UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

AMERICAN ORTHOTIC & PROSTHETIC ASSOCIATION, INC. **Plaintiff,**	)	
v.	)	**Civil No. 13-697 (RCL)**
KATHLEEN SEBELIUS, Secretary of the Department of Health and Human Services, **Defendant.**	)	

MEMORANDUM OPINION

Plaintiff—the American Orthotic & Prosthetic Association, Inc. ("AOPA")—is an association of individual suppliers of prosthetic devices to Medicare patients who have lost limbs to disease or injury. Consistent with its mission to secure "favorable treatment of the orthotic and prosthetic business in laws, regulations, and services," Compl. ¶ 11, AOPA filed the present action seeking declaratory, injunctive, and mandamus relief against Kathleen Sebelius, Secretary of the Department of Health and Human Services ("HHS"), for violations of Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395–1395iii ("the Medicare Act"); the Administrative Procedure Act, 5 U.S.C. §§ 701 *et seq.* ("APA"); the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"); and the Regulatory Flexibility Act, 5 U.S.C. §§ 601 *et seq.* ("RFA"). Currently before the Court is the defendant's Motion to Dismiss [7] the Complaint for lack of subject matter jurisdiction and failure to state a claim upon which relief can be granted. Upon consideration of the Motion [7], the plaintiff's Opposition thereto [8], the defendant's Reply [9], and supplemental briefs submitted by both parties [14, 15, 16], the Court GRANTS the defendant's Motion to Dismiss.

I. BACKGROUND

The Medicare Act provides that payment or reimbursement for prosthetic devices is permitted only where it is "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y (a)(1)(A). To assist with the millions of payment claims received by HHS annually, the Act authorizes the Secretary to delegate certain functions to contractors, including the development of local coverage determinations ("LCDs") as to whether particular medical products or services are covered by Medicare. *Hays v. Sebelius*, 589 F.3d 1279, 1280 (D.C. Cir. 2009); *see also* 42 U.S.C. § 1395kk-1(a)(4); 42 U.S.C. § 1395ff(f)(2)(B). The Act also allows the Secretary, at her discretion, to employ contractors to make initial decisions on whether medical services or products are reasonable and necessary. 42 U.S.C. § 1395kk-1(a)(4).

The Secretary has designated four contractors to perform these functions with respect to claims for durable medical equipment, including prostheses. 42 C.F.R. § 421.210. These contractors are known as Durable Medical Equipment Medicare Administrative Contractors ("DME MACs") and are responsible for four separate geographic regions. In making payment and coverage determinations, including whether payment for prosthetic devices should be authorized, the DME MACs are guided by statutes, regulations, and the Medicare Program Integrity Manual ("MPIM" or "the Manual"). The Manual provides that, as a prerequisite to Medicare coverage for durable medical equipment, "the patient's medical record must contain sufficient documentation of the patient's medical condition," including, but not limited to, the "duration of the patient's condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, [and] past experience with related items." Def.'s Mot. to Dismiss., Ex. 2 (MPIM), at § 5.7. Moreover, the

"patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, or [home health agency] records and records from other health care professionals." *Id.* Standing alone, "neither a physician's order . . . nor a supplier prepared statement . . . provides sufficient documentation of medical necessity." *Id.* "There must be information in the patient's medical record that supports the medical necessity for the item." *Id.* Finally, the Manual makes clear that the burden is on the supplier to "obtain as much documentation from the patient's medical record as they determine they need to assure themselves that coverage criteria for an item have been met." *Id.* at § 5.8. This is key because, with certain exceptions not relevant here, the supplier is liable for the cost of the prosthesis if a claim is rejected because the information in the patient's medical record does not adequately support the medical necessity for the item. *Id.* The LCDs echo the Manual's directives, stating that the patient's medical record must sufficiently document the medical necessity for a prosthetic device and reflect the patient's functional ability based on the reasonable expectation of the prosthetist *and* treating physician. Def.'s Mot. to Dismiss., Ex. 5 (LCDs).

In August 2011, the Office of the Inspector General for the Department of Health & Human Services completed an investigation of questionable billing by suppliers of lower limb prostheses. The study was prompted by the fact that between 2005 and 2009, Medicare spending for prostheses increased by 27% while the number of Medicare beneficiaries receiving prostheses decreased by 2.5%. Def.'s Mot. to Dismiss, Ex. 1 (Questionable Billing by Suppliers of Lower Limb Prostheses, Aug. 2011), at i [hereinafter OIG Rep.]. The Inspector General found that in 2009, Medicare inappropriately paid $43 million for prostheses that were not reasonable and necessary and an additional $61 million for beneficiaries with no claims from

their treating physicians. *Id*. at ii. The investigation also revealed questionable billing practices by at least 267 prosthesis suppliers. *Id.*

In response to the report, and pursuant to their statutory authority to provide "education and technical assistance" to medical providers and suppliers, 42 U.S.C. § 1395kk-1(a)(4)(F), the DME MACs distributed a letter to physicians on August 11, 2011 ("Dear Physician Letter"). It is this letter that forms the basis of AOPA's Complaint.

The Dear Physician Letter, posted on each of the DME MAC's websites, stated that

> Since the prosthetist is a supplier, the prosthetist's records must be corroborated by the information in your patient's medical record. It is the treating physician's records, not the prosthetist's, which are used to justify payment.

Def.'s Mot. to Dismiss., Ex. 3 (Dear Physician Letter, Aug. 11, 2011), at 1 [hereinafter Dear Physician Letter]. The letter also directed physicians to detail each patient's rehabilitation potential and other diagnostic information in order to provide a full record of each patient's physical condition. *Id*. And, in keeping with the Inspector General's recommendations, the DME MAC's also increased scrutiny and auditing of claims for prostheses. Prior to the report and the Dear Physician Letter, AOPA claims that almost 100% of such claims were approved. Compl. ¶ 76. By contrast, one DME MAC reported an 86% denial rate in November 2011, with 96% of those denials attributed to inadequate physician documentation. *Id.*

AOPA argues that the Dear Physician Letter "changed the standards for validating Medicare claims for prosthetic devices" because "no longer would prosthetist notes be accepted to determine the medical necessity of the prosthetic device." Pl.'s Opp'n to Def.'s Mot. to Dismiss, ECF No. 8, at 1 [hereinafter Pl.'s Opp'n]. And because the letter was issued outside of the formal rulemaking process, AOPA charges that the Secretary has violated the Medicare Act and a host of other statutes.

The Secretary moves to dismiss the Complaint under Federal Rules of Civil Procedure 12(b)(1), because this Court lacks subject matter jurisdiction, and 12(b)(6) because AOPA has failed to state a claim for which relief can be granted. For the reasons stated herein, the Court holds that AOPA has failed to establish that this Court has jurisdiction over its claims and therefore finds it unnecessary to reach the Secretary's 12(b)(6) motion.

II. LEGAL PRINCIPLES

"Federal courts are courts of limited jurisdiction. They possess only that power authorized by Constitution and statute, which is not to be expanded by judicial decree. It is to be presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) (internal citations omitted). A Rule 12(b)(1) motion tests whether this burden has been met and "imposes on the court an affirmative obligation to ensure that it is acting within the scope of its jurisdictional authority." *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13–14 (D.D.C. 2001). As such, "the plaintiff's factual allegations in the complaint will bear closer scrutiny in resolving a 12(b)(1) motion than in resolving a 12(b)(6) motion for failure to state a claim." *Id*. (internal alterations and citations omitted). In undertaking this scrutiny, "the court need not limit itself to the allegations of the complaint" and "may consider such materials outside the pleadings as it deems appropriate to resolve the question whether it has jurisdiction in the case." *Id.*

III. ANALYSIS

The Secretary advances two arguments in support of her 12(b)(1) motion: (1) that the plaintiff's claims are not redressible by judicial action, and thus, the plaintiff lacks standing under Article III of the Constitution; and (2) that the plaintiff has failed to properly present its

claims and exhaust administrative remedies as required by the Medicare Act. The Court will address each of these arguments in turn.

A. Redressability

Article III, § 2, of the Constitution limits federal court jurisdiction to cases and controversies. *Raines v. Byrd*, 521 U.S. 811, 818 (1997). Demonstrating the existence of a case or controversy, or standing, requires that the plaintiff establish (1) an "injury in fact" that is (2) "fairly traceable to the challenged action of the defendant" and is (3) likely to be "redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992) (internal quotations and citations omitted). The third element, redressability, requires an examination of "whether the relief sought, assuming that the court chooses to grant it, will likely alleviate the particularized injury alleged." *Cnty. of Delaware, Pa. v. Dep't of Transp.*, 554 F.3d 143, 149 (D.C. Cir. 2009). Here, Counts I through IV of the plaintiff's complaint allege that AOPA members have suffered increased audits and denials of prostheses claims as a result of the Dear Physician Letter. The question whether AOPA's injury is redressible therefore turns upon whether invalidation of the letter would alleviate the audits and claim denials.

The Secretary argues that because the guidance provided in the Dear Physician Letter merely restates standards previously set forth in the MPIM and LCDs, nullifying the letter would have no effect on the processing of prostheses claims. AOPA makes three arguments in support of the opposite position—that the letter drastically changed the standards for evaluated prostheses claims.

First, AOPA argues that "prior to August 2011 nothing in the MPIM, LCDs, or Supplier Manuals called for corroboration of the prosthetist's records beyond the physician's signature on the prescription and work order for the prosthesis." Pl.'s Opp'n at 10. Not so. The importance

of the treating physician's records is clear from the MPIM, which requires a full and complete medical record of the patient's diagnosis, clinical course, prognosis, and other therapeutic interventions. MPIM § 5.7. The creation of such records requires the judgment and expertise of physicians—not simply suppliers. AOPA draws much of the fuel for its argument from the manual's apparent effort to encourage a holistic evaluation of each patient by not limiting the record to the treating physician's records. *See id.* ("The patient's medical record is not limited to the physician's office records. It may include hospital, nursing home, or HHA records and records from other health care professionals."). The creation of an inclusive medical record does not, however, diminish the importance of the treating physician's input and certainly does not reduce the physician's role to a mere signatory or rubber stamp. As further evidence that the MPIM required more extensive records from the *physician*—over and above what the physician shared with the supplier—the manual notes that the "documentation in the patient's medical record does not have to be routinely sent to the supplier . . . . However, the DME MACs . . . may request this information in selected cases." *Id.* This defeats AOPA's argument that prior to the Dear Physician Letter, prosthetist records *alone* were sufficient to prove medical necessity. Even before the Dear Physician Letter—and indeed even if the letter did not exist—the Secretary reserved the right to demand more medical documentation from the physician.

Next, AOPA points to language in the LCDs and MPIM that addresses the prosthetist's duty to obtain and retain records supporting the medical necessity of prostheses. *See, e.g.*, LCDs at 5 ("Coverage is extended only if there is sufficient clinical documentation of functional need for the technologic or design feature of a given type of [prosthesis]. This information must be *retained* in the physician's *or* prosthetist's files.") (emphasis added). In AOPA's view, this language means that the LCDs treat the "prosthetist as interchangeable with the physician and

the prosthetist records as equivalent to the physician's." Pl.'s Opp'n at 11. Again, this is not so. The MPIM undoubtedly requires *both* physicians and prosthetists to keep adequate records. But it does not follow that those records are interchangeable or that the physician's records are wholly irrelevant. Moreover, the MPIM explicitly places the onus on the supplier to maintain appropriate records from the treating physician and directs the supplier to "obtain as much documentation from the patient's medical record as they determine they need to assure themselves that the coverage criteria for an item have been met." MPIM § 5.8. This makes sense given that it is the supplier who submits the Medicare claim and, in the event of an audit or denial of a claim, it is the supplier that is liable for the cost of the prosthesis. *Id*. at § 5.7. Thus, the language pinpointed by AOPA does not mean that, prior to the Dear Physician Letter, prosthetists were interchangeable with physicians; rather, it means that the suppliers bore the greatest responsibility of—and had the greatest financial interest in—retaining adequate records. *See id.* at § 5.8 (directing the *suppliers* to retain medical records for seven years).

Third, AOPA points to the LCDs' statement that "a determination of the type of [foot/knee] for the prosthesis will be made by the treating physician and/or the prosthetist based on the functional needs of the patient." LCDs at 5; *see also id*. ("There must be information about the patient's history and current condition which supports the designation of the functional level by the prosthetist."). This statement simply recognizes that the prosthetist is an appropriate expert to determine the type of prosthesis that is best for a patient. It does not amount to a pronouncement that the prosthetist alone can determine the medical necessity of a prosthesis in the first instance.

The insufficiency of prosthetist records to establish medical necessity is apparent from the LCDs and MPIM as they existed prior to the Dear Physician Letter. In January 2013,

however, the LCDs were revised to make this even more explicit. Because standing is "assessed as of the time a suit commences," *Del Monte Fresh Produce Co. v. United States*, 570 F.3d 316, 324 (D.C. Cir. 2009), the Court may consider the revised LCDs—which were produced before the Complaint was filed in May 2013—in its determination. The revised LCDs state that "[r]ecords from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for the purpose of determining that an item is reasonable and necessary." Def.'s Supp. Br. in Supp. of Mot. to Dismiss, Ex. 1 (Revised LCDs), at 7.

It is therefore clear that, even in the absence of the Dear Physician Letter, claims submitted without adequate physician records or solely on the basis of a supplier recommendation would be properly subject to denial or audit. The agency admits that it has "focused more resources on claims for prosthetic devices . . . to more effectively tamp down waste, fraud, and abuse." Def.'s Mot. at 21. A decision to increase enforcement of existing standards is entirely within the agency's discretion—*see, e.g.*, *Heckler v. Chaney*, 470 U.S. 821, 831 (1985)—and HHS would be free to exercise this discretion with or without the Dear Physician Letter. Accordingly, the Court holds that the violations alleged in Counts I through IV of the Complaint are incapable of redress by a favorable judicial decision and are therefore dismissed. Even if plaintiff's claims were redressible, the Court alternatively finds that jurisdiction is lacking because the plaintiff failed to satisfy the Medicare Act's prerequisites to judicial review.

B. Presentment & Exhaustion

The Medicare Act places strict limits on the jurisdiction of federal courts to decide "any claims arising under" the Act. 42 U.S.C. § 405(h). A claim arises under the Medicare Act where

the provisions of the Act provide "both the standing and the substantive basis" for the complaint. *Weinberger v. Salfi*, 422 U.S. 749, 761 (1975). And, significantly for the present case, the jurisdiction-limiting provisions of the Medicare Act apply even where the plaintiff raises Medicare-based claims under other statutes. *Heckler v. Ringer*, 466 U.S. 602, 620–22 (1984) (federal question jurisdiction and the APA are not alternative jurisdictional bases for judicial review of claims arising under the Medicare Act); *Action Alliance of Senior Citizens v. Leavitt*, 483 F.3d 852, 858 (D.C. Cir. 2007) ("[T]he existence of an administrative remedy under [the Medicare Act] precludes the exercise of mandamus, which is available only if no other adequate remedy [is] available to plaintiff."). As all of AOPA's claims are substantively based in the Medicare Act, satisfaction of the Act's conditions regarding judicial review is required.

There are two prerequisites to federal jurisdiction over claims arising under the Medicare Act. First, the plaintiff must meet the "nonwaivable requirement that a claim for benefits shall have been presented to the Secretary." *Heckler*, 466 U.S. at 617. The second requirement, that the plaintiff exhaust all remedies available under the Act, may be waived by the Secretary, or by the Court "in certain special cases." *Id*. at 618. AOPA argues that it has met the first requirement and urges the Court to waive the second.

As to presentment, AOPA argues that it satisfied this requirement by submitting general complaints regarding the Dear Physician Letter.[1] Compl. ¶¶ 74–78. In support of its contention that such generalized complaints are sufficient to satisfy the presentment requirement, AOPA cites *Action Alliance of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33, 40 (D.D.C. 2009).

[1] In its Complaint, AOPA also avers that individual AOPA members have challenged the denial of claims before the agency, Compl. § 81; however, the Complaint does not reveal whether those appeals presented the same questions presented here. And, in response to the presentment arguments raised by the Secretary's motion, AOPA did not argue that these individual appeals satisfied the presentment requirement. In any event, because the Court also finds that AOPA has not exhausted all administrative remedies, dismissal for lack of subject matter jurisdiction is appropriate even if the individual appeals constitute proper presentment.

There, the district court, without explanation, declared that an association's letters to the agency established presentment. *Id*. In affirming the district court's decision, the Circuit summarily noted that a prior jurisdictional defect had been cured but offered no opinion on whether and why generalized letters were sufficient. *Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (D.C. Cir. 2010). The lack of explanation in both cases is likely because the precise question presented here—whether generalized grievance letters rather than discrete claims are sufficient to satisfy presentment—was not raised by the parties in *Action Alliance*, and the Court therefore questions the precedential value of those opinions. *See, e.g*., *Arizona Christian Sch. Tuition Org. v. Winn*, 131 S. Ct. 1436, 1448 (2011) ("When a potential jurisdictional defect is neither noted nor discussed in a federal decision, the decision does not stand for the proposition that no defect existed."). However, even if the Circuit's opinion in *Action Alliance* were binding on this Court, it is easily distinguishable from the case-at-hand because, unlike AOPA's letters, the letters relied upon by Action Alliance presented HHS with factually detailed letters regarding discrete claims on behalf of individuals. In this way, the *Action Alliance* letters were closer to the "concrete claim for reimbursement" that the Supreme Court has held is required for proper presentment. *Heckler*, 466 U.S. at 622; *see also id*. at 625 ("Congress . . . has . . . expressly set up a scheme that requires the presentation of a concrete claim to the Secretary."). Because they were not tied to any concrete claims, AOPA's self-described "detailed critiques of the 'Dear Physician' letter," Pl.'s Opp'n at 18, are insufficient to establish presentment.

AOPA has likewise failed to establish exhaustion. Exhaustion is a common principle of administrative law that requires channeling of legal challenges through the agency before seeking recourse with the federal courts. In ordinary challenges to agency action, the exhaustion requirement "may be waived only in the most exceptional circumstances." *UDC Chairs*

Chapter, Am. Ass'n of Univ. Professors v. Bd. of Trustees of Univ. of D.C., 56 F.3d 1469, 1475 (D.C. Cir. 1995). Courts have often waived exhaustion upon a finding that agency review would be futile; however, such a finding requires certainty—not simply probability—that the claim will be denied by the agency. *Id.* And, in cases arising under the Medicare Act, the requirement for "exceptional cases" and certainty are even more stringent because "the bar of § 405(h) reaches beyond ordinary administrative law principles [such as] exhaustion of administrative remedies" and "demands the channeling of virtually all legal attacks through the agency." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000); *see also Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992) (noting that the Act's requirement of a final decision is "more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility."). This is consistent with Congress's intent to assure "the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts applying ripeness and exhaustion exceptions case by case." *Id.*

Against this background, AOPA has presented this Court with a complaint that fails to cite even a single supplier out of its 816 members that has exhausted *all* of the administrative remedies available through the agency.[2] AOPA asks the Court to waive the exhaustion requirement because any administrative appeal would be "unquestionably futile." Pl.'s Opp'n at 23. This claim of futility is belied by the facts detailed in the Complaint, which states that "AOPA members have challenged the denial of claims for artificial limbs in administrative appeals [and] have won a significant percentage of those appeals." Compl. ¶ 81. Proving futility

[2] AOPA attached an affidavit from Sara Beck, an employee of a prosthetic supplier represented by AOPA, to its response to defendant's supplemental brief. Ms. Beck avers that she has appealed claim denials through the ALJ stage but has yet to present her issues to the Medicare Appeals Council, which is the final decision maker for claims arising under the Medicare Act. 42 U.S.C. § 405.904(a)(2).

requires demonstration that defeat is certain, which the plaintiff cannot demonstrate if its members are succeeding in appeals before the agency. In addition, this fact is sufficient to distinguish this case from the futility case relied upon by AOPA, *Tataranowicz v. Sullivan*, 959 F.2d 268 (1992). In *Tataranowicz*, the Circuit waived exhaustion in a case arising under the Medicare Act where there was "no reason to believe that the agency machinery might accede to the plaintiff's claims." *Id*. at 274. And *Tataranowicz* relied heavily upon the Supreme Court's waiver of exhaustion in *Mathews v. Diaz*, 426 U.S. 67 (1976) after the Secretary averred to the Court that the petitioner's claim would certainly be denied based upon the challenged statutory provision, which the Court held was "tantamount to . . . a waiver of the exhaustion requirements," *id*. at 76–77. None of this can be said about the present case. The Secretary has neither promised the denial of AOPA members' claims nor waived the exhaustion requirements; rather, she has pressed her statutory right to resolve these issues in the context of discrete claims that proceed through the proper administrative channels. And given the significant success of AOPA's members' appeals, there is, unlike in *Tataranowicz*, reason to believe that the "agency machinery might accede to the plaintiff's claims." 959 F.2d at 274. In addition to its reliance on *Tataranowicz*, AOPA points to its "limited" administrative options, Pl.'s Opp'n at 21, and the hardship suffered by prostheses suppliers while awaiting a final decision from the agency, *id*. at 15. To the first point, the Act permits several layers of administrative review for suppliers, including redetermination, 42 C.F.R. § 405.940; reconsideration by a qualified independent contractor, 42 C.F.R. § 405.904(a)(2); a hearing before an administrative law judge, 42 C.F.R. § 405.1000(a); and final review by the Medicare Appeals Council, 42 U.S.C. § 405.904(a)(2). The Court therefore disagrees with AOPA's characterization of suppliers' appeal options as "limited." And further, even if AOPA's characterization were apt, there is no exception to

exhaustion due to limited options—even limited options, however imperfect, must be exhausted before a federal court can interfere with the Secretary's right to apply, interpret, and/or revise agency regulations and policies in the context of concrete factual claims. AOPA's second point was addressed in *Illinois Council*, where the Supreme Court held that "delay-related hardship" was the price to be paid for the agency review required by Congress. 529 U.S. at 13.

The Court therefore holds that the plaintiff has failed to demonstrate that it has fully exhausted administrative remedies. The Complaint is dismissed in its entirety.

A separate Order consistent with this Memorandum Opinion shall issue this date.

Signed by Royce C. Lamberth, United States District Judge, on August 4, 2014.