IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

STATE OF MISSISSIPPI, *et al.*,

Plaintiffs,

v.

XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, *et al.*,

Defendants.

Civil Action No. 1:22-cv-00113-HSO-RPM

REPLY IN FURTHER SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Plaintiffs' challenge to the rule fails at the threshold because Plaintiffs lack standing, and it is otherwise without merit because the challenged MIPS clinical practice improvement activity is not *ultra vires*. First, as to standing, after this Court denied Defendants' motion to dismiss, the Supreme Court held that a conflict between state and federal law does not suffice to establish a state's standing to challenge a federal policy, *Haaland v. Brackeen*, 143 S. Ct. 1609, 1640 (2023). Plaintiffs' attempt to distinguish *Brackeen* based on the nature of the claim alleged is unavailing. Second, Plaintiffs submitted no evidence of actual harm to meet their evidentiary burden as to standing at the summary judgment stage. Third, any theoretical harm would be traceable to the independent choices of clinicians, not to Defendant Centers for Medicare & Medicaid Services ("CMS").

As to the merits, the Court should reject Plaintiffs' effort to mischaracterize the rule as encouraging the creation of "racial-prioritization plans." The rule encourages clinicians to create and implement "anti-racism plans," which are designed to create health equity, not to prioritize the health of any individual or group of individuals. And Defendants previously showed that there is ample evidence in the Administrative Record, as well as outside the record, that this new activity meets the statutory definition, and Plaintiffs' arguments to the contrary misapply the canons of statutory construction and are without merit. Finally, the major questions doctrine does not apply to the creation of a single optional activity in the massive MIPS program.

ARGUMENT

I. PLAINTIFF STATES HAVE FAILED TO CARRY THEIR BURDEN TO ESTABLISH STANDING AT THE SUMMARY JUDGMENT STAGE

1. Plaintiffs' alleged injuries are not cognizable. Mem. in Support of Defs.' Cross-Mot. for Summ. J. at 8-10 (ECF No. 91) ("Defs.' Mem."). Just this summer, the Supreme Court

held that states lack standing to challenge federal actions based solely on a conflict between state and federal law. *Haaland v. Brackeen*, 143 S. Ct. 1609, 1640 (2023). Plaintiffs' attempt to distinguish *Brackeen* is unpersuasive. Although it is true that Texas brought a different legal claim in *Brackeen* than Plaintiffs bring here (an equal protection claim as opposed to an *ultra vires* claim), Pls.' Combined Reply in Supp. of Mot. for Summ. J. & Opp'n to Defs.' Cross-Mot. for Summ. J. at 12-13 (ECF No. 108) ("Pls.' Opp'n"), that is irrelevant to the standing analysis. The implication of Plaintiffs' novel argument that this Court is not bound by *Brackeen*'s holding because this case presents a different substantive claim is that, for example, lower courts would be bound by the imminence requirement of *Clapper v. Amnesty International, USA*, 568 U.S. 398, 410 (2013), only in cases with First and Fourth Amendment claims. *But see, e.g.*, *Crawford v. Hinds Cnty. Bd. of Supervisors*, 1 F.4th 371, 375 (5th Cir. 2021) (applying *Clapper* to ADA claim). In *Brackeen*, the Supreme Court held that Texas lacked a cognizable injury to challenge the Indian Child Welfare Act based on its allegation that the statute conflicted with the state's antidiscrimination law. 143 S. Ct. at 1640. Plaintiffs here allege the same injury with respect to the challenged rule—that it conflicts with their interest in their antidiscrimination laws. Thus, *Brackeen*'s limitation on state standing applies fully to Plaintiffs' challenge.

The rule announced in *Brackeen* is consistent with the "history and tradition" of federal jurisdiction. *Cf. United States v. Texas*, 143 S. Ct. 1964, 1970 (2023) (recognizing that for Article III jurisdiction, plaintiff's "asserted injury [must be] traditionally redressable in federal court"). The Supremacy Clause, Art. VI, cl. 2, instructs that "state law is naturally preempted to the extent of any conflict with a federal statute." *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372 (2000). It would be inconsistent with Article VI of the Constitution for federal courts to exercise Article III jurisdiction to hear challenges where the only alleged injury is a conflict between state

and federal law. *See Texas*, 143 S. Ct. at 1972 n.3 ("[F]ederal courts must remain mindful of bedrock Article III constraints in cases brought by States against an executive agency or officer.").

Plaintiffs' alleged injury is even more attenuated than the injury the Court refused to recognize in *Brackeen*. There, Texas was involved in enforcing the allegedly unlawful federal statute, but that was still not a sufficiently "concrete" and "particularized" injury. 143 S. Ct. at 1640. Here, Plaintiffs do not allege any involvement with enforcing the clinical practice improvement activity they allege would injure them. Accepting Plaintiffs' theory would effectively allow states to manufacture standing by interpreting state laws in a manner that conflicts with federal programs. *See id.* (criticizing injury theory where "a State would always have standing" to challenge federal policies); *see also Texas*, 143 S. Ct. at 1972 n.3 ("in our system of dual federal and state sovereignty," federal policies often have "indirect effects" without giving rise to state standing).

Plaintiffs also argue that they have a cognizable "interest in the health and 'economic well-being'" of their citizens that their state laws protect, Pls.' Opp'n at 5. But this is a *parens patriae* claim, and "a State does not have standing as *parens patriae* to bring an action against the Federal Government.'" *Brackeen*, 143 S. Ct. at 1640 (quoting *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 610 n.16 (1982)) (cleaned up). *Brackeen* abrogated the various Fifth Circuit cases that ignored *Snapp*'s clear statement, upon which this Court relied at the motion to dismiss stage.

Assuming without conceding that Plaintiffs' alleged injuries were cognizable under Fifth Circuit precedent when this Court decided Defendants' motion to dismiss, *Colville v. Becerra*, No. 1:22-cv-113, 2023 WL 2668513, at *15 (S.D. Miss. Mar. 28, 2023); *but see* Defs.' Mot. to Dismiss (ECF No. 37), *Brackeen* and *Texas* changed the law. This Court lacks jurisdiction to decide the

States' claim, because the States fail to allege an injury that survives *Brackeen*. No more is necessary to decide this case.

2. Even if a conflict between state and federal law could give rise to Article III standing in some instances, Plaintiffs have not introduced any *evidence* of an actual conflict here that causes a state harm. Defs.' Mem. at 10. "The plaintiff can establish standing at the summary judgment stage only by setting forth by affidavit or other evidence specific facts, which, taken as true, support each element of the standing analysis." *Ortiz v. Am. Airlines, Inc.*, 5 F.4th 622, 628 (5th Cir. 2021) (cleaned up and citation omitted). "General allegations," which were enough at the motion to dismiss stage, are no longer sufficient. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

The record contains no evidence of a "concrete" and "particularized" injury to any state. The only record evidence that Plaintiffs point to is the CMS Disparities Impact Statement ("DIS") mentioned in the challenged rule. Pls.' Opp'n at 14-15. But the DIS itself provides no evidence of a conflict with any state law, much less a conflict that causes concrete harm to a state. Plaintiffs have not introduced any evidence of clinicians creating and implementing anti-racism plans in their States, plans (or parts of plans) that conflict with state law, concrete harms experienced by Plaintiff States from any such plans, or harms experienced by Plaintiff States without allegedly conflicting state laws. *See id.* at 14 n.2 (identifying only five Plaintiff States with allegedly conflicting antidiscrimination laws).[1] Because Plaintiffs have not introduced any evidence to meet their burden to prove injury, the Court should grant Defendants' motion for summary judgment.

3. In any event, any injury resulting from a hypothetical conflict between the voluntary federal clinical practice improvement activity to create and implement an anti-racism

[1] The record also does not show that any of the Plaintiff States enforce their antidiscrimination laws against health care providers.

plan and state law would be traceable to the clinician who chooses to implement a plan that contravenes state law, not the challenged rule. Plaintiffs' allegations depend on "several layers of decisions by third part[y]" clinicians. *See Little v. KPMG LLP*, 575 F.3d 533, 541 (5th Cir. 2009). It is purely speculative that clinicians in Plaintiff States would choose to create anti-racism plans in a manner that conflicts with state law. And, contrary to Plaintiffs' assertion, Pls.' Opp'n at 15, such a conflict would not be a "predictable effect of" the challenged rule. As an initial matter, no clinician in any state must create an anti-racism plan. The challenged improvement activity is one of more than 100 MIPS improvement activities from which clinicians can choose, and they generally need only complete two to four such activities to receive full credit towards MIPS payment. 42 C.F.R. § 414.1380(b)(3). Moreover, nothing in the rule requires or encourages clinicians to create anti-racism plans that violate state antidiscrimination laws. Thus, there is no reason to predict that any clinician in the Plaintiff States who decides to develop an anti-racism plan would create a plan that violates state law. If a clinician were to make the independent choice to create a plan that conflicts with a state law, and that conflict caused a state harm, that harm would be traceable to the clinician rather than to Defendants.

4. The Court need not reach the issue of "special solicitude" because, as Plaintiffs do not dispute, "special solicitude" does not relieve states of their obligation to establish a cognizable injury in fact. *See* Defs.' Mem. at 11.

Still, Plaintiffs are not entitled to "special solicitude." The Court "should just leave that idea on the shelf." *Texas*, 143 S. Ct. at 1977 (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment). Plaintiffs' claim for "special solicitude" also fails on its own terms. Plaintiffs' alleged injuries are fundamentally unlike the "quasi-sovereign" injury in *Massachusetts v. EPA*, 549 U.S. 497, 518 (2007). *Massachusetts* involved an alleged invasion of a state's sovereign interest: its territory. *Id.* An alleged conflict between state and federal law does not

encroach on a state's sovereign prerogative in the same way, given that the Supremacy Clause resolves such disputes in favor of the federal government. Moreover, Plaintiffs lack the procedural right required for "special solicitude." The standing analysis in *Massachusetts* "do[es] not control" because "[t]he issue there involved a challenge to the denial of a statutorily authorized petition for rulemaking." *Texas*, 143 S. Ct. at 1975 n.6. Plaintiffs' *ultra vires* challenge is not an equivalent procedural right to challenge the improvement activity. *See generally id.* (rejecting states' APA challenge that federal policy was unlawful).

II. CMS'S PROMULGATION OF THE ACTIVITY TO CREATE AND IMPLEMENT AN ANTI-RACISM PLAN WAS NOT *ULTRA VIRES*

Even if Plaintiffs have standing, however, Defendants are still entitled to summary judgment because CMS's promulgation of the new activity to create and implement an anti-racism plan was not *ultra vires.* As Defendants previously showed, there is ample evidence in the Administrative Record, as well as outside the record, that the creation and implementation of an anti-racism plan has been identified by "relevant eligible professional organizations and other relevant stakeholders . . . as improving clinical practice or care delivery" and has been determined by CMS to be, "when effectively executed, . . . likely to result in improved outcomes." 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III). Therefore, adding the activity of creating and implementing an anti-racism plan to the MIPS improvement activities inventory—that is, providing a financial incentive to engage in such an activity—was well within CMS's statutory authority. Plaintiffs' arguments to the contrary are without merit.

1. Plaintiffs' merits arguments largely boil down to a mischaracterization of the rule. According to Plaintiffs, the rule unambiguously directs clinicians to create and implement "racial-prioritization plans" that prioritize the treatment of certain patients based on race or ethnicity. *See, e.g.,* Pls.' Opp'n at 1. But Plaintiffs cannot rewrite the rule to obtain an order invalidating it. The

rule CMS actually promulgated encourages clinicians to create and implement an "anti-racism plan" designed to create health equity, not to prioritize the health of any individual or group of individuals over others. As explained in the rule, an anti-racism plan can further health equity by, among other things, providing "ongoing training on anti-racism and/or other processes to support identifying explicit and implicit biases in patient care and addressing historic health inequities experienced by people of color" or "improv[ing] language access and accessibility to ensure services are accessible and understandable for those seeking care." 86 Fed. Reg. 64,996, 65,970 (Nov. 19, 2021), AR0005-0006.

Plaintiffs' effort to rewrite the rule is not based on the language of the rule itself, but rather on the DIS that CMS cited as one possible "planning tool[]" for creating an anti-racism plan, 86 Fed. Reg. at 65,969, AR00004. *See, e.g.*, Pls.' Opp'n at 8, 11, 14, 19. Plaintiffs' focus on the DIS and certain phrases in it is misguided. First, the rule does not require clinicians to use the DIS; instead, it explicitly permits clinicians flexibility to use "other anti-racism planning tools" when drafting their anti-racism plans. 86 Fed. Reg. at 65,969, AR00004.

Second, the DIS, as well as more generally any anti-racism plan developed by clinicians, is intended to focus clinicians' efforts on increasing access to health care for underserved populations (for which clinicians can receive enhanced payment under MIPS). These efforts do not require provision of lesser care to other populations served by those clinicians but seek to optimize access to care for everyone. Health equity, the goal of the anti-racism plan activity and of the DIS, means "the attainment of the highest level of health for *all* people, where everyone has a fair and just opportunity to attain their optimal health." *See* CMS Framework for Health Equity 2022-2023, at 1, https://perma.cc/SDM8-TBVJ ("CMS Framework") (emphasis added). Helping underserved populations achieve optimal health does not require a reduction in the services to other populations.

2. Plaintiffs' contentions that the anti-racism plan activity does not meet the statutory definition of "clinical practice improvement activity" are wrong for several reasons.

a. First, Plaintiffs are wrong that the anti-racism plan activity is not sufficiently similar to the kinds of activities listed as examples in the statute. Pls.' Opp'n at 19-20. They argue that the statutory examples focus on "improving care for patients generally, not a subset of them," whereas the challenged activity focuses on "prioritizing patients of one race over patients of another, all divorced from physiology." *Id.* Plaintiffs mischaracterize the purpose of an anti-racism plan, which is designed to create health equity, not to prioritize the treatment of certain races over others. Moreover, the anti-racism plan activity is not dissimilar to the statutory examples simply because it may focus on a "subset" of patients. At least one example in the statute, "the establishment of care plans for individuals with complex care needs," 42 U.S.C. § 1395w-4(q)(2)(b)(iii)(IV), also focuses on a subset of patients—those with complex care needs.

In any event, the doctrine of *noscitur a sociis* on which Plaintiffs rely is not applicable here because "[t]he subsections' disparate verbs and objects defy any attempt to group them together." *United States v. Fischer*, 64 F.4th 329, 346 (D.C. Cir. 2023). And, even if the doctrine did apply in these circumstances, Plaintiffs' identification of the purported common quality in the statutory list of activities—as "improving care for patients *generally*"—has no basis in the language of the statute. The definition of clinical practice improvement activity refers to activities that improve "clinical practice or care delivery," not to whether an activity must apply to all patients or a subset thereof, and the examples listed in the statute also do not specify general applicability. Indeed, other clinical practice improvement activities promulgated by CMS over the years focus on specific diseases or populations, such as, *e.g.*, "Diabetes Screening" "for people with schizophrenia or bipolar disease who are using antipsychotic medication," "Anticoagulant Management Improvements," or "Implementation of Integrated Patient Centered Behavioral Health Model" "to

support patients with behavioral health needs who also have conditions such as dementia or other poorly controlled chronic illnesses." *See* CMS, Traditional MIPS: Explore Measures and Activities, https://perma.cc/NT9A-LZLW. Plaintiffs do not seek invalidation of all these activities.

Plaintiffs argue that their view as to the significance of the statutory examples of clinical practice improvement activities should prevail to avoid constitutional concerns, which otherwise would arise if "*any* activity can be a clinical practice improvement activity." Pls.' Opp'n at 22-23 (emphasis supplied). But Defendants do not contend that the statute permits "*any* activity [to] be a clinical practice improvement activity." Rather, as the statute plainly provides, a clinical practice improvement activity must be an activity that "relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, is likely to result in improved outcomes." 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III). The doctrine of constitutional avoidance is a "tool for choosing between competing *plausible* interpretations of a statutory text." *Clark v. Martinez*, 543 U.S. 371, 381 (2005) (emphasis added). It does not permit Plaintiffs to convert Defendants' plausible interpretation into an implausible one based on a hyperbolic extension, and then ask the Court to reject Defendants' interpretation. Accordingly, the constitutional-avoidance doctrine has no applicability here. *Milavetz, Gallop & Milavetz, P.A. v. United States*, 559 U.S. 229, 239 (2010) (In applying the canon of constitutional avoidance, "we will consider only those constructions of a statute that are fairly possible.") (cleaned up and citation omitted).

b. Second, Plaintiffs argue that the anti-racism plan activity fails the statutory definition because relevant organizations did not identify this activity as improving clinical practice or care delivery "*before Defendants acted*," as allegedly required by the statute. Pls.' Opp'n at 20 (emphasis in original). But the comments appearing in the Administrative Record that identify this activity as improving clinical practice or care delivery (*see* Defs.' Mem. at 15) were

made *before the Secretary finalized the new activity* and hence were made before the Secretary's final decision.

There is no support in the language of the statute for Plaintiffs' alternative assertion that support by relevant organizations must be articulated before the Secretary even "proposed" the new activity. Pls.' Opp'n at 21. In any event, some of the materials relied on by the Secretary did promote anti-racism approaches before the Secretary proposed the new activity in July 2021. *See* AR2296; AR2282. And Plaintiffs' claim that the Secretary cannot propose an activity based on his understanding of "what professionals think" "before" those professionals formally identify an activity as improving clinical practice or care delivery (Pls.' Opp'n at 20) ignores that the Secretary and professionals often work simultaneously with one another to improve the healthcare system. *See* CMS Framework, at 7 (stating that CMS's health-equity efforts have been "informed by . . . years of stakeholder input, evidence review, and knowledge and understanding gained through the Agency's work").

Plaintiffs also mischaracterize Defendants' position as arguing that "any activity is a clinical practice improvement activity if relevant organizations say it's a good thing and the Secretary agrees." Pls.' Opp'n at 20 n.15. In fact, the statute does not grant the Secretary unfettered discretion in establishing improvement activities; rather, the statute requires the Secretary to find that an activity, "when effectively executed, is likely to result in improved outcomes." 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III). The Secretary made such a determination here, 86 Fed. Reg. at 65,969, and Plaintiffs do not meaningful challenge that fact.

c. Third, Plaintiffs argue that the anti-racism plan activity fails the definition of "clinical practice improvement activity" because commenters did not specifically say that anti-racism plans would *improve* clinical practice or care delivery, only that they *supported* the activity. Pls.' Opp'n at 21-22. Plaintiffs read the comments too narrowly, however. Those comments make

clear that organizations supported the anti-racism plan activity as a measure that would address health inequity, which leads to disparities in quality of care. *See* Am. Hosp. Ass'n, Equity of Care: A Toolkit for Eliminating Health Care Disparities, cited at AR0351 ("Adopting activities to enhance patients' access . . . is essential for reducing disparities and reaching the ultimate goal of building a health care system that delivers the highest quality of care to every patient . . . ."); AR0146 (comment by the Association of American Medical Colleges that the anti-racism plan activity will "address systemic racism as a root cause of inequity"); AR2296 (article stating that "actively working against racism, by evaluating curricula, practices, training models, behaviors, and actions through a lens of anti-racism" will address "systems that have structurally been designed to do harm").

3. There is also evidence outside the record, pre-dating the proposal of the new activity, that anti-racism programs are likely to improve treatment outcomes and hence "clinical practice or care delivery." Defs.' Mem. at 22 (citing Thatcher Declaration, ECF No. 62-9, which discusses a 2017 report). Plaintiffs' contention that the Court should disregard these materials outside the Administrative Record, Pls.' Opp'n at 17-18, should be rejected. Plaintiffs assert that one aspect of their *ultra vires* claim purportedly "arises under [section 706 of] the" Administrative Procedure Act ("APA") because they are asserting that the activity is "not in accordance with law" under 5 U.S.C. § 706(2)(A) or is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" under 5 U.S.C. § 706(2)(C). They therefore contend that section 706's limitation of review to the Administrative Record governs review of this aspect of their claim.

But Plaintiffs cannot have it both ways. They cannot avoid 42 U.S.C. § 1395w-4(q)'s jurisdictional bar on review of all claims (including APA claims) regarding the identification of

[2] Defendants' Memorandum at page 17 incorrectly identified this quote as appearing on AR1398.

clinical practice improvement activities by asserting an *ultra vires* claim while at the same time contending that their *ultra vires* claim must be adjudicated pursuant to the dictates of the APA. The Court's consideration of whether the anti-racism plan activity falls within the statutory definition of a clinical practice improvement activity is a question of statutory interpretation concerning the agency's jurisdiction and authority to regulate. For such claims, the Court's review is not limited to the factual record before the agency but rather is guided by standard statutory interpretation principles. *See City of Arlington, Tex. v. FCC*, 569 U.S. 290, 301 (2013) (addressing "questions about the scope of agencies' regulatory jurisdiction"); *see also Amgen, Inc. v. Smith*, 357 F.3d 103, 114, 117 (D.C. Cir. 2004) (addressing issues regarding the scope of the Secretary's equitable adjustment authority by analyzing the "plain text" of the statute). Therefore, courts routinely evaluate whether an agency has exceeded its statutory authority without being limited to the Administrative Record. *See generally Midship Pipeline Co., L.L.C. v. FERC*, 45 F.4th 867, 870 (5th Cir. 2022); *Indep. Turtle Farmers of La., Inc. v. U.S.*, 703 F. Supp. 2d 604, 621 (W.D. La. 2010). Although the Court need not reach this issue, as it can uphold the new activity based on the information included in the Administrative Record, it is not limited to those materials only here.

4. Finally, the major questions doctrine is not implicated here. The major questions doctrine applies only in "extraordinary cases" involving "major policy decisions" of "vast economic and political significance" with "assertions of extravagant statutory power over the national economy," *West Virginia v. EPA*, 142 S. Ct. 2587, 2608–09 (2022) (citation omitted), such as when an agency "claim[s] to discover in a long-extant statute an unheralded power representing a transformative expansion in its regulatory authority," *id.* at 2610 (citation omitted). In such extraordinary cases, an agency "must point to 'clear congressional authorization' for the power it claims," rather than a "merely plausible textual basis." *Id*. at 2609.

CMS's decision to add another voluntary activity to a list of more than 100 other such activities does not come remotely close to the "extraordinary cases" described by the Supreme Court, like the EPA's assertion of authority to regulate millions of sources that emit greenhouse gases, or OSHA's assertion of authority to require 84 million Americans either to obtain a COVID–19 vaccine or undergo weekly testing. *West Virginia*, 142 S. Ct. at 2608–09 (citing *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302 (2014), and *NFIB v. OSHA*, 142 S. Ct. 661 (2022)). But even if this case could be viewed as involving a "major policy decision[]" of "vast economic and political significance," it would not matter. Congress clearly gave the Secretary the authority to "establish" MIPS and to "develop a methodology for assessing" performance under MIPS, as well as to "identify" clinical practice improvement activities and "specify[] criteria for such activities." 42 U.S.C. § 1395w-4(q)(1)(A), (2)(C)(v)(I). And the anti-racism plan activity promulgated by the Secretary is not "novel" but rather like historical exercises of the same statutory authority, and is within the agency's expertise. For example, CMS has previously promulgated activities such as "Create and Implement a Plan to Improve Care for Lesbian, Gay, Bisexual, Transgender, and Queer Patients," "Participation in Population Health Research," "Practice Improvements that Engage Community Resources to Address Drivers of Health," and "Regular Review Practices in Place on Targeted Patient Population Needs," all of which are directed at improving health equity across populations. *See* https://perma.cc/NT9A-LZLW.

The case relied on by Plaintiffs, *Texas v. Becerra*, 575 F. Supp. 3d 701 (N.D. Tex. 2021), actually supports Defendants. Similar to the rule challenged here, the rule at issue in that case applied only to facilities that participate in Medicare and Medicaid; it required those facilities to establish policies and procedures for ensuring COVID-19 vaccination of certain staff in the facilities. The Supreme Court upheld the rule without reference to or application of the major questions doctrine, *Biden v. Missouri*, 142 S. Ct. 647 (2022) (per curiam).

III. ANY RELIEF MUST BE TAILORED ONLY TO REDRESS PLAINTIFFS' INJURIES

Plaintiffs cite only two binding authorities in attempting to rebut Defendants' argument that the APA does not authorize universal vacatur; neither case carries the day. Pls.' Opp'n at 25-26. In those cases, no party argued that the APA does not authorize universal vacatur. *See Data Mktg. P'ship, LP v. U.S. Dep't of Labor*, 45 F.4th 846, 859 (2022) (noting that the defendant agency "ma[de] no developed argument" that vacatur was not the proper remedy); Brief for Appellant, *Franciscan All., Inc. v. Becerra*, 21-11174 (C.A.5), (March 28, 2022). It is well established that "a panel's assumption"—that the APA permits universal vacatur—"'is not binding if the adverse party did not challenge and [the panel] did not consider' that issue." *Ochoa-Salgado v. Garland*, 5 F.4th 615, 619 (5th Cir. 2021) (collecting cases). This remains true even when the assumption was necessary to the decision. *See Lefebure v. D'Aquilla*, 15 F.4th 650, 657 (5th Cir. 2021), *cert. denied*, 142 S. Ct. 2732 (2022). Three Justices on the Supreme Court have recently recognized that there are "serious" arguments that the APA does not "empower[] courts to vacate agency action." *Texas*, 143 S. Ct. at 1980-83 (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment). The statute does not permit vacatur, for the reasons Defendants have explained. *See* Defs.' Mem. at 24-25.

Alternatively, if a remedy is appropriate and even if the Court holds that the APA authorizes vacatur, the Court should instead grant remand without vacatur. Plaintiffs do not dispute that vacatur of the rule could cause significant disruption by unexpectedly leaving clinicians facing lower reimbursement from HHS for the past payment years and the current payment year and potentially requiring Defendants to attempt to recoup spent funds. This disruption is sufficient to justify remand without vacatur. *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240,

270 (D.D.C. 2015) ("There is no rule requiring either the proponent or opponent of vacatur to prevail on both factors.").

Plaintiffs instead focus on whether Defendants will be able to cure any legal defect on remand. *See* Pls.' Opp'n at 25-26. Given the difficulty of predicting the specifics of any adverse order, Defendants respectfully suggest that, if the Court concludes that the challenged rule is unlawful and the disruption from vacatur Defendants have identified is not sufficient in itself to warrant remand without vacatur, the Court should permit the parties to file short supplemental briefs limited to the question of whether HHS can cure the identified legal defect(s).[3]

At a minimum, any necessary relief should be limited to the parties that prove an injury. Plaintiffs do not contest that vacatur of the rule in the Plaintiff States that have allegedly conflicting antidiscrimination laws would adequately redress those States' injuries. Pls.' Opp'n at 26. The Court should follow the normal rules of equity and tailor any remedy to address any proven injuries. *See, e.g.*, *Gill v. Whitford*, 138 S. Ct. 1916, 1933 (2018). Indeed, where "party-specific relief can adequately protect the plaintiff's interests," entering "broader relief is an abuse of discretion." *Texas*, 143 S. Ct. at 1980, 1986 (Gorsuch, J., concurring). To the extent Plaintiffs suggest that the meaning of "set aside" within the APA means to nullify an agency action universally, Defendants have explained why that is wrong. *See supra*; Defs.' Mem. at 24. There is ample precedent for setting aside agency action pursuant to Section 706(2) of the APA only as to the plaintiffs that have established standing. *See, e.g., GBX Assocs., LLC v. United States*, No. 1:22-CV-401, 2022 WL 16923886, at *18 (N.D. Ohio Nov. 14, 2022) (setting aside agency action only as to the plaintiff); *Skyworks, Ltd. v. CDC*, 542 F. Supp. 3d 719, 735-36 (N.D. Ohio 2021)

[3] As just one example, if the Court identifies a legal flaw with the Disparities Impact Statement, CMS may be able to address that issue by revising the Statement to remove language that the Court finds is problematic.

(noting that "the lack of a firm foundation for nationwide vacatur in the language, structure, and history of the [APA] is striking" and, accordingly, setting aside agency action only with respect to "the parties and their members"), *appeal dismissed*, No. 21-3563, 2021 WL 4305879 (6th Cir. Sept. 21, 2021); *cf. Virginia Soc'y for Hum. Life, Inc. v. FEC*, 263 F.3d 379, 394 (4th Cir. 2001) (holding that "[n]othing in the language of the APA" requires universal vacatur and directing the district court on remand to limit the scope of its permanent injunction to the plaintiff), *overruled on other grounds by Real Truth About Abortion, Inc. v. FEC*, 681 F.3d 544 (4th Cir. 2012). This Court should limit any vacatur to the Plaintiff States that have allegedly conflicting antidiscrimination laws.

Finally, Plaintiffs have abandoned their request for injunctive relief by not responding to Defendants' argument that the Court should not issue an injunction, Defs.' Mem. at 24. *See Kellam v. Servs.*, No. 3:12-CV-352-P, 2013 WL 12093753, at *3 (N.D. Tex. May 31, 2013) ("Generally, the failure to respond to arguments constitutes abandonment or waiver of the issue.") (citation omitted).

CONCLUSION

For the reasons set forth above and in Defendants' opening memorandum, Defendants are entitled to summary judgment, and Plaintiffs' motion for summary judgment should be denied.

Dated: October 19, 2023

Respectfully submitted,

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