECF No. 66 (N.D. Tex. Jan. 19, 2022). The State of Florida likewise has noticed the dismissal of its complaint, “[g]iven the United States Supreme Court’s decision in *Biden v. Missouri*.” Notice of Dismissal, *Florida v. U.S. Dep’t of Health & Human Servs.*, No. 3:21-cv-2722-MCR-HTC, ECF No. 26 (N.D. Fla. Feb. 4, 2022).

Plaintiffs now seek leave to file a second amended complaint, for the purpose of adding allegations that the vaccination rule is invalid as a result of factual developments arising after the rule was issued, adding a challenge to the validity of a separate guidance document that CMS has issued to state survey agencies, and adding two new plaintiffs.

II. CMS’S IMPLEMENTATION OF THE VACCINE RULE.

CMS has adjusted the implementation schedule for the vaccine rule in response to the litigation developments described above. Following the Fifth Circuit’s partial grant of a stay of this Court’s preliminary injunction order on December 15, 2021, and the Northern District of Texas’s grant of a preliminary injunction on the same day with respect to the State of Texas, *see Louisiana v. Becerra*, Order, No. 21-30734 (5th Cir. Dec. 15, 2021); *Texas v. Becerra*, Order, No. 2:21-cv-00229-Z (N.D. Tex. Dec. 15, 2021), health care facilities in 25 states were covered by one of the preliminary injunctions then in force, but no injunction applied with respect to health care facilities in the remainder of the country. With respect to this latter group of health care facilities, CMS announced on December 28, 2021, that, as an exercise of enforcement discretion, the agency would implement and enforce the vaccination rule on a modified timeline, with the deadline for Phase 1 implementation set at January 27, 2022, and the deadline for Phase 2 implementation at February 28, 2022. *See* CMS, Current Emergencies: Litigation Update for CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule, Update #2, *available at* <https://perma.cc/SG58-SANF>. On the same day, CMS issued guidance to State Survey Agency Directors

regarding enforcement of the rule in those states in which the rule was effective. *See* CMS, Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination (Dec. 28, 2021), *available at* <https://perma.cc/K79Z-SATG>. The December 28 guidance set forth markers for enforcement at 30, 60, and 90 days after the issuance of the guidance, and explained that CMS would “follow current enforcement procedures based on the level of deficiency cited during a survey.” *Id.*

After the Supreme Court entered its stay of the preliminary injunctions issued by this Court and by the Eastern District of Missouri on January 13, 2022, and following Texas’s voluntary dismissal of its case on January 19, 2022, CMS issued a series of additional guidance documents and FAQs regarding the vaccination rule. *See* CMS, Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination (Jan. 14, 2022) (“Jan. 14, 2022 Guidance”), *available at* <https://perma.cc/3DTA-59QP>; CMS, Guidance for the Interim Final Rule – Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination (Jan. 20, 2022) (“Jan. 20, 2022 Guidance”), *available at* <https://perma.cc/K3DZ-GEMX>; CMS, External FAQ: CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (Updated Jan. 20, 2022), *available at* <https://perma.cc/ETC6-CABH>. The new guidance explained that for the 24 States previously covered by either this Court’s preliminary injunction or that of the Eastern District of Missouri, the agency, as an exercise of enforcement discretion, would begin monitoring and enforcing compliance on the following modified timeline: a February 14, 2022 deadline for the first vaccine shot, and a March 15, 2022 deadline for the second shot. *See* CMS, External FAQ: CMS Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (Updated Jan. 20, 2022), *available at* <https://perma.cc/PUW4-Y39E>. The new guidance explained that for Texas, the agency, again as an exercise of enforcement discretion, would begin monitoring and enforcing compliance on the following modified timeline: a February 22, 2022 deadline for the first shot, and a March 21, 2022 deadline for the second. *Id.* The guidance documents to the State Survey Directors set forth the same markers for enforcement as had the December 28 guidance memorandum, but anchored the 30, 60, and 90 day markers to the issuance dates of the January 14 and January 20 memoranda. *See* Jan. 14, 2022 Guidance; Jan. 20, 2022 Guidance.

III. CMS ISSUES GENERAL GUIDANCE TO STATE SURVEYORS ON JANUARY 25, 2022.

Separately from the foregoing, on January 25, 2022, CMS issued a guidance document to State Survey Agency Directors. *See* CMS, Vaccination Expectations for Surveyors Performing Federal Oversight (Jan. 25, 2022), attached hereto as Ex. A. The January 25 memorandum was not based on—and does not even mention—the interim final rule discussed above. It does not in any way amend or modify conditions of participation or conditions for coverage governing Medicare and Medicaid-participating facilities. Instead, it is a general guidance document of the sort that CMS regularly provides to State Survey Agency Directors for States that enter into an agreement (known as a “Section 1864 Agreement”) with the federal government under which each state health agency (or other appropriate state or local agency) agrees to conduct periodic surveys to determine whether providers meet Medicare’s conditions of participation. 42 U.S.C. § 1395aa(a); *see also* 42 C.F.R. § 488.10(a). A State’s decision to enter into a Section 1864 Agreement is wholly voluntary. *See* 42 U.S.C. § 1395aa(a) (authorizing agreements with “any State which is able and willing to do so”). If the State enters into such an agreement, however, it obliges itself to conduct surveys to “assess compliance with Federal health, safety and quality standards,” 42 C.F.R. § 488.26(c)(1), using “the survey methods, procedures, and forms that are prescribed by CMS,” *id.* § 488.26(d). The agreement provides that the Secretary will reimburse the State for the costs incurred by the State for performing the functions under the agreement.

A state survey agency’s failure to review for provider compliance does not disqualify providers in that state from program participation. All Medicare and Medicaid certified facilities are assumed to be in compliance until a survey (which could be performed by a CMS contractor, by an accreditation organization, or—if a State voluntarily takes on this role—by a state survey agency) makes an initial finding of a violation. Even then, the facility would remain certified while it has the opportunity to correct any violations by submitting “a plan of correction” to CMS. *See* 42 C.F.R. § 488.11 (state survey agency functions do not include enforcement).

As the January 25 memorandum makes clear on its face, it was built upon prior guidance in which CMS has stated its expectations regarding precautions that surveyors should take when

performing onsite inspections, including steps to ensure the proper use of personal protective equipment and to ensure that symptomatic individuals do not enter facilities. Jan. 25 Mem. at 1. The memorandum states CMS's expectation that "[s]urveyors who are not fully vaccinated," and are not persons for whom "vaccination is medically contraindicated" or who are "legally entitled to a reasonable accommodation under federal civil rights laws because they have a disability or sincerely held religious beliefs, practices, or observances that conflict with the vaccination requirement[,] should not participate as part of the onsite survey team performing federal oversight of certified providers and suppliers." *Id.* at 2. The memorandum further states CMS's expectation that such staff "may be used, at the State Survey Agency's . . . discretion, for offsite survey or enforcement activities." *Id.*

The January 25 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 its terms. 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 only "State Survey Agencies . . . are ultimately responsible for compliance with this expectation." *Id.* at 3 (emphasis omitted). The memorandum informs providers to address any questions they have about a State's implementation of the guidance to their State Survey Agency. *Id.* The January 25 memorandum applies generally to a "state's activities in conducting federal program responsibilities under the 1864 Agreement." *Id.*

STANDARD OF REVIEW

In deciding whether to grant leave to amend under Rule 15(a), courts consider a variety of factors, including "undue delay, bad faith or dilatory motive on the part of the movant, repeated failures to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment, and futility of the amendment." *Jones v. Robinson Prop. Grp., L.P.*, 427 F.3d 987, 994 (5th Cir. 2005). "Under Rule 15(d), the court may permit a party to file a supplemental pleading setting forth transactions or occurrences or events which have happened since the date of the pleading sought to be supplemented." *Burns v. Exxon Corp.*, 158 F.3d 336, 343 (5th Cir. 1998) (citing Fed. Rule Civ. P. 15(d)). "While the text of Rule 15(a) provides that leave should be freely

granted, the text of Rule 15(d) does not similarly provide.” *Id.*; see *Schoemann v. Murrell*, No. CIV.A. 09-0802, 2009 WL 3711257, at *1 (E.D. La. Nov. 4, 2009) (quoting *Burns* and denying motion to supplement). Nevertheless, the factors courts consider in deciding whether to permit supplementation are the same as those for the amendment of pleadings. See *Lewis v. Knutson*, 699 F.2d 230, 239 (5th Cir. 1983) (citing factors).

ARGUMENT

I. DEFENDANTS’ NOTICE OF APPEAL DEPRIVES THIS COURT OF JURISDICTION TO GRANT PLAINTIFFS LEAVE TO AMEND.

The Court’s modified preliminary injunction order is currently pending before the Fifth Circuit. As a result, this Court lacks jurisdiction to consider Plaintiffs’ motion to amend and supplement their original complaint.

It is hornbook law that once an appeal is noticed, the district court is divested of jurisdiction over any matter related to the appeal, and the matter is transferred immediately to the appellate court. *Farmband v. Anel Eng’g Indus., Inc.*, 693 F.2d 1140, 1145 (5th Cir. 1982); *Mazurek v. United States*, No. Civ. 99-2003, 2001 WL 616668 (E.D. La. Apr. 20, 2001). A “federal district court and a federal court of appeals should not attempt to assert jurisdiction over a case simultaneously.” *Griggs v. Provident Consumer Discount Co.*, 459 U.S. 56, 58 (1982). After an appeal has been lodged, the district court cannot take any action that would “alter the status of the case as it rests before the Court of Appeals.” *Dayton Indep. Sch. Dist. v. U.S. Mineral Prods. Co.*, 906 F.2d 1059, 1063 (5th Cir. 1990) (citation omitted); see also *Wooten v. Roach*, 964 F.3d 395, 403 (5th Cir. 2020) (holding that district court lacked jurisdiction to permit the filing of an amended complaint while interlocutory appeal was pending). The amendment or supplementation of a complaint while an appeal of a preliminary injunction is pending may alter the status of the case before the court of appeals. See *Wooten*, 964 F.3d at 403; see also *Sciacca v. Louisiana*, No. CV 02-3627, 2005 WL 8173897, at *2 (E.D. La. July 22, 2005) (citing Allan Ides, *The Authority of a Federal District Court to Proceed After a Notice of Appeal has Been Filed*, 143 F.R.D. 307, 308 (1992) (listing the following actions as acts that would impermissibly alter the status of the case in violation of the jurisdictional transfer principle: “grant leave to amend a complaint, grant a motion for

summary judgment, reconsider a prior disposition of a motion, dismiss a case pursuant to a stipulation of settlement, enjoin a state court action, materially amend an opinion or order, [and] vacate a dismissal”).

For example, in *Dayton*, defendants filed an interlocutory appeal regarding plaintiffs’ ability to state a claim under a certain federal statute. While the appeal was pending, plaintiffs amended their complaint to drop the federal statutory claim and the lone non-diverse defendant, and moved to dismiss the pending appeals as moot. 906 F.2d at 1062-63. The Fifth Circuit rejected the plaintiffs’ mootness argument after concluding that the amendments were null and void since the district court had abused its discretion in permitting the amendments to the pleadings that had “significantly changed the status of the appeals.” *Id.* at 1063.

Here, Plaintiffs’ attempt to amend and supplement their pleadings would similarly alter the status of the case before the Court of Appeals, and so this Court is foreclosed from granting Plaintiffs’ motion. The issues currently on appeal include whether the vaccination rule is within the Secretary’s authority; whether the rule is arbitrary and capricious; whether the Secretary had good cause to issue the rule without advance notice and comment; whether the rule presents a serious constitutional issue; and whether Plaintiffs carried their burden on other preliminary injunction factors. *See* Appellants’ Br. at 14-27; *see also* Mem. Order on Mot. to Stay Proceedings at 4-5, ECF No. 46 (explaining that the court found, *inter alia*, that Plaintiffs were likely to succeed on their claims that the Secretary failed to proceed through notice-and-comment rulemaking, acted arbitrarily and capriciously, and violated the Tenth Amendment Police Power and Non-Delegation Doctrine). All of those same issues are raised in Plaintiffs’ proposed amended and supplemental complaint. *Compare* Proposed 2d Am. & Suppl. Compl. Counts I (Notice and Comment Violation), II (Arbitrary and Capricious Violations), III-V (Spending Clause, Anti-Commandeering Doctrine and Tenth Amendment); *with* Compl. Count III (Notice and Comment Violation), Count V (Arbitrary and Capricious Violations), Counts VIII-X (Spending Clause, Anti-Commandeering Doctrine and Tenth Amendment). The Court is simply jurisdictionally barred from granting Plaintiffs’ motion, for to do so would fundamentally contravene the long-standing principle that a “federal district court and a federal court of appeals should not

attempt to assert jurisdiction over a case simultaneously.” *Griggs*, 459 U.S. at 58.

Plaintiffs’ proposed amendment would also alter the status of the case before the court of appeals.¹ Their proposed amendments are grounded in their view that “the situation has changed” in light of the Omicron variant and that these changed circumstances expose what they believe to be a “structural defect in the rule—its one-size-fits-all approach doesn’t account for developing data and circumstances.” *See* Proposed 2d Am. & Suppl. Compl. ¶ 4, ECF No. 51-1; *see also id.* ¶¶ 1-3, 5-6, 102, 122-28, 142-44; 150, 160-61. But the Omicron variant was discussed in the briefing before the Supreme Court, and the Court was well aware of the emergence of this variant when it heard argument and issued its decision last month. For the reasons explained below, these proposed allegations are futile as they concern events that post-date the Secretary’s action; the new allegations are not relevant in review of agency rulemaking under the APA, which is based solely on the record that existed at the time that the rule was issued. In any event, at the outset, under the jurisdictional transfer doctrine, this Court is jurisdictionally barred from addressing Plaintiffs’ attempt to reframe their challenge to the vaccination rule, and thereby reframing the appeal currently pending before the Fifth Circuit.

Even if this Court is inclined to entertain the second amended complaint, this Court may do no more than enter an indicative ruling, which would state that the Court would allow amendment if the court of appeals were to permit it to do so. *See* Fed. R. Civ. P. 62.1(a)(3); *see Moore v. Tangipahoa Par. Sch. Bd.*, 836 F.3d 503, 504 (5th Cir. 2016) (per curiam). Plaintiffs could then provide notice to the court of appeals of this Court’s indicative ruling, and could seek a remand from that court for the purpose of allowing this Court to issue its order. *See* Fed. R. Civ. P. 62.1(b); Fed. R. App. P. 12.1(a), (b). Upon the entry of that remand order, this Court could then rule on the motion for leave to amend. *See* Fed. R. Civ. P. 62.1(c); *see also* Mem. Order on Mot. to Stay Proceedings at 6, ECF No. 46 (noting the uncertainty as to whether the Fifth Circuit will remand the matter to this Court). Until such a remand order is entered, however, this Court lacks jurisdiction to grant the motion for leave to amend.

¹ If Plaintiff had filed a motion for leave to amend their complaint only to raise challenges to the January 25 memorandum, and had otherwise left undisturbed their challenge to the vaccination rule, such a motion likely would not be precluded under the jurisdictional transfer rule (although a challenge to the January 25 memorandum would still be meritless, for the reasons explained below).

II. THE PROPOSED COMPLAINT'S AMENDED CHALLENGE TO THE INTERIM FINAL RULE IS FUTILE.

Even if this Court had jurisdiction to grant Plaintiffs' motion, the motion for leave to amend and supplement Plaintiffs' claims challenging the vaccination rule still should be denied under Federal Rules of Civil Procedure 15(a) and (d). *See S&W Enters., L.L.C. v. S. Tr. Bank of Ala., NA*, 315 F.3d 533, 536 (5th Cir. 2003); *Burns*, 158 F.3d at 343; *Lewis*, 699 F.2d at 239. Plaintiffs' proposed amended claims challenging the IFR are futile.

In *Biden v. Missouri*, 142 S. Ct. 647 (2022), the Supreme Court granted the federal government's applications to stay the preliminary injunction that this Court had granted in this case. In so ruling, the Supreme Court effectively resolved each of the issues that had been presented in Plaintiffs' original complaint, and that are presented in Plaintiffs' motion to amend, in the federal government's favor. The Supreme Court's resolution of the merits of these issues demonstrates that the motion to amend is futile.

In granting the stay of this Court's preliminary injunction, the Supreme Court held, *first*, that "the Secretary's rule falls within the authorities that Congress has conferred upon him." *Id.* at 652. It noted that the Secretary of Health and Human Services is granted the "general statutory authority to promulgate regulations 'as may be necessary to the efficient administration of the functions with which [he] is charged.'" *Id.* at 650 (quoting 42 U.S.C. § 1302(a)). "One such function—perhaps the most basic, given the Department's core mission—is to ensure that the healthcare providers who care for Medicare and Medicaid patients protect their patients' health and safety." *Id.* "To that end, Congress authorized the Secretary to promulgate, as a condition of a facility's participation in the programs, such 'requirements as [he] finds necessary in the interest of the health and safety of individuals who are furnished services in the institution.'" *Id.* (quoting 42 U.S.C. § 1395x(e)(9)).

The Supreme Court noted that, "[r]elying on these authorities, the Secretary has established long lists of detailed conditions with which facilities must comply to be eligible to receive Medicare and Medicaid funds." *Id.* "Such conditions have long included a requirement that certain providers maintain and enforce an 'infection prevention and control program designed . . . to help prevent the

development and transmission of communicable diseases and infections.” *Id.* at 650-51 (quoting 42 C.F.R. § 483.80).

The Supreme Court cited the Secretary’s findings that the vaccine rule “will substantially reduce the likelihood that healthcare workers will contract the virus and transmit it to their patients,” and that “a vaccine mandate is necessary to promote and protect patient health and safety in the face of the ongoing pandemic.” *Id.* at 652 (citing Medicare & Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination, 86 Fed. Reg. 61,555, 61,557-61,558, 61,613 (Nov. 5, 2021)). The Court concluded that:

[t]he rule thus fits neatly within the language of the statute. After all, ensuring that providers take steps to avoid transmitting a dangerous virus to their patients is consistent with the fundamental principle of the medical profession: first, do no harm. It would be 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.

Id. (quoting *Florida v. Dep’t of Health & Human Servs.*, 19 F.4th 1271, 1288 (11th Cir. 2021)). Under the circumstances of the COVID-19 pandemic, the vaccination rule “is a straightforward and predictable example of the ‘health and safety’ regulations that Congress has authorized the Secretary to impose.” *Id.* at 653.

Second, the Supreme Court held that the Secretary had good cause to issue the vaccination rule as an interim final rule, because “the Secretary’s finding that accelerated promulgation of the rule in advance of the winter flu season would significantly reduce COVID-19 infections, hospitalizations, and deaths . . . constitutes the ‘something specific,’ . . . required to forgo notice and comment.” *Id.* at 654. Further, the Court rejected the States’ argument that “the two months the agency took to prepare a 73-page rule constitutes ‘delay’ inconsistent with the Secretary’s finding of good cause.” *Id.*

Third, the Supreme Court “agree[d] with the Secretary that he was not required to ‘consult with appropriate State agencies,’ 42 U.S.C. § 1395z, in advance of issuing the interim rule. Consistent with the existence of the good cause exception, which was properly invoked here, consultation during the deferred notice-and-comment period is permissible.” *Id.*

Fourth, the Supreme Court “similarly concur[red] with the Secretary that he need not prepare

a regulatory impact analysis discussing a rule's effect on small rural hospitals when he acts through an interim final rule; that requirement applies only where the Secretary proceeds on the basis of a 'notice of proposed rulemaking,' followed by a 'final version of [the] rule.'" *Id.* (quoting 42 U.S.C. § 1302(b)(1), (b)(2)).

Fifth, the Supreme Court concluded that "the interim rule is not arbitrary and capricious. Given the rulemaking record, it cannot be maintained 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." *Id.* at 653-54 (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). The Court also disagreed "that the Secretary 'entirely failed to consider' that the rule might cause staffing shortages, including in rural areas." *Id.* at 654 (quoting *State Farm*, 463 U.S. at 43). Finally, the Court rejected criticism of other parts of "the Secretary's analysis, particularly concerning the nature of the data relied upon," *id.*, reasoning that in reviewing arbitrary and capricious challenges, courts must "simply ensur[e] that the agency has acted within a zone of reasonableness." *Id.* (quoting *FCC v. Prometheus Radio Project*, 141 S. Ct. 1150, 1158 (2021)).

Finally, the Court held that it "disagree[d] with respondents' remaining contentions in support of the injunctions entered below." *Id.* at 653. These remaining contentions included several constitutional arguments. The federal government fully discussed Plaintiffs' constitutional arguments in its application for a stay to the Supreme Court. And in their briefing before the Supreme Court, Plaintiffs likewise reiterated their challenge to the constitutionality of the interim final rule on multiple grounds, including each of the grounds that they now seek to revive in their proposed amended complaint. *See* Response to Application for a Stay Pending Appeal, *Becerra v. Louisiana*, Nos. 21A240, 21A241 (U.S. Dec. 30, 2021). They argued, *inter alia*, that the rule violated the Spending Clause, *id.* at 26-27; unconstitutionally intruded on the states' police powers, *id.* at 23-24, 27; violated the Tenth Amendment, *id.* at 1; and violated the non-delegation doctrine, *id.* at 27. The Supreme Court effectively rejected each of these claims. *Biden v. Missouri*, 142 S. Ct. at 653. The Plaintiffs had also argued that

these constitutional concerns required the Court to construe the Secretary's statutory authorities to exclude the authority to impose the vaccination rule. The Supreme Court saw no reason to adopt Plaintiffs' suggestion, concluding that the rule "is a straightforward and predictable example of the 'health and safety' regulations that Congress has authorized the Secretary to impose," *id.* at 653, and that "the Secretary's rule falls within the authorities that Congress has conferred upon him." *Id.* at 652.

The Supreme Court's decision effectively forecloses each of the claims that Plaintiffs now seek to assert in their proposed amended complaint to challenge the interim final rule. Plaintiffs seek to revive their claims that the Secretary lacked good cause to issue the rule as an interim final rule, or that the rule was arbitrary and capricious. The Supreme Court has flatly held to the contrary on both counts. *Biden v. Missouri*, 142 S. Ct. at 653-54. Plaintiffs also seek to revive their constitutional claims, but the Supreme Court's rejection of each of "the respondents' remaining contentions," *id.* at 653, effectively forecloses these claims as well. *See, e.g., In re Felt*, 255 F.3d 220, 225 (5th Cir. 2001) ("The law of the case doctrine applies not only to issues decided explicitly, but also to everything decided 'by necessary implication.'") (quoting *Browning v. Navarro*, 887 F.2d 553, 556 (5th Cir. 1989)).² Likewise, the Supreme Court's grant of a stay of the preliminary injunction forecloses any attempt by Plaintiffs to seek an additional preliminary injunction of the same rule.

The Supreme Court's rejection of the constitutional claims should be unsurprising, because the rule presents no constitutional problem. The Supreme Court has long acknowledged—and the Constitution expressly provides—that "Congress has authority under the Spending Clause to appropriate federal moneys to promote the general welfare" and "to see to it that taxpayer dollars appropriated under that power are in fact spent for the general welfare." *Sabri v. United States*, 541 U.S. 600, 605 (2004). The Supreme Court has also long recognized that when Congress acts pursuant to its

² This Court has recognized that the Supreme Court's decision forecloses Plaintiffs' statutory and APA challenges to the vaccination rule, and that the Supreme Court disagreed with each of Plaintiffs' remaining contentions in defense of the preliminary injunction. Mem. Order on Mot. to Stay Proceedings at 5, ECF No. 46. This Court expressed its belief that the Supreme Court had not resolved constitutional challenges to the vaccination rule. *Id.* At the time that this Court so stated, it likely did not have before it Plaintiffs' briefing before the Supreme Court. As explained above, in that briefing, Plaintiffs directly raised constitutional challenges to the vaccination rule, and the Supreme Court implicitly rejected those challenges.

Spending Clause power, it may do so in ways that serve objectives traditionally thought of as within the police power of the States. *South Dakota v. Dole*, 483 U.S. 203, 207 (1987). Congress’s power to impose conditions on the acceptance of federal funds applies regardless of whether Congress legislates “in an area historically of state concern.” *Sabri*, 541 U.S. at 608 n.*.

In light of these authorities, the Supreme Court rejected the Plaintiffs’ assertion that they had insufficient notice that the Secretary might impose a funding condition like the vaccination rule. The Supreme Court explained that the rule “is not a surprising one.” *Biden v. Missouri*, 142 S. Ct. at 653. The Secretary “routinely imposes conditions of participation that relate to the qualifications and duties of healthcare workers themselves.” *Id.* “Vaccination requirements are a common feature of the provision of healthcare in America” *Id.* And Plaintiffs made no attempt to square their Spending Clause or non-delegation doctrine arguments with the Secretary’s “longstanding litany of health-related participation conditions,” the validity of which Plaintiffs did not contest. *Id.* The Supreme Court’s conclusion that the rule “is a straightforward and predictable example of the ‘health and safety’ regulations that Congress has authorized the Secretary to impose,” *id.*, likewise effectively forecloses any contention that Congress’s grant of these statutory authorities to the Secretary poses any issue under the non-delegation doctrine. See *Big Time Vapes, Inc. v. FDA*, 963 F.3d 436, 441 (5th Cir. 2020), *cert. denied*, 141 S. Ct. 2746 (2021).

Plaintiffs cannot avoid the binding effect of *Biden v. Missouri* by asserting, less than a month after the Supreme Court issued its decision, that the Court got the facts wrong. Plaintiffs have not filed a petition for rehearing in the Supreme Court, and have not sought a remand of the pending appeal in the Fifth Circuit. *Cf.* Mem. Order on Mot. to Stay Proceedings at 6, ECF No. 46. Despite failing to pursue either of these options, Plaintiffs now ask this Court to revisit the Supreme Court’s holdings by asserting that the emergence—in December 2021 and January 2022—of the Omicron variant³ of the SARS-CoV-2 virus demonstrates that the Secretary acted arbitrarily and capriciously—

³ On November 24, 2021, South Africa reported to the World Health Organization (WHO) the identification of a new COVID-19 variant, B.1.1.529, which was first detected in specimens collected on November 11, 2021 in Botswana and on November 14, 2021 in South Africa. CDC, *Omicron*

in early November 2021—when he issued his rule, or that he lacked good cause to do so at that time. The Plaintiffs’ request fundamentally misconstrues the nature of this Court’s review of rulemaking under the APA.

“Agency action is to be upheld, if at all, on the basis of the record before the agency *at the time it made its decision.*” *La. ex rel. Guste v. Verity*, 853 F.2d 322, 327 n.8 (5th Cir. 1988) (emphasis added); *see also Texas v. United States*, 300 F. Supp. 3d 810, 851 (N.D. Tex. 2018) (A “[c]ourt determines whether an agency action is arbitrary and capricious ‘solely on the basis of the agency’s stated rationale at the time of its decision.’”) (quoting *Luminant Generation Co. v. U.S. EPA*, 675 F.3d 917, 925 (5th Cir. 2012)), *aff’d in part, rev’d in part on other grounds sub nom. Texas v. Rettig*, 987 F.3d 518 (5th Cir. 2021). This is because “the focal point for judicial review should be the administrative record already in existence, not some new record made initially in the reviewing court.” *Camp v. Pitts*, 411 U.S. 138, 142 (1973); *see also Sierra Club v. U.S. Fish & Wildlife Serv.*, 245 F.3d 434, 444 (5th Cir. 2001); *Walter O. Boswell Mem’l Hosp. v. Heckler*, 749 F.2d 788, 792 (D.C. Cir. 1984) (“If a court is to review an agency’s action fairly, it should have before it neither more nor less information than did the agency when it made its decision. . . . To review more than the information before the Secretary at the time she made her decision risks our requiring administrators to be prescient or allowing them to take advantage of post hoc rationalizations.”).

The Supreme Court reviewed the “administrative record already in existence,” *Camp v. Pitts*, 411 U.S. at 142, as of the time of the Secretary’s issuance of the rule, and held that, “[g]iven the rulemaking record, it cannot be maintained that the Secretary [had] failed to examine the relevant data,” or that he had committed any other procedural or substantive violation. *Biden v. Missouri*, 142 S. Ct. at 653-54 (citation omitted). That holding remains binding on this Court, and requires the denial of the motion for leave to amend.

The Supreme Court’s holding in *Biden v. Missouri* would be binding on this Court even if there

Variant: What You Need to Know, <https://perma.cc/U3A6-WQLA>. On November 26, 2021, WHO gave the B.1.1.529 variant the name “Omicron,” and identified it as a variant of concern. *Id.* On December 1, 2021, the first confirmed case of the Omicron variant in the United States was identified. *Id.*

were some good reason to believe that the factual circumstances had changed. *Auer v. Robbins*, 519 U.S. 452 (1997), makes clear that Plaintiffs may not challenge the validity of a rule on the basis of later-arising facts. In *Auer*, there was no dispute that the challenged regulation was substantively or procedurally lawful at the time that it was issued; the plaintiffs there asserted instead that subsequent developments had rendered the regulation arbitrary and capricious. The Supreme Court rejected this claim, holding that “there is no basis for the court to set aside the agency’s action prior to any application for relief addressed to the agency itself” through a petition for a new rulemaking under 5 U.S.C. § 553(e). 519 U.S. at 459. See also *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016) (a “party cannot challenge [an] agency’s failure to amend its rule in light of changed circumstances without first seeking relief from the agency”); *Alon Refin. Krotz Springs, Inc. v. EPA*, 936 F.3d 628, 643 (D.C. Cir. 2019) (“Those kinds of arguments—that recent developments compel the amendment of an older regulation—are always cognizable through review of the denial of a petition to amend.”), cert. denied, *Valero Energy Corp. v. EPA*, 140 S. Ct. 2792 (2020). Plaintiffs have not filed a petition for rulemaking here, and that failure forecloses their claim under *Auer*.

But, in any event, there is no reason to doubt the correctness of the Supreme Court’s decision or the reasonableness of the Secretary’s rulemaking now. First, when formulating the rule, the Secretary explicitly considered the potential emergence of new variants and determined that such possibility supported the rule itself and the finding of good cause. See, e.g., 86 Fed. Reg. at 61,583, 61,584. For this reason, as well as for the many other factors explicitly considered by the Secretary, Plaintiffs’ assertion that the Delta variant alone provided “the rationale for the [vaccination rule],” Proposed 2d Am. & Suppl. Compl. ¶ 128, cannot be supported by the record.

Second, contrary to Plaintiffs’ characterizations of the Omicron variant as “mild,” January 2022 was among the deadliest months on record in the pandemic; at least 42,000 Americans died as a result of COVID-19 during that month alone. Centers for Disease Control & Prevention (“CDC”), *COVID-19 Mortality Overview*, <https://perma.cc/485U-4S42>. These deaths occurred predominantly among unvaccinated people; the most recent data available shows that unvaccinated people are 15 times as likely to die from COVID-19 as vaccinated people are. CDC, *Rates of COVID-19 Cases and*

Deaths by Vaccination Status, <https://perma.cc/DA62-DYA6>. The rate of hospitalization for COVID-19 for unvaccinated people, even after the emergence of the Omicron variant, is 5.3 times higher than the rate for fully vaccinated people who have not had a booster shot, and 23 times higher than fully vaccinated people who have had a booster shot. Phoebe Danza et al., *SARS-CoV-2 Infection and Hospitalization Among Adults Aged ≥ 18 Years, by Vaccination Status, Before and During SARS-CoV-2 B.1.1.529 (Omicron) Variant Predominance — Los Angeles County, California, November 7, 2021–January 8, 2022*, 71 Morbidity and Mortality Weekly Report 177 (Feb. 4, 2022). Unvaccinated people—again, after the emergence of the Omicron variant—are 3.1 times more likely to contract COVID-19 than are fully vaccinated persons. Amelia G. Johnson, et al., *COVID-19 Incidence and Death Rates Among Unvaccinated and Fully Vaccinated Adults with and Without Booster Doses During Periods of Delta and Omicron Variant Emergence — 25 U.S. Jurisdictions, April 4–December 25, 2021*, 71 Morbidity and Mortality Weekly Report 132 (Jan. 28, 2022), available at <https://perma.cc/Y9XF-DSE3>. And, although the Omicron variant is highly transmissible, vaccinated people are significantly less likely to transmit the Omicron variant than are unvaccinated people. *Omicron subvariant BA.2 more infectious than 'original', Danish study finds*, Reuters (Jan. 31, 2022).

There is no reason, then, to doubt the accuracy of the Secretary’s findings that the vaccination rule “is necessary to promote and protect patient health and safety in the face of the ongoing pandemic,” *Biden v. Missouri*, 142 S. Ct. at 652 (citing 86 Fed. Reg. at 61,557-61,558, 61,613), or the Supreme Court’s holding that the Secretary had “acted within a zone of reasonableness” in so finding, *id.* at 654 (citation omitted). The Supreme Court’s decision is binding on this Court, and this Court should reject Plaintiffs’ invitation to defy the precedential decision that the Supreme Court has issued in this very case.

As noted above, following the Supreme Court’s decision, the plaintiffs in other cases have voluntarily dismissed their challenges to the vaccination rule, citing the binding effect of that decision. The State of Texas moved for voluntary dismissal of its complaint, “in light of the Supreme Court’s ruling in *Biden v. Missouri*.” Pls.’ Mot. for Dismissal, *Texas v. Becerra*, No. 21-cv-00229-Z, ECF No. 63 (N.D. Tex. Jan. 18, 2022). The district court granted the motion, similarly reciting that “[c]onsidering

the U.S. Supreme Court’s ruling in *Biden v. Missouri*, . . . [this] Court finds that Plaintiffs’ Motion to Dismiss should be and hereby is **GRANTED**.” Order, *Texas v. Becerra*, No. 21-cv-00229-Z, ECF No. 66 (N.D. Tex. Jan. 19, 2022). The State of Florida likewise has noticed the dismissal of its complaint, “[g]iven the United States Supreme Court’s decision in *Biden v. Missouri*.” Notice of Dismissal, *Florida v. U.S. Dep’t of Health & Human Servs.*, No. 3:21-cv-2722-MCR-HTC, ECF No. 26 (N.D. Fla. Feb. 4, 2022). These plaintiffs and these courts have recognized that no challenge to the vaccination rule remains viable after the Supreme Court’s decision. This Court should do the same.

III. THE PROPOSED COMPLAINT’S SUPPLEMENTAL CHALLENGE TO THE JANUARY 25 MEMORANDUM IS FUTILE.

The Court should also deny Plaintiffs’ attempt to supplement their amended complaint with new claims challenging the January 25 memorandum. Because jurisdiction over Plaintiffs’ claims challenging the January 25 memorandum is lacking for several reasons, leave to supplement to add these claims should be denied as futile. *See Burns*, 158 F.3d at 343; *Lewis*, 699 F.2d at 239.

First, jurisdiction is lacking over Plaintiffs’ challenges to the January 25 memorandum, as that document is not final agency action. The APA permits judicial review only over a “final agency action.” 5 U.S.C. § 704. As the Fifth Circuit has repeatedly held, “[i]n this circuit, whether an agency action is final is a jurisdictional issue, not a merits question.” *Texas v. Equal Emp. Opportunity Comm’n*, 933 F.3d 433, 440 n.8 (5th Cir. 2019) (citing *Peoples Nat’l Bank v. Off. of the Comptroller of the Currency of the U.S.*, 362 F.3d 333, 336 (5th Cir. 2004)); *Peoples Nat’l Bank*, 362 F.3d at 336 (“If there is no ‘final agency action,’ a federal court lacks subject matter jurisdiction.”) (quoting *Am. Airlines, Inc. v. Herman*, 176 F.3d 283, 287 (5th Cir. 1999)). An agency action is “final” under the APA when it *both* (1) “mark[s] the consummation of the agency’s decisionmaking process,” *and* (2) is an action “by which rights or obligations have been determined, or from which legal consequences will flow.” *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (citations omitted); *see also Luminant Generation Co. v. U.S. EPA*, 757 F.3d 439, 441 (5th Cir. 2014).

The January 25 memorandum is not a final agency action because no “rights or obligations have been determined” by it, and no “legal consequences will flow” from it. *Bennett*, 520 U.S. at 178

(quoting *Port of Boston Marine Terminal Ass'n v. Rederiaktiebolaget Transatlantic*, 400 U.S. 62, 71 (1970)). As the memorandum makes plain on its face, it imposes no obligations or requirements on anyone. For example, the subject of the memorandum reads “Vaccination *Expectations* for Surveyors Performing Federal Oversight” Jan. 25 Mem. at 1 (emphasis added). The memorandum repeatedly makes clear that it is communicating CMS’s *expectations* for states and surveyors, rather than imposing any *requirements*. See, e.g., *id.* at 2 (explaining that unvaccinated staff “should not” (rather than “must not”) participate in onsite survey activities); *id.* (explaining that states “should have a process” for evaluating exemption request). In fact, the only mandatory language in the memo consists of the bolded text stating that “**certified providers and suppliers are not permitted to ask surveyors for proof of their vaccination status as a precondition for entry.**” *Id.* at 3. In this regard, Plaintiffs’ characterizations of the January 25 memorandum as a “Mandate,” see, e.g., Proposed 2d. Am. & Suppl. Compl. ¶ 129 & n.3; *id.* ¶¶ 173-75, is flatly contradicted by the document itself.⁴

Furthermore, the memorandum neither establishes nor even mentions any penalty for a party that does not meet the stated “expectations.” Jan. 25 Mem. at 1-3. The memorandum also makes clear that “State Survey Agencies and [Accrediting Organizations] are ultimately responsible for compliance with this expectation,” *id.* at 3. In other words, CMS will not even be responsible for monitoring state survey agencies for compliance with the expectations stated in the document. *Contra U.S. Army Corps of Eng’rs v. Hawkes Co.*, 578 U.S. 590, 600 (2016) (finding “final agency action” requirement satisfied even before enforcement “where such proceedings carry the risk of ‘serious criminal and civil penalties’”) (quoting *Abbott Labs. v. Gardner*, 387 U.S. 136, 153 (1967)).

For similar reasons, Plaintiffs lack Article III standing to challenge the validity of the

⁴ Similarly wrong is Plaintiffs’ allegation that the January 25 memorandum “follows directly from the . . . IFR.” Proposed 2d Am. & Suppl. Compl. ¶ 133. The memo does not purport to implement the vaccination rule, nor does it even cite that rule. See *generally* Jan. 25 Mem. That both concern vaccination merely reflects the agency’s considered judgment regarding “the importance of vaccination as a primary means for reducing the incidence and spread of COVID-19 in health care facilities.” See *id.* at 1-2. And, as Plaintiffs acknowledge, “CMS invokes the States’ ‘activities in conducting federal program responsibilities’ under the [state survey] agreements as a basis for its January 25 Guidance Mandate.” Proposed 2d Am. & Suppl. Compl. ¶ 133 (quoting the January 25 memorandum at 3).

memorandum. In the memorandum itself, CMS disclaims any role in enforcing its terms; the responsibility for compliance with the document's "expectations" rests solely with the state survey agencies themselves. Plaintiffs do not suffer an injury in fact from a document that merely sets forth expectations and that will not lead in any way to any enforcement action. Because Plaintiffs "have not pointed to any way in which the defendants . . . will act to enforce" the memorandum, "they have not shown that any kind of Government action or conduct has caused or will cause the injury they attribute to" that document. *California v. Texas*, 141 S. Ct. 2104, 2114 (2021).

But even if the January 25 memorandum had imposed any requirements on state survey agencies, Plaintiffs' proposed second amended complaint nonetheless fails to allege that Plaintiffs are harmed by that document. Establishing that one has suffered a concrete injury is one of the three elements of the "irreducible constitutional minimum" of standing necessary to fall under the subject-matter jurisdiction of a federal court. *See, e.g., Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992). Only persons "suffering legal wrong because of . . . , or adversely affected or aggrieved by" the challenged agency action are "entitled to judicial review thereof" under the APA. 5 U.S.C. § 702; *see also Sierra Club v. Morton*, 405 U.S. 727, 741 (1972). Plaintiffs are unable to meet these jurisdictional requirements for two reasons.

First, Plaintiffs' allegations that they suffer injury because the January 25 memorandum purportedly "commandeer[s]" state employees, Proposed 2d Am. & Suppl. Compl. ¶¶ 173-75, relies on a mischaracterization of the role of state survey agencies. The statute permits States to enter agreements with the Secretary to survey facilities' compliance with the conditions of participation in Medicare and Medicaid. These agreements are entirely voluntary. *See* 42 U.S.C. § 1395cc(a). States remain free to choose to operate as state surveyors or not to do so, at their preference.

Nor is Plaintiffs' assertion that the January 25 memorandum "impos[es] new conditions on States under the threat of lost funding," Proposed 2d Am. & Suppl. Compl. ¶ 112, remarkable, even if it were true (which it is not, because the memorandum imposes no requirements). The only "funding" that would be lost if a State declined to fulfill the role of a survey agency would be the compensation for the state surveyor activities themselves. *Contra Nat'l Fed'n of Indep. Businesses v.*

Sebelius, 567 U.S. 519, 584 (2012) (“NFIB”); see *Gruver v. La. Bd. of Supervisors for La. State Univ. Agric. & Mech. Coll.*, 959 F.3d 178, 184 (5th Cir.), *cert. denied*, 141 S. Ct. 901 (2020).

Second, although Plaintiffs insinuate that they are injured because the vaccination status of their survey staff renders it impossible for the States to comply with the memorandum’s expectations, they have not plausibly alleged any such injury. They fail to allege that they lack sufficient staff to perform onsite duties consistent with the memorandum’s expectations. The January 25 memorandum states that “[s]urveyors who are not fully vaccinated,” and are not persons for whom “vaccination is medically contraindicated” or who are “legally entitled to a reasonable accommodation under federal civil rights laws because they have a disability or sincerely held religious beliefs, practices, or observances that conflict with the vaccination requirement[,] should not participate as part of the onsite survey team performing federal oversight of certified providers and suppliers.” Jan. 25 Mem. at 2. The memorandum clarifies that such personnel “may be used, at the State Survey Agency’s or AO’s discretion, for offsite survey or enforcement activities.” *Id.* In the Proposed Amended Complaint, Plaintiffs nowhere allege that their Survey Agencies lack sufficient numbers of staff who are (1) vaccinated; (2) persons for whom “vaccination is medically contraindicated,” *id.*; or (3) “legally entitled to a reasonable accommodation under federal civil rights laws because they have a disability or sincerely held religious beliefs, practices, or observances that conflict with the vaccination requirement,” *id.*, to conduct the onsite surveys. See Proposed 2d Am. & Suppl. Compl. ¶ 131 (only vaguely alleging that “many” of Plaintiffs’ “employees tasked with performing these survey functions” “are not vaccinated against COVID-19 and do not wish to undergo the vaccination procedure”). This deficiency renders Plaintiffs’ challenge to the January 25 memorandum jurisdictionally lacking under both Article III and 5 U.S.C. § 702. See, e.g., *Lujan*, 504 U.S. at 560; *Sierra Club*, 405 U.S. at 740–41.

CONCLUSION

For the foregoing reasons, Plaintiffs’ Motion should be denied.

Dated: February 7, 2022

Respectfully submitted,

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EXHIBIT A

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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Center for Clinical Standards and Quality

Ref: QSO-22-10-ALL

DATE: January 25, 2022

TO: State Survey Agency Directors

FROM: Directors,
Quality, Safety & Oversight Group (QSOG) and Survey & Operations Group (SOG)

SUBJECT: Vaccination Expectations for Surveyors Performing Federal Oversight

Memorandum Summary

- ***CMS is committed to taking critical steps to protect vulnerable Americans to ensure America's health care facilities are prepared to respond to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).***
- ***While many State Survey Agencies and Accrediting Organizations (AOs) have taken early action to implement their own surveyor vaccination requirements, national guidance is necessary to maintain the safety of surveyors as well as of staff and patients/residents within the certified providers and suppliers they inspect as part of CMS' vital oversight and enforcement mission.***

Background

The Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE) presents a unique challenge for healthcare institutions and the surveyors charged with evaluating their compliance with Medicare requirements. Therefore, CMS is using every tool at our disposal to ensure these vital facilities are able to safely manage and care for their patients. CMS recognizes the importance of ensuring that surveyors who are charged with investigating compliance with Medicare and Medicaid health and safety requirements are also mitigating the risk of COVID-19.

Discussion

Previous CMS guidance (<https://www.cms.gov/files/document/qso-20-14-nh-revised.pdf>) highlighted the additional precautions necessary for surveyors when performing onsite inspections, including proper use of Personal Protection Equipment (PPE) and the prohibitions on entering facilities if symptomatic (such as fever, cough, sore throat, etc.). Current data (<https://data.cms.gov/covid-19/covid-19-nursing-home-data>) shows a strong correlation between the number of COVID-19 cases in nursing homes and lower staff vaccination rates. This demonstrates the importance of vaccination as a primary means for reducing the incidence and

spread of COVID-19 in health care facilities.

Guidance for State Survey Agency and Accrediting Organization Surveyors

CMS is expanding on the exclusionary criteria for all surveyors (including CLIA and Life Safety Code surveyors) entering provider and supplier locations to include vaccination status.

Surveyors who are not fully vaccinated (unless vaccination is medically contraindicated or the individual is legally entitled to a reasonable accommodation under federal civil rights laws because they have a disability or sincerely held religious beliefs, practices, or observances that conflict with the vaccination requirement) should not participate as part of the onsite survey team performing federal oversight of certified providers and suppliers (including accreditation surveys performed under an AO's deeming authority).

Unvaccinated personnel may be used, at the State Survey Agency's or AO's discretion, for offsite survey or enforcement activities.

Current performance and timeliness standards for State Survey Agencies and AOs remain, and consideration will not be provided for failures to meet these expectations due to a lack of vaccinated surveyors to complete the mandated workload.

States should have a process by which staff may request exemption from COVID-19 vaccination based on recognized clinical contraindications (<https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html#Contraindications>) or because they are legally entitled to a reasonable accommodation under federal civil rights laws because they have a disability or sincerely held religious beliefs, practices, or observances that conflict with the vaccination requirement (<https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws>). This process should clearly identify how an exemption is requested, and to whom the request is made. States should also have a process for collecting and evaluating such requests, including the tracking and secure documentation of information provided by those staff who have requested exemption, and the determination of the request, and any reasonable accommodations that are granted.

Surveyors who have a COVID-19 vaccination exemption, as identified above, may continue surveying while observing additional safeguards, as determined and documented by the state (such as mandatory testing, limitation to conducting survey activities that limit patient/resident contact such as record review, limitation to conducting offsite activities, or re-assignment or work modification). All surveyors are expected to use appropriate PPE while surveying.

Per the Centers for Disease Control and Prevention (CDC), individuals should be vaccinated regardless of a previous COVID-19 diagnosis because research has not yet shown how long individuals are protected from getting COVID-19 again after being infected. Also, vaccination helps protect individuals even if they have already had COVID-19. One study suggested that unvaccinated people who already had COVID-19 may be more than two times as likely as fully vaccinated people to get COVID-19 again¹. Anyone treated for COVID-19 with monoclonal antibodies or convalescent plasma should wait 90 days before getting a COVID-19 vaccine. For more CDC information on vaccines, see <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>.

¹ MMWR *Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination – Kentucky, May-June 2021* [Reduced Risk of Reinfection with SARS-CoV-2 After COVID-19 Vaccination — Kentucky, May–June 2021 | MMWR \(cdc.gov\)](https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6810a1.htm)

The State Survey Agencies and AOs are ultimately responsible for compliance with this expectation. **Therefore, certified providers and suppliers are not permitted to ask surveyors for proof of their vaccination status as a precondition for entry.** Providers and suppliers may have questions about the process a state or AO is using to implement this guidance, including verification of surveyor vaccination, mitigation expectations for unvaccinated staff with approved exemptions, and ensuring proper tracking of vaccination status. Those questions should be addressed to the State Survey Agency or AO. We encourage State Survey Agencies and AOs to proactively communicate with providers and suppliers about their efforts to implement this guidance.

This guidance applies to the state's activities in conducting federal program responsibilities under the 1864 Agreement.

Contact: Questions about this memorandum should be addressed to your CMS Location.

Effective Date: Within 30 calendar days of issuance. This policy should be communicated to all survey and certification staff and managers immediately.

/s/

Karen L. Tritz
Director, Survey & Operations Group

David R. Wright
Director, Quality, Safety & Oversight Group

cc: Survey and Operations Group Management
Office of Program Operations and Local Engagement (OPOLE)
Centers for Clinical Standards and Quality (CCSQ)