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

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| AMBER COLVILLE, *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, *et al.*,<br><br>Defendants. | Civil Action No. 1:22-cv-00113-HSO-RPM |

**DEFENDANTS' REPLY IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS**

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# INTRODUCTION

From the simple use of the word "anti-racism" in the Medicare improvement activity at issue (part of the Merit-based Incentive Payment System ("MIPS")), Plaintiffs jump to the conclusion that Defendants have incorporated into that activity the philosophy of Ibram X. Kendi that "[t]he only remedy to past discrimination is present discrimination." Pls.' Opp'n Defs.' Mot. Dismiss 1 (ECF No. 43) ("Pls.' Opp'n"). Plaintiffs therefore insist that the activity at issue encourages discrimination on the basis of race. But Plaintiffs cite no evidence that Kendi's specific philosophy motivated Defendants' actions here or that it is supposed to be incorporated therein. The only authority they cite for their conclusion that the government has "decided to inject Kendi's ideology into the Federal Register" is a Federal Register notice promulgated by the Department of *Education* on an entirely different topic. *Id.* (citing 86 Fed. Reg. 20,349). In fact, the term "anti-racism" does not denote a particular philosophy but rather means, simply, "opposed to racism." *See* https://www.merriam-webster.com/dictionary/anti-racism (last visited Dec. 15, 2022).

Plaintiffs also misread the Department of Health and Human Services' ("HHS's") statement that race is a "political and social construct, not a physiological one." 86 Fed. Reg. 64,996, 65,970 (Nov. 19, 2021). Plaintiffs argue that this statement "tells providers to consider race in ways that have no 'physiological,' *i.e.*, medical, relevance." Pls.' Opp'n 1-2. But the actual improvement activity does nothing of the kind. Instead, it asks clinicians to consider whether their practices impose barriers to care for a variety of disadvantaged groups, including but not limited to racial minorities.

Stripped of Plaintiffs' unfounded rhetoric about racism, their arguments on the legal issues can be seen for what they are, meritless. Regarding standing, Plaintiffs continue to ignore the fact that the clinical practice improvement activity to create and implement an anti-racism plan is completely voluntary, and therefore the existence of such an optional activity cannot cause

clinicians, or their states, any harm. As for Dr. Colville specifically, as shown in the attached declaration, she has apparently misconstrued her past performance in this MIPS category. In fact, she has achieved a full score in the clinical practice improvement activities category for the performance years 2017-2020, disproving her allegations that adding this new activity puts her at a financial or competitive disadvantage because it enables other clinicians to achieve a full score while she cannot.

As to the alleged harm to the States, Plaintiffs rely here as well on their unfounded claim that the activity will encourage race-based decision making in medical care. In the absence of any evidence that the activity will encourage such decision making, however, the States' standing claim fails as well, even accounting for the "special solicitude" due states in some circumstances. And, to the extent that the States have asserted a harm to their financial interests not based on their claim of discrimination, they have not provided sufficient detail as to how the existence of an optional activity will impact them financially to raise this assertion above the purely speculative. Their generalized allegations regarding financial harm are therefore insufficient to confer standing.

Even if Plaintiffs had standing, however, Plaintiffs' claims are barred by 42 U.S.C. § 1395w-4(q)(13)(B). Plaintiffs' arguments that the activity at issue does not meet the statutory definition of a "clinical practice improvement activity" are garden-variety issues of statutory interpretation within the terms of the jurisdictional bar and do not rise to the level of an egregious statutory violation sufficient to warrant application of the *ultra vires* exception.

## STANDARD OF REVIEW

In assessing jurisdiction at the pleading stage, "the district court is to accept as true the allegations and facts set forth in the complaint." *Choice Inc. of Tex. v. Greenstein*, 691 F.3d 710, 714 (5th Cir. 2012). "Additionally, 'the district court is empowered to consider matters of fact which may be in dispute.'" *Id.* (citation omitted). "The district court consequently has the power

to dismiss for lack of subject matter jurisdiction on any one of three separate bases: (1) the complaint alone; (2) the complaint supplemented by undisputed facts evidenced in the record; or (3) the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Id*. (citation omitted). As discussed further below, the Court should not resolve the question of Dr. Colville's standing based solely on the allegations in the First Amended Complaint but should consider the facts presented by Defendants in the declaration submitted herewith.

## ARGUMENT

### I. PLAINTIFFS LACK STANDING

#### A. Dr. Colville Lacks Standing

Dr. Colville asserts that, "[i]n the last three years, she reported no more than one improvement activity and did not receive the full 40 points on this metric." Am. Compl. ¶ 9. She asserts that "[h]er score would increase if she submitted an anti-racism plan," which she will not do, and that the scores of her competitors may increase if they select this option. *Id.* ¶¶ 9-10. However, Dr. Colville's allegations are not consistent with CMS's records. Those records reveal that Dr. Colville qualifies as a small practice and that she received a full score in the improvement activities category in the 2017-2020 performance periods (data are not yet publicly available for more recent periods). *See* Decl. of Aucha Prachanronarong ¶¶ 14-16 ("Prachanronarong Decl.").[1] Notably, she submitted one high-weighted activity in 2018-2020. *Id.*, attachment. As a small practice, she was required to submit only one high-weighted activity or two medium-weighted activities to achieve a full score in this category. *Id.* ¶ 14.

[1] This Declaration does not contain new evidence as Defendants already alluded to Dr. Colville's circumstances in their opening brief. *See* Mem. Supp. Defs.' Mot. Dismiss 13-14 (ECF No. 37) ("Defs.' Mem.") (citing exception for small practices). In addition, such evidence was always within Plaintiffs' possession and is publicly available. Prachanronarong Decl. ¶¶ 11-12.

Dr. Colville, like any eligible clinician, cannot receive higher than a full score in any MIPS category. Prachanronarong Decl. ¶¶ 9, 14. As she received a full score in the improvement activities category for 2017-2020, her ability to achieve a full score is therefore not affected by the addition of a new optional activity to create and implement an anti-racism plan. Regardless of this new activity, Dr. Colville can continue to receive a full score in the improvement activity category in subsequent years by submitting the same activity she submitted for 2018-2020 (or any number of other activities). *Id.* ¶ 17. Her arguments that she is financially and competitively penalized for refusing to submit an anti-racism plan because her "score would increase if she submitted an anti-racism plan," Pls.' Opp'n 9, are therefore incorrect.

To be sure, Dr. Colville's ultimate MIPS adjustment and hence reimbursement rate is, as a general matter, affected by the performance of other clinicians given the budget neutrality of the program. Prachanronarong Decl. ¶ 8. But Dr. Colville's allegations that other clinicians exist who were not able previously to obtain a full score in the improvement activities category but who now "can be reimbursed at higher rates" if they choose to create and implement an anti-racism plan (Am. Compl. ¶ 10) rely on unfounded speculation as to the status and actions of third parties not before the Court. In the absence of any plausible allegation that there actually exist clinicians with less-than-full scores in this category who plan to increase their prior scores solely by submitting anti-racism plans, this theory is entirely too speculative to grant her standing. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 410 (2013) (rejecting theory of standing that relied on "highly attenuated chain of possibilities" involving speculation as to governmental actions). Even more speculative are her allegations of competitive injury (Am. Compl. ¶ 10; Pls.' Opp'n 10-12) based on her fact-free conjectures that *her direct competitors* would be likely to increase their MIPS scores solely through submission of anti-racism plans. *See Little v. KPMG LLP*, 575 F.3d 533, 541 (5th Cir. 2009) (rejecting competitors' claim of lost business as too speculative). Accordingly, Dr. Colville

can show neither financial nor competitive injury from the new activity, and her claims should be dismissed for lack of standing.[2]

**B. The States Lack Standing**

Plaintiff States assert that the improvement activity to create and implement an anti-racism plan harms them in "three ways." Pls.' Opp'n 6. First, because the activity allegedly "encourag[es] Medicare providers to make medical decisions based on race," "the States must 'either enforce their rules against providers who submit anti-racism plans (and deprive their citizens of needed care), or stop enforcing their rules barring racial discrimination.'" *Id.* Second, because providers who fail to submit these plans allegedly "'will get reimbursed at lower rates,' the States 'and their citizens' will suffer 'increased costs.'" *Id*. Third, because the activity allegedly "encourag[es] race-based decisionmaking in medicine," it "decreas[es] the quality and availability of medical care" in their States. *Id*. As Defendants argued in their opening brief (pp. 17-21), in the absence of details of actual plans being implemented by clinicians or of estimates of how many providers in each State will choose or not choose this option, none of these allegations set forth a sufficiently "'real and immediate,' not 'conjectural' or 'hypothetical'" injury sufficient to confer standing. *City of Los Angeles v. Lyons*, 461 U.S. 95, 101-02 (1983) (citations omitted).

Plaintiff States' opposition brief further illustrates the deficiency in their standing claims. First, the opposition makes clear that Plaintiffs' first and third arguments are based on Plaintiffs' entirely unfounded assumption that the activity *encourages* race-based decision making. *See* Pls.' Opp'n 6, 16-17. As nothing in the terms of the activity supports this conclusion, Plaintiff States' assertion of injuries caused by the activity's alleged race-based character is illusionary. And

[2] Should the Court decline to consider Defendants' declaration, Defendants still argue that, taking Dr. Colville's allegations at face value, she has not established that the addition of this activity injures her or that she has identified at most a self-inflicted injury. Defs' Mem. 13-14.

Plaintiffs barely mention their second argument, that the new activity will result in increased costs borne by the States; indeed, they only suggest that there may be "limited" financial loss. *Id.* at 14 (citation omitted). They further miss the point in responding to Defendants' argument that they have failed to provide sufficient credible allegations as to how the decisions of a few clinicians might negatively impact the States financially. Plaintiffs assert that "[o]nce injury is shown, no attempt is made to ask whether the injury is outweighed by benefits the plaintiff has enjoyed from the relationship with the defendant." Pls.' Opp'n 16. However, the impact on the States is necessarily the result of the net impact on clinicians across the State, and in such circumstances, as suggested by the very case Plaintiffs cite, the States cannot rely on an alleged negative impact on a few clinicians without considering potential positive impacts on others. *See Texas v. United States*, 809 F.3d 134, 155 (5th Cir. 2015) (stating that courts will consider "those offsetting benefits that are of the same type and arise from the same transaction as the costs").

Rather than providing the necessary detailed allegations, or hewing to the actual facts, Plaintiff States rely on the "special solicitude in the standing analysis" allegedly due the States, citing *Massachusetts v. EPA*, 549 U.S. 497 (2007). Pls.' Opp'n 13. However, this "special solicitude" applies only to the standing elements of imminence and redressability, *see Texas v. United States*, 40 F.4th 205, 216 (5th Cir. 2022) (denying stay pending appeal), *cert. granted before jdgmt.*, 143 S. Ct. 51 (2022); it does not allow a state to circumvent the bedrock requirement of a concrete, nonspeculative injury. In any event, the "special solicitude" applies, if at all, only when the State can meet two requirements: (1) the State must have a procedural right to challenge the action; and (2) the challenged action must affect one of the State's quasi-sovereign interests. Although, under Fifth Circuit precedent, the first requirement is met here by virtue of the Administrative Procedure Act, *see Texas*, 809 F.3d at 152, the States fail to meet the second requirement, that the challenged action affects one of the States' quasi-sovereign interests.

A state's quasi-sovereign interests include interests in "the health and well-being—both physical and economic—of its residents" and in "not being discriminatorily denied its rightful status in the federal system." *Alfred L. Snapp & Son, Inc. v. Puerto Rico ex rel. Barez*, 458 U.S. 592, 607 (1982). Regardless of its character, though, "[a] quasi-sovereign interest must be sufficiently concrete to create an actual controversy between the State and the defendant." *Id.* at 602. Thus, Plaintiffs cannot use the "special solicitude" due the States to circumvent the requirement of a "concrete" injury sufficient enough to create an "actual controversy." The States here have not alleged a sufficiently concrete injury to their quasi-sovereign interests.

First, they allege that hypothetical anti-racism plans will create a conflict with unidentified state laws. Pls.' Opp'n 14. However, Plaintiffs have failed to allege a sufficiently concrete conflict. As stated above, Plaintiffs' allegations that the activity to create and implement an anti-racism plan will encourage race-based decision making are not well taken. Given the stated goal of anti-racism plans "to prevent and address racism," 86 Fed. Reg. at 65,970, more must be alleged to establish a sufficient conflict between the new activity and state anti-discrimination laws. The cases Plaintiffs cite are distinguishable because there the courts found a "quasi-sovereign" interest where the state was expressly preempted from regulating in the area or was directly pressured to change state law. *See Texas v. United States*, 50 F.4th 498, 516 (5th Cir. 2022) (preemption as to immigration laws); *Texas v. EEOC*, 933 F.3d 433, 447 (5th Cir. 2019) (EEOC guidance pressured Texas to abandon its laws and policies); *Texas*, 809 F.3d at 153 (preemption as to immigration laws); *Louisiana v. Becerra*, 577 F. Supp. 3d 483, 492 (W.D. La. 2022) (federal mandate "specifically preempts state laws"), *appeal docketed*, No. 22-30748 (5th Cir. Nov. 21, 2022); *Texas v. Becerra*, 575 F. Supp. 3d 701, 713 (N.D. Tex. 2021) (same). No such preemption or direct pressure (or even identifiable conflict) is present here.

Plaintiffs have also not established that they are entitled to special solicitude on the basis of their claim that anti-racism plans will decrease the quality of medical care in their States and hence affect their citizens' well-being. The States' interest in their citizens' health and welfare can in some circumstances support State standing as *parens patriae* in a suit against *another state or a private entity*. *See Snapp*, 458 U.S. at 607. However, "[a] State does not have standing as *parens patriae* to bring an action against the Federal Government." *Id*. at 610 n.16. Under principles of federalism, because a state's citizens are also citizens of the United States, the state cannot enforce their "rights in respect of their relations with the federal government." *Massachusetts v. Mellon*, 262 U.S. 447, 485-86 (1923). In the case cited by Plaintiffs, the court *agreed* with this statement of the law but went on to find standing because in addition to its *parens patriae* claim, the State also claimed preemption of state law as well as a variety of other injuries. *Louisiana*, 577 F. Supp. 3d at 492 (finding standing based on a variety of injuries to state interests). But, as stated, there is no claim of preemption here.

To be sure, courts in this Circuit have held that a state may bring a *parens patriae* action against the federal government where the states are seeking to enforce—rather than prevent the enforcement of—a federal statute. *Texas v. United States*, 86 F. Supp. 3d 591, 626 (S.D. Tex. 2015); *see also Louisiana v. Becerra*, No. 3:21-CV-04370, 2022 WL 4370448, at *5 (W.D. La. Sept. 21, 2022) ("[S]tates have *parens patriae* standing where the state is bringing an action on behalf of citizens to enforce rights guaranteed by a federal statute."). But that is not the situation here. In sum, Plaintiff States are not entitled to "special solicitude" based on an interest in their citizens' well-being.

Defendants have already explained that Plaintiff States' claim that the anti-racism plan option will result in increased costs is wrong and too conclusory, and Plaintiffs do not seriously contest that conclusion. Defs.' Mem. 17-21. The Fifth Circuit's decision in *Crane v. Johnson*, 783

F.3d 244, 252 (5th Cir. 2015), is instructive here. There, the court held that Mississippi lacked standing to challenge the federal Deferred Action for Childhood Arrivals ("DACA") policy under a theory that DACA would cause increases in illegal immigration, which Mississippi alleged would "cost the state money because the state provides social benefits to illegal immigrants." *Id*. The court found that such a generalized claim that was "not supported by any facts" did not establish standing because it was "purely speculative." *Id*. Plaintiff States' claims here to standing on the basis of financial impact are similarly doomed by the lack of specificity.

## II. PLAINTIFFS' CLAIMS ARE PRECLUDED BY 42 U.S.C. § 1395w-4(a)(13)(B)

Even if Plaintiffs have standing, this case must be dismissed for lack of subject-matter jurisdiction because review is barred by 42 U.S.C. § 1395w-4(q)(13)(B). This subsection explicitly precludes judicial review of "[t]he identification of measures and activities specified under [MIPS]." 42 U.S.C. § 1395w-4(q)(13)(B)(iii). This provision unambiguously applies to the "identification" of the "activity" to create and implement an anti-racism plan. Plaintiffs' attempts to avoid the operation of this bar are unavailing.

First, Plaintiffs argue that this case falls outside the statutory bar because the activity at issue does not meet the definition of a "clinical practice improvement activity." Pls.' Opp'n 19. However, the very definitional inquiry that Plaintiffs are asking this Court to conduct falls within the jurisdictional bar because the interpretation of that definition is part of the process of the agency's "identification of measures and activities." The case is thus similar to *Texas Alliance for Home Care Services v. Sebelius*, 681 F.3d 402, 408-10 (D.C. Cir. 2012), where the statute stated "[t]here shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of ... the awarding of contracts under this section." Plaintiffs there sought review of the agency's regulation setting forth how financial eligibility would be determined in evaluating contract bids. The court concluded that "financial standards are

indispensable to 'the awarding of contracts'" and interpreted the statute to prohibit review of those standards. *Id.* at 410.

In any event, Plaintiffs' arguments that the activity to create and implement an anti-racism plan does not meet the definition of a clinical practice improvement activity are wrong. Plaintiffs assert that developing an anti-racism plan does not meet the definition because it does not relate to "clinical practice or care delivery." Pls.' Opp'n 19. However, in the Federal Register notice, HHS explicitly linked this improvement activity to "improv[ing] clinical practice and care delivery … because it supports MIPS eligible clinicians in identifying health disparities and implementing processes to reduce racism and provide equitable quality health care." 86 Fed. Reg. at 65,969. Plaintiffs do not address this statement by HHS, and instead return to their spurious (and easily rejected) claim that the activity is not related to clinical practice or care delivery because it encourages the use of race "in a way that does not relate to physiolog[y]." Pls' Opp'n 19.

Plaintiffs also argue that the activity to develop an anti-racism plan does not meet the definition of "clinical practice improvement activity" because "'CMS … failed to identify' any … organizations or stakeholders who identified anti-racism plans as improving practice and care." Pls.' Opp'n 19. This also is incorrect as Plaintiffs ignore the authorities expressly cited by CMS in promulgating the activity. *See* 86 Fed. Reg. at 65,977 nn.1-4. The cited article by C. P. Jones discusses how "[a]nswering the question, 'How is racism operating here?' can be a powerful approach to identifying levers for potential intervention" and then discusses "[o]rganizing and [s]trategizing to [a]ct." *See* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6092166/. The cited CDC website, "Racism and health," now located at https://www.cdc.gov/minorityhealth/racism-disparities/, addresses how "[r]acism is a [s]erious [t]hreat to the [p]ublic's [h]ealth" and contains links to other pages (as well as to outside websites) discussing racism in more detail and discussing methods to address it to improve health outcomes. The outside webpages include one from NIH

publishing its own plan for addressing structural racism. *See* https://www.nih.gov/ending-structural-racism. Therefore, it is incorrect to state that HHS failed to identify any organizations or stakeholders that "identified anti-racism plans as improving practice and care." While the results from MIPS eligible clinicians implementing such plans are not yet in, these stakeholders identified plans as useful methods to address racism and thereby improve the practice of health care and the care provided to patients. HHS is not required to have found actual "improvement" with scientific certainty. *See Indus. Union Dep't v. Am. Petroleum Inst*., 448 U.S. 607, 656 (1980) ("OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty.").

Second, Plaintiffs assert that the exception to a jurisdictional bar for *ultra vires* action applies here. Plaintiffs criticize Defendants' use of the test articulated by then-Judge Kavanagh of the D.C. Circuit in *Nyunt v. Chairman, Broadcasting Board of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009), suggesting that the Fifth Circuit's test is "different" and that, in this Circuit, "[w]hen determining whether the ultra vires exception applies, the question is simply whether 'an agency has exceeded its delegated powers or "on its face" violated a statute.'" Pls' Opp'n 22 (quoting *Kirby Corp. v. Pena*, 109 F.3d 258, 268-69 (5th Cir. 1997)). However, another court has asserted that the Fifth Circuit has focused on two factors (both present in *Nyunt*)—(1) whether the claimant can obtain "meaningful judicial review" of the agency's decision and (2) whether the agency "exceed[ed] the scope of its delegated authority or violate[d] a clear statutory mandate." *Crane v. Beers*, No. 3:12-cv-3247-O, 2013 WL 12123944, at *3 (N.D. Tex. Dec. 9, 2013), *aff'd on other grounds sub nom. Crane v. Johnson,* 783 F.3d 244 (5th Cir. 2015). A consideration of whether the statutory bar is implied or express (the first *Nyunt* factor) is also generally supported by Fifth Circuit precedent. *See Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 532 (5th Cir. 2012) (first determining that "Congress expressly precluded the Secretary's determinations from

judicial review"); *Kirby Corp.*, 109 F.3d at 261-68 (examining text, structure, and legislative history of review preclusion provision). Taking these decisions into account, the Fifth Circuit's test is not substantively different from the *Nyunt* test.

Even under Plaintiffs' one-part test, however, establishing an activity to create and implement an anti-racism plan is not so far outside of Defendants' statutory authority under the MIPS statute as to warrant a finding that they "exceeded [their] delegated powers or 'on its face' violated a statute." *Kirby Corp.*, 109 F.3d 268-69. A viable *ultra vires* claim must assert that the agency "has plainly and openly crossed a congressionally drawn line in the sand." *Fed. Express Corp. v. U.S. Dep't of Com.*, 39 F.4th 756, 765 (D.C. Cir. 2022). On the other hand, "a dispute over whether an agency charged with a statute's implementation has interpreted it correctly … is not the sort of 'egregious' error envisioned by the Supreme Court in" *Leedom v. Kyne*, 358 U.S. 184 (1958). *Am. Airlines, Inc. v. Herman*, 176 F.3d 283, 293 (5th Cir. 1999); *see also id.* ("[R]eview of an agency action allegedly in excess of authority must not simply involve a dispute over statutory interpretation.") (quoting *Kirby Corp.*,109 F.3d at 269) (internal quotation marks omitted)). As discussed above, Plaintiffs' claim here is one concerning the proper interpretation of the statute and does not rise to the level of an "egregious" crossing of a line.

Plaintiffs' assertions to the contrary are wrong or overstated. Plaintiffs assert that the definition of "clinical practice improvement activity" has nothing to do with race, apparently referring to the necessary connection to clinical practice or care delivery. *See* Pls.' Opp'n 23. But Defendants do not assert that the definition incorporates or requires some consideration of race, but rather have asserted that the anti-racism-plan activity is related to improving clinical practices by removing barriers to the delivery of care to a variety of disadvantaged groups, including but not limited to racial minorities, which is entirely consistent with the definition Plaintiffs rely on. Plaintiffs assert that "enumerated examples in the statute clarify that anti-racism plans do not

qualify," *id.*, but ignore that the Secretary has, as permitted, added new subcategories, including that of "Achieving Health Equity," and that the anti-racism activity belongs to this undisputedly legitimate subcategory. *See* Defs.' Mem. 5, 7. Finally, Plaintiffs assert that the new activity "rules out considerations of race that are medically relevant." Pls.' Opp'n 23. Whether or not that is true, in fact, HHS's premise for the activity is that differences in health outcomes that were previously attributed to race may in fact not be a result of race, *see* 86 Fed. Reg. at 65,969 ("it is important to acknowledge systemic racism as a root cause for differences in health outcomes between socially-defined racial groups"), and that clinical practices and care delivery may be best served by not making any presumptions in that regard. Plaintiffs do not explain how this determination by HHS violates any specific statute or is beyond the Secretary's authority under the statute.

In sum, Plaintiffs fail to identify any way in which Defendants have violated "an unambiguous and mandatory provision of the statute." *Am. Airlines, Inc.*, 176 F.3d at 293. At best, their claims concern the proper statutory interpretation of the phrases "clinical practice improvement activity" and "clinical practice and care delivery." Such interpretational issues are not issues that fall within the "very limited" *ultra vires* exception. *See Paladin Cmty. Mental Health Ctr.*, 684 F.3d at 532 (interpretation of the "'based on ... hospital costs' language found in § 1395l(t)(2)(C) … is not the 'extraordinary' situation that falls within the very limited *Kyne* exception"). Plaintiffs' warning that Defendants' position could lead to the nonreviewability of MIPS activities that encourage the *denial* of care to African Americans and Hispanics based on race (Pls.' Opp'n 20) posits a slippery slope that does not exist. Aside from the fact that, unlike the present activity, any such activity would not be recommended by stakeholders, nor would it be plausibly related to improving clinical practice or care delivery, denial of care on such bases would violate a host of federal and state laws and be actionable on that basis.

## CONCLUSION

For the foregoing reasons and for the reasons cited in Defendants' opening memorandum, the First Amended Complaint should be dismissed.

Dated: December 15, 2022

Respectfully submitted,

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

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| AMBER COLVILLE, *et al.*,<br><br>Plaintiffs,<br><br>v.<br><br>XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, *et al.*,<br><br>Defendants. | Civil Action No. 1:22-cv-00113-HSO-RPM |

**DECLARATION OF AUCHA PRACHANRONARONG IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT**

I, Aucha Prachanronarong, make the following declaration based on my personal knowledge and information made available to me in the course of my official duties:

1. I am the Director of the Division of Electronic and Clinician Quality (DECQ) in the Quality Measurement and Value-based Incentives Group (QMVIG) in the Center for Clinical Standards and Quality (CCSQ) at the Centers for Medicare & Medicaid Services (CMS) within the Department of Health and Human Services (HHS). I have been a division director in QMVIG since 2011. Prior to that, I was the lead analyst in QMVIG responsible for developing policies and writing the regulations for the Physician Quality Reporting System (PQRS), one of the legacy Medicare quality reporting programs that preceded the Merit-based Incentive Payment System (MIPS). DECQ's primary responsibility is the administration of all aspects of the MIPS program from policy development to program operations.

2. I am submitting this declaration to provide information about Medicare's MIPS program and the historical participation of Dr. Amber Colville, a plaintiff in this matter, in this

program, in support of Defendants' Motion to Dismiss Plaintiffs' First Amended Complaint. The information I discuss below regarding Dr. Colville's participation and performance in MIPS is only that which is publicly available.

3. To "improv[e] Medicare payment for physicians' services" under Medicare Part B, the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) directed CMS to create a "Merit-based Incentive Payment System" for payments for covered professional services furnished by MIPS eligible professionals (which CMS refers to as "MIPS eligible clinicians") on or after January 1, 2019. Pub. L. No. 114-10, § 101(c)(1), 129 Stat. 87, 92 (2015), codified at 42 U.S.C. § 1395w-4(q). Specifically, CMS was directed to link payments to performance in four categories that focus on the quality and cost of patient care provided by the MIPS eligible clinician—quality, resource use (which CMS now refers to as "cost"), clinical practice improvement activities, and meaningful use of certified electronic health records (EHR) technology (which CMS now refers to as "promoting interoperability"). 42 U.S.C. § 1395w-4(q)(2). Thus, starting in 2019, positive, neutral, or negative adjustments to payments to MIPS eligible clinicians have been determined based on their performance in these four performance categories: quality, cost, clinical practice improvement activities, and promoting interoperability.

4. To be considered a MIPS eligible clinician, and therefore required to participate in MIPS, a clinician must: be identified as a MIPS eligible clinician type on Medicare Part B claims; have enrolled in Medicare within the Provider Enrollment, Chain, and Ownership System (PECOS) and have submitted claims under Medicare prior to the start of the performance period; not be a Qualifying Alternative Payment Model Participant; and exceed the low-volume threshold, which is based on the amount of allowed charges billed by the clinician, the number of Medicare Part B patients treated by the clinician, and the number of items and services furnished

to Medicare Part B patients during the determination periods established by CMS. 42 U.S.C. § 1395w-4(q)(1)(C); 42 C.F.R. § 414.1310.

5. Each MIPS eligible clinician receives a final score of 0 to 100 points for a performance period for a MIPS payment year. 42 U.S.C. § 1395w-4(q)(5)(A), (6)(A). The MIPS payment year is the calendar year in which the MIPS payment adjustment, and if applicable, the additional MIPS payment adjustment for exceptional performance, for a given performance period are applied to a MIPS eligible clinician's Medicare Part B payments. 42 C.F.R. § 414.1405(a). Generally, the MIPS payment adjustments for a MIPS payment year are based on the MIPS eligible clinician's final score from a performance period that occurred two years prior to the MIPS payment year. *See id.*; *see also* 42 C.F.R. § 414.1320. Subject to CMS's authority to assign different scoring weights in certain circumstances, the clinical practice improvement activities performance category has always accounted for 15 percent of a MIPS eligible clinicians' MIPS final score. 42 U.S.C. § 1395w-4(q)(5)(E)(i)(III), (F); 42 C.F.R. § 414.1355(b)(1). The other three performance categories (i.e., quality, cost, and promoting interoperability) account for the remaining 85 percent of the final score. 42 U.S.C. § 1395w-4(q)(5)(E), (F).

6. For each year of MIPS, CMS specifies a performance threshold to which a MIPS eligible clinician's final score is compared for purposes of determining whether that clinician's Medicare payments will receive a positive, neutral, or negative payment adjustment. Beginning in the sixth year of the program (i.e., the 2022 performance period/2024 MIPS payment year), CMS is required to set the performance threshold at the mean or median of the final scores from a prior performance period. 42 U.S.C. § 1395w-4(q)(6)(D)(i). Prior to that, CMS had some flexibility in terms of how we set the performance threshold as long as the performance

thresholds for the 2021, 2022, and 2023 MIPS payment years ensure a gradual and incremental transition towards the expected mean or median that must be used to establish the performance threshold for the 2024 MIPS payment year. *See* 42 U.S.C. § 1395w-4(q)(6)(D)(iii), (iv). MIPS eligible clinicians with a final score at or above the performance threshold receive a zero (neutral) or positive MIPS payment adjustment factor, respectively. MIPS eligible clinicians with a final score below the performance threshold receive a negative MIPS payment adjustment factor. 42 U.S.C. § 1395w-4(q)(6). As specified at 42 C.F.R. § 414.1405(b), the performance thresholds for the 2019 through the 2025 MIPS payment years are as follows: 3 points for 2019 to help ease clinicians' transition into MIPS; 15 points for 2020; 30 points for 2021; 45 points for 2022; 60 points for 2023; 75 points for 2024; and 75 points for 2025.

7. In addition, for the 2019 MIPS payment year and each subsequent year through the 2024 MIPS payment year, CMS specifies an additional performance threshold for purposes of determining an additional positive MIPS adjustment factor for exceptional performance. 42 U.S.C. § 1395w-4(q)(6)(C) and (D)(ii). This provides MIPS eligible clinicians with final scores higher than the additional performance threshold with higher additional positive MIPS payment adjustment factors. The additional performance thresholds for the 2019 through the 2024 MIPS payment years are as follows: 70 points for the 2019 and 2020 MIPS payment years; 75 points for 2021; 85 points for the 2022 and 2023 payment years; and 89 points for 2024. 42 C.F.R. § 414.1405(d).

8. Positive payment adjustment percentages vary to maintain budget neutrality and are subject to a scaling factor. Additionally, $500 million is available for additional payment adjustments for exceptional performance for each payment year 2019 through 2024. 42 U.S.C. § 1395w-4(q)(6)(F). Due to the budget neutrality requirements, the magnitude of a MIPS

eligible clinician's payment adjustment is influenced by the pool of funds available from those who are subject to a negative payment adjustment and the distribution of final scores across all MIPS eligible clinicians in comparison to the performance threshold for a given year.

9. To obtain full credit in the clinical practice improvement activities performance category at issue in this case, clinicians must generally report that they have completed either two high-weighted activities, four medium-weighted activities, or one high-weighted and two medium-weighted activities. 42 C.F.R. § 414.1380(b)(3). However, non-patient facing MIPS eligible clinicians, small practices (as defined in 42 C.F.R. § 414.1305), and practices located in rural areas and geographic Health Professional Shortage Areas need only complete one high-weighted activity or two medium-weighted activities to obtain a full score under the improvement activities performance category. The highest potential score for the improvement activities performance category is 40 points. *Id.* § 414.1380(b)(3). Completing additional activities does not give a clinician a score above 40 points.

10. For the current 2022 performance period, there are 105 widely varying improvement activities from which a clinician may choose to obtain credit under this performance category (down from 106 earlier this year). *See* https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2022 (last visited December 14, 2022).

11. MIPS eligible clinicians have until March 31 (or later date specified by CMS) following the close of a performance period to report data to CMS for the quality, improvement activities, and promoting interoperability performance categories. Throughout the data submission period for a given performance period, CMS provides preliminary feedback on clinicians' scores for measures and activities that have been submitted. After the close of the submission period, CMS analyzes the data received for the performance period as well as our

administrative claims data to calculate scores for each performance category, a final score, and the MIPS payment adjustment. CMS typically releases these results confidentially to MIPS eligible clinicians during a performance feedback period, which typically occurs during the summer following the close of a performance period. This triggers the beginning of a 60-day targeted review period during which a MIPS eligible clinician may request a targeted review of CMS' calculation of the MIPS payment adjustment and, as applicable, CMS' calculation of the additional MIPS payment adjustment. As a result of targeted review requests, CMS may recalculate, to the extent feasible and applicable, the scores of MIPS eligible clinicians regarding measures, activities, performance categories, and the final score, as well as the MIPS payment adjustments. 42 C.F.R. § 414.1385. MIPS eligible clinicians will start seeing the MIPS payment adjustments for a given performance period applied to their Medicare Part B payments beginning in the corresponding MIPS payment year for that performance period.

12. CMS also is required to, at a minimum, post a MIPS eligible clinician's final score and scores for each performance category on the Physician Compare (or successor) website that CMS maintains. *See* https://data.cms.gov/provider-data/search?theme=Doctors%20and%20clinicians. Prior to the public posting, CMS also must provide clinicians an opportunity to review and submit corrections for the information to be made public. 42 U.S.C. § 1395w-4(q)(9). This 30-day preview period typically occurs after all targeted review requests are adjudicated and is followed by the public posting of data some time during the MIPS payment year.

13. According to Medicare records, Dr. Amber Colville is an internal medicine clinician practicing in Ocean Springs, Mississippi, under the organizational name New Wave Internal Medicine Clinic, PLLC. She has been a MIPS eligible clinician for the 2017-2021

performance periods and has participated in MIPS as an individual clinician. Data is publicly available on Dr. Colville's MIPS participation for performance periods 2017-2020. CMS has not yet made a final determination regarding Dr. Colville's MIPS eligibility for the 2022 and 2023 performance periods. *See* "QPP Participation Status Tool" at https://qpp.cms.gov/participation-lookup?py=2022.

14. According to Medicare records, Dr. Colville meets the definition of a "small practice" under 42 C.F.R. § 414.1305 for the 2017-2022 performance periods because the number of clinicians associated with her practice is below the maximum set forth in the definition. Therefore, Dr. Colville needs to, and has only needed to, complete one high-weighted activity or two medium-weighted activities to obtain a full score under the improvement activities performance category (i.e., to obtain the entire 40 points). *Id.* § 414.1380(b)(3). Completing additional activities does not give a clinician a score above a full score.

15. Attached to this declaration is a chart reflecting Dr. Colville's MIPS performance for the 2017-2020 performance periods (2019-2022 payment periods). This chart only reflects information that is publicly available.

16. As noted on the chart, for each of the calendar year performance periods 2017-2020, Dr. Colville received a full score of 40 points in the clinical practice improvement activities category.

17. As Dr. Colville did for the 2018-2020 performance periods, a MIPS eligible clinician each year can submit the same activity or activities under the improvement activities category from year to year. Accordingly, Dr. Colville can continue to submit the same high-weighted activity she has in the past at least through 2023—and for future performance periods, as long as the activity continues to be a part of the MIPS improvement activities inventory for

later years. *See* https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2022#measures; *see also* 87 Fed. Reg. 69,404, 70,058-59 (Nov. 18, 2022) (adopting other modifications to the Improvement Activity Inventory for performance period 2023 but making no change to the availability of the improvement activity Dr. Colville submitted for past performance years).

18. Beginning with the 2018 MIPS performance period/2020 MIPS payment year, CMS established policies that allow CMS to reweight the quality, cost, promoting interoperability, and improvement activities performance categories to 0% for clinicians facing "extreme and uncontrollable circumstances" (EUC), such as natural disasters or public health emergencies. If a MIPS eligible clinician demonstrates through an application submitted to CMS that he or she was subject to an EUC "that prevented [them] from collecting information that [they] would submit for a performance category or submitting information that would be used to score a performance category for an extended period of time," the performance category would not contribute to the clinician's final score, unless the clinician submitted data for the category. 42 C.F.R. § 414.1380(c)(2)(i)(A)(6); *see* 82 Fed. Reg. 53,568, 53,780-83 (Nov. 16, 2017) (CMS refers to this as "the MIPS application-based EUC policy"). Under this policy, if asked by a MIPS eligible clinician, CMS would reweight the affected performance category or performance categories to 0% for the affected performance period. Similarly, if a MIPS eligible clinician was "located in an area affected by extreme and uncontrollable circumstances as identified by CMS," CMS would automatically reweight the performance categories to 0% and the performance categories would not contribute to the clinician's final score, unless the clinician submitted data for a category or categories. 42 C.F.R. § 414.1380(c)(2)(i)(A)(8); *see* 83 Fed. Reg. 59,452, 59,874-75 (Nov. 23, 2018) (CMS refers to this as the "MIPS Automatic EUC policy"). These

MIPS EUC policies have been applied throughout the COVID-19 public health emergency to provide relief for MIPS eligible clinicians and provide opportunities to have the quality, cost, promoting interoperability, and improvement activities performance categories reweighted to 0% so that the clinicians receive a neutral payment. 42 C.F.R. § 414.1380(c)(2)(i)(A)(6), (8); *see* https://qpp.cms.gov/mips/exception-applications.

19. For the 2019, 2020, and 2021 performance periods, CMS applied the MIPS Automatic EUC policy such that MIPS eligible clinicians who did not submit 2019, 2020, or 2021 MIPS data by the specified submission deadlines automatically had all four performance categories reweighted and received neutral payment adjustments. MIPS eligible clinicians reporting as individuals who only submitted 2019, 2020, or 2021 MIPS data for one performance category by the submission deadlines also automatically received neutral payment adjustments. MIPS eligible clinicians reporting as individuals who submitted 2019, 2020, or 2021 MIPS data for two or more performance categories by the submission deadlines received a final score based on the performance categories for which data was submitted and were subject to a negative, neutral, or positive payment adjustment.

20. CMS also automatically reweighted the cost performance category to 0% for the 2019, 2020, and 2021 performance periods after determining that we could not reliably calculate a score for the cost measures as a result of the COVID-19 public health emergency. 42 C.F.R. § 414.1380(c)(2)(i)(A)(2).

21. Because we received data for the quality, improvement activities, and promoting interoperability performance categories for Dr. Colville for the 2019 performance period, we applied the performance category weights described at 42 C.F.R. § 414.1380(c)(2)(ii)(C) in

calculating her final score. Dr. Colville received full credit for the improvement activities performance category for 2019.

22. For the 2020 performance period, we applied the performance category weights described at 42 C.F.R. § 414.1380(c)(2)(ii)(D) in calculating her final score because we again received data for the quality, improvement activities, and promoting interoperability performance categories. Dr. Colville again received full credit for the improvement activities performance category for 2020.

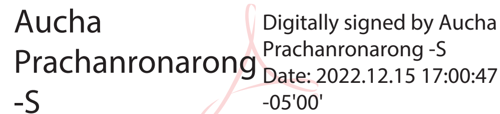
23. The MIPS automatic EUC policy continued to be in effect for the 2021 performance period. CMS has not made 2021 MIPS performance period data publicly available yet.

24. For each year that there is publicly available data, Dr. Colville achieved a full score for the improvement activities performance category. That is, she earned 40 points for the improvement activities performance category for the 2017, 2018, 2019, and 2020 MIPS performance periods. However, achieving a full score for the improvement activities performance category does not necessarily guarantee that she will receive a positive payment adjustment. The improvement activities performance category accounted for only 15% of her final score during each of these years. Dr. Colville's final score must exceed the established performance threshold in order to receive a positive payment adjustment for a given MIPS performance period/MIPS payment year. Her final score exceeded the performance threshold established by CMS for all years in which data are publicly available, thereby earning her a positive MIPS payment adjustment. In addition to achieving the full score for the improvement activities performance category for each of the 2017-2020 performance periods and exceeding the performance threshold established by CMS for each of these years, Dr. Colville's final scores

also exceeded the additional performance threshold established by CMS for the 2017-2019 performance periods, meaning that she received an additional positive MIPS adjustment for exceptional performance for each of the first three years of the program (2019-2021 MIPS payment years) but she did not for the 2020 performance period/2022 MIPS payment year.

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the foregoing is true and correct to the best of my knowledge.

Executed this 15th day of December, 2022.

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