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

AMBER COLVILLE, *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-TBM-RPM

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

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INTRODUCTION

Plaintiffs, two physicians and eight states, seek to challenge under the Administrative Procedure Act 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. The part of the rule at issue sets forth an optional new "improvement activity," called "create and implement an anti-racism plan," which physicians and other eligible professionals may select, among 105 other such activities, to qualify for payment enhancement under MIPS. *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).

The Court lacks subject-matter jurisdiction over Plaintiffs' claims for two reasons. First, Plaintiffs lack Article III standing because they have not, and cannot, sufficiently allege that the addition of this optional activity causes them any concrete financial harm attributable to the federal government defendants that this Court can redress. The state plaintiffs further lack standing because their alleged nonfinancial injuries, based on the purported discriminatory nature and other adverse impact of any forthcoming anti-racism plans, depend on the actions of third parties not before the Court (clinicians who do or do not choose to create such plans) and are entirely speculative at this point where the states do not allege that they are aware of any such plans, let alone provide the details of any such plans. Second, the suit is barred by a provision of the statute creating MIPS, 42 U.S.C. § 1395w-4(q)(13)(B), which bars judicial review of "[t]he identification of … activities specified" as constituting improvement activities. For both reasons, therefore, this case should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1). *See Home Builders Ass'n of Miss., Inc. v. City of Madison*, 143 F.3d 1006, 1010 (5th Cir. 1998) (Rule 12(b)(1) requires dismissal of a complaint where the court "lacks the statutory or constitutional power to adjudicate the case.") (citation omitted).

BACKGROUND

I. STATUTORY BACKGROUND

Title XVIII of the Social Security Act, commonly known as Medicare, 42 U.S.C. §§ 1395 *et seq*., provides federally subsidized health insurance coverage to the elderly and disabled. Medicare Part A pays for inpatient hospital services and other institutional care. *Id*. §§ 1395c to 1395i-5. Part B is a supplemental program that pays for other health care services such as physician visits, outpatient services, and durable medical equipment. *Id*. §§ 1395j to 1395w-4.

To "improv[e] Medicare payment for physicians' services" under Medicare Part B, the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA")[1] 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 a MIPS-eligible professional 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, HHS 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 professional—quality, resource use, 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); *see* 83 Fed. Reg. 59,452, 59,720 (Nov. 23, 2018). Starting in 2019, positive, neutral, or negative adjustments to payments to MIPS-eligible professionals are determined based on their performance in these four categories. The maximum negative adjustment was 4% in 2019, gradually rising to 9% in 2022 and subsequent

[1] Plaintiffs refer to MACRA in the Complaint as the "Medicare Access Act." *See* Compl. ¶ 26 (ECF No. 1).

years. *Id.* § 1395w-4(q)(6)(B). Positive adjustments vary to maintain budget neutrality[2] and are subject to a scaling factor, with $500 million available for additional adjustments for exceptional performance for each of 2019 through 2024. *Id.* § 1395w-4(q)(6)(F).

The MIPS performance category at issue in this suit is the "clinical practice improvement activities" or "improvement activities" category. Compl. ¶ 28. 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." 42 U.S.C. § 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." *Id.* § 1395w-4(q)(2)(B)(iii). Congress directed HHS to "use a request for information to solicit recommendations from stakeholders to identify activities described in . . . subparagraph [(q)(2)(B)(iii), *i.e.*, clinical practice improvement activities] and specifying criteria for such activities." *Id.* § 1395w-4(q)(2)(C)(v)(I). HHS is also permitted to contract with outside entities to assist in identifying improvement activities, specifying criteria for such activities, and determining whether a professional meets such criteria. *Id.* § 1395w-4(q)(2)(C)(v)(II). The

[2] Specifically, MACRA requires that the estimated aggregate yearly increase in payments attributable to positive adjustments equals the estimated aggregate yearly decrease in payments attributed to negative adjustments. 42 U.S.C. § 1395w-4(q)(6)(F)(ii)(I); *see* 81 Fed. Reg. 77,008, 77,016 (Nov. 4, 2016) (explaining that CMS, for the 2019 MIPS payment year, "estimate[s] that MIPS payment adjustments will be approximately equally distributed between negative MIPS payment adjustments ($199 million) and positive MIPS payment adjustments ($199 million) to MIPS eligible clinicians, to ensure budget neutrality").

improvement activities performance category accounts for 15 percent of a MIPS-eligible professional's MIPS final score,[3] subject to HHS's authority to assign different scoring weights in certain circumstances. *Id.* § 1395w-4(q)(5)(E)(i)(III), (F).

Regarding judicial review, 42 U.S.C. § 1395w-4 further provides:

> Except as provided for in subparagraph (A), there shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of the following:
>
> (i) The methodology used to determine the amount of the MIPS adjustment factor under paragraph (6)(A) and the amount of the additional MIPS adjustment factor under paragraph (6)(C) and the determination of such amounts.
>
> (ii) The establishment of the performance standards under paragraph (3) and the performance period under paragraph (4).
>
> (iii) The identification of measures and activities specified under paragraph (2)(B) and information made public or posted on the Physician Compare Internet website of the Centers for Medicare & Medicaid Services under paragraph (9).
>
> (iv) The methodology developed under paragraph (5) that is used to calculate performance scores and the calculation of such scores, including the weighting of measures and activities under such methodology.

Id. § 1395w-4(q)(13)(B).

II. REGULATORY BACKGROUND

To the subcategories identified by MACRA under the "improvement activities" performance category, HHS, through CMS, added through rulemaking some additional subcategories, including the subcategory of "Achieving Health Equity." 42 C.F.R.

[3] The quality and resource use performance categories each account for 30% of the final score and the promoting interoperability category accounts for 25%. 42 U.S.C. 1395w-4(q)(5)(E)(I), (II), (IV).

§ 414.1365(a)(7); *see* 81 Fed. Reg. at 77,188-89. CMS has also yearly published and regularly updated an inventory of clinical practice improvement activities that MIPS-eligible professionals (collectively 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 77,817-30 (Appendix, Table H); 82 Fed. Reg. 53,568, 54,175-229 (Nov. 16, 2017) (Appendix, Tables F & G); 83 Fed. Reg. at 60,286-303 (Appendix 2); 84 Fed. Reg. 62,568, 63514-38 (Nov. 15, 2019) (Appendix 2); 85 Fed. Reg. 84,472, 85,370-77 (Dec. 28, 2020) (Appendix 2); 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.

CMS determined to allot a relative weight of either "high" or "medium" to each improvement activity. 81 Fed. Reg. at 77,015. CMS further established that, to obtain full credit in the improvement activities performance category, a professional must do either two high-weighted activities, four medium-weighted activities, or one high-weighted and two medium-weighted activities (with lower requirements for professionals in certain categories, such as small or rural practices). 42 C.F.R. § 414.1380(b)(3). Each activity must be conducted for at least a continuous ninety-day period during the performance year. *Id.* § 414.1320. For the current 2022 performance period, there are 106, widely varying improvement activities from which a clinician may choose to obtain credit under this performance category. https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2022#measures.[4] High-weighted activities include "CDC Training on CDC's Guideline for Prescribing Opioids for Chronic Pain (IA_PSPA_22)"

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[4] The Court may take judicial notice of official government websites. *See Hawk Aircargo, Inc. v. Chao*, 418 F.3d 453, 457 (5th Cir. 2005)

and "Provide 24/7 Access to MIPS Eligible Clinicians or Groups Who Have Real-Time Access to Patient's Medical Record (IA_EPA_1)"; medium-weighted activities include "Depression Screening (IA_BMH_4)" and "Implementation of a Personal Protective Equipment (PPE) Plan (IA_ERP_4)." *Id.*

All MIPS-eligible clinicians are required to participate in MIPS. 42 U.S.C. § 1395w-4(q)(1). However, beginning with the 2020 MIPS payment year, CMS established policies that essentially exempt MIPS-eligible clinicians from compliance with the quality, cost, and improvement activities performance categories for "extreme and uncontrollable circumstances" ("EUC"). If a MIPS-eligible clinician demonstrates that they were subject to 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. at 53,780-83. Similarly, if a MIPS-eligible clinician was "located in an area affected by extreme and uncontrollable circumstances as identified by CMS," those 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. at 59,874-75. These EUC policies have been applied during the COVID-19 public health emergency to essentially exempt MIPS-eligible clinicians from complying with the requirements for the quality, cost, and improvement activities performance categories. 42 C.F.R. § 414.1380(c)(2)(i)(A)(6), (8); *see* https://qpp.cms.gov/mips/exception-applications.

III. 2021 RULEMAKING

On July 23, 2021, as part of its yearly rulemaking addressing physician payment policies under Medicare Part B, CMS proposed adding an improvement activity to its inventory in the "Achieving Health Equity" subcategory titled "create and implement an anti-racism plan." 86 Fed. Reg. 39,104, 39,345, 39,855 (July 23, 2021). CMS stated that this proposed activity "aims to address systemic inequities, including systemic racism, as called for in Executive Order 13985: Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, published January 20, 2021."[5] *Id.* at 39,855. 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 "[t]his improvement activity acknowledges it is insufficient to gather and analyze data by race, and document disparities by different population group," *id.* at 39,345, and "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.

CMS received several comments expressing support for the proposal to adopt this improvement activity, and for the high weight assigned to it, as well as a couple of comments raising issues with the proposal. CMS responded to the comments and finalized the improvement activity in the subsequent final rule, 86 Fed. Reg. 64,996 (Nov. 19, 2021). As finalized, the activity is described as follows:

> 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

[5] Executive Order 13,985 directed the federal government to undertake a variety of measures to "recognize and work to redress inequities in [federal] policies and programs that serve as barriers to equal opportunity." 86 Fed. Reg. 7009 (Jan. 20, 2021).

> 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. More information about elements of the CMS Disparities Impact Statement is detailed in the template and action plan document at https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Disparities-Impact-Statement-508-rev102018.pdf.

86 Fed. Reg. at 65,970.

IV. THIS CASE

On May 5, 2022, two individuals and eight states filed the present suit seeking to challenge the new improvement activity for creating and implementing an anti-racism plan. The individual plaintiffs are two physicians, one from Mississippi and one from Kentucky, who participate in MIPS but have not submitted anti-racism plans to CMS and who allege financial injury. Compl. ¶¶ 7, 9, 10. The eight states, Mississippi, Alabama, Arizona, Arkansas, Kentucky, Louisiana, Missouri, and Montana, allege both a financial injury and an injury to their ability to enforce their discrimination laws and to their quasi-sovereign interest in their citizens' health and well-being. *Id.* ¶¶ 12, 13. Plaintiffs contend that the addition of this new improvement activity is contrary to law, specifically, MACRA, and in excess of statutory jurisdiction, authority, or limitations provided by that law, and is arbitrary and capricious, in violation of the Administrative Procedure

Act ("APA"), 5 U.S.C. § 706(2)(A), (C). Defendants now move to dismiss this Complaint for lack of subject-matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1).

LEGAL STANDARDS

To survive a motion to dismiss for lack of subject-matter jurisdiction under Rule 12(b)(1), a plaintiff bears the burden of establishing the court's jurisdiction "with the manner and degree of evidence required at the successive stages of the litigation." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992). Courts should "presume that [they] lack jurisdiction unless the contrary appears affirmatively from the record." *Renne v. Geary*, 501 U.S. 312, 316 (1991) (citations and internal quotation marks omitted). "In assessing jurisdiction, 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). "In deciding a motion to dismiss[,] the court may consider documents attached to or incorporated in the complaint and matters of which judicial notice may be taken." *United States ex rel. Willard v. Humana Health Plan of Tex. Inc*., 336 F.3d 375, 379 (5th Cir. 2003).

A motion to dismiss for lack of standing is properly brought under Federal Rule of Civil Procedure 12(b)(1). *See, e.g., Ramming v. United States*, 281 F.3d 158, 161 (5th Cir. 2001). A motion to dismiss because suit against the United States is barred by statute is also properly brought under Rule 12(b)(1). A statutory bar to judicial review of federal government action means the United States retains its sovereign immunity from suits within the scope of the statute. *St. Tammany Par. ex rel. Davis v. Fed. Emergency Mgmt. Agency*, 556 F.3d 307, 321-22 (5th Cir. 2009) (where statutory bar is applicable, "the government retains sovereign immunity for claims" alleged under the APA). Because sovereign immunity "deprives the court of jurisdiction," the court considers a motion to dismiss based on application of a statutory bar under Rule 12(b)(1). *Warnock v. Pecos Cnty.*, 88 F.3d 341, 343 (5th Cir. 1996).

ARGUMENT

I. PLAINTIFFS LACK STANDING

The doctrine of constitutional standing, an essential aspect of the Article III case-or-controversy requirement, demands that a plaintiff have "a personal stake in the outcome of the controversy [so] as to warrant his invocation of federal-court jurisdiction." *Warth v. Seldin*, 422 U.S. 490, 498 (1975) (citation and internal quotation marks omitted). At its "irreducible constitutional minimum," the doctrine requires a plaintiff, as the party invoking the Court's jurisdiction, to establish three elements: (1) a concrete and particularized injury-in-fact, either actual or imminent; (2) a causal connection between the injury and defendants' challenged conduct, such that the injury is fairly traceable to the challenged action of the defendant; and (3) a likelihood that the injury suffered will be redressed by a favorable decision. *Defs. of Wildlife*, 504 U.S. at 560.

"At the pleading stage, allegations of injury are liberally construed." *Little v. KPMG LLP*, 575 F.3d 533, 540 (5th Cir. 2009). However, "standing cannot be inferred argumentatively from averments in the pleadings, but rather . . . it is the burden of the party who seeks the exercise of jurisdiction in his favor … clearly to allege facts demonstrating that he is a proper party to invoke judicial resolution of the dispute." *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990) (citations and internal quotation marks omitted); *see also Pennie v. Obama*, 255 F. Supp. 3d 648, 660 (N.D. Tex. 2017) ("[C]onclusory allegations are insufficient to confer standing.").

"Abstract injury" is insufficient to confer standing; rather, a plaintiff must show that he or she has "sustained or is immediately in danger of sustaining some direct injury." *City of Los Angeles v. Lyons*, 461 U.S. 95, 101-02 (1983) (citation omitted). "[T]he injury or threat of injury must be both 'real and immediate,' not 'conjectural' or 'hypothetical.'" *Id*. Thus, an injury that

is based on a "speculative chain of possibilities" does not confer Article III standing. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 414 (2013). Moreover, a plaintiff cannot establish neither the necessary causal connection between an alleged injury and defendants' conduct nor the necessary redressability where plaintiff's allegations rely on the independent actions of third parties not before the Court. *See Little*, 575 F.3d at 541.

Plaintiffs have not met their burden to show the necessary real, nonspeculative injury-in-fact fairly attributable to government action and redressable by the Court here.

A. <u>The Individual Physicians Lack Standing</u>

The individual plaintiffs are two physicians who participate in MIPS but have not submitted anti-racism plans to CMS. Compl. ¶ 7. They allege that their refusal to submit anti-racism plans place them at "a direct disadvantage vis-à-vis their competitors," who do submit such plans and therefore allegedly "can be reimbursed at higher rates, while the individual plaintiffs cannot." *Id.* ¶ 9. The individual plaintiffs further allege that they "are penalized in their improvement activity MIPS score" for not submitting anti-racism plans, which "takes money out of their practices." *Id.* ¶ 10.

Plaintiffs' allegations are based on a misunderstanding of the MIPS program. To obtain a full score under the improvement activities performance category, Plaintiffs need only do two high-weighted, or four medium-weighted, activities, or a combination of one high-weighted and two medium-weighted activities, from an inventory of 106 total activities. Therefore, they can still obtain a full score under this performance category even if they decline to submit an anti-racism plan and even if their competitors do submit such plans. Plaintiffs can simply choose two to four other activities of the other 105 available, for a full score. The addition of the anti-racism plan improvement activity neither deprives them of the ability to obtain a full score in the

improvement activities performance category nor does it give clinicians who do chose that activity a competitive advantage in the MIPS program.

In plain terms, the inclusion of an optional activity in the 106-item inventory does not harm the individual physician plaintiffs, even if they find that one activity objectionable. Thus, "under ordinary Article III standing analysis, the plaintiffs lack Article III standing for a simple, commonsense reason," *Thole v. U. S. Bank N.A.*, 140 S. Ct. 1615, 1622 (2020)—the individual plaintiffs do not credibly allege, let alone will they be able to show, that they are suffering or will suffer any "perceptible harm" from the action challenged. *Defs. of Wildlife*, 504 U.S. at 566. "[A] 'concrete' injury must be '*de facto*'; that is, it must actually exist." *Spokeo, Inc. v. Robins*, 578 U.S. 330, 340 (2016) (citing Black's Law Dictionary 479 (9th ed. 2009)). When the very regulatory scheme at issue provides options for the individual plaintiffs to avoid the provisions they find objectionable, and still to receive a full score, plaintiffs cannot claim a credible injury, even at the pleading stage. *See Thole*, 140 S. Ct. at 1622 (finding no standing where "[w]inning or losing this suit would not change the plaintiffs' monthly pension benefits"); *see also California v. Texas*, 141 S. Ct. 2104, 2114 (2021) (finding plaintiffs lacked an injury-in-fact for standing purposes to challenge the Affordable Care Act's minimum essential coverage requirement once the penalty for failure to comply was set at $0); *Int'l Tape Mfrs. Ass'n v. Gerstein*, 494 F.2d 25, 28 (5th Cir. 1974) (explaining that standing to challenge a statute requires a "realistic possibility that the challenged statute will be enforced to [the plaintiff's] detriment").

In addition, given the many options available to them, any failure by the individual plaintiffs to achieve a full score in the improvement activities category would constitute, not an injury caused by the government defendants, but rather a self-inflicted injury, which cannot confer standing, *Inclusive Cmtys. Project, Inc. v. Dep't of Treasury*, 946 F.3d 649, 655 (5th Cir. 2019).

Moreover, Plaintiffs' injury would not be redressed by Court invalidation of the improvement activity they challenge, as Plaintiffs would still need to choose 2-4 of the remaining 105 activities to obtain a full score. *See California v. Texas*, 141 S. Ct. at 2116 (finding that "injunctive relief [that] could amount to no more than a declaration that the statutory provision they attack is unconstitutional, i.e., a declaratory judgment … is the very kind of relief that cannot alone supply jurisdiction otherwise absent"). Accordingly, the individual plaintiffs lack standing and their claims should be dismissed pursuant to Rule 12(b)(1).

B. The States Lack Standing

The state plaintiffs' allegations of injury similarly fail to establish the necessary standing. Echoing the individual plaintiffs' stated concern, the state plaintiffs also assert as one of their injuries that, because "[p]roviders who fail to submit" anti-racism plans "will get reimbursed at lower rates," the state plaintiffs and their citizens will have to bear increased costs. Compl. ¶ 12. This allegation fails to establish standing for the same reason the individual plaintiffs' allegations of financial injury failed—clinicians who do not want to select this improvement activity will not be reimbursed at lower rates because they can select sufficient activities from the remainder of the 106-item inventory to satisfy the improvement activities requirement, meaning that, to the extent the states rely on this theory, they lack an injury caused by the federal government defendants and redressable by the Court.

Even if there were some adverse effect from clinicians failing to select this option (and, to be clear, there is not), the states do not sufficiently allege how the decisions of some clinicians, which might possibly be balanced out by different decisions by other in-state clinicians, would create a net negative impact for the state as a whole, particularly in view of the fact that MIPS is required to be budget neutral. *See DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 344 (2006)

(finding claims of injury too "conjectural or hypothetical" where "it is unclear that tax breaks of the sort at issue here do in fact deplete the treasury"). In the absence of some credible allegations as to how the decisions of a few clinicians might negatively impact the state plaintiffs, this theory is too speculative and hypothetical to confer standing.

The state plaintiffs also claim that some or all of clinicians' anti-racism plans will violate their own state laws against racial discrimination, forcing the states to choose between not enforcing their laws or enforcing their laws against clinicians that implement anti-racism plans but thereby depriving citizens of "needed care" in some unspecified way. Compl. ¶ 12. The state plaintiffs further assert that clinicians' creation of anti-racism plans will lead to "race-based decisionmaking in medicine," which will "decreas[e] the quality and availability of medical care" in their state, thereby harming their "quasi-sovereign interest" in the health and well-being of their citizens. *Id.* ¶ 13. However, these allegations as well are too speculative to establish standing.

These theories of standing rest on the states' unsupported (and nonspecific) speculation about what the anti-racism plans developed by clinicians who select this improvement activity will actually provide—that is, whether they will constitute racial discrimination in violation of state law or lead to impermissible or inappropriate race-based decisionmaking in medicine. The state plaintiffs do not allege that any in-state clinicians have yet submitted anti-racism plans, nor do they present any details of any such plans. In the absence of any suggestion that there are any anti-racism plans in existence, let alone that those plans are inconsistent with state law, the state plaintiffs' claims of injury lack "sufficient immediacy and reality" to satisfy constitutional requirements, *Golden v. Zwickler*, 394 U.S. 103, 108 (1969), and are therefore too speculative. *See Blum v. Yaretsky*, 457 U.S. 991, 1001 (1982) (holding plaintiffs lacked standing where "[n]othing in the record ... suggest[ed] that any of the individual [plaintiffs] have been either

transferred to more intensive care or threatened with such transfers" and that, although "it is not inconceivable that [plaintiffs] will one day confront this eventuality," "assessing the possibility now would 'tak[e] us into the area of speculation and conjecture'"); *see also Pub. Citizen, Inc. v. Bomer*, 274 F.3d 212, 218 (5th Cir. 2001) (Plaintiffs' allegations of injury caused by Texas system of electing judges were "too abstract and speculative" where they "point to no past case in which a judgment was tainted by contributions; they mention no current litigation in which an opposing party or lawyer contributed to the judge's campaign; and they merely speculate as to the future.").[6]

These allegations also fail the causation prong of the standing inquiry because plaintiffs' theory of harm depends on the actions of third parties not before the Court, that is, clinicians who choose to create and implement anti-racism policies. When "a plaintiff's asserted injury arises from the government's allegedly unlawful regulation (or lack of regulation) of *someone else*," "standing is not precluded, but it is ordinarily 'substantially more difficult' to establish." *Defs. of Wildlife*, 504 U.S. at 562. When "[t]he existence of one or more of the essential elements of standing depends on the unfettered choices made by independent actors not before the courts, ... it becomes the burden of the plaintiff to adduce facts showing that those choices have been or will be made in such manner as to produce causation and permit redressability of injury." *Id.* Plaintiffs have not met this burden here. Rather, their allegations depend on "several layers of decisions by third parties" (*Little*, 575 F.3d at 541)—namely, clinicians—and none of those layers or decisions

[6] Even if the state plaintiffs were to come forward with allegations regarding specific anti-racism plans implemented by clinicians in their states under MIPS, those allegations would still likely not be sufficient to confer standing under either a theory of interference with the state's interest in enforcing its laws or a theory of harm to the state's quasi-sovereign interest in the health and well-being of its citizens. The state plaintiffs will still be unable to show a conflict between the states and the federal scheme (and a resultant injury) since both Medicare and the state share the same goal of fostering discrimination-free and effective health care.

contain any details at this point. Such an undeveloped, hypothetical chain of events involving independent third parties is not only too speculative, but it presents a line of causation leading from government action that is too "attenuated" and "weak" to support standing. *See Allen v. Wright*, 468 U.S. 737, 759 (1984) (finding chain of causation too weak where it "involve[d] numerous third parties … who may not even exist in respondents' communities and whose independent decisions may not collectively have a significant effect"). Accordingly, the states' claims must be dismissed for this reason as well. *See also Peters v. St. Joseph Servs. Corp.*, 74 F. Supp. 3d 847, 857 (S.D. Tex. 2015) (dismissing claim for lack of standing when "the allegation is conclusory and fails to account for the sufficient break in causation caused by … third parties").

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

This case also should be dismissed for lack of subject-matter jurisdiction because review is barred by 42 U.S.C. § 1395w-4(q)(13)(B). In mandating the establishment of MIPS, Congress explicitly precluded judicial review of claims challenging key aspects of the new system. As relevant here, Congress explicitly precluded judicial review of "[t]he identification of measures and activities specified under paragraph (2)(B)." 42 U.S.C. § 1395w-4(q)(13)(B)(iii). "[P]aragraph (2)(B)," entitled "Measures and activities specified for each category," includes subparagraph (iii) which addresses "Clinical practice improvement activities." *Id.* § 1395w-4(q)(2)(B)(iii). The current suit seeks to challenge an "activit[y] specified" for the clinical practice improvement activities performance category. Accordingly, it is expressly barred by the review preclusion provision.

Section 1395w-4(q)(13)(B)'s preclusion of review expressly extends beyond the Medicare statute to encompass Plaintiffs' APA claims. The statute states that there "shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, *or*

otherwise …." 42 U.S.C. § 1395w-4(q)(13)(B) (emphasis added). The review bar is therefore not limited to review sought under the Medicare statute (*i.e.*, Sections 1395ff or 1395oo). Rather, by including the "or otherwise" language, Congress made clear that the bar on judicial review extends to challenges brought under other statutes, including the Administrative Procedure Act, and cannot be evaded by challenging the Secretary's actions on the basis of alleged violations of such other statutes. Moreover, judicial review under the APA is subject to limitation by other statutes. *See* 5 U.S.C. § 701(a) (stating that the APA does not apply "to the extent that … statutes preclude judicial review"). Accordingly, the fact that Plaintiffs assert claims based upon alleged violations of the APA does not place their claims outside the judicial review preclusion language here. *See* *Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408-10 (D.C. Cir. 2012) (affirming dismissal of APA claims in light of similar provision at 42 U.S.C. § 1395w-3(b)(11) precluding judicial review and citing 5 U.S.C. § 701(a)(1)); *Knapp Med. Ctr. v. Burwell*, 192 F. Supp. 3d 129, 133, 135 (D.D.C. 2016) (holding that the same "or otherwise" language in another similar provision, 42 U.S.C. § 1395nn(i)(3)(I), barred judicial review of a claim under the Mandamus Act), *aff'd sub nom. Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125 (D.C. Cir. 2017), *and reh'g en banc denied*, No. 16-5234 (2018).

To be sure, there is a "strong presumption that Congress intends judicial review of administrative action." *Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 531 (5th Cir. 2012) (quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986)). However, "[s]ubject to constitutional constraints, Congress can, of course, make exceptions to the historic practice whereby courts review agency action." *Paladin*, 684 F.3d at 531 (quoting *Mich. Acad.*, 476 U.S. at 672). The presumption may therefore be overcome by, inter alia, "specific language or specific legislative history that is a reliable indicator of congressional intent, or a specific

congressional intent to preclude judicial review that is fairly discernible in the detail of the legislative scheme." *Paladin*, 684 F.3d at 531 (quoting *Mich. Acad*., 476 U.S. at 673) (internal quotation marks omitted).

Here, section 1395w-4(q)(13)(B) could not be a "more clear" prohibition of judicial review sufficient to overcome any presumption that such review should be allowed. *Painter v. Shalala*, 97 F.3d 1351, 1356 (10th Cir. 1996) (finding similar no-review provision in 42 U.S.C. § 1395w-4(i)(1)(C) "plain and unambiguous"). Courts have applied similar review-preclusion provisions in the Medicare statute to bar challenges like the one brought here. *See Paladin*, 684 F.3d at 531 (holding that 42 U.S.C. § 1395*l*(t)(12) showed "clear congressional intent" to bar judicial review of challenge to HHS's establishment of, and annual adjustments to, relative payment weights for partial hospitalization services); *Am. Soc'y of Cataract & Refractive Surgery v. Thompson*, 279 F.3d 447, 452 (7th Cir. 2002) (finding 42 U.S.C. § 1395w-4(i)(1)(C) barred judicial review of HHS's formula for setting "relative value units," including review under the APA of an HHS regulation); *Painter*, 97 F.3d at 1356 (Section 1395w-4(i)(1)'s bar against review of challenges to the "determination of conversion factors" clearly indicates "Congress' intent to preclude administrative and judicial review."); *Am. Soc'y of Anesthesiologists v. Shalala*, 90 F. Supp. 2d 973 (N.D. Ill. 2000) (upholding 42 U.S.C. § 1395w-4(i)(1)(C)'s "express prohibition against judicial review").

In removing judicial scrutiny, Congress did not, however, leave the Secretary to act without oversight. To the contrary, Congress intended that it would itself carefully monitor and review implementation of the MIPS system, to this end, requiring GAO to submit a number of reports assessing MIPS. Pub. L. No. 114-10, § 101(c)(2), 129 Stat. at 113. In addition, Congress provided in subsection (A) of (q)(13) for "targeted review," directing the Secretary to "establish a process

under which a MIPS eligible professional may seek an informal review of the calculation of the MIPS adjustment factor (or factors) applicable to such eligible professional under this subsection for a year."

Because Section 1395w-4(q)(13)(B) expressly precludes judicial review under the Medicare statute "or otherwise" of claims challenging "[t]he identification of … activities specified under paragraph (2)(B)[(iii)]," addressing clinical practice improvement activities, there is no review available under the APA of HHS's addition of the optional improvement activity of creating and implementing an anti-racism plan. The case should be dismissed for this reason as well.

CONCLUSION

For the reasons set forth above, the Complaint should be dismissed for lack of subject-matter jurisdiction.

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Respectfully submitted,

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