

The Medicare Modernization Act (“MMA”), Pub. L. No. 108-173, 117 Stat. 2066 (2003), requires that payments made to providers for most drugs under Medicare Part B be calculated based on average sale price (“ASP”) data reported by manufacturers. Generally, Part B drugs—including oncological drugs, Compl. ¶ 16—are reimbursed at 106 percent of the ASP. *Id.* § 1395w-3a(b)(1)-(4). The MMA also contains a section precluding administrative and judicial review. *See* 42 U.S.C. § 1395w-3a(g)(1).

The Balanced Budget and Emergency Deficit Control Act of 1985 was designed to “eliminate the federal budget deficit by 1991.” *National Ass'n of Counties v. Baker*, 842 F.2d 369, 372 (D.C. Cir. 1988). That act was amended by the Budget Control Act of 2011, which provides sequestration provisions, triggered by various statutory conditions, which are designed to reduce budgetary resources. *See* 2 U.S.C. §§ 901-903. Pursuant to the Budget Control Act, the Office of Management and Budget (“OMB”) prepares the proposed sequestration for the President’s order and subsequent application through Executive Branch agencies. 2 U.S.C. § 901a (5)-(6). However, the statute limits reductions in spending on some Medicare programs to two percent. *Id.* § 901a(6)(A). This two-percent limit applies to “individual payments for services furnished” as part of Medicare Part B. *Id.* §§ 901a(6)(A), 906(d)(1)(A).

In 2013, after Congress failed to pass a budget, the statutory conditions were triggered, and OMB issued a report on sequestration calculations to be ordered. Compl. ¶ 27. This report required a two-percent reduction in Medicare payments. *Id.* ¶ 28. HHS applied the sequestration cut to Part B drugs, thereby “reduc[ing] the pertinent Part B drug statutory reimbursement formula from ASP plus 6% to ASP plus 4.3%.” *Id.* ¶ 31. The sequestration order has been extended numerous times and is scheduled to continue into 2027. *Id.* ¶ 19.

Plaintiff Community Oncology Alliance, Inc.—a non-profit corporation representing “more than 5,000 healthcare providers who are independent, community-based oncologists,” Compl. ¶¶ 1, 9—sued Defendants—the Office of Management and Budget; Mick Mulvaney, in his representative capacity; the U.S. Department of Health and Human Services; and Alex M. Azar II, in his representative capacity—alleging, *inter alia*, that the sequestration of funds for Medicare Part B drugs was unauthorized by Congress, because 42 U.S.C. § 906(d)(1)(A) “expressly permits a reduction only in payment ‘for services.’” Compl. ¶ 24 (emphasis omitted). Plaintiff contends that because “[t]here is no express mention of Part B drug reimbursement in this section . . . [t]his [omission] exhibits Congress’ intent not to interfere with the statutory reimbursement formula of ASP plus 6% for Part B drugs.” *Id.* (citation omitted). Plaintiff argues that therefore the “sequestration order as applied to Medicare Part B drugs, which is tantamount to an executive legislation drafting, represents a separation-of-powers violation by the Executive Branch, providing for Defendants’ intrusion into Congress’ legislative sphere.” *Id.* ¶ 56.

Defendants have moved to dismiss for lack of subject matter jurisdiction on four grounds: 1) the Medicare Modernization Act expressly precludes judicial review of Plaintiff’s claims concerning determinations of reimbursements paid by Medicare for Part B drugs; 2) review of such claims is permitted only in accordance with exclusive judicial-review provisions of the Medicare statute, that confer jurisdiction only to review final decisions by HHS about individual claims for reimbursement presented by or on behalf of healthcare service providers, and Plaintiff has not alleged compliance with the requirements for presentment and administrative review; 3) Plaintiff’s claims do not fall within the jurisdictional scope of the Balanced Budget Act’s judicial review provisions; and 4) Plaintiff has not established associational standing to seek declaratory

and injunctive relief. Because Defendants prevail on the first ground, the court need not reach the merits of the others.

II. Legal Standard for Rule 12(b)(1)

A motion pursuant to Federal Rule of Civil Procedure 12(b)(1) “presents a threshold challenge to the court’s jurisdiction.” *Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987). The plaintiff bears the burden of establishing jurisdiction by a preponderance of the evidence. *Lujan v. Defs. of Wildlife*, 504 U.S. 55, 56 (1992). The court “assume[s] the truth of all material factual allegations in the complaint and construe[s] the complaint liberally, granting plaintiff the benefit of all inferences that can be derived from the facts alleged, and upon such facts determine[s] jurisdictional questions.” *Am. Nat’l Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011) (quotation marks and citations omitted).

III. Analysis

While courts must “presume the Congress intends that agency action be judicially reviewable, . . . that presumption, like all presumptions used in interpreting statutes, may be overcome by specific language . . . that is a reliable indicator of congressional intent.” *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1128 (D.C. Cir. 2017) (quotation marks and citations omitted); *see also id.* (“[T]he strong presumption that Congress intends judicial review of administrative action . . . is therefore rebuttable by a clear statement of congressional intent to preclude review.”) (quotation marks and citations omitted) (alteration in original).

Section 1395w-3a of the MMA provides the method for determining Medicare Part B drug reimbursements. *See* 42 U.S.C. § 1395w-3a. That section states that “[t]here shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of . . . determinations of payment amounts under this section.” 42 U.S.C. § 1395w-

3a(g)(1). The D.C. Circuit has found that this type of language precludes judicial review. *See, e.g., Knapp Med. Ctr.*, 875 F.3d at 1127, 1132 (finding that the language “[t]here shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise” precludes judicial review); *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1066 (D.C. Cir. 2018) (same); *Fla. Health Scis. Ctr., Inc. v. Sec’y of Health & Human Servs.*, 830 F.3d 515, 518 n.1, 518-19 (D.C. Cir. 2016) (same); *Tex. All. For Home Car Servs. v. Sebelius*, 681 F.3d 402, 409 (D.C. Cir. 2012) (same).

While Plaintiff attempts to portray its challenge as one arising under the sequestration provisions of the Budget Control Act, *see* Compl. ¶¶ 51-56, this labeling does not allow Plaintiff to evade the Medicare statute’s provision precluding judicial review. When “interpreting a provision that precludes judicial review, [courts] must determine whether the challenged agency action is of the sort shielded from review.” *Knapp Med. Ctr.*, 875 F.3d at 1128; *Mercy Hosp., Inc.*, 891 F.3d at 1067 (“Designing a pleading so that it circumvents a statutory bar to review will not override Congress’s decision to deny jurisdiction.”). To determine whether a challenged action is covered by a statute that precludes judicial review, the D.C. Circuit instructs courts to use a “functional analysis” that avoids “frustrating the Congress’s desire to place certain administrative actions beyond review.” *Knapp Med. Ctr.*, 875 F.3d at 1131. “The dispositive issue is whether the challenged [action is] inextricably intertwined with an action that all agree is shielded from review, regardless of where that action lies in the agency’s decision tree.” *Fla. Health Scis. Ctr., Inc.*, 830 F.3d at 521 (emphasis in original). Plaintiff’s claims effectively challenge the payments made for Medicare Part B drugs. *See* Compl. ¶ 10 (“COA brings this suit to stop the impermissible reduction in reimbursement for Part B drugs and the consequent destructive effects that threaten cancer patients from being able to obtain affordable cancer care

in their own communities.”). Therefore, § 1395w-3a(g)(1) applies because HHS’s reduced payments due to sequestration cuts are “inextricably intertwined” with HHS’s determination of payment amounts under the section.

Plaintiff contends that it “is not challenging determinations of payment amounts made under Section 1395w-3a,” but instead “is challenging the reduction of the ASP plus 6% payment formula made in connection with the separate Balanced Budget Act.” Pl.’s Opp’n. to Defs.’ Mot. to Dismiss at 19-20, ECF No. 28. This argument is unconvincing, because Plaintiff is, in fact, challenging the government’s interpretation of HHS’s responsibilities to provide reimbursements under the Medicare Act. *See* Compl. ¶ 34 (“[U]sing the BCA’s sequestration tool to reduce spending for Part B drugs constitutes a de facto amendment to the MMA’s statutory formula and thereby violates the Constitution’s Presentment Clause (Article I, Section 7).”).

IV. Conclusion

Because Plaintiff cannot circumvent the statutory bar to judicial review of HHS’s payment determinations for prescription drugs under Medicare Part B, the court **GRANTS** Defendants’ Motion to Dismiss, ECF No. 26.

A corresponding Order will issue separately.

Date: March 31, 2019

Tanya S. Chutkan
TANYA S. CHUTKAN
United States District Judge