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

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

FEDERAL STATUTES

STATE STATUTES

STATE CONSTITUTIONS

RULES

OTHER AUTHORITIES

INTRODUCTION

The States' challenge to a rule creating one of 106 voluntary clinical practice improvement activities fails on both jurisdictional and merits-based grounds.

As to Article III standing, the States claim, based largely on the Disparities Impact Statement, that the challenged rule encourages racial prioritization in violation of state law. But this Court already held that Statement was insufficient to establish an injury in fact and instructed the States on the evidence that they must adduce to carry their burden—actual plans from clinicians in a Plaintiff State that violate state law. *Mississippi v. Becerra*, 727 F. Supp. 3d 559, 586 (S.D. Miss. 2024). The States failed to uncover such evidence, so they ignore this Court's instructions; indeed, it is telling that the States fail to cite this Court's prior summary-judgment opinion even once in their Opposition and Reply ("Opp."), ECF No. 184. Instead, the States provide anodyne emails from Defendants encouraging clinicians to improve the care being delivered to individuals and groups experiencing substandard care, and two example plans that disclaim racial prioritization and pursue optimal health outcomes for all patients. In fact, one example from Arkansas implements a language-access plan as Arkansas's own Department of Health encourages. The States thus fail to show that the challenged rule conflicts with state law.

But even if the States could establish an injury based on language in the Disparities Impact Statement, which the challenged rule does not require clinicians to use, Defendants' subsequent revisions to the Statement resolve that injury and thus moot this case. The States do not dispute that the revisions unequivocally prohibit racial discrimination, and instead assert that clinicians will continue to rely on the outdated Statement. This speculation is baseless. The Centers for Medicare & Medicaid Services ("CMS") promulgated a bulletin informing clinicians and other stakeholders of the revisions, and CMS's website links only to the revised statement.

The States fare no better on the merits. The Court should reject the States' efforts to mischaracterize the rule as encouraging racial-prioritization plans because, as the example plans demonstrate, the rule encourages clinicians to pursue optimal health outcomes for all, not to prioritize the health of any particular group. And Defendants previously showed that there is ample

evidence in the administrative record, as well as outside the record, that this activity meets the statutory definition of a clinical practice improvement activity. Accordingly, the canon of constitutional avoidance cannot trump the plain meaning of the statute, and in any event, Defendants' construction does not raise constitutional concerns. Nor does the major-questions doctrine apply to the creation of a single optional activity in a massive program.

ARGUMENT

I. The States Have Not Carried Their Burden To Establish Article III Standing.

A. The States Fail To Establish An Injury In Fact.

The States fail to establish an injury in fact, continuing to assert that the challenged activity requires race prioritization in violation of state law without providing any of the supporting evidence that this Court instructed the States to provide. Mem. in Opp'n to Pls.' Mot. & in Supp. of Defs.' Cross-Mot. ("Defs.' Mem.") at 8-14, ECF No. 170. The States' efforts to rewrite this Court's summary-judgment opinion—without even once acknowledging that decision—and the applicable legal framework fail.

1. The States are wrong (Opp. 3-8) that the challenged activity encourages clinicians to prioritize patients based on race in violation of state law. *See* Defs.' Mem. 8-9. The States' claim (Opp. 3) that the Disparities Impact Statement "proves the States had standing in 2022" both misconstrues the Statement and, in any event, has already been rejected by this Court. *Mississippi*, 727 F. Supp. 3d at 587 ("[E]ven if a justifiable inference could properly be drawn from the Disparities Impact Statement that some races might in theory be prioritized over others in healthcare . . ., the Court is not persuaded this is sufficient on the present record for Plaintiffs to withstand summary judgment on the basis of standing."). Accordingly, the relevant question is whether the States have shown something more.

They have not. None of the "behind-the-scenes conduct" that the States cite (Opp. 5) comes close to an instruction for racial prioritization—rather, the documents reflect Defendants' efforts to encourage clinicians to address treatment disparities that the States do not dispute result in health outcome disparities. In context, for example, the CMS Health Equity Technical

Assistance emails that the States cite make clear that the Disparities Impact Statement is broadly intended to improve substandard treatments, not prioritize any particular race:

> This is a straightforward step-by-step worksheet that organizations of all sizes and types can use with a quality improvement/plan-do-study-act approach to reducing a disparity among those you serve. It walks you through how to find a disparity, set some goals, and plan and monitor an intervention to improve the care you're delivering to a particular group of patients.

ECF No. 167-8 at 211-12. In short, the emphasis is on improving substandard care, not prioritizing patients. Other emails likewise demonstrate that the "intervention for a particular population" the States reference (Opp. 5) is only one of many "possible solutions to address a disparity," including "training modules, and other strategies to improve the ability of your workforce to effectively treat the patients you serve." ECF No. 167-8 at 218-19. Indeed, the States even misleadingly excise (Opp. 5) language from Defendants' discovery responses to suggest that Defendants admitted they encourage clinicians to focus on "individuals of a particular race or ethnicity." But the response admits only "that a valid anti-racism plan . . . could include *the identification of a health disparity* that affects individuals of a particular race or ethnicity," and further specifies that "addressing disparities experienced by some individuals or some populations does not mean discriminating against or lessening treatment afforded to other[s]." ECF No. 167-7 (emphasis added).

The States also speculate (Opp. 4-5) that the challenged activity encourages clinicians to create the equivalent of "a suicide-prevention plan to prioritize 'white patients.'" But the challenged rule in fact calls for clinicians to identify and address "prioritized issues and gaps," AR0005, not particular racial groups. Indeed, the States' *evidence* refutes their hypothetical. As part of its long-term goal to create "equal healthcare for all," one sample plan states that one of the health disparities it intends to address is "mental health" and sets as a short-term goal to "implement access plans for . . . mental health." ECF No. 167-11 at 4-5. This demonstrates that mental health issues can be addressed through the challenged activity without racial prioritization.

The two sample plans that the States cite (Opp. 5-6) as engaging in racial prioritization do nothing of the sort. The first plan from an Arkansas clinician implements a language-access plan

that seeks to "train staff on translator app or software" to improve treatment for "patients whose primary language is Spanish." ECF No. 167-11 at 4, 8. The States do not argue that this violates state law, *see* Defs.' Mem. 9, and any attempt to do so would be baseless given Arkansas' own language-access program in health care. *See* Greensboro *Amicus* Br. at 10, ECF No. 177 (citing Ark. Dep't of Health, *Minority Health Resources: Language Assistance*, https://perma.cc/UKP3-5YV3). Instead, the States assert that whether "the clinicians ultimately picked means that would otherwise have been permissible . . . doesn't refute that the Rule provoked, at the outset, a race-based *intent*." Opp. 5. This makes no sense. The point of identifying example plans should have been to show—as this Court instructed the States to do—that clinicians in a Plaintiff State adopted "anti-racism plan[s] [that] violated that Plaintiff State's anti-discrimination laws." *Mississippi*, 727 F. Supp. 3d at 586. That clinicians implemented the challenged activity without violating the relevant State's law demonstrates that there is no actual conflict between the rule and State anti-discrimination law, and thus no injury *in fact*.

The States get no further with their second example plan. Defs.' Mem. 9-10. The States ignore that that plan expressly calls for "optimal health" for "everyone," as "[e]quity is not a zero-sum reality." *See* ECF No. 167-12 at 5-6. And the States make no effort to explain how a goal to "prioritize and integrate the voices and ideas of people and communities experiencing great injustice" effects racial discrimination. *Id.* at 6. Indeed, the States ignore how "equality" is an improper goal in the provision of health care because different medical conditions necessarily require different treatments. Defs.' Mem. 10. Straining for some link to racial prioritization, the States characterize (Opp. 6) this plan as "affirmative action." That is a misnomer for the types of interventions called for by that plan; as the plan itself illustrates, providing documents in larger print for individuals with low vision does not even affect—much less discriminate against—individuals without vision impairments. ECF No. 167-12 at 13. The same is true of other efforts to improve the care provided to individuals and groups that currently receive substandard care.

In any event, even if the States' evidence construing the challenged rule were credited, they could at most establish ambiguity as to whether the activity encourages racial prioritization. But

to the extent there is ambiguity, this Court must resolve that ambiguity in Defendants' favor. *Kisor v. Wilkie*, 588 U.S. 558, 573 (2019) (plurality op.) ("[W]e presume that Congress intended for courts to defer to agencies when they interpret their own ambiguous rules."). The States are incorrect (Opp. 3-4) that an agency must first invoke such deference because the proper construction of the challenged regulation goes to this Court's subject-matter jurisdiction, which cannot be waived. *Arbaugh v. Y&H Corp.*, 546 U.S. 500, 514 (2006) ("[S]ubject-matter jurisdiction, because it involves a court's power to hear a case, can never be forfeited or waived."). And even if this deference were invoked on the merits, it would not have been forfeited. "As the *Kisor* Court noted, deference under *Auer* is a 'presumption' regarding congressional intent." *Wolfington v. Reconstructive Orthopaedic Assocs. II PC*, 935 F.3d 187, 204 n.104 (3d Cir. 2019). "Thus, the burden rests on the party challenging the application of *Auer*," and "the relevant forfeiture" can only be that party's "failure to rebut the presumption of deference." *Id.*[1]

2. Absent an actual conflict between the challenged activity and any State's laws, the States fail to establish harm to their sovereign interests. Defs.' Mem. 11-14. In response, the States attempt (Opp. 8) to lower the bar such that they need "only show that their laws 'plausibly' or 'at least arguably conflict' with the" challenged rule. But that is not the law at the summary-judgment stage, as this Court already held. *Mississippi*, 727 F. Supp. 3d at 584 ("[E]ven if one were to construe the Rule as conflicting with any of State Plaintiffs' laws, 'what has traditionally counted as an injury to a sovereign interest does not include every act of disobedience to a state's edicts.'") (quoting *Harrison v. Jefferson Par. Sch. Bd.*, 78 F.4th 765, 770 (5th Cir. 2023)).[2] Regardless, the

[1] *Texas v. Biden*, 20 F.4th 928, 961 (5th Cir. 2021), *rev'd and remanded*, 597 U.S. 785 (2022), is not to the contrary. That case addressed deference to agency interpretations of statutes under the Supreme Court's now-abrogated decision in *Chevron, USA, Inc. v. NRDC*, 467 U.S. 837 (1984), which rested on different bases and operated differently than *Kisor*/*Auer* deference.

[2] The States bizarrely describe *Harrison* as Defendants' "lead case." Opp. 9. But that is the authority that this Court relied on to set the standard for sovereign injury, *Mississippi*, 727 F. Supp. 3d at 584, at the States' own behest, having cited *Harrison* extensively during the prior round of summary-judgment briefing, *see* Pls.' Reply and Opp. at 1, 12, 13, ECF No. 108. Both this Court and the States (previously) were correct to rely on that authority: *Harrison*'s articulation of what constitutes a sovereign injury did not turn on the identity of the defendant. Defs.' Mem. 11-12.

States cannot clear even the lower bar they set for themselves: given that one of the States' two examples seeks to implement a language-access plan just as the relevant State Plaintiff (Arkansas) encourages, there is not even a plausible conflict here.

The States are also unsuccessful in their efforts (Opp. 9-10) to distinguish *Haaland v. Brackeen*, 599 U.S. 255 (2023), which forecloses their assertion of injury. Although it is true that Texas brought a different legal claim in *Brackeen* than the States bring here (an equal protection claim as opposed to an *ultra vires* claim), the claim asserted is not relevant to the cognizability of a plaintiff's injury. Indeed, if the States were correct that an analysis of injury turned on the claim asserted, 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. That is not the law. *See, e.g.*, *Crawford v. Hinds Cnty. Bd. of Supervisors*, 1 F.4th 371, 375 (5th Cir. 2021) (applying *Clapper* to Americans with Disabilities Act claim).

Instead, it is the type of injury asserted that is relevant to Article III standing. And the States here assert the exact same injury as Texas in *Brackeen*: an alleged conflict between the challenged federal statute (here, a federal regulation) and state law prohibiting discrimination. *See* Br. for Pet'r at 41, *Haaland v. Brackeen*, No. 21-376 (U.S. May 26, 2022) ("ICWA's placement preferences prevent Texas from enforcing [Tex. Fam. Code § 162.015(a)] when Indian children – or non-Indians seeking to foster or adopt such children – are involved in those proceedings."); Reply Br. for Pet'r at 14-15, *Haaland v. Brackeen*, No. 21-376 (U.S. Oct. 3, 2022) ("This injures Texas by requiring it to break its promise to its citizens that it will be colorblind in child-custody proceedings. *See* TEX. CONST. art. I, § 3a; Tex. Fam. Code § 162.015(a)."). As the Supreme Court held in *Brackeen*, "this is not the kind of 'concrete' and 'particularized' 'invasion of a legally protected interest' necessary to demonstrate an 'injury in fact.'" 599 U.S. at 295. So too here.[3]

[3] The States argue (Opp. 10) that Defendants "conflate" the sovereign-injury theory of standing with the bar on *parens patriae* standing. It is the States, however, who conflate the various holdings in *Brackeen*, attempting to group them all under the *parens patriae* bar. While it is true that the Supreme Court rejected Texas's assertion of "equal protection claims on behalf of its

Finally, the States (Opp. 10-11) assert as distinct injuries "preemption" and "'federal assertions of authority to regulate matters' traditionally left to the States." But the States do not dispute that these injuries require a conflict between federal action and state law. *See* Defs.' Mem. 12-13. These auxiliary injuries therefore rise and fall with the States' ability to establish an actual conflict, which they fail to do. Thus, these alleged injuries do not independently confer standing.

B. The States Fail To Establish Redressability And Traceability.

The States also fail to establish an injury in fact traceable to the challenged improvement activity and redressable by the relief sought. Defs.' Mem. 14-17. To begin, the States are wrong (Opp. 12-13) that no heightened showing is necessary on these prongs. As the Supreme Court has instructed, "[w]hen . . . a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else,* much more is needed." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992). That is indisputably the case here, as states do not complete clinical improvement activities. The States nonetheless attempt (Opp. 12-13) to cabin this doctrine to the facts of *United States v. Texas*, 599 U.S. 670, 678 (2023), in which the plaintiff states asserted an injury in the form of costs. But the heightened-showing requirement originates in *Lujan*, a case that did not involve a cost-based injury whatsoever. *Texas* instead stands for a different proposition independent of the injury asserted: that the heightened-showing requirement for traceability and redressability trumps any leniency on those elements of standing that the States may claim under the special solicitude doctrine. Defs.' Mem. 16-17. The States cannot make that heightened showing here because any violations of state law are traceable to unlawful decisions of particular clinicians, not the challenged activity.

The States respond (Opp. 11) that their asserted injury does not depend on clinicians engaging in racial discrimination, but instead concerns only the enforceability of state laws. The Court's prior summary-judgment opinion forecloses this argument. If the States could establish

---

citizens" as an impermissible *parens patriae* claim, the Court separately addressed a distinct injury—that the challenged statute prevented Texas from enforcing its own law—and held that injury insufficient to confer standing. 599 U.S. at 294. That holding controls, and adopting it does not require this Court to conclude that *Brackeen* implicitly overruled Supreme Court precedent.

an injury by asserting that the challenged rule infringed on the enforceability of a state's law, this Court would not have denied the States' motion for summary judgment for lack of standing with instructions to adduce evidence of clinicians that in fact "violated that Plaintiff State's anti-discrimination laws . . . as they would be enforced by that State." *Mississippi*, 727 F. Supp. 3d at 586. Thus, as this Court has already held, the States are wrong that "the Rule causes injury even if no 'clinician created a discriminatory anti-racism plan in violation of state law.'" Opp. 11.

This Court's prior summary-judgment decision also forecloses the States from relying (Opp. 12) on language in the Court's motion-to-dismiss decision. While standing may exist at the motion-to-dismiss stage based "on the predictable effect of Government action on the decisions of third parties," *Colville v. Becerra*, No. 1:22-cv-113, 2023 WL 2668513, at *17 (S.D. Miss. Mar. 28, 2023) (citation omitted), it is now necessary for the States to establish through evidence that the alleged violations of state law were caused by the challenged activity. *Mississippi*, 727 F. Supp. 3d at 586. But the States fail to show that, even assuming their two examples violated state law (they do not), those violations are the result of instructions in the challenged improvement activity rather than the unlawful decisions of particular clinicians. The States have therefore failed to establish traceability and redressability.

II. Even If The States Could Establish Standing Based On The Disparities Impact Statement, Revisions To That Statement Would Render This Action Moot.

If the States establish standing based only on the likelihood that clinicians will construe (or have construed) the former Disparities Impact Statement as encouraging racial prioritization, this action is now moot because CMS has issued a revised Statement and accompanying bulletin foreclosing any such construction. Defs.' Mem. 17-19. Indeed, the States do not dispute that the revised materials unequivocally prohibit racial prioritization. *See* Declaration of Susan Hill ("Hill Decl.") ¶¶ 3, 7-9, ECF No. 169-1. The States nonetheless quibble (Opp. 13-14) over which version of the Statement is operative, claiming that clinicians will still use the prior version.

The States are wrong that there exists any ambiguity as to whether the Statement has been formally revised. As the Hill Declaration explains, CMS released a revised Disparities Impact

Statement as part of its regular cycle of review of available resources and publicized the release of that update through an accompanying bulletin. Hill Decl. ¶¶ 5-6. Moreover, CMS's website links only to the revised version, which became the "CMS Disparities Impact Statement" as of August 20, 2024. *See* CMS, *Quality Improvement & Interventions*, https://www.cms.gov/priorities/health-equity/minority-health/resource-center/health-care-professionals-researchers/quality-improvement-interventions (last visited Jan. 6, 2025). And the States do not dispute that Defendants, "as governmental entities," are "presume[d]" to "act in good faith" when changing challenged conduct. *FFRF v. Abbott*, 58 F.4th 824, 833 (5th Cir. 2023).

That the outdated Statement still exists in the administrative record (Opp. 13-14) is irrelevant. The States offer no basis to conclude that a clinician intending to use the Statement to complete the challenged activity would sift through this Court's docket to uncover the prior Statement in the administrative record instead of utilizing the revised Statement that CMS maintains on its website. Nor does the challenged rule itself require clinicians to use any particular version of the Statement (or, indeed, any specific tool at all)—it refers only to the "CMS Disparities Impact Statement," AR0005-6. The revised version is now that Statement. In any event, CMS releases every year a new improvement activity inventory with a description of the activity referencing, in the case of the challenged activity, the Statement. *See* ECF No. 167-8 at 4, 21 (2023 Improvement Activities inventory). Thus, any clinician completing the activity in the future will refer to the future Improvement Activities inventory and, if that clinician wants to use the Statement to complete the improvement activity, will use the revised Statement referenced in the inventory. The revised Statement therefore renders moot the States' action insofar as it is premised on the prior Statement. *FFRF*, 58 F.4th at 832 ("[T]his case is moot because the [plaintiff's] asserted injury was tied to the existence of the" now-closed forum.).

The States' authorities (Opp. 13-14) do not compel a different result. In *Pool v. City of Houston*, the Fifth Circuit emphasized that "[t]here is no evidence that" the defendant "approved the . . . form published on the City's website, so we do not know how permanent—or legally effective—the new form and editor's note are." 978 F.3d 307, 314 (5th Cir. 2020). Here, there is

no dispute of fact that CMS revised the Statement. Hill Decl. ¶¶ 6-9. And in *Speech First, Inc. v. Schlissel*, the defendant "ha[d] not affirmatively stated that it does not intend to reenact the challenged definitions." 939 F.3d 756, 769-70 (6th Cir. 2019). Here, CMS has submitted a sworn declaration attesting that "CMS has no intention of instructing clinicians to deny resources or interventions to patients based on a person's race, color, national origin, sex, age, or disability, or to otherwise engage in unlawful discrimination." Hill Decl. ¶ 9. Accordingly, even if the prior Statement could be read to instruct clinicians to engage in racial prioritization (and it should not be), it is certain that the prior Statement's instructions will not be reimplemented.[4]

III. The Challenged Improvement Activity Is Lawful.

The challenged improvement activity falls squarely within the statutory definition of a clinical practice improvement activity because (1) it was identified by "relevant eligible professional organizations and other relevant stakeholders . . . as improving clinical practice or care delivery," and (2) it 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). The States' four arguments to the contrary are incorrect, *see* Defs.' Mem. 19-26, and the States' efforts to rehabilitate those arguments are unavailing.

a. The States' insistence (Opp. 16-17) that the challenged improvement activity cannot satisfy the statutory requirements because it does not resemble the statute's examples is both irrelevant and incorrect. It is irrelevant because the States identify no language in the statute that requires a clinical practice improvement activity to resemble one of the enumerated examples to qualify, and the inclusive statutory language refutes any such construction. *See* Defs.' Mem. 21. The States are also incorrect (Opp. 17) that the challenged activity does not aim to "improve

[4] The Fifth Circuit's instruction in *Dierlam v. Trump* for lower courts to avoid conflating the merits with mootness concerned the motion-to-dismiss stage where a court "need only ask whether the plaintiff's requested relief is 'so implausible that it may be disregarded on the question of jurisdiction.'" 977 F.3d 471, 477 (5th Cir. 2020). That plausibility standard has no relevance at the summary-judgment stage, as the States now must adduce competent evidence to create a dispute of fact. Fed. R. Civ. P. 56(a). In any event, determining that the revised Statement remedies any injury attributable to the prior Statement is a jurisdictional, not merits-based, holding.

'clinical practice or care delivery.'" The States do not dispute that there exist significant treatment disparities resulting in sub-optimal health outcomes for many patients. *See* Defs.' Mem. 22; AR2296 (Black patients are less likely to have their symptoms and pain correctly diagnosed); AR2287 (certain algorithms used in kidney diagnoses overstate kidney function in Black patients, resulting in higher rates of end-stage kidney disease); AR0502 (rural residents receive worse clinical care for colorectal screening). Nor do the States dispute that the challenged improvement activity will help clinicians address those treatment—and therefore those outcome—disparities. Defs.' Mem. 22. Accordingly, the challenged activity improves both clinical practice and care delivery. To take just one example in the administrative record, a plan could educate clinicians on treatment algorithms that overstate kidney function in Black patients, decreasing reliance on those algorithms and improving treatment to prevent end-stage kidney disease. *See* AR2287.[5]

For this reason, the States err (Opp. 17-18) in analogizing the challenged improvement activity to SEC rules that required disclosures about the diversity characteristics of companies' directors and set diversity objectives. When holding those rules unlawful, the Fifth Circuit determined that the SEC failed to establish that those rules "protect[ed] investors or the public from the kinds of harms that the Exchange Act explicitly lists as its targets—that is, speculation, manipulation, fraud, anticompetitive exchange behavior." *All. for Fair Bd. Recruitment v. Sec. & Exch. Comm'n* (*AFBR*), --- F. 4th ----, 2024 WL 5078034, at *13 (5th Cir. Dec. 11, 2024). Here, the record amply demonstrates that the challenged activity serves the statutorily prescribed purpose of "improving clinical practice or care delivery" and "improv[ing] outcomes." 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III).

Although not necessary to refute the States' argument, evidence outside the administrative record—including evidence that predates the proposal of the challenged activity—further confirms

[5] Instead of engaging with any of these materials in the administrative record, the States construct (Opp. 18) a strawman, claiming "race-based targets are too far removed . . . to count as clinical practice improvement activities." But the States cite nothing that resembles a "race-based target"—rather, as their own evidence explains, "[e]quity," the goal of the challenged activity, "is not a zero-sum reality that continues to create a set of winners and losers." ECF No. 167-12 at 6.

the challenged activity will improve the quality of clinical care and health outcomes. Defs.' Mem. 22-23. The States do not engage with this evidence, instead arguing (Opp. 15-16) that it is not properly before the Court because the States have purportedly brought an APA claim, not a stand-alone *ultra vires* claim. But the States themselves chose to style their complaint as alleging only "one claim: the [challenged activity] is ultra vires." Plfs.' Mem. in Supp. of Mot. for Summ. J. at 6, ECF No. 79. In any event, the Court's consideration of whether the anti-racism plan improvement 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. *See City of Arlington v. FCC*, 569 U.S. 290, 301 (2013) (addressing "questions about the scope of agencies' regulatory jurisdiction"). Therefore, courts routinely evaluate whether an agency has exceeded its statutory authority without being limited to the administrative record. *See generally Midship Pipeline Co. 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).

b. The States are also wrong (Opp. 18-19) that relevant stakeholders did not identify the challenged activity as improving clinical practice or care delivery. Numerous organizations supported creation of the challenged activity, *see* Defs.' Mem. 23-24, and the Intersocietal Accreditation Commission specifically "recommend[ed] [its] inclusion," AR0215. This is precisely the endorsement of the "*means* expressly incorporated into the Rule," Opp. 19, that the States claim is lacking. *See also* Suppl. AR2421 (comment by Association of Black Cardiologists, Inc. supporting the improvement activity because "[e]veryday racism . . . in health care[] results in higher rates of coronary heart disease, diabetes, stroke and end-stage renal disease"). The States nonetheless assert (Opp. 18) that the authorities on which the Secretary relied supported "anti-racism approaches," not "plans that prioritize patients based on race or ethnicity." But this amounts to a concession by the States—as Defendants have explained, Defs. Mem. 10, the challenged improvement activity is precisely such an "anti-racism approach," not a prioritization scheme.

Nor may the States transform the Court's motion-to-dismiss order into a summary-judgment ruling on the administrative record. This Court at the motion-to-dismiss stage did not consider any organization's endorsement of the challenged activity, and instead evaluated only "an article by Camara Phyllis Jones and . . . a CDC webpage," *Colville*, 2023 WL 2668513, at *20. Those materials are a far cry from the extensive expressions of support from stakeholders in the administrative record, *supra* p. 12.

c. The canon of constitutional avoidance does not apply here. As an initial matter, the States have not presented a plausible construction of the statute that would prohibit the challenged activity. Defs.' Mem. 25. Because (1) "relevant eligible professional organizations and other relevant stakeholders" identified the challenged activity "as improving clinical practice or care delivery," and (2) CMS determined that the activity, "when effectively executed," is "likely to result in improved outcomes," 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III), the challenged activity satisfies the plain meaning of the statute. And that plain meaning controls. *See Jennings v. Rodriguez*, 583 U.S. 281, 298 (2018) ("Spotting a constitutional issue does not give a court the authority to rewrite a statute.").

Moreover, the premise of the States' argument—that Defendants' construction of the statute "'could' permit race preferences in medicine if stakeholders and Defendants say they're a good thing or would reduce disparities," Opp. 19—is wrong. The statute requires more than a determination that the proposed activity "is a good thing or would reduce disparities," and the record establishes that more has been provided here. *See* AR0005 (CMS determination that the proposed activity is likely to result in improved outcomes).

To shoehorn in the canon nonetheless, the States misconstrue the final rule as requiring "race preferences" to assert Defendants' construction must raise constitutional issues. But the final rule does no such thing. Unlike in the zero-sum university admissions context the States invoke repeatedly (Opp. 19-20), improving treatment for individuals and groups currently experiencing treatment disparities does not require denying or limiting treatment to anyone else. *See, e.g.*, Defs.' Mem. 10. Indeed, in asserting that the challenged rule requires racial prioritization, the States

misleadingly suggest that the prior Disparities Impact Statement encourages physicians *only* to "promote health equity for racial and ethnic minorities." Opp. 20 (quoting AR2247). But the actual sentence in the prior Statement does not stop there: it continues to list "people with disabilities, sexual and gender minorities, individuals with limited English proficiency, and rural populations." AR2247. This makes clear that the challenged rule, as Defendants have explained, promotes "the consistent and systematic fair, just, and impartial treatment of *all individuals*." AR0003 (emphasis added). Thus, the challenged rule does not require clinicians to prioritize any race and does not raise constitutional concerns.

d. The States' invocation of the major-questions doctrine similarly misses the mark because the challenged improvement activity does not involve a major policy decision of vast economic and political significance. Defs.' Mem. 25-26. In response, the States rely heavily (Opp. 20-21) on *AFBR*, in which the Fifth Circuit applied the major-questions doctrine when considering mandatory disclosure rules that all companies listed on the Nasdaq stock exchange would be required to follow, 2024 WL 5078034, at *1. But the Fifth Circuit in that case emphasized that those rules "come close to regulating 'the entire economy'" because they "attempt to transform the internal structure of many of the largest corporations." *Id.* at *16. The States here, on the other hand, challenge a rule creating one out of more than 100 *voluntary* activities that clinicians *may* complete for credit towards a *fraction* of those clinicians' overall MIPS score, which in turn *may* result in fractional adjustments to Medicare payments. *See* Defs.' Mem. 3. The attenuated economic impact of the challenged rule pales in comparison to Nasdaq disclosure requirements.

The States also claim (Opp. 20-21) that the doctrine applies whenever agency action "intrudes into an area that is the particular domain of state law" in reliance on *Alabama Association of Realtors v. HHS*, 594 U.S. 758 (2021) (per curiam). But that case involved an eviction moratorium that implicated "[a]t least 80% of the country," *id.* at 764, and the Supreme Court did not purport to hold that every statutory construction implicating health, the medical profession, or private discrimination presented a major question. Indeed, if the States' contention were correct, the major-questions doctrine would apply whenever a court reviews any HHS regulation involving

Medicare and Medicaid. That is not and cannot be the law. *See, e.g.*, *Biden v. Missouri*, 595 U.S. 87 (2022) (per curiam) (declining to apply major-questions doctrine to Medicare and Medicaid vaccine rule despite plaintiffs' heavy reliance on the doctrine); Defs.' Mem. 26.

IV. Any Relief Must Be Tailored To Redress Only The States' Proven Injuries.

a. If the States prevail on summary judgment, relief should be limited to a declaratory judgment determining that the challenged activity is unlawful because that relief would fully remedy the States' proven injuries and broader relief would therefore violate principles of equity and Article III. Defs.' Mem. 26-27. The States' sole response (Opp. 22) is to note that vacatur is the "default" remedy under the APA. Even if the APA applied to the States' *ultra vires* claim (and it does not, *supra* p. 12), the APA did not displace foundational principles of equity. Congress explicitly reserved in the APA "the power or duty of the court to . . . deny relief on any . . . equitable ground." 5 U.S.C. § 702(1). Accordingly, that vacatur is the "default" remedy does not mean it is always required. *See, e.g.*, *Cent. & S.W. Servs., Inc. v. EPA*, 220 F.3d 683, 692 (5th Cir. 2000) (declining to enter vacatur in favor of remand).

Here, principles of equity and Article III preclude vacatur because that relief would be broader than necessary to remedy the States' alleged injuries. *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 353 (2006) ("'remedy must . . . be limited to the inadequacy that produced the injury in fact that the plaintiff has established'"). Indeed, another district court in the Fifth Circuit recently refused to vacate agency regulations implementing a statutory provision that the court found unconstitutional, and instead enjoined the agency from enforcing that provision. *Nuziard v. Minority Bus. Dev. Agency*, 721 F. Supp. 3d 431, 501 (N.D. Tex. 2024). In doing so, that court chose to "exercise[] its equitable discretion to decline a remedy with nebulous authority in favor of remedies with clear authority." *Id.* The States do not dispute that declaratory relief would function as an injunction here because it would prevent Defendants from prospectively infringing on state law by granting credit for the challenged activity. *See* Defs.' Mem. 26-27. This Court should therefore follow an approach that tracks that taken in *Nuziard* and decline to vacate the challenged rule.

b. If this Court grants relief beyond a declaratory judgment, it should remand without vacatur because Defendants could remedy the deficiency on remand and because vacatur would cause significant disruptive consequences. *See* Defs.' Mem. 27-28.[6] As to the likelihood that Defendants could fix the challenged rule on remand, the States argue (Opp. 23) only that the challenged rule "incorporates the Disparities Impact Statement and therefore expressly permits race-prioritization plans." But even if the States are correct (they are not), this illustrates precisely how the challenged rule could be remedied: Defendants could clarify that clinicians may not use the prior Statement to obtain credit for completing the improvement activity and may instead use the revised Statement, which unequivocally prohibits racial prioritization.

The States are similarly wrong (Opp. 23) that vacatur would not be disruptive. Even if vacatur were prospective such that CMS would not be required to recoup already-distributed funds, vacatur would waste the resources of clinicians who already completed the improvement activity for the year in which vacatur took effect. Remand without vacatur is the appropriate remedy in those circumstances. *Am. Great Lakes Ports Ass'n v. Schultz*, 962 F.3d 510, 519 (D.C. Cir. 2020) ("remand without vacatur . . . is appropriate when vacatur would disrupt settled transactions").

c. Finally, and even if this Court vacates the challenged rule, this Court should specify that vacatur is prospective only to avoid potentially requiring Defendants to recoup prior payments. *See* Defs.' Mem. 27-28. The States concede the propriety of such a limitation, acknowledging that the vacatur they seek "wouldn't take effect until 2025 at the earliest," Opp. 23.

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.

[6] The States argue (Opp. 23) that Defendants must satisfy both factors to obtain remand without vacatur. But an "opponent of vacatur" need not "prevail on both factors." *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 270 (D.D.C. 2015). *Cent. & S.W. Servs.*, 220 F.3d at 692, is not to the contrary because that court did not consider whether a strong showing on one factor would be sufficient. In any event, Defendants satisfy both factors here.

Dated: January 16, 2025

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General

MICHELLE BENNETT
Assistant Director, Federal Programs Branch

/s/ Alexander W. Resar
ALEXANDER W. RESAR
Trial Attorney
U.S. Department of Justice
Civil Division, Federal Programs Branch
1100 L Street, NW, Washington D.C. 20005
Tel: (202) 616-8188
alexander.w.resar@usdoj.gov

Counsel for Defendants