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 PLAINTIFFS' FIRST AMENDED COMPLAINT

TABLE OF CONTENTS

INTRODUCTION 1

BACKGROUND 2

I. STATUTORY BACKGROUND 2

II. REGULATORY BACKGROUND 5

III. 2021 RULEMAKING 7

IV. THIS CASE 8

LEGAL STANDARDS 9

ARGUMENT 11

I. PLAINTIFFS LACK STANDING 11

A. Individual Plaintiff Colville Lacks Standing 12

B. The States Lack Standing 17

II. PLAINTIFFS' CLAIMS ARE PRECLUDED BY 42 U.S.C. § 1395w-4(q)(13)(B) 21

A. 42 U.S.C. § 1395w-4(q)(13)(B) Expressly Bars Review of Plaintiffs' Claims 21

B. The *Ultra Vires* Exception to Review Preclusion Does Not Apply 22

CONCLUSION 29

TABLE OF AUTHORITIES

Cases

Aid Association for Lutherans v. United States Postal Service,
321 F.3d 1166 (D.C. Cir. 2003) 23

Allen v. Wright,
468 U.S. 737 (1984) 16, 17, 20

American Airlines, Inc. v. Herman,
176 F.3d 283 (5th Cir. 1999) 23, 26

American Clinical Laboratory Association v. Azar,
931 F.3d 1195 (D.C. Cir. 2019) 26

American Society of Anesthesiologists v. Shalala,
90 F. Supp. 2d 973 (N.D. Ill. 2000) 22

American Society of Cataract and Refractive Surgery v. Thompson,
279 F.3d 447 (7th Cir. 2002) 22

Amgen, Inc. v. Smith,
57 F.3d 103 (D.C. Cir. 2004) 23, 27, 28

Ascension Borgess Hospital v. Becerra,
557 F. Supp. 3d 122 (D.D.C. 2021 28

Ashcroft v. Iqbal,
556 U.S. 662 (2009) 10

Bell Atlantic Corporation v. Twombly,
550 U.S. 544 (2007) 10

Blum v. Yaretsky,
457 U.S. 991 (1982) 19

Brotherhood of Locomotive Engineers and Trainmen v. Surface Transportation Board,
457 F.3d 24 (D.C. Cir. 2006) 16

Buchholz v. Meyer Njus Tanick, PA,
946 F.3d 855 (6th Cir. 2020) 15

Cameron County Housing Authority v. City of Port Isabel,
No. 19-40717, 2021 WL 1972609 (5th Cir. May 18, 2021) 15

Choice Inc. of Texas v. Greenstein,
691 F.3d 710 (5th Cir. 2012) 9

City of Los Angeles v. Lyons,
461 U.S. 95 (1983)..... 18

Clapper v. Amnesty International USA,
568 U.S. 398 (2013)..... 15, 18

DaimlerChrysler Corp. v. Cuno,
547 U.S. 332 (2006)..... 18

DCH Regional Medical Center v. Azar,
925 F.3d 503 (D.C. Cir. 2019) 23, 28

Federal Express Corporation v. United States Department of Commerce,
39 F.4th 756 (D.C. Cir. 2022) ..... *passim*

Florida Health Sciences Center, Inc. v. Secretary of Health and Human Services,
830 F.3d 515 (D.C. Cir. 2016).....25, 27, 28

Funk v. Stryker Corp.,
631 F.3d 777 (5th Cir. 2011) 10

FW/PBS, Inc. v. Dallas,
493 U.S. 215 (1990)..... 11

Gentilello v. Rege,
627 F.3d 540 (5th Cir. 2010) 10

Golden v. Zwickler,
394 U.S. 103 (1969)..... 19

Griffith v. Federal Labor Relations Authority,
842 F.2d 487 (D.C. Cir. 1988) 23, 24

H. Lee Moffitt Cancer Center and Research Institute Hospital, Inc. v. Azar,
324 F. Supp. 3d 1 (D.D.C. 2018) 23

Hartz Mountain Corporation v. Dotson,
727 F.2d 1308 (D.C. Cir. 1984) 24

Kalispel Tribe of Indians v. United States Department of the Interior,
999 F.3d 683 (9th Cir. 2021).....27

Key Medical Supply, Inc. v. Burwell,
764 F.3d 955 (8th Cir. 2014) 25, 26

Kirby Corporation v. Pena,
109 F.3d 258 (5th Cir. 1997) 23, 26

Kitty Hawk Aircargo, Inc. v. Chao,
418 F.3d 453, 457 (5th Cir. 2005) 6

Knapp Medical Center v. Burwell,
192 F. Supp. 3d 129 (D.D.C. 2016) *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). 22

Local 130, International Union of Electrical, Radio & Machine Workers, AFL-CIO v. McCulloch,
345 F.2d 90 (D.C. Cir. 1965) 23

Little v. KPMG LLP,
575 F.3d 533 (5th Cir. 2009) 11, 20

Lujan v. Defenders of Wildlife,
504 U.S. 555 (1992) ..... *passim*

McConnell v. Federal Election Commission,
540 U.S. 93 (2003) 15

Mittleman v. Postal Regulatory Commission,
757 F.3d 300 (D.C. Cir. 2014) 23

Motor Vehicle Manufacturers Association of United States, Inc. v. State Farm Mutual Automobile Insurance Co.,
463 U.S. 29 (1983) 27

National Association of Postal Supervisors v. United States Postal Service,
26 F.4th 960 (D.C. Cir. 2022) 24

North Oaks Medical Center, LLC v. Azar,
No. CV 18-9088, 2020 WL 1502185 (E.D. La. Mar. 25, 2020) 25, 28

Nyunt v. Chairman, Broadcasting Board of Governors,
589 F.3d 445 (D.C. Cir. 2009) 24, 26, 28

Painter v. Shalala,
97 F.3d 1351 (10th Cir. 1996) 22, 24

Paladin Community Mental Health Center v. Sebelius,
684 F.3d 527 (5th Cir. 2012) 22

Pennie v. Obama,
255 F. Supp. 3d 648 (N.D. Tex. 2017) 11

Peters v. St. Joseph Services Corporation,
74 F. Supp. 3d 847 (S.D. Tex. 2015) 20

Plotkin v. IP Axess Inc.,
407 F.3d 690 (5th Cir. 2005) 10

Public Citizen, Inc. v. Bomer,
274 F.3d 212 (5th Cir. 2001) 19

Ramming v. United States,
281 F.3d 158 (5th Cir. 2001) 9

Renne v. Geary,
501 U.S. 312 (1991) 9

St. Tammany Parish ex rel. Davis v. Federal Emergency Management Agency,
556 F.3d 307 (5th Cir. 2009) 10

Taylor v. Sackler Family of Purdue Ownership,
No. 3:21-CV-3175-EBN, 2021 WL 6883212 (N.D. Tex. Dec. 28, 2021) 15

Texas Alliance for Home Care Services v. Sebelius,
681 F.3d 402 (D.C. Cir. 2012) 22, 24

Thole v. U.S. Bank N.A.,
140 S. Ct. 1615 (2020) 13

United States ex rel. Willard v. Humana Health Plan of Texas, Inc.,
336 F.3d 375 (5th Cir. 2003) 10

United States Department of Justice v. Federal Labor Relations Authority,
981 F.2d 1339 (D.C. Cir. 1993) 23

Warnock v. Pecos County,
88 F.3d 341 (5th Cir. 1996) 10

Warth v. Seldin,
422 U.S. 490 (1975) 11, 15

Zimmerman v. City of Austin, Texas,
881 F.3d 378 (5th Cir. 2018) 15

Statutes

5 U.S.C. § 701 21

5 U.S.C. § 706 9

42 U.S.C. § 1395 *et seq.* 2

42 U.S.C. §§ 1395c-1395i-5 2

42 U.S.C. §§ 1395j-1395w-4 2

42 U.S.C. § 1395*l* 22

42 U.S.C. § 1395nn 22

42 U.S.C. § 1395w-3 22

42 U.S.C. § 1395w-4 ..... *passim*

Medicare Access and Chip Reauthorization Act of 2015,
Pub. L. No. 114-10, 129 Stat. 87 (2015), *codified at* 42 U.S.C. § 1395w-4 2

Rule

Federal Rule of Civil Procedure 12 ..... *passim*

Administrative and Executive Materials

42 C.F.R. § 414.1305 ..... 5, 13

42 C.F.R. § 414.1320 5

42 C.F.R. § 414.1365 5

42 C.F.R. § 414.1380 ..... *passim*

Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,
Executive Order 13,985, 86 Fed. Reg. 7009 (Jan. 20, 2021) 7

Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models,
81 Fed. Reg. 77,008 (Nov. 4, 2016) 3, 5

Medicare Program; CY 2018 Updates to the Quality Payment Program; and Quality Payment Program: Extreme and Uncontrollable Circumstance Policy for the Transition Year, 82 Fed. Reg. 53,568 (Nov. 16, 2017) 5, 6

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions…, 83 Fed. Reg. 59,452 (Nov. 23, 2018) 3, 5, 6

Medicare Program; CY 2020 Revisions to Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies…, 84 Fed. Reg. 62,568 (Nov. 15, 2019) 5

Medicare Program; CY 2021 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies…, 85 Fed. Reg. 84,472 (Dec. 28, 2020) 5

Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies, 86 Fed. Reg. 39,104 (July 23, 2021) 7, 15

Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes, 86 Fed. Reg. 64,969 (Nov. 19, 2021) 1, 5, 8

Other Authorities

About Quality Payment Program (QPP) Exceptions, *Extreme and Uncontrollable Circumstances Exception*, https://qpp.cms.gov/mips/exception-applications 7

Explore Measures & Activities, *2022 Improvement Activities: Traditional MIPS*, https://qpp.cms.gov/mips/explore-measures?tab=improvementActivities&py=2022 5

Opioids, *Interactive Training Series for Healthcare Providers* https://www.cdc.gov/opioids/providers/training/interactive.html 14

INTRODUCTION

Plaintiffs, one physician and eight 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. The part of the rule at issue sets forth an optional new "clinical practice 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). In response to a prior motion to dismiss for lack of subject-matter jurisdiction filed by Defendants, Plaintiffs have now filed a First Amended Complaint (ECF No. 28) recasting and reducing their claims to one claim, that the rule is *ultra vires* because it does not relate to patient health and safety, which Plaintiffs allege is the underlying purpose of the MIPS statute. However, Plaintiffs' attempt to craft a claim over which this Court has jurisdiction is unavailing. Defendants again move for dismissal for lack of subject-matter jurisdiction, for essentially the same reasons as before, as well as, in the alternative, for failure to state a claim.

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 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 clinical practice improvement activities. And Plaintiffs have not adequately plead an *ultra vires* violation sufficient to surmount this bar on judicial review.

For both reasons, therefore, this case should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(1). In the alternative, it should be dismissed pursuant to Rule 12(b)(6) for failure to state a claim upon which relief can be granted.

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") 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 years. 42 U.S.C. § 1395w-4(q)(6)(B). Positive adjustments vary to maintain budget neutrality[1] 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. Am. Compl. ¶ 44. 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

[1] 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").

activities described in … subparagraph [(q)(2)(B)(iii), *i.e.*, clinical practice improvement activities,] and specify[] 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 improvement activities performance category accounts for 15 percent of a MIPS eligible professional's MIPS final score,[2] 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).

[2] 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).

II. REGULATORY BACKGROUND

To the subcategories identified by MACRA under the "clinical practice improvement activities" performance category, HHS, through CMS, added through rulemaking some additional subcategories, including the subcategory of "Achieving Health Equity." 42 C.F.R. § 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 (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. *See* https://qpp.cms.gov/mips/

explore-measures?tab=improvementActivities&py=2022 (last visited Sept. 23, 2022).[3] High-weighted activities include "CDC Training on CDC's Guideline for Prescribing Opioids for Chronic Pain (IA_PSPA_22)" 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 "Improved Practices that Engage Patients Pre-Visit (IA_BE_22)" and "Engagement of Patients, Family, and Caregivers in Developing a Plan of Care (IA_BE_15)." *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

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

improvement activities performance categories. 42 C.F.R. § 414.1380(c)(2)(i)(A)(6), (8); *see* https://qpp.cms.gov/mips/exception-applications (last visited Sept. 23, 2022).

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."[4] *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

[4] 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).

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 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

Plaintiffs initially filed the present suit on May 5, 2022, seeking to challenge the new improvement activity for creating and implementing an anti-racism plan. *See* Compl., ECF No. 1. On July 11, 2022, Defendants moved to dismiss for lack of subject matter jurisdiction pursuant to Federal Rule Civil Procedure 12(b)(1). Defs.' Mot. to Dismiss, ECF No. 15. In response, Plaintiffs filed their First Amended Complaint. The current Plaintiffs are one individual and eight states. The individual plaintiff, Amber Colville, is a physician from Mississippi, who alleges she works in a "small office specializing in internal medicine." Am. Compl. ¶¶ 7, 9. She participates in

MIPS but has not chosen to create and implement an anti-racism plan and alleges she is financially penalized for refusing to do so. *Id.* ¶¶ 8-10. 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, in violation of the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2)(A), (C). *Id.* ¶ 58. Plaintiffs further contend that the new improvement activity is *ultra vires* as it is outside the bounds of CMS's statutory authority. *Id.* ¶ 60. Defendants now move to dismiss the First Amended Complaint for lack of subject-matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1) or, in the alternative, for failure to state a claim pursuant to Rule 12(b)(6).

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).

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).

Alternatively, to survive a motion to dismiss pursuant to Rule 12(b)(6) for failure to state a claim, the "complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible if the plaintiff alleges facts that, accepted as true, allow a court "to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft*, 556 U.S. at 678. While the court must accept the facts in the complaint as true, it will "not accept as true conclusory allegations, unwarranted factual inferences, or legal conclusions." *Gentilello v. Rege*, 627 F.3d 540, 544 (5th Cir. 2010) (quoting *Plotkin v. IP Axess Inc.*, 407 F.3d 690, 696 (5th Cir. 2005)). When reviewing motions to dismiss under both Rule 12(b)(1) and Rule 12(b)(6), "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); *see also Funk v. Stryker Corp.*, 631 F.3d 777, 783 (5th Cir. 2011).

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.").

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

A. Individual Plaintiff Colville Lacks Standing

The individual plaintiff, Amber Colville, is a physician who alleges that she participates in MIPS but has chosen not to create and implement an anti-racism plan. Am. Compl. ¶¶ 7-8. She alleges that her refusal to create an anti-racism plan "financially penalize[s]" her because it places her at "a direct disadvantage vis-à-vis [her] competitors," who may choose to create such plans, and attest to CMS to doing so, and therefore allegedly "can be reimbursed at higher rates, while she cannot." *Id.* ¶¶ 9-10. Dr. Colville further alleges that the fact that her competitors can get higher MIPS scores injures her more generally as the "score alone 'has a significant impact on both the reputation and the finances of [a] practice' because 'CMS publishes MIPS results … to help consumers evaluate and compare clinicians.'" *Id.* ¶ 10. She explains that "[g]iven the nature of her practice, she is eligible and able to complete only a limited number of MIPS improvement activities" and 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." *Id.* ¶ 9. Plaintiffs further generally allege that the activity to create and implement an anti-racism plan is "available to more clinicians because it is not constrained to certain specialties or practices [a]nd it is easy to complete—requiring clinicians to explain their commitment to antiracism on a worksheet—compared to many other improvement activities that require more tangible improvements for patients." *Id.* ¶ 53.

At the outset, Dr. Colville's allegations appear to be based on a misunderstanding of the MIPS program. As correctly understood, the addition of an optional improvement activity should never injure clinicians. The addition of a new activity neither deprives a clinician such as Dr. Colville of the ability to obtain a full score nor does it give clinicians who do chose that activity a competitive advantage. Clinicians who object to the new activity can simply choose other activities from the other 105 available to satisfy the requisite number of activities needed for a full

score. In plain terms, the inclusion of an optional activity in the 106-item inventory does not harm Dr. Colville, even if she finds that one activity objectionable. Thus, "under ordinary Article III standing analysis, [she] lack[s] Article III standing for a simple, commonsense reason," *Thole v. U. S. Bank N.A.*, 140 S. Ct. 1615, 1622 (2020)—she does not credibly allege, let alone will she be able to show, that she is suffering or will suffer any "perceptible harm" from the action challenged. *Defs. of Wildlife*, 504 U.S. at 566.

The burden (and hence perception of injury) may be even less in Dr. Colville's case. Dr. Colville's allegations suggest that her practice may meet the definition of a "small practice" under 42 C.F.R. § 414.1305. If that is the case, she need only complete one high-weighted activity or two medium-weighted activities to obtain a full score under the improvement activities performance category, whereas non-small practice clinicians must complete two high-weighted or four-medium weighted activities (or a combination thereof) for full credit in the category. *Id.*§ 414.1380(b)(3). Therefore, the one activity that she alleges she has been able to report, *see* Am. Compl. ¶ 9, may be sufficient for her to have obtained a full score in this performance category. As she can continue to submit this same activity in subsequent years, she may be able to continue to receive a full score even if she declines to attest to creation of an anti-racism plan and even if her competitors do attest to such plans in the future. Thus, the addition of this new improvement activity should have even less of an impact on most clinicians in Dr. Colville's circumstances.

In any event, to the extent that Dr. Colville alleges she has been unable to obtain a full score in the improvement activities performance category in the past, her allegations that the addition of the optional anti-racism-plan activity injures her because it will enable other clinicians to get higher scores while she cannot as easily increase her score, tries unsuccessfully to blame a

self-inflicted injury on CMS's actions. Dr. Colville alleges she has been unable to achieve a full score under the improvement activities performance category even though there were and are dozens of possible other activities in the list of available activities, and she is required only to attest to a maximum of four such activities (and possibly to as few as one) to obtain a full score. Am. Compl. ¶ 9. She does not explain the reason why she could only complete one activity for the last three years, other than to refer vaguely to the "nature of her practice." *Id.* But, to the extent she believes her practice precludes compliance with this category, she does not address whether she is eligible for a reduced requirement as set forth in 42 C.F.R. § 414.1380(b)(3) or whether she has sought an exemption from the requirement due to the pandemic or any other reason, *see* 42 C.F.R. § 414.1380(c)(2)(i)(A)(6)-(8).

The First Amended Complaint also implies that she believes that the anti-racism plan improvement activity is easier to complete than other improvement activities, *see* Am. Compl. ¶ 53, but Dr. Colville does not address the perceived difficulty of the other activities that she might select, some of which seem similarly straightforward. For example, the requirement to complete "CDC Training on CDC's Guideline for Prescribing Opioids for Chronic Pain (IA_PSPA_22)" simply entails completing 14 modules of a self-paced course available on the Internet. *See* https://www.cdc.gov/opioids/providers/training/interactive.html (last visited Sept. 23, 2022). And the requirement to create "Improved Practices that Engage Patients Pre-Visit (IA_BE_22)" requires only "[i]mplementation of workflow changes that engage patients prior to the visit, such as a pre-visit development of a shared visit agenda with the patient, or targeted pre-visit laboratory testing," which may require some reorganization of her practice's workflow but with the benefit of greater efficiencies.

In sum, if Dr. Colville has been unable to obtain a full score in the improvement activities category for years prior to the creation of the new optional activity to which she objects, she does not provide any concrete allegations to explain why. In these circumstances the addition of this one activity to the 106-item inventory does not further disadvantage Dr. Colville. Her claimed injury—lower MIPS scores and correspondingly lower payments than other clinicians—is not caused by the government action she seeks to challenge, but rather is self-inflicted. Therefore, she fails to satisfy the causation prong of the standing inquiry.

The causation requirement demands that plaintiff's claimed injury have "resulted," in some "concretely demonstrable way" from the challenged practice – that the injury is "the consequence of the defendants' actions." *Warth*, 422 U.S. at 504-05. A self-inflicted injury thus does not satisfy this requirement because it is not caused by defendants' actions. *See, e.g., Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 418 (2013) ("[R]espondents' self-inflicted injuries are not fairly traceable to the Government's purported activities."); *Zimmerman v. City of Austin, Texas*, 881 F.3d 378, 389 (5th Cir. 2018) ("[S]tanding cannot be conferred by a self-inflicted injury."). Dr. Colville's allegations do not show that her alleged inability to achieve a full score in the improvement activities category is attributable to any of Defendants' actions. In other words, if Dr. Colville is in "a pinch" because of her inability to achieve a full score in the improvement activities category "it was a pinch of [her] own making" and does not confer standing. *Cameron Cnty. Hous. Auth. v. City of Port Isabel*, 997 F.3d 619, 623 (5th Cir. 2021); *Taylor v. Sackler Fam. of Purdue Ownership*, No. 3:21-cv-3175-E-BN, 2021 WL 6883212, at *3 (N.D. Tex. Dec. 28, 2021) (holding that plaintiff's voluntary criminal activities were "sufficient independent causes of [her] alleged injuries" to defeat the causation requirement); *see also McConnell v. Fed. Election Comm'n*, 540 U.S. 93, 228 (2003) (no standing for political candidates where injury was caused by "their own

personal 'wish' not to solicit or accept large contributions"); *Buchholz v. Meyer Njus Tanick, PA*, 946 F.3d 855, 865-867 (6th Cir. 2020) "[T]he anxiety that Buchholz alleges is not traceable to anyone but him" because "he chose not to pay his debts."); *Bhd. of Locomotive Engineers & Trainmen v. Surface Transp. Bd.*, 457 F.3d 24, 28 (D.C. Cir. 2006) (Union's inability to bargain, which Union agreed to in collective bargaining agreement, "was entirely self-inflicted and therefore insufficient to confer standing upon the Union.").

Nor, relatedly, would a court order invalidating the anti-racism-plan improvement activity change Dr. Colville's ability to obtain a full score and thereby redress her alleged injury. *See Allen v. Wright*, 468 U.S. 737, 753 n.19 (1984) ("The 'fairly traceable' and 'redressability' components of the constitutional standing inquiry were initially articulated by this Court as 'two facets of a single causation requirement'"). If the anti-racism plan activity is invalidated, Dr. Colville will be in essentially the same position as she is now, with the only difference being that she will be required to choose improvement activities for a full score from among 105 other activities, rather than from 106. By her own account, despite the variety of options available to her before inclusion of the anti-racism plan, in all of the past three years she has only chosen to attest to the completion of one activity. Am. Compl. ¶ 9.

Dr. Colville may argue that such relief would nevertheless aid her by preventing competitors from being able to use this (allegedly easier) improvement category to achieve better scores than she can (and hence higher compensation). However, such speculation about what her competitors may do with regard to anti-racism plans cannot support Dr. Colville's standing. Plaintiff must show that it is "'likely,' as opposed to merely 'speculative,' that the injury will be "redressed by a favorable decision.'" *Defs. of Wildlife*, 504 U.S. at 561 (citation omitted). Moreover, 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.* at 562 (internal quotation marks and citations omitted).

Dr. Colville has not met these burdens here. She does not allege that she is aware that any of her competitors have chosen to create and attest to anti-racism plans, let alone that they have received higher scores than previously, and which are sufficient to impact her own level of Medicare payments, given the budget-neutral nature of the MIPS program. Rather, she merely speculates that sufficient competitors will choose the anti-racism plan improvement activity as long as such an activity is available to them, and that this will somehow harm her. But such speculation about the behavior of third parties is insufficient to confer standing. *See Allen*, 468 U.S. at 759 (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, Dr. Colville lacks standing, and her claims should be dismissed pursuant to Rule 12(b)(1).

B. <u>The States Lack Standing</u>

The state plaintiffs' allegations of injury similarly fail to establish the necessary standing. Echoing Dr. Colville's stated concern, the state plaintiffs first 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. Am. Compl. ¶ 12. This allegation fails to establish any of the three standing requirements—injury-in-fact, causation, or redressability. Clinicians who do not want to select this improvement activity will not be

reimbursed at lower rates simply for that reason. 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. And, as with Dr. Colville's injuries, to the extent that clinicians are unable to satisfy the improvement activities requirement, that injury is not caused by the addition of the anti-racism plan activity to the list of available activities, nor would it be redressed by a court order invalidating that activity.

In any event, even if there were some adverse effect from clinicians within the plaintiff states 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. To satisfy the standing requirements, "the injury or threat of injury must be both 'real and immediate,' not 'conjectural' or 'hypothetical.'" *City of Los Angeles v. Lyons*, 461 U.S. 95, 101-02 (1983) (citation omitted); *see also 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"). An injury that is based on a "speculative chain of possibilities" does not confer Article III standing. *Clapper*, 568 U.S. at 414. In the absence of some credible allegations as to how the decisions of a few clinicians might negatively impact the state plaintiffs, the state plaintiffs' "chain of possibilities" 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. Am. 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 created 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.").[5]

The state plaintiffs' allegations also fail the causation and redressability prongs 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 plans. As explained in the preceding section, a plaintiff can 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 and speculative actions of third parties not before the Court. *See Defs. of Wildlife*, 504 U.S. at 562; *Little*, 575 F.3d at 541. Here, Plaintiffs' 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 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*, 468 U.S. at 759 (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

[5] 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.

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)

A. 42 U.S.C. § 1395w-4(q)(13)(B) Expressly Bars Review of Plaintiffs' Claims

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, for example, APA claims. Specifically, 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. 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 a claim based upon an alleged violation 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). Thus, courts have applied similar review-preclusion provisions in the Medicare statute to bar challenges like the one brought here. *See Paladin Cmty. Mental Health Ctr. v. Sebelius*, 684 F.3d 527, 531 (5th Cir. 2012) (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 v. Shalala*, 97 F.3d 1351, 1356 (10th Cir. 1996) (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").

B. The *Ultra Vires* Exception to Review Preclusion Does Not Apply

In an attempt to avoid the jurisdictional bar, Plaintiffs combine their allegation of an APA violation with a claim that Defendants have acted *ultra vires.* Am. Compl. ¶¶ 58-60. Some courts, including the Fifth Circuit, have recognized that "the APA's stricture barring judicial review 'to the extent that statutes preclude judicial review,' . . . 'does not repeal the review of *ultra vires* actions.'" *Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1173 (D.C. Cir. 2003) (citations omitted); *see also Am. Airlines, Inc. v. Herman*, 176 F.3d 283, 293 (5th Cir. 1999) (discussing "narrow exception" allowing *ultra vires* review where the agency's challenged action is "so contrary to the terms of the relevant statute that it necessitates judicial review independent of the review provisions of the relevant statute") (quoting *Kirby Corp. v. Pena*, 109 F.3d 258, 269 (5th Cir. 1997)). Because the courts presume Congress "rarely intends to foreclose review of action exceeding agency authority," they will construe bars on judicial review to extend "no further than the Secretary's statutory authority" to make the challenged determination. *Amgen, Inc. v. Smith*, 357 F.3d 103, 112 (D.C. Cir. 2004).

However, "[s]uch *ultra vires* review is 'quite narrow.'" *H. Lee Moffitt Cancer Ctr. & Rsch. Inst. Hosp., Inc. v. Azar*, 324 F. Supp. 3d 1, 11 (D.D.C. 2018) (quoting *Mittleman v. Postal Regulatory Comm'n*, 757 F.3d 300, 307 (D.C. Cir. 2014)). As a general rule, courts "have interpreted [the *ultra vires* exception] as sanctioning [review] in a very narrow situation in which there is a 'plain' violation of an unambiguous and mandatory provision of the statute." *Am. Airlines, Inc.*, 176 F.3d at 293; *see also DCH Reg'l Med. Ctr. v. Azar*, 925 F.3d 503, 509 (D.C. Cir. 2019) (quoting *U.S. Dep't of Just. v. FLRA*, 981 F.2d 1339, 1342 (D.C. Cir. 1993)) ("very limited scope"); *Griffith v. FLRA*, 842 F.2d 487, 493 (D.C. Cir. 1988) ("extremely limited scope"); *Hartz Mountain Corp. v. Dotson*, 727 F.2d 1308, 1312 (D.C. Cir. 1984) ("extraordinarily narrow").

Challengers must show more than the type of routine error in "statutory interpretation or challenged findings of fact" that would apply if Congress had allowed APA review. *Fed. Express Corp. v. U.S. Dep't of Com.*, 39 F.4th 756, 765 (D.C. Cir. 2022) (quoting *Loc. 130, Int'l Union of Elec., Radio & Mach. Workers, AFL-CIO v. McCulloch*, 345 F.2d 90, 95 (D.C. Cir. 1965)). *Ultra vires* review looks at whether the agency's statutory construction is "utterly unreasonable." *Nat'l Ass'n of Postal Supervisors v. U.S. Postal Serv.*, 26 F.4th 960, 971, 975 (D.C. Cir. 2022). "Garden-variety errors of law or fact are not enough." *Griffith*, 842 F.2d at 493. "In other words, *ultra vires* claimants must demonstrate that the agency has plainly and openly crossed a congressionally drawn line in the sand." *Fed. Express Corp*, 39 F.4th at 765.

The D.C. Circuit has held that this "*ultra vires* exception" applies only when three requirements are met: "(i) the statutory preclusion of review is implied rather than express …; (ii) there is no alternative procedure for review of the statutory claim …; and (iii) the agency plainly acts 'in excess of its delegated powers and contrary to a specific prohibition in the' statute that is 'clear and mandatory.'" *Nyunt v. Chairman, Broad. Bd. of Governors*, 589 F.3d 445, 449 (D.C. Cir. 2009) (citations omitted). Using this framework for analysis here, the statutory preclusion of review set forth in section 1395w-4(q)(13)(B) is express and could not be "more clear" as to prohibition of judicial review. *See Painter*, 97 F.3d at 1356 (finding a similar no-review provision in 42 U.S.C. § 1395w-4(i)(1)(C) "plain and unambiguous"). Congress expressly stated that "there shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise of" "[t]he identification of measures and activities specified under paragraph (2)(B)," which includes subparagraph (iii) addressing "Clinical practice improvement activities." 42 U.S.C. § 1395w-4(q)(13)(B)(iii). The current suit seeks to challenge the Secretary's identification and creation of an anti-racism plan as an "activit[y] specified" under

the clinical practice improvement activities performance category. The MIPS review preclusion provision clearly and expressly covers this action. *See Tex. All. for Home Care Servs*, 681 F.3d at 409 ("[T]hat there be 'no administrative or judicial review' under the … statutes '*or otherwise*' unequivocally precludes review of the Secretary's actions [listed in the judicial-review bar].").

Plaintiffs do not contest the reach of the review preclusion statute but rather focus on the third element of the above analysis, whether the agency has patently exceeded its delegated powers. *N. Oaks Med. Ctr., LLC v. Azar*, No. 18-9088, 2020 WL 1502185, at *7 (E.D. La. Mar. 25, 2020) ("To challenge agency action on the ground that it is *ultra vires*, Plaintiff must show a 'patent violation of agency authority.'" (quoting *Fla. Health Scis. Ctr. v. Sec'y of Health & Hum. Servs.,* 830 F.3d 515, 522 (D.C. Cir. 2016))). Because the preclusion provision is express, the Court need not consider whether the third element is met.[6] However, in any event, Plaintiffs cannot satisfy this element either.

Plaintiffs contend that the anti-racism plan activity does so because it does not "remotely fall" under the definition of "clinical improvement activities" as it does not "relate to clinical practice or care delivery.'" Am. Compl. ¶¶ 61-62. In creating this activity, however, Defendants found otherwise, stating that "systemic racism [is] a root cause for differences in health outcomes between socially-defined racial groups" and finding that creating an anti-racism plan could help clinicians to "tak[e] real steps to naming and eliminating the causes of the disparities identified." 86 Fed. Reg. at 39,855. Given CMS's express findings that the new activity was related to clinical practice and care delivery, Plaintiffs' argument about whether the activity is a "clinical improvement activity" as defined in the MIPS statute is a "mere fight[] over statutory

[6] Defendants do not contest the second element, that there is no alternative procedure for review of the statutory claim.

interpretation" of phrases such as "clinical practice" and "care delivery," *Key Med. Supply, Inc. v. Burwell*, 764 F.3d 955, 963 (8th Cir. 2014) ("[A] broad and general bar on jurisdiction cannot be avoided by characterizing mere fights over statutory interpretation as *ultra vires* claims."), and not a genuine *ultra vires* claim that the agency "has plainly and openly crossed a congressionally drawn line in the sand." *Fed. Express Corp*, 39 F.4th at 765; *see* also *Am. Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195, 1208 (D.C. Cir. 2019) (In adopting a certain approach to the statutory term "laboratory," "HHS did not clearly step so far outside the scope of the task that Congress gave it as to have acted *ultra vires*."); *Key Med. Supply, Inc.*, 764 F.3d at 964 (Because "all *ultra vires* arguments Key Medical raises in this case[] present[] a matter of statutory interpretation rather than a clear statutory violation, we must reject Key Medical's attempt to avoid the bar on review under an *ultra vires* theory.").

Indeed, the relevant paragraphs of the First Amended Complaint essentially ask the Court to engage in standard statutory interpretation analysis using interpretive canons. *See* Am. Compl. ¶ 62. But "review of an agency action allegedly in excess of authority must not simply involve a dispute over statutory interpretation." *Am. Airlines, Inc.*, 176 F.3d at 293 (quoting *Kirby Corp.*, 109 F.3d at 269) (internal quotation marks omitted). Plaintiffs have failed to show that their case is anything other than a routine case raising an issue of statutory interpretation. They have not shown that CMS has acted "so far outside" the scope of the task given it by Congress, *Am. Clinical Lab'y Ass'n*, 931 F.3d at 1208, or acted "contrary to a specific prohibition in the statute that is clear and mandatory." *Nyunt*, 589 F.3d at 449. Accordingly, the bar on review of their claim is not overcome by their characterizing the Secretary's action as *ultra vires*.

Plaintiffs also attempt to establish a "patent" violation of agency authority by arguing that Defendants improperly relied on Executive Order 13985 as an impetus for the new improvement

activity, failed to identify "relevant eligible professional organizations and other relevant stakeholders" supporting this activity, and ignored that the MIPS statute itself does not reference race. Am. Compl. ¶¶ 63-65. But these criticisms amount to claims that CMS "relied on factors which Congress has not intended it to consider [or] entirely failed to consider an important aspect of the problem" when creating this new improvement activity, that is, that it acted arbitrarily and capriciously. *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co*., 463 U.S. 29, 43 (1983).

Given that the MIPS statute identifies a broad range of factors that the Secretary can consider in developing such improvement activities, *see* 42 U.S.C. § 1395w-4(q)(2)(C)(v)(I), (III) (referencing eligible professional organizations and other relevant stakeholders); *id.* § 1395w-4(q)(2)(C)(v)(II) (stating that the Secretary can contract with an outside entity to identify activities); *id.* § 1395w-4(q)(2)(C)(iii) (stating that the Secretary can specify categories in addition to those stated in the statute), these allegations also do not state a claim that CMS "plainly and openly crossed a congressionally drawn line in the sand." *Fed. Express Corp*, 39 F.4th at 765; *see Kalispel Tribe of Indians v. U.S. Dep't of the Interior*, 999 F.3d 683, 692 (9th Cir. 2021) (argument that "the Secretary improperly exercised the authority Congress delegated by failing to consider the factors required by IGRA" was "most properly considered not as an *ultra vires* challenge but as a challenge to the Secretary's exercise of authority as arbitrary and capricious under the APA"). In other words, Plaintiffs are asking the Court "to engage in the kind of 'case-by-case review of the reasonableness or procedural propriety of the Secretary's [decision]' that Congress intended to bar." *Fla. Health Scis. Ctr.*, 830 F.3d at 522; *Amgen*, 357 F.3d at 113 ("If a no-review provision shields particular types of administrative action, a court may not inquire whether a challenged agency decision is arbitrary, capricious, or procedurally defective … .").

A claim that agency action is *ultra vires* in an attempt to overcome a statute precluding judicial review "is essentially a Hail Mary pass—and in court as in football, the attempt rarely succeeds." *Nyunt*, 589 F.3d at 449. The case law is full of examples where courts declined to entertain *ultra vires* claims where a statutory review preclusion provision existed. *See DCH Reg'l Med. Ctr*, 925 F.3d at 508–09 (no review under *ultra vires* exception of agency's methodology for calculating disproportionate share hospital ("DSH") payment); *Fla. Health Scis. Ctr.,* 830 F.3d at 522 (no review of the appropriateness of the data the Secretary used to calculate hospital's DSH payment); *Amgen, Inc.*, 357 F.3d at 114 (Secretary's "adjustment" to hospital payment was "other adjustment[]" under review preclusion statute and not *ultra vires*); *Fed. Express Corp.*, 39 F.4th at 767 (holding plaintiffs "failed to demonstrate the type of blatant error necessary for an *ultra vires* challenge to succeed"); *Ascension Borgess Hosp. v. Becerra*, 557 F. Supp. 3d 122, 136 (D.D.C. 2021) (judicial review not permitted under *ultra vires* exception where "plaintiffs have not shown that the Secretary 'plainly' acted contrary to the Medicare Act's notice-and-comment requirement"), *appeal docketed*, No. 21-5246 (D.C. Cir. Nov. 4, 2021); *N. Oaks Med. Ctr., LLC*, 2020 WL 1502185, at *8 ("[E]ven if the Secretary's use of North Oaks' 2013 cost report in calculating Plaintiff's DSH payments for FFY 2016 was arbitrary and capricious, it is not clearly the type of violation … that constitutes *ultra vires* action."). The present case is not such a rare case where judicial review of an *ultra vires claim* is permitted.

In sum, 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. Plaintiffs' attempt to argue that the Court should

nevertheless review their *ultra vires* claim must fail given the clear language of the review preclusion provision and Plaintiffs' failure to establish a "patent" violation of agency authority. 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 or, in the alternative, for failure to state a claim.

Dated: September 23, 2022

Respectfully submitted,

BRIAN M. BOYNTON
Principal Deputy Assistant Attorney General
Civil Division

MICHELLE BENNETT
Assistant Director, Federal Programs Branch

/s/ Carol Federighi
CAROL FEDERIGHI
Senior Trial Counsel
United States Department of Justice
Civil Division, Federal Programs Branch
P.O. Box 883
Washington, DC 20044
Phone: (202) 514-1903
Email: carol.federighi@usdoj.gov

Counsel for Defendant

Of Counsel

SAMUEL R. BAGENSTOS
General Counsel

JANICE L. HOFFMAN
Associate General Counsel

SUSAN MAXSON LYONS
Deputy Associate General Counsel
for Litigation

DEBRA M. LABOSCHIN
Attorney

United States Department of Health & Human Service