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

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT AND IN SUPPORT OF DEFENDANTS' CROSS-MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

Seven state Plaintiffs (the "States") challenge a rule promulgated by the Centers for Medicare & Medicaid Services ("CMS") implementing part of the Merit-based Incentive Payment System ("MIPS") for physician payments under Medicare Part B. Physicians who elect to participate in MIPS in 2024 may select from a list of 106 clinical practice improvement activities to qualify for payment enhancement. The States challenge a rule establishing one of those activities, "create and implement an anti-racism plan." *See* Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes, 86 Fed. Reg. 64,996, 65,969 (Nov. 19, 2021), Administrative Record (AR) 0001, 0004. This activity encourages clinicians to create and implement a plan to address health outcome disparities.

The States' challenge to this activity is premised on a fundamental mischaracterization—that the activity encourages or even requires racial prioritization and discrimination. Nothing in the final rule itself supports this conception of the challenged activity. Instead, the States grasp at the definition of "anti-racism" used by an unrelated scholar, who CMS never cited at any point in the rulemaking process, and language in an auxiliary document, the Disparities Impact Statement. But the Disparities Impact Statement is a voluntary aid that clinicians may use to assist with the challenged activity and, in any event, has since been updated to clarify that it prohibits discrimination. Accordingly, when evaluated in light of the record, the anti-discriminatory purpose of the final rule is clear: to aid clinicians in promoting health equity and eliminating the treatment disparities that contribute to the suboptimal health outcomes that certain patients and populations experience. Put simply, improving the health of patients and populations experiencing suboptimal health outcomes does not impair the health of other patients and populations. As one example plan explains, "[e]quity is not a zero-sum reality that continues to create a set of winners and losers in health." ECF No. 167-12 at 5.

The States' mischaracterization of the challenged activity undermines every aspect of the States' action, from this Court's jurisdiction to the merits:

First, as to Article III standing, the States' theory of injury rests on an asserted conflict between state antidiscrimination laws and the challenged activity. But the States adduce no evidence that clinicians have discriminated against any patients in violation of state law by creating or implementing anti-racism plans, and the States thus cannot establish standing. Indeed, after denying the States' prior motion for summary judgment, this Court authorized jurisdictional discovery for the States to prove that the activity necessarily entails racial discrimination. The States adduce no such evidence, and instead invoke the same words in the outdated Disparities Impact Statement that this Court held insufficient to confer standing. For the reasons this Court already gave, the States cannot obtain an advisory opinion on the legality of a caricature.

Second, and even if the States could establish a traceable injury necessary to confer Article III standing at the time the suit was filed, the subsequent revisions to the Disparities Impact Statement resolve that injury, rendering this action moot. Those revisions clarified that the Statement is intended to "improv[e] the health of all people" and that any interventions taken pursuant to the Statement must be available to all patients, "without regard to a person's race, ethnicity, color, national origin, sex, age, or disability." Declaration of Susan Hill, Ex. B at 1-2.

Third, on the merits, the States fall well short of the high bar necessary to establish that CMS violated a clear statutory mandate and therefore acted *ultra vires*. To the contrary, there is ample evidence in the record that the creation and implementation of an antiracism plan satisfies both statutory requirements: (1) "relevant eligible professional organizations and other relevant stakeholders" identified the 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).

For these reasons, explained further below, Defendants are entitled to summary judgment.

BACKGROUND

I. Statutory And Regulatory Background

In 2015, to "improv[e] Medicare payment for physicians' services" under Medicare Part B, Congress directed the United States Department of Health and Human Services ("HHS") to

create a "Merit-based Incentive Payment System" for payments for covered professional services furnished by MIPS eligible professionals on or after January 1, 2019. Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), Pub. L. No. 114-10, § 101(c)(1), 129 Stat. 87, 92-93 (2015), *codified at* 42 U.S.C. § 1395w-4(q). Specifically, Congress directed that HHS link payments to performance in four categories related to the quality and cost of patient care provided by the MIPS-eligible professional: quality, resource use, clinical practice improvement activities, and meaningful use of certified electronic health records technology. 42 U.S.C. § 1395w-4(q)(2); *see* 83 Fed. Reg. 59,452, 59,720 (Nov. 23, 2018). The improvement activities performance category accounts for 15 percent of a MIPS eligible professional's MIPS final score,[1] subject to HHS's authority to assign different scoring weights in certain circumstances. 42 U.S.C. § 1395w-4(q)(5)(E)(i)(III), (F). Starting in 2019, positive, neutral, or negative adjustments to payments to MIPS eligible professionals are determined based on their performance in these four categories, with adjustments varying to maintain budget neutrality. *Id.* § 1395w-4(q)(6).

Plaintiffs in this action challenge a CMS rule creating one of the 106 currently available clinical practice improvement activities. MACRA defines "clinical practice improvement activity" as "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." *Id.* § 1395w-4(q)(2)(C)(v)(III). The statute further specifies that the performance category of clinical practice improvement activities shall include subcategories "specified by the Secretary," but must include those of "expanded practice access," "population management," "care coordination," "beneficiary engagement," "patient safety and practice assessment," and "participation in an alternative payment model," and lists examples for each subcategory. *Id.* § 1395w-4(q)(2)(B)(iii).

Pursuant to that statutory authority, CMS through rulemaking added further subcategories to those contained in MACRA, including the subcategory of "Achieving Health Equity." 42 C.F.R.

[1] The quality and resource use performance categories each account for 30% of the final score and the health records technology category accounts for 25%. 42 U.S.C. § 1395w- 4(q)(5)(E)(i).

§ 414.1355(c)(7); *see* 81 Fed. Reg. 77,008, 77,188-90 (Nov. 4, 2016). CMS also yearly publishes and regularly updates an inventory of clinical practice improvement activities that MIPS-eligible professionals (referred to by CMS as "clinicians," *see* 42 C.F.R. § 414.1305) can complete under this MIPS performance category. *See, e.g.*, 81 Fed. Reg. at 77,817-31 (Appendix, Table H); 86 Fed. Reg. at 65,969-97 (Appendix 2). These activities have been developed based on a wide range of sources, including input from stakeholders, internal research and review, and comments received in response to rulemakings. *See, e.g.*, 81 Fed. Reg. at 77,190.

On January 20, 2021, the President issued Executive Order ("EO") 13985, Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, 86 Fed. Reg. 7009 (Jan. 25, 2021). This EO directed the federal government to "advanc[e] equity" by undertaking a variety of measures to "recognize and work to redress inequities in [federal] policies and programs that serve as barriers to equal opportunity." *Id.* The EO defined "equity" to mean "the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment" and listed examples of such underserved communities. *Id.*

Subsequently, on July 23, 2021, CMS proposed adding an improvement activity to its inventory in the "Achieving Health Equity" subcategory titled "create and implement an antiracism plan." 86 Fed. Reg. 39,104, 39,345, 39,855 (July 23, 2021), AR0241-44. This activity aims "to address systemic inequities, including systemic racism, as called for in Executive Order 13985." *Id.* at 39,855, AR0244. CMS explained that "[t]his activity begins with the premise that it is important to acknowledge systemic racism as a root cause for differences in health outcomes between socially-defined racial groups." *Id.* CMS further explained that this improvement activity "is intended to help clinicians move beyond analyzing data to taking real steps to naming and eliminating the causes of the disparities identified." *Id.* at 39,855, AR0244. CMS received comments largely expressing support for the proposal to adopt this improvement activity and for the high weight assigned to it. AR0031-240. The States did not comment on the proposed rule.

CMS responded to the public comments and finalized the improvement activity in the subsequent final rule, 86 Fed. Reg. at 64,996, AR0001-0006. To obtain credit for the activity as finalized, clinicians must:

> Create and implement an anti-racism plan using the CMS Disparities Impact Statement or other anti-racism planning tools. The plan should include a clinic-wide review of existing tools and policies, such as value statements or clinical practice guidelines, to ensure that they include and are aligned with a commitment to anti-racism and an understanding of race as a political and social construct, not a physiological one.
>
> The plan should also identify ways in which issues and gaps identified in the review can be addressed and should include target goals and milestones for addressing prioritized issues and gaps. This may also include an assessment and drafting of an organization's plan to prevent and address racism and/or improve language access and accessibility to ensure services are accessible and understandable for those seeking care. The MIPS eligible clinician or practice can also consider including in their plan 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.

86 Fed. Reg. at 65,970, AR0005.

The CMS Disparities Impact Statement referenced in the rule is "a quality improvement tool that can be used to improve population health." *See* Hill Decl., Ex. A. Health care stakeholders may use the Statement broadly "to promote efforts to eliminate health disparities while improving the health of people from all populations that experience disparities, including people from racial and ethnic minorities; people with disabilities; members of the lesbian, gay, bisexual, and transgender communities; sexual and gender minorities; individuals with limited English proficiency; and rural, tribal, and geographically isolated communities." *Id.* On August 20, 2024, CMS updated the Statement as part of its "regular cycle of review of available resources in order to provide the most up to date information available." *Id.* The update "is clearer about the purpose for the resource and offers more examples of potential use." *Id.* The update also emphasizes that "organizations must ensure any interventions are available to individuals without regard to a person's race, ethnicity, color, national origin, sex, age, or disability." *Id.*

II. This Action

The current Plaintiffs are Mississippi, Alabama, Arkansas, Kentucky, Louisiana, Missouri, and Montana. The States raise a single claim, alleging that the new improvement activity is *ultra vires* as outside the bounds of the authority that Congress provided CMS in MACRA. Am. Compl. ¶ 60, ECF No. 28. Defendants previously moved to dismiss the Amended Complaint for lack of standing, or, in the alternative, on the ground that the statutory bar in 42 U.S.C. § 1395w-4(q)(13)(B)(iii) precluded judicial review. *See* ECF Nos. 36 & 37. The Court denied the motion to dismiss for lack of standing as to the States. *Colville v. Becerra*, No. 1:22-cv-113-HSO, 2023 WL 2668513, at *18 (S.D. Miss. Mar. 28, 2023). The Court also held that the statutory review bar "does not preclude judicial review of the question whether the promulgated activity falls within the statutory definition of a 'clinical practice improvement activity.'" *Id.* at *19.

On June 9, 2023, Plaintiffs moved for summary judgment. ECF Nos. 78 & 79. Defendants opposed and cross-moved. *See* ECF Nos. 90 & 91. On March 28, 2024, this Court denied the States' motion for summary judgment, holding that Plaintiffs "have not demonstrated that they have standing to bring the present suit." *Mississippi v. Becerra*, --- F. Supp. 3d ----, No. 1:22-cv-113-HSO-RPM, 2024 WL 1335084, at *1 (S.D. Miss. Mar. 28, 2024). The Court denied Defendants' cross-motion for summary judgment without prejudice and permitted "limited discovery solely as to the question of State Plaintiffs' standing." *Id.* To guide that discovery, this Court precisely articulated the showing that the States must make to establish standing in the context of an alleged injury to a state's legal code.

"To vindicate a sovereign interest," this Court explained, "at least one State Plaintiff must satisfy the ordinary requirements of Article III standing, including injury in fact to their own sovereign, proprietary, or private interests." *Id.* at *15. This Court made clear that a mere violation of state law resulting from the challenged improvement activity does not constitute a cognizable injury: "a violation of state law does not become an injury until a state brings an enforcement action against the violator to bring the violator into compliance, and the violator or another entity hinders the State from doing so." *Id.* at *16. Thus, "to show standing for a direct suit, at a

minimum the State Plaintiffs would need to present competent evidence that: (1) at the time they brought suit; (2) one or more clinicians in one of their States had created, or were about to create, an anti-racism plan under the Anti-Racism Rule; and (3) the anti-racism plan violated that Plaintiff State's anti-discrimination laws, (4) as they would be enforced by that State." *Id.* at *17.

This Court held that the States failed to clear that bar because the States "have adduced no evidence in the summary judgment record that, at the time suit was filed, any clinician in any of those States had in fact violated any State Plaintiff's discrimination law by adopting a plan under the Anti-Racism Rule or the CMS Disparities Impact Statement, or that such a violation was imminent." *Id.* Nor had the States "submitted any evidence to indicate or explain how they enforce, or have enforced, their laws in the context of the healthcare industry in order to demonstrate how such enforcement would be impeded or hindered by the Anti-Racism Rule." *Id.* Accordingly, because "[n]o State Plaintiff has cited or pointed to an example of a State intending to enforce its discrimination laws based upon a professional's implementation of a clinical practice improvement activity under the Anti-Racism Rule, or of a State wishing to do so but refraining from enforcement," the States failed to adduce "sufficient competent summary judgment evidence to show that . . . any State['s] asserted injury was sufficiently concrete and particularized." *Id.*

LEGAL STANDARD

Summary judgment is appropriate if "there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Hanks v. Rogers*, 853 F.3d 738, 743 (5th Cir. 2017) (citation omitted). Where "the disputed issue in th[e] case is purely legal, it [is] appropriately resolved through summary judgment." *Neff v. Am. Dairy Queen Corp.*, 58 F.3d 1063, 1065 (5th Cir. 1995).

ARGUMENT

I. The States Fail To Establish Article III Standing.

"To establish standing under Article III of the Constitution, a plaintiff must demonstrate (1) that he or she suffered an injury in fact that is concrete, particularized, and actual or imminent, (2) that the injury was caused by the defendant, and (3) that the injury would likely be redressed

by the requested judicial relief." *Thole v. U.S. Bank N.A.*, 590 U.S. 538, 540 (2020). A "[f]ailure to establish any" of the elements of standing "deprives the federal courts of jurisdiction to hear the suit." *Rivera v. Wyeth-Ayerst Lab'y*, 283 F.3d 315, 318-19 (5th Cir. 2002). At the summary judgment stage, a plaintiff "can no longer rest on . . . 'mere allegations'" as to standing but must "'set forth' by affidavit or other evidence 'specific facts'" to meet his burden. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). The States fail to carry that burden here.

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

The States argue that "federal permission to prioritize patients based on race" injures "the States' sovereign interests" because state laws prohibit racial discrimination. Mem. in Supp. of Mot. for Summ. J. ("Mem.") at 11, ECF No. 168. This theory of standing suffers from a fundamental defect: nothing in the challenged improvement activity authorizes—much less requires—either prioritizing patients based on race or any form of discrimination. This Court recognized as much in denying the States' prior motion for summary judgment, authorizing jurisdictional discovery for the States to seek competent evidence establishing, "at a minimum," that "(1) at the time they brought suit; (2) one or more clinicians in one of their States had created, or were about to create, an anti-racism plan under the Anti-Racism Rule; and (3) the anti-racism plan violated that Plaintiff State's anti-discrimination laws, (4) as they would be enforced by that State." *Mississippi*, 2024 WL 1335084, at *17.

The States largely ignore this Court's directive and instead rehash (Mem. 10) arguments about the words "priority" and "prioritize" in the Disparities Impact Statement. But this Court already rejected those arguments once: "[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." *Mississippi*, 2024 WL 1335084, at *18. This Court got it right the first time. Article III courts do not exist to issue advisory opinions on injuries that exist only "in theory." *See Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 101 (1998) ("Hypothetical jurisdiction produces nothing more than a hypothetical judgment.").

Accordingly, speculation that the Disparities Impact Statement encourages discrimination cannot confer standing. *See Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 409 (2013). Indeed, that is precisely why this Court permitted discovery—so that the States could attempt to find facts to substantiate their theory that clinicians apply the Disparities Impact Statement in a discriminatory manner.

That jurisdictional fishing expedition came up empty. The States do not identify any implemented improvement activities that in fact violate any State's laws; to the contrary, the two example anti-racism plans that the States provide *discourage* racial discrimination. The first plan lists "equal healthcare for all" as its long-term goal. ECF No. 167-11 at 4. The action plan for that activity seeks to "identify [and] target patients whose primary language is Spanish," and the specific action steps are to "run a report within the EHR to identify patients who told us their primary language is Spanish" and "train staff on translator app or software." *Id.* at 8. Those steps do not involve racial prioritization or discrimination—rather, they seek to improve the quality of care provided to a group of patients that may receive substandard care absent such an intervention, just as the improvement activity intends. To argue otherwise, the States cherry-pick (Mem. 7) from the document the words "target priority populations." But read in context, that phrase merely recognizes that certain populations may be receiving substandard care, and the States offer no explanation as to how identifying patients who primarily speak Spanish and training staff on translation applications constitutes unlawful discrimination under the relevant state's laws.

The only other example the States provide (Mem. 7) is an "Organizational Strategic Plan to Embed Racial Justice and Advance Health Equity" prepared by the American Medical Association. *See* ECF No. 167-12 (Ex. 12). The States again fixate (Mem. 7) on the word "prioritize," but fail to explain how a call to "prioritize and integrate the voices and ideas of people and communities experiencing great injustice" constitutes a call for racial discrimination in the provision of healthcare. *See* ECF No. 167-12 at 5. Indeed, that plan expressly refutes the misunderstanding at the core of the States' action, explaining that "[e]quity is not a zero-sum reality that continues to create a set of winners and losers in health." *Id.* And that plan states that

its goal is "a nation in which all people live in thriving communities where resources work well; systems are equitable and create no harm nor exacerbate existing harms; where everyone has the power, conditions, resources, and opportunities to achieve optimal health …" *Id.*

The States nonetheless fault that plan for rejecting the goal of "[s]eeking to treat everyone the 'same.'" Mem. 7 (quoting ECF No. 167-12 at 11-12). But read in context, the plan merely explains that different patients with different conditions cannot be treated the same: "high-quality and safe care for a person with a disability does not translate to 'equal' care" because an individual without a disability would not require the same care. ECF No. 167-12 at 12. The plan provides another example that further illustrates the point, explaining that "[a] person with low vision receiving the 'same' care might receive documents that are illegible, depriving them of the ability to safely consent to and participate in their own treatment." *Id.* Of course, providing documents in larger print for individuals with low vision does not discriminate against individuals without vision impairments. Nor does the plan "malign" (Mem. 7) patients or groups that have not experienced health disparities—to the contrary, the same section endorses a "call[] for just opportunities, conditions, resources and power *for all people* to be as healthy as possible." ECF No. 167-12 at 12 (emphasis added); *see also id.* at 23 ("Embedding racial justice and equity at the core of our AMA strategy means we value all people equally . . . .").

Absent evidence of an actual conflict, the States rest (Mem. 11) on their declarants' assertions of a conflict between the interventions purportedly encouraged by their reading of the improvement activity and state antidiscrimination laws. As an initial matter, "conclusory assertions . . . in an affidavit" are insufficient to resist summary judgment. *Salas v. Carpenter*, 980 F.2d 299, 305 (5th Cir. 1992). And conclusory assertions are all the States offer: the relevant part of each declaration contains only three paragraphs, identical across declarations except for the name of the state referenced, asserting that the improvement activity "incentivizes clinicians in [each state] to prioritize by race or ethnicity." This conclusion is based on a recitation of the same

phrases in the Disparities Impact Statement and final rule that this Court has already considered, *supra* 8-9, none of which encourage racial discrimination.[2]

In any event, this Court held when denying the States' prior motion for summary judgment that the mere assertion of a conflict between state and federal law is not sufficient to establish an injury in fact because "a violation of state law does not become an injury until a state brings an enforcement action against the violator to bring the violator into compliance, and the violator or another entity hinders the State from doing so." *Mississippi*, 2024 WL 1335084, at *16. *See also id.* ("[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.'"). The discovery record forecloses any such showing. Each State admitted that it "has not taken any enforcement action"—with enforcement action defined as "a lawsuit brought under the public accommodation statute" of the relevant state—"against any MIPS eligible professional due to an anti-racism plan they completed." Declaration of Alexander Resar, Ex. A at 3, 4, 5, 7, 8, 9, 11; *id.* Ex. B at 14. Indeed, six of the seven States admitted that they had not taken any enforcement action, defined in the same manner, against *any* "health care provider for racial discrimination" since, at the latest, 2020. Resar Decl., Ex. B at 14. Accordingly, just as on the prior motion for summary judgment, the States fail to "submit[] any evidence to indicate or explain how they enforce, or have enforced, their laws in the context of the healthcare industry in order to demonstrate how such enforcement would be impeded or hindered by the Anti-Racism Rule." *Mississippi*, 2024 WL 1335084, at *17.

Unable to meet the bar this Court set, the States instead ask (Mem. 15) this Court to rewrite its prior opinion. Specifically, the States claim that the requirement for evidence of an actual conflict in the form of an enforcement action that this Court derived from *Harrison v. Jefferson*

[2] The States note that a court should not "reject, in the guise of standing analysis, the States' respective construction of their own laws." Mem. 13 (citation omitted). But Defendants do not dispute that at least some state laws prohibit racial discrimination. The dispositive question is instead whether the improvement activity promotes racial discrimination. On that question, the States receive no deference.

Parish School Board, 78 F.4th 765 (5th Cir. 2023), exists only in suits brought by a state against a subordinate local government. But there is no principled reason why the identity of the party that allegedly violated a state's sovereign interests would alter the showing of injury that a state must make, and *Harrison* does not suggest otherwise. Indeed, the Fifth Circuit there applied the same Supreme Court precedent on which the States' theory of injury rests here. *Compare* 78 F.4th at 772 (quoting *Alfred L. Snapp & Son, Inc. v. Puerto Rico*, 458 U.S. 592, 601 (1982), for the proposition that the States have a sovereign interest "to create and enforce a legal code") *with* Mem. 11 (same). Accordingly, this Court should find a lack of standing, just as the Fifth Circuit found in *Harrison*, because "no . . . challenge to the enforceability of [state] law is present." 78 F.4th at 772.

In any event, this Court need not rely on *Harrison* at all because the Supreme Court reached a similar conclusion in *Haaland v. Brackeen*, 599 U.S. 255 (2023), which is controlling. The Supreme Court in that case rejected Texas's attempt to establish standing to challenge the requirements of the Indian Child Welfare Act ("ICWA") based on an alleged conflict between that statute and state law prohibiting discrimination. *See* Reply Brief for Petitioner at 14-15, *Haaland v. Brackeen*, No. 21-376 (Oct. 3, 2022); *see also Brackeen*, 599 U.S. at 295. The Supreme Court concluded that such an asserted conflict between state and federal law is "not the kind of 'concrete' and 'particularized' 'invasion of a legally protected interest' necessary to demonstrate an 'injury in fact.'" *Brackeen*, 599 U.S. at 295-96. Indeed, the States' asserted sovereign injury here is even more attenuated than the injury that the Court held insufficient in *Brackeen*. There, Texas helped enforce the allegedly unlawful federal statute, while the States here do not administer the clinical practice improvement activity from which they claim injury.

The absence of any actual conflict between the States' laws and the improvement activity is also fatal to the States' (Mem. 12-14) other two theories of sovereign injury: (1) regulation in areas of traditionally "local concern" and (2) preemption. As to the former, the States effectively concede that federal action in areas of traditionally local concern only effects a cognizable injury when that federal action conflicts with state law. *See* Mem. 12. Indeed, if any federal action

concerning "'the protection of the lives, limbs, health, comfort, and quiet of all persons,'" *id.*, effected a sovereign injury, every state would have standing to challenge every federal action. That is not and cannot be the law. *See United States v. Texas*, 599 U.S. 670, 680 n.3 (2023) (explaining that "in our system of dual federal and state sovereignty, federal policies frequently generate indirect effects"); *Brackeen*, 599 U.S. at 295 (criticizing injury theory where "a State would always have standing" to challenge federal policies). And the same is true of the States' preemption theory. In that context, the Supreme Court instructs that "a court should not find pre-emption too readily in the absence of clear evidence of a conflict." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 885 (2000); *id.* at 884 ("[C]onflict pre-emption" requires "'actual conflict.'").

Nor do the States' authorities (Mem. 12-14) support these theories of sovereign injury on the facts here. In *Kentucky v. Biden*, the Sixth Circuit held that the plaintiff states had "shown that each of the states follows its own, contrary vaccination policy, and that the contractor mandate threatens to override those policies." 23 F.4th 585, 599 (6th Cir. 2022). It is the second of those showings—that the challenged federal action overrides state policies—that the States fail to make here. *Louisiana v. Becerra* also involved a vaccine requirement, and the court in that case found injury because the challenged requirement "specifically preempts state laws with regard to COVID-19 Vaccine requirements." 577 F. Supp. 3d 483, 492 (W.D. La. 2022). Similarly, the Sixth Circuit in *Tennessee v. Department of Education*, found an actual conflict was likely between state laws that separated students "based on biological sex" and Department of Education materials that, *inter alia*, explained that state funding recipients could be investigated for "preventing a 'transgender high school girl' from using the 'girls' restroom.'" 104 F.4th 577, 586, 594 (6th Cir. 2024). Indeed, the court emphasized that this conflict was not merely hypothetical because the Department had "made clear that it will investigate states not in compliance with its new regime, thus putting the Plaintiff States on a collision course with the federal government." *Id.* at 595. In *Daily Wire, LLC v. Department of State*, the court found standing at the motion-to-dismiss stage based on "allegations that Defendants . . . are encouraging social media platforms to violate H.B. 20." No. 6:23-CV-609-JDK, 2024 WL 2022294, at *6 (E.D. Tex. May 7, 2024). Allegations that

Defendants here encouraged clinicians to violate state law may have been sufficient to survive a motion to dismiss, but establishing standing at the summary judgment stage requires actual evidence of such violations. *Lujan*, 504 U.S. at 561. And in *Louisiana v. EEOC*, the states were "directly regulated" by the challenged federal action, 705 F. Supp. 3d 643, 652 (W.D. La. 2024), which is not the case here.

Finally, in an attempt to lower the bar that they must meet to establish an injury in fact, the States invoke (Mem. 8-9) the doctrine of "special solicitude." But special solicitude does not relieve states of their obligation to establish a cognizable injury in fact. *See Gov't of Manitoba v. Bernhardt*, 923 F.3d 173, 182 (D.C. Cir. 2019) (noting that, in *Massachusetts v. EPA*, 549 U.S. 497 (2007), the State was "entitled to 'special solicitude' because" it had "a quasi-sovereign interest in 'preserv[ing] its sovereign territory,'" but it still demonstrated "its own harm to establish an injury-in-fact"). Indeed, this Court instructed the States on the showings that must be made to establish a cognizable injury *after* accounting for the special solicitude that the States receive. *See Mississippi*, 2024 WL 1335084, at *14. The States failed to make those showings and therefore lack standing.[3]

B. The States Fail To Establish That Any Injury In Fact Is Traceable To The Challenged Improvement Activity Or Redressable By The Relief Sought.

Even if the States could establish an injury in fact, the States are unable to make the heightened showings of traceability and redressability applicable in actions brought by parties that are not the direct subject of the challenged regulation. "When 'a plaintiff's asserted injury arises

[3] This Court's summary judgment opinion also set the bar for the States to establish standing on a *parens patriae* theory of injury. *See Mississippi*, 2024 WL 1335084, at *17 (requiring evidence that "clinicians in one of the Plaintiff States had not obtained a full score in reimbursement activities and did not create an anti-racism plan because of a dilemma with the Plaintiff State's anti-discrimination laws" in a way that "harmed a 'sufficiently substantial segment' of the State's population" or "threatened the State's economy"). Defendants respectfully maintain that "States do not have 'standing as *parens patriae* to bring an action against the Federal Government' on behalf of their citizens," as the Supreme Court recently reiterated in *Murthy v. Missouri*, 144 S. Ct. 1972, 1997 (2024). In any event, the States waived their ability to "advance a theory of standing based on increased costs incurred from MIPS eligible professionals not completing an anti-racism plan." Resar Decl., Ex. B at 16.

from the government's allegedly unlawful regulation (or lack of regulation) of someone else, much more is needed' to establish standing." *Texas*, 599 U.S. at 678. *See also Murthy*, 144 S. Ct. at 1992 n.8 ("The whole purpose of the traceability requirement is to ensure that 'in fact, the asserted injury was the consequence of the defendants' actions,' rather than of 'the independent action' of a third party.").

Accordingly, even if the States could establish that a clinician created a discriminatory anti-racism plan in violation of state law (and they have not identified any that did so), that injury would be traceable to the unlawful conduct of that clinician, not the existence of the challenged improvement activity. Put simply, nothing in the challenged improvement activity encourages—much less requires—racial discrimination. To the contrary, a clinician would violate federal by creating and implementing the challenged activity in a racially discriminatory way. *See* 42 U.S.C. § 18116(a); Hill Decl. ¶ 9. Any injury the States suffered is therefore traceable to the unlawful decisions of "actors not before the court," not the challenged improvement activity. *See Tel. & Data Sys., Inc. v. FCC*, 19 F.3d 42, 48 (D.C. Cir. 1994) (rejecting standing theory that "invite[d] [the court] 'to presume illegal activities' on the part of actors not before the court"); *Clapper*, 568 U.S. at 414 n.5 ("Plaintiffs cannot rely on speculation about the unfettered choices made by independent actors" for causation).

For these same reasons, the States fail to establish that the relief sought would redress the asserted injury of clinicians engaging in racial discrimination in violation of state law. *See Food & Drug Admin. v. All. for Hippocratic Med.*, 602 U.S. 367, 380 (2024) ("The second and third standing requirements—causation and redressability—are often 'flip sides of the same coin.'"). Indeed, "it is a bedrock principle that a federal court cannot redress 'injury that results from the independent action of some third party not before the court.'" *Murthy*, 144 S. Ct. at 1986. That principle forecloses standing here: because the challenged improvement activity does not require racial discrimination, there is no reason to believe that any clinician engaged in racial discrimination would stop if the rule creating the improvement activity did not exist.

The States' authorities are not to the contrary. In *Texas v. Becerra*, the state plaintiff adduced evidence establishing that enforcement of a federal vaccine requirement would result in staff shortages that would undermine Texas's ability "to efficiently operate its state-run healthcare institutions." 575 F. Supp. 3d 701, 713 (N.D. Tex. 2021). And Texas established the traceability of this concrete injury to the federal requirement through "affidavits from healthcare workers who resigned when . . . vaccine requirements were enforced" and "an affidavit from a Texas healthcare worker who confirms that he will resign if forced to receive the COVID-19 vaccine." *Id.* That evidence is a far cry from the States' conclusory assertions in declarations that the improvement activity requires racial discrimination, *supra* 10-11. *Texas v. NRC* is even further afield, as the Fifth Circuit in that case found a direct "enforceability conflict between the [challenged] license and operation of the facility, which authorizes storage of high-level radioactive waste in Texas, and H.B. 7, which proscribes such storage." 78 F.4th 827, 836 (5th Cir. 2023), *cert. granted*, No. 23-1300, 2024 WL 4394124 (U.S. Oct. 4, 2024). The challenged improvement activity is not a license for clinicians to racially discriminate.

Nor does special solicitude (Mem. 8-9) absolve the States of their obligation to adduce evidence of traceability and redressability. As an initial matter, the heightened showing that must be made on those components of Article III standing when a party claims injury from federal regulation of nonparties trumps any reduced showing derived from the special solicitude doctrine. *United States v. Texas*, of course, involved a state plaintiff and the Supreme Court nonetheless emphasized the heightened standard that applies when a state challenges "the government's allegedly unlawful regulation . . . of someone else." 599 U.S. at 678. Regardless, even if the bar for those showings were lowered for states,[4] the States must still, at a minimum, establish through competent evidence that the challenged action influenced or contributed to the States' injury. *See*

[4] *But see United States v. Texas*, 599 U.S. at 688-89 (Gorsuch, J., joined by Thomas and Barrett, JJ., concurring in the judgment) ("Before *Massachusetts v. EPA*, the notion that States enjoy relaxed standing rules' had no basis in our jurisprudence.' Nor has 'special solicitude' played a meaningful role in this Court's decisions in the years since. . . . And it's hard not to think, too, that lower courts should just leave that idea on the shelf in future ones.") (citation omitted).

Murthy, 144 S. Ct. at 1989 (holding state plaintiffs lacked standing where "[t]here is . . . no evidence to support the States' allegation that Facebook restricted the state representative pursuant to the CDC-influenced policy"). Here, the States fail to carry that burden because any unlawful discrimination carried out by clinicians implementing the challenged improvement activity would be the result of decisions made by those clinicians, particularly as the available resources pertaining to the rule prohibit discrimination, *infra* 17-18.

II. Even If The States Could Establish Standing, The Updated Disparities Impact Statement Renders This Action Moot.

"Mootness is 'the doctrine of standing in a time frame. The requisite personal interest that must exist at the commencement of litigation (standing) must continue throughout its existence (mootness).'" *Ctr. for Individual Freedom v. Carmouche*, 449 F.3d 655, 661 (5th Cir. 2006). Thus, "having Article III standing at the *outset* of litigation is not enough. 'There must be a case or controversy through all stages of a case'—not just when a suit comes *into* existence but *throughout* its existence." *Yarls v. Bunton*, 905 F.3d 905, 909 (5th Cir. 2018). No case or controversy continues to exist here, and this Court therefore lacks subject matter jurisdiction. *Carr v. Saucier*, 582 F.2d 14, 16 (5th Cir. 1978).

a. Both the States' brief and supporting declarations identify the outdated Disparities Impact Statement as the sole source of the purported instruction for clinicians "to prioritize by race or ethnicity." *See, e.g.*, Mem. 10; Decl. of Whitney Lipscomb ¶¶ 6-7, ECF No. 167-19. The States identify no aspect of the improvement activity itself that requires or encourages racial prioritization, and none exists. Indeed, the rule refers to "addressing prioritized issues and gaps," not populations. 86 Fed. Reg. at 65,969, AR0005.[5] The States' speculation that the improvement

[5] The States also emphasize the definition of "anti-racism" employed in a book that the challenged rule does not cite. *See* Mem. 1 & 3 (citing Kendi, *How to Be an Antiracist* 19 (2019)). But the rule is clear that it does not employ "anti-racism" in that manner: rather, the rule envisions "equity," its ultimate aim, "as 'the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities who have been denied such treatment.'" 86 Fed. Reg. at 65,383, AR0003.

activity encourages or requires racial prioritization in violation of state law—the lynchpin of their standing theory—thus hinges on the Disparities Impact Statement.

Accordingly, even if the States could establish standing based on an injury caused by the Disparities Impact Statement (and they cannot, *supra* 8-9), the updated Disparities Impact Statement moots this case by clearly prohibiting racial prioritization. The updated Statement requires that clinicians "ensure any interventions are available to individuals without regard to a person's race, ethnicity, color, national origin, sex, age, or disability." *See* Hill Decl., Exs. A & B. And the Statement makes clear that it is to be used "to promote efforts to identify and address health disparities while improving the health of *all people*." Hill Decl., Ex. B (emphasis added). The updated Statement also eliminates any possible ambiguity arising from the words "priority" or "prioritize" in the prior Disparities Impact Statement, instructing health care stakeholders to "identify health disparities and affected populations." Hill Decl., Ex. B. The example that the Statement provides—to "[r]educe unnecessary emergency department visits among patients who screen positive for a health-related social need," *id.* at 3—further illustrates that it does not encourage racial prioritization. Indeed, this update "addresses any misreading of the prior Disparities Impact Statement to make clear that any interventions taken pursuant to that Statement must be 'available to all individuals.'" Hill Decl. ¶ 7. The updated Statement therefore "eliminates actual controversy after the commencement of the lawsuit." *DeOtte v. Nevada*, 20 F.4th 1055, 1064 (5th Cir. 2021).

b. The voluntary-cessation exception to mootness does not apply here because Defendants' actions are not mere "litigation posturing." *Yarls*, 905 F.3d at 910. As "governmental entities," Defendants "bear a 'lighter burden' in proving that the challenged conduct will not recur once the suit is dismissed as moot" because courts "presume that state actors . . . act in good faith." *Freedom From Religion Found., Inc. v. Abbott*, 58 F.4th 824, 833 (5th Cir. 2023); *see also Yarls*, 905 F.3d at 910 ("[W]e 'are justified in treating a voluntary governmental cessation of possibly wrongful conduct with some solicitude.'"). Indeed, "'without evidence to the contrary, we assume that

formally announced changes to official governmental policy are not mere litigation posturing.'" *Yarls*, 905 F.3d at 911.

Here, CMS formally announced the updated Statement as part of its "regular cycle of review of available resources in order to provide the most up to date information available." Hill Decl., Ex. A. And "[a]s the updated Disparities Impact Statement makes clear, 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. For that reason, there is no reason to suspect CMS would revert to the earlier Statement. That is particularly true because such discrimination would violate federal law, *id.* *Cf. Republic Nat'l Bank of Miami v. U.S.*, 506 U.S. 80, 97 (1992) (White, J., concurring) (explaining government officials can be "expect[ed]" to "satisfy their obligations"). In any event, Defendants' mere "ability to reimplement the statute or regulation at issue is insufficient to prove the voluntary-cessation exception." *Freedom from Religion Found.*, 58 F.4th at 833.

III. Congress Barred Judicial Review Of CMS's Creation Of Clinical Practice Improvement Activities.

The Court held that it has jurisdiction to review whether a promulgated activity falls within the statutory definition of a "clinical practice improvement activity," notwithstanding the judicial review bar in 42 U.S.C. § 1395w-4(q)(13)(B)(iii). *Colville*, 2023 WL 2668513, at *18-20. Defendants maintain that this review bar forecloses jurisdiction over the States' suit and incorporate their previous arguments. *See* ECF No. 37 at 21-29. However, Defendants accept for the purposes of this motion that the Court's prior conclusion regarding the review bar applies, and thus address the merits of Plaintiffs' *ultra vires* claim.

IV. The Challenged Improvement Activity Is Not *Ultra Vires*.

CMS's promulgation of the new activity to create and implement an anti-racism plan falls squarely within the scope of CMS's authority. As further discussed below, there is ample evidence that the creation and implementation of an anti-racism plan satisfies the statutory definition of an improvement activity: (1) it has been 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). Indeed, the States do not contest that CMS determined the activity would likely result in improved outcomes when effectively executed.[6]

Instead, the States' operative complaint contains a single count: that the challenged activity is *ultra vires* because it is not related to clinical practice or care delivery and lacked sufficient organizational support. *See* Am. Compl. ¶¶ 57-65. As an initial matter, the States must carry a heavy burden on this claim because, as even the States' authorities acknowledge, courts "have only rarely exercised their jurisdiction" on *ultra vires* claims and "have limited [those claims'] application to situations in which an agency has exceeded its delegated powers or 'on its face' violated a statute." *Kirby Corp. v. Pena*, 109 F.3d 258, 268-69 (5th Cir. 1997) (cited at Mem. 26). At most, the States can show a disagreement over statutory construction as to whether the challenged activity is sufficiently similar to enumerated example activities or a factual disagreement over whether relevant organizations sufficiently identified the improvement activity. But neither showing is enough to prevail on an *ultra vires* claim—rather, the Fifth Circuit has emphasized that the *ultra vires* "exception . . . must remain narrow, and 'agency action allegedly 'in excess of authority' must not simply involve a dispute over statutory interpretation or challenged findings of fact.'" *Id.* at 269 (quoting *Dart v. United States*, 848 F.2d 217, 231 (D.C. Cir. 1988)); *see also Larson v. Domestic & Foreign Com. Corp.*, 337 U.S. 682, 690 (1949) (explaining that the *ultra vires* doctrine is grounded on "the officer's lack of delegated power" and not "[a] claim of error in the exercise of that power").

Regardless, and under any applicable standard of review, Defendants are entitled to summary judgment because the challenged activity falls well within the statutory definition of an

[6] Nor could they do so. In promulgating the activity, CMS stated that it "believe[s] this activity has the potential to improve clinical practice or care delivery and is likely to result in improved outcomes." 86 Fed. Reg. at 65,969, AR0005.

improvement activity. The States' arguments (Mem. 21-25) to the contrary are unavailing for the following reasons:

a. The States first argue (Mem. 21) that the challenged activity is unlawful because it does not "reasonably relate" to the examples of activities provided in 42 U.S.C. § 1395w-4(q)(2)(B)(iii). But the statute prefaces these examples with the words "include," "at least," and "such as," indicating that the examples are meant to be non-exhaustive. *Cox v. City of Dallas*, 256 F.3d 281, 293 (5th Cir. 2001) ("It is hornbook law that the use of the word including indicates that the specified list . . . that follows is illustrative, not exclusive.") (citing *Cobell v. Norton*, 240 F.3d 1081, 1100 (D.C. Cir. 2001)). Moreover, the examples cited in the statute span a wide spectrum of activities from the relatively discrete activity of "same day appointments" to broader, more open-ended activities such as "establishment of care plans for individuals with complex care needs" or "using shared decision-making mechanisms." 42 U.S.C. § 1395w-4(q)(2)(B)(iii). Accordingly, there is no basis to conclude that "a string of statutory terms" should "raise[] the implication that the 'words grouped in a list should be given related meaning.'" *See S.D. Warren Co. v. Me. Bd. of Envt'l Prot.*, 547 U.S. 370, 378 (2006) (quoting *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 36 (1990)). Rather, the wide variety of example activities listed establishes that Congress did not intend to impose any requirement that the activities share a common attribute other than their general relation to clinical practice or care delivery.

Relatedly, the States are wrong in asserting (Mem. 21) that the challenged activity is *ultra vires* because it does not seek to "improv[e] care for patients generally." The States identify no such requirement in the statute, and none exists. To the contrary, Congress expressly acknowledged that improvement activities could be targeted at specific categories of patients. *See, e.g.*, 42 U.S.C. §1395w-4(q)(2)(B)(iii)(IV) (providing as example improvement activity "the establishment of care plans for individuals with complex care needs"). Like that enumerated activity, the aim of creating and implementing an anti-racism plan—to "achiev[e] equity in healthcare outcomes," 86 Fed. Reg. 65,383, AR0003—seeks to improve the quality of clinical care provided to a category of patients, specifically those patients experiencing health disparities.

Indeed, the States do not (and cannot) dispute that the administrative record establishes the existence of health outcome disparities. *See, e.g.*, AR2296 (infant mortality rates for Black infants are twice those of White infants); AR0268 (COVID-19-related mortality rates for Black and Hispanic adults are nearly double the rate for White adults); AR0498 (summarizing rural-urban health outcome disparities). Nor do the States dispute that the administrative record establishes that treatment disparities contribute to these health outcome disparities. *See, e.g.*, 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). Lastly, the States do not dispute that the record establishes that the challenged activity will help clinicians address those treatment and health outcome disparities. *See, e.g.*, Am. Hosp. Ass'n, Equity of Care: A Toolkit for Eliminating Health Care Disparities, cited at AR0351 ("Adopting activities to enhance patients' access to culturally and linguistically appropriate services 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, regardless of race, ethnicity, culture or language."). Accordingly, there is no dispute that the challenged activity, when properly implemented, will improve health outcomes.

But even if the administrative record were insufficient (and it is not) to support CMS's determination that the challenged activity will improve the quality of clinical care and health outcomes, evidence outside the record provides additional support. Here, there is extensive extra-record evidence that racism within the medical system contributes to health disparities. *See* Mot. to Intervene, at 3, 7, ECF No. 62. There is also evidence showing that anti-racism programs can help to address these disparities and thereby improve treatment outcomes. *See* Thatcher Decl. ¶¶ 14-17, ECF No. 62-9 (discussing impact of anti-racism interventions evaluated in one study, which showed that "a racial equity plan had a substantial impact on successful treatment"); *id.* ¶ 23 (stating that one physician reported that "his medical practice has meaningfully improved as a result of attending . . . anti-racism trainings"); Simelton Decl. ¶ 5, ECF No. 62-2 ("Reducing racial

discrimination and insensitivity in the medical profession would likely improve the quality of care that some of our members receive."). And this evidence is properly before the Court because *ultra vires* claims do not arise under the APA and therefore are not governed by the APA's record-review rule. *Texas v. Biden*, No. 2:21-cv-00067-Z, 2021 WL 4552547, at *6 (N.D. Tex. July 19, 2021); *Texas v. U.S. Dep't of Homeland Sec.*, No. 6:23-cv-00007, 2023 WL 2842760, at *1 (S.D. Tex. Apr. 7, 2023).

b. The States also argue (Mem. 21-24) that relevant organizations did not identify the improvement activity before CMS created it. Not so. The comments submitted in response to CMS's proposed rule establish "that relevant eligible professional organizations and other relevant stakeholders" identified the activity of creating and implementing an anti-racism plan "as improving clinical practice or care delivery." 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III). The Intersocietal Accreditation Commission (an accreditation standards development organization) "recommends the inclusion of the proposed improvement activity titled 'create and implement an anti-racism plan,'" which it stated "is an opportunity to recognize clinicians for developing and implementing processes to reduce racism and discrimination to ensure equitable health care." AR0215. Similarly, the American Academy of Dermatology Association commented that the challenged improvement activity has "important objectives grounded in better meeting the diverse needs of patients and clinicians and [is] commendable." AR0210. That comment also refutes the States' suggestion (Mem. 23-24) that organizations were supporting the activity for reasons "that have little to do with . . . improving clinical practice or care delivery." Of course, better meeting the needs of patients improves clinical practice and care delivery. And many other organizations expressed support for the rule.[7] Accordingly, because CMS issued the final rule creating the

[7] *See* AR0046 (comment by the American College of Radiology "agree[ing] with including improvement activities in MIPS that address creating and implementing anti-racism plans"); AR0146 (comment by the Association of American Medical Colleges "agree[ing] that the inclusion of a proposed improvement activity titled 'create and implement an anti-racism plan' is an important activity that will address systemic racism as a root cause of inequity"); AR0191 (comment by the American Society for Radiation Oncology "support[ing] the addition of the

improvement activity only after those comments were received, the challenged activity satisfies the stakeholder-related statutory requirement.[8]

The States nonetheless argue (Mem. 21-22) that MACRA requires relevant organizations to express support for the improvement activity before CMS proposes the activity. No language in the statutory definition of an improvement activity supports that reading. *See* 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III). The States (Mem. 22) instead cite language elsewhere in MACRA instructing CMS, "[i]n initially applying" the statute, to "use a request for information to solicit recommendations from stakeholders." 42 U.S.C. §1395w-4(q)(2)(C)(v)(I). But that mandate had expired by the time CMS created the challenged activity years after CMS had "initially appl[ied]" the statute when first creating the MIPS system. Accordingly, that Congress specified that CMS should use a request for information when initially applying the statute indicates that Congress did not intend to require CMS to use such requests when creating subsequent improvement activities. *Bates v. United States*, 522 U.S. 23, 29-30 (1997) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion.").

The States also suggest (Mem. 22) that this Court's ruling at the motion to dismiss stage conclusively established the absence of organizational support for the challenged rule. But at that stage in the proceeding, this Court did not have the benefit of the administrative record, including the extensive evidence of organizational support. Instead, it construed the pleadings and incorporated materials that composed the record at that stage "in the light most favorable to

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proposed improvement activit[y]"); AR0233 (comment by MarsdenAdvisors "applaud[ing] CMS's proposal to include this IA in the inventory in 2022"); Supp. 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").

[8] Indeed, CMS did not receive a single comment opposing the proposal, and the States did not submit any comment whatsoever on the proposed rule. For reasons Defendants previously provided, *see* ECF No. 91 at 23-24, Defendants maintain that the States waived their claim by failing to raise it during the notice-and-comment period if the Fifth Circuit re-considers its administrative waiver precedent.

Plaintiffs." *Colville*, 2023 WL 2668513, at *20. Of course, that is not the standard to be applied on cross-motions for summary judgment, *supra* 7.

c. The States next argue (Mem. 24) that the statute must be read to exclude the challenged activity under the canon of constitutional avoidance because otherwise "any activity can be a clinical practice improvement activity . . . if a stakeholder says they're a good thing." That misstates Defendants' construction of the statute, which requires both that relevant stakeholders identify the activity and that CMS determine that the activity, "when effectively executed," is "likely to result in improved outcomes." 42 U.S.C. § 1395w-4(q)(2)(C)(v)(III). Accordingly, CMS's construction of the statute would not permit it to incentivize "turning white patients away," Mem. 24, because CMS would not conclude that doing so is likely to result "in improved outcomes."[9]

In any event, 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). The States' construction of the statute as prohibiting any improvement activities targeted at specific groups of patients is not plausible given the statute's enumeration of such an activity, *supra* 21.

d. Finally, the States argue (Mem. 24-25) that the major-questions doctrine requires the Court to rule in their favor "even if Defendants' reading had 'a colorable textual basis.'" But that 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," such as where an agency "claim[s] to discover in a long-extant statute an unheralded power representing a transformative expansion in its regulatory authority." *West Virginia v. EPA*, 597 U.S. 697, 716-24 (2022) (citation omitted). In those extraordinary cases, an agency "must point to 'clear congressional authorization' for the power it claims," rather than a

[9] Independently, the States' parade of horribles (Mem. 24) could never come to pass because federal law prohibits clinicians receiving federal funds or participating in CMS-administered programs from engaging in unlawful discrimination. *See* 42 U.S.C. § 18116(a); Hill Decl. ¶ 9.

"merely plausible textual basis." *Id*. at 723. CMS's decision to add another voluntary activity to a list of more than 100 such activities does not come close to the extraordinary cases described by the Supreme Court, which addressed EPA's assertion of authority to regulate millions of sources that emit greenhouse gases, and OSHA's assertion of authority to require 84 million Americans either to obtain a COVID-19 vaccine or undergo weekly testing. *Id.* at 721-24 (citing *Utility Air Regulatory Grp. v. EPA*, 573 U.S. 302 (2014), and *NFIB v. OSHA*, 595 U.S. 109 (2022)).

For similar reasons, the States' reliance (Mem. 24) on *Texas*, 575 F. Supp. 3d 701, is unavailing. That case involved a challenge to a rule that required facilities participating in Medicare and Medicaid to establish policies and procedures for ensuring COVID-19 vaccination of certain staff. After *Texas* was decided, the Supreme Court upheld that rule, *Biden v. Missouri*, 595 U.S. 87 (2022) (per curiam), notwithstanding the plaintiffs' heavy reliance on the major-questions doctrine, invalidating the reasoning in *Texas*. *See* Response to Application for a Stay Pending Appeal, *Becerra v. Louisiana*, Nos. 21A240, 21A241, 2021 WL 8939385, at *22-24 (U.S. Dec. 30, 2021); Response to Application for a Stay, *Biden v. Missouri*, No. 21A240, 2021 WL 8946189, at *22-24 (U.S. Dec. 30, 2021). Moreover, the improvement activity at issue is far more limited in scope than the vaccine rule because it is only relevant to those clinicians that choose the activity from a list of 106 options, and thus it is even further from a major question.

V. If The States Prevail On The Merits, Relief Must Be Limited In Accordance With Principles Of Article III And Equity.

a. If the States prevail on the merits, relief should be limited to a declaratory judgment determining the clinical practice improvement activity is unlawful. Article III and principles of equity require this Court to tailor any remedy to address only proven injuries. *Gill v. Whitford*, 585 U.S. 48, 66 (2018) ("[A] plaintiff's remedy must be 'limited to the inadequacy that produced [his] injury in fact.'"); *Califano v. Yamasaki*, 442 U.S. 682, 702 (1979) (equitable remedy must be "no more burdensome to the defendant than necessary to provide complete relief to the plaintiffs"). Such declaratory relief would fully remedy the States' claimed injuries because there would no longer exist any conflict between federal law and the law of any state. *See Comm. on Judiciary of*

U.S. House of Representatives v. Miers, 542 F.3d 909, 911 (D.C. Cir. 2008) ("[W]e have long presumed that officials of the Executive Branch will adhere to the law as declared by the court. As a result, the declaratory judgment is the functional equivalent of an injunction."). Accordingly, if declaratory relief were awarded, Defendants could not on a prospective basis infringe on state law by granting credit for the challenged activity.

b. If further relief is necessary to remedy the States' injuries (and it is not), this Court should remand without vacatur. "To determine whether to remand without vacatur," courts consider "the 'seriousness of the [action's] deficiencies" and "the likely 'disruptive consequences' of vacatur." *Am. Great Lakes Ports Ass'n v. Schultz*, 962 F.3d 510, 518-19 (D.C. Cir. 2020). Both considerations favor that relief here.

First, insofar as this Court determines that the final rule is unlawful, "there is at least 'a serious possibility' that [CMS] on remand could explain" the final rule in a new manner "that is consistent with the statute . . . , a factor that favors remanding rather than vacating." *Milk Train, Inc. v. Veneman*, 310 F.3d 747, 756 (D.C. Cir. 2002). For example, if the Court were to conclude that relevant stakeholders did not identify the challenged activity as improving clinical practice or care delivery, CMS could on remand solicit additional feedback, as *amici* submissions make clear the extent of organizational support for the challenged activity, *supra* 22-23.

Second, vacatur would cause significant disruptive consequences for both Defendants and clinicians around the country. If the challenged activity is vacated, and the Court does not specify that any vacatur is prospective only, CMS may be required to recoup funds from clinicians who created anti-racism plans to increase their MIPS scores in the performance periods in which the challenged activity has been in effect (2022-2024). These already-distributed funds amount to a "quintessential disruptive consequence" favoring remand without vacatur. *Am. Great Lakes Ports Ass'n*, 962 F.3d at 519; *Sugar Cane Growers Co-op. of Fla. v. Veneman*, 289 F.3d 89, 97 (D.C. Cir. 2002) (remanding without vacatur where "[t]he egg has been scrambled"). Indeed, this disruption alone 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.").

At a minimum, that funds have been issued in reliance on the validity of the challenged activity favors vacatur that is prospective only. *See In re Long-Distance Tel. Serv. Fed. Excise Tax Refund Litig.*, 853 F. Supp. 2d 138, 144-45 (D.D.C. 2012), *aff'd*, 751 F.3d 629 (D.C. Cir. 2014) (granting only "prospective vacatur" because defendant agency "continues to receive, each week, a significant number of requests for payment under" challenged action); *Ctr. for Biological Diversity v. Regan*, --- F. Supp. 3d ----, No. 21-cv-119 (RDM), 2024 WL 1602457, at *42 (D.D.C. Apr. 12, 2024) ("vacatur should be prospective and should not call into question previously issued Section 404 permits").

CONCLUSION

For the foregoing reasons, Defendants are entitled to summary judgment, and Plaintiffs' motion for summary judgment should be denied.

Dated: November 5, 2024

Respectfully submitted,

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