IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN ORTHOTIC & PROSTHETIC ASSOCIATION, INC.,	)	
Plaintiff,	)	
v.	)	Case No. 1:13-CV-697 (RCL)
KATHLEEN SEBELIUS,	)	
Defendant.	)	

MOTION TO DISMISS

Defendant hereby moves for dismissal under Federal Rules of Civil Procedure 12(b)(1) and 12(b)(6). The bases for this motion are explained in the accompanying memorandum.

DATED: July 19, 2013

Respectfully submitted,

STUART F. DELERY
Acting Assistant Attorney General

RONALD C. MACHEN JR
United States Attorney

SHEILA LIEBER
Deputy Director, Federal Programs Branch, Civil Division

/s/ Justin M. Sandberg
JUSTIN M. SANDBERG
(Ill. Bar No. 6278377)
Trial Attorney
U.S. Dept. of Justice, Civil Division,
Federal Programs Branch
20 Mass. Ave., NW, Rm. 7302
Washington, DC 20001

(202) 514-5838 phone
(202) 616-8202 fax
justin.sandberg@usdoj.gov

Attorneys for Defendant

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN ORTHOTIC & PROSTHETIC ASSOCIATION, INC.,	)	
Plaintiff,	)	
v.	)	Case No. 1:13-CV-697 (RCL)
KATHLEEN SEBELIUS, Secretary of the Department of Health and Human Services,	)	
Defendant.	)	

MEMORANDUM IN SUPPORT OF MOTION TO DISMISS FOR LACK OF JURISDICTION AND FAILURE TO STATE A CLAIM

INTRODUCTION

Something has changed in the processing of Medicare claims for prostheses. That is the premise of the complaint filed by the American Orthotic & Prosthetic Association (AOPA) on behalf of its members (suppliers of orthotic and prosthetic supplies). Compl., May 13, 2013. And on that point, Secretary Sebelius[1] and plaintiff can agree. But the Secretary cannot agree with plaintiff about what has changed – because plaintiff is wrong. Plaintiff contends that the Secretary substantively changed the rules for documenting claims seeking payment from the Medicare program for prosthetic devices. The alleged agent of change: An August 2011 open letter addressed to doctors, not prosthetic suppliers, from four contractors that help process Medicare claims for prostheses. In fact, though, the "Dear Physician" letter (also "Letter") did not change the

[1] As plaintiff sues the Secretary in her official capacity, the memorandum also refers to the Secretary as the U.S. Department of Health and Human Services, or "HHS."

rules. Nor could it have, because contractors cannot issue rules. Rather, something else changed, namely, the enforcement of the existing claim documentation standards.

In August 2011, the Inspector General for the Department of Health and Human Services issued a report. It recommended that the Secretary more carefully scrutinize Medicare claims for lower limb prostheses to (i) ensure that the prostheses are "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), and, thereby, (ii) eliminate waste, fraud, and abuse. This report spurred the contractors not only to issue the open letter reiterating the existing standards for documenting claims for prosthetic devices, but also to more closely scrutinize such claims by more frequently requesting proof of medical necessity. Of course, nothing prevents the Secretary, or her contractors, from enforcing existing standards to improve the operation of the Medicare program. Indeed, that is their job.

That is the basic story. Here are a few more specifics. As noted, plaintiff maintains that the Letter changed the rules for documenting Medicare claims for prosthetic devices. But as the Letter was not preceded by notice and an opportunity for comment, plaintiff insists that the Secretary violated the rulemaking provisions of the Medicare statute, 42 U.S.C. § 1395hh, and the Administrative Procedure Act (APA), 5 U.S.C. § 503 *et seq*. Compl. ¶¶ 82-87 (Count I), 93-95 (Count III). Plaintiff also insists that the "new" rules contradict statutory authority and have been improperly applied. *Id.* ¶¶ 88 (Count I), 89-92 (Count II), 95-97 (Count III). Next, plaintiff alleges that the Regulatory Flexibility Act (RFA) required HHS to conduct an analysis of the impact of the "new" rules on small businesses, like some AOPA members. Compl. ¶ 100-105

(Count IV). Finally, in the last count of its Complaint, plaintiff raises a claim slightly different from the rest. This Count does not focus on the letter, but on regulations that the Secretary has not enacted. To be specific, plaintiff contends that a law, the Medicare, Medicaid and SCHIP Improvement and Protection Act of 2000 ("BIPA), 114 Stat. 2763, Pub. L. 106-554, required the Secretary to enact regulations regarding minimum qualification standards that prosthetic suppliers must meet to receive payment from Medicare. Compl. ¶¶ 39-43, 106-110 (Count V). The connection between that claim and the others is that plaintiff insists that the qualification standards are the only tool that the Secretary may use to prevent waste, fraud, and abuse with respect to claims for prosthetic devices. *See* Compl. ¶¶ 38-39.

The Court should dismiss plaintiff's complaint for lack of jurisdiction. Plaintiff has not alleged that any member on whose behalf it sues has presented a claim to HHS or exhausted the available administrative remedies, as required by the Medicare statute, 42 U.S.C. §§ 405(g), 405(h),1395ff(b), 1395ii. Thus, the Court lacks jurisdiction over all of plaintiff's claims. The Court lacks jurisdiction over plaintiff's complaint for another reason: Plaintiff has not specifically identified a member who would have standing to sue. Finally as to jurisdiction, because the "Dear Physician" letter simply restated existing documentation standards, plaintiff cannot establish that an order striking down the Letter will redress the injury allegedly caused by it, *i.e.*, the delaying or denial of payment to AOPA members as a result of the "new" rules it announced. In other words, the Secretary can treat Medicare claims for prosthetic devices the same way regardless of what happens to the letter. This eliminates plaintiff's standing to raise Counts I through IV of the Complaint. Compl. ¶¶ 82-105.

On the merits, Counts I through IV fail because the Letter does not constitute reviewable agency action. This is so for two reasons: (i) contractors do not have the authority to issue rules; and (ii) the Letter merely restated existing standards. Counts I through IV fail for other reasons as well, including, for example, that the RFA obligates an agency to conduct a small business impact analysis only with regard to entities subject to the requirements of a rule and, even if the "Dear Physician" letter announces rules, prosthetic suppliers are not subject to it – doctors are. For these reasons, as elaborated below, the Court should dismiss this action for lack of jurisdiction, or dismiss Counts I-IV for failure to state a claim upon which relief can be granted.

BACKGROUND

In August 2011, the Inspector General for the Department of Health and Human Services issued a report entitled "Questionable Billing by Suppliers of Lower Limb Prostheses."[2] Dep't of Health and Human Svcs., OIG, ("OIG Rpt.") OEI-02-10-00170 (2011) (attached as Ex. 1). Medicare will provide coverage and payment for a prosthesis under certain conditions, including that the prosthesis is medically necessary. 42 U.S.C. §§ 1395k(a)(2)(I), 1395y(a)(1)(A). To ensure those conditions were being met with respect to lower limb prostheses, the OIG studied claims for individuals who received those devices in 2009. OIG Rpt. at ii. The Inspector General concluded that Medicare paid $61 million in claims in circumstances that "raise[d] questions about whether . . . the [prosthetic] devices were medically necessary." *Id.* When would a particular prosthetic device be medically unnecessary? To take one example, if a person has ailments that render him sedentary, such as heart disease, he need not be outfitted with an

[2] "Lower limb prostheses are [devices] designed to replace, as much as possible, the function of a missing limb." OIG Rpt. at i.

artificial limb designed for high impact exercise, rather than a less expensive one more suited to his capabilities. The report recommended that HHS "strengthen monitoring of billing for lower limb prostheses." *Id.* at 18-19. HHS agreed with this recommendation. *Id.*, Appendix B, at 23-23.

To strengthen its "monitoring of billing," HHS needed the cooperation of its contractors. Medicare receives hundreds of millions of claims every year. *Almy v. Sebelius*, 679 F.3d 297, 304 (4th Cir. 2012). Given the volume of claims, Congress has authorized HHS to enlist contractors to help it process them. *See* 42 U.S.C. § 1395kk-1. These contractors are called Medicare Administrative Contractors, or MACs. *Id.* Different contractors assist with different products or services covered by Medicare. Four MACs are responsible for processing claims for durable medical equipment, orthotics, prosthetic devices, and supplies (DMEPOS). *See* 42 C.F.R. § 421.210. Each of these four contractors – called a DME MAC – processes DMEPOS claims for a different region of the country. *See* 42 U.S.C. § 1395m(a)(12).

As part of their duties, the contractors educate suppliers, determine the amount of money that will be paid for Medicare claims (at least initially), including claims for prostheses, and make payments. 42 U.S.C. § 1395kk-1(a)(4). In determining the payment amounts, the contractors are bound by statutes, agency regulations, and the Medicare Program Integrity Manual ("Manual"). The Medicare statute states that, with respect to prostheses, only those devices that are "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member" can be covered. 42 U.S.C. § 1395y(a)(1)(A). The Manual provides guidance regarding the meaning of this provision, as it sets out (among other things)

information that should be included in the medical record to substantiate the medical need for the item. Manual, ch. 5, § 5.7 (attached as Ex. 2). And "'[t]o provide [further] guidance to the public and the medical community within their jurisdictions' as to the 'clinical circumstances' under which 'a service is considered to be reasonable and necessary," contractors develop and publish "'administrative and educational tools'" called local coverage determinations. *Willowood of Great Barrington, Inc. v. Sebelius*, 638 F. Supp. 2d 98, 106 (D. Mass. 2009) (quoting Manual, ch. 13, § 13.1.3)). In other words, local coverage determinations – which are specifically authorized by statute, 42 U.S.C. § 1395ff(2)(B) – state whether or not, and under what circumstances, a particular contractor will authorize payment for an item. *Id.*; *Willowood*, 638 F. Supp. 2d at 106. When determining whether payment for a claim would accord with the standard established by these various sources, a DME MAC may perform a medical audit, during which it asks the prosthetic supplier to provide medical records that corroborate the reasonableness and necessity of the prosthetic device provider. Manual, ch. 5, § 5.7; 42 U.S.C. §§ 1395kk-1(a)(4)(G), 1395l(e).[3] Now, back to August 2011.

The four DMEPOS contractors responded to the Inspector General's Report in August 2011 by issuing a letter to physicians regarding the "Documentation of Artificial Limbs." Letter from DMEPOS contractors to Physicians ("Dear Physician" letter or Letter), Aug. 11, 2011(attached to complaint, and to this memorandum as Ex. 3). The Letter explains that "[i]n the event of an audit, the Medicare contractor may request medical records to demonstrate that the prosthetic arm or leg was reasonable and

[3] Other Medicare contractors, such as Medicare recovery audit contractors, can also perform medical audits. *See* 42 U.S.C. § 1395ddd. Recovery audit contractors work to recover overpayments to improve the fiscal integrity of the Medicare program. *See Palomar Medical Center v. Sebelius*, 693 F.3d 1151, 1156 -1157 (9th Cir. 2012).

necessary." *Id.* at 1. It then reviews the information that must be present in the physician's record to justify payment. *Id.* To be more specific, the record must contain information about the patients' "functional capabilities" as measured on a scale of zero to four, and "the patient's physical and cognitive capabilities," including information on the "[s]ymptoms limiting ambulation or dexterity" and the "diagnoses [of what conditions are] causing these symptoms. *Id.* at 1-2. The Letter closes by reminding doctors that "when [they] are unable to provide the requested documentation to the supplier, the suppliers receive denials for the items billed which could result in your patients being financially responsible for all or part of the charges for the items/services received." *Id.* at 2.

The authority to issue the Letter derives from the contractor's authority to offer "education and technical assistance," 42 U.S.C. § 1395kk-1, as the Letter educated prosthetics suppliers on existing standards for documenting claims for prosthetic devices. *See* Letter from Marilyn Tavenner, Acting Administrator, Center for Medicare and Medicaid Services, HHS, to Thomas Mills, counsel for plaintiff, May 9, 2013, at 1 (attached as Ex. 4). The Medicare statute, 42 U.S.C. §§ 1395kk-1(a)(4)(G), 1395l(e), and the Manual, ch. 5, § 5.7, had already provided the authority for contractors to audit claims to determine if the item claimed is "reasonable and necessary," 42 U.S.C. § 1395y(a)(1)(A). The local coverage determinations for lower limb prostheses, all four of which were identical, OIG Rpt. at 3 n.10, and the Manual had already established that the physician had to corroborate the reasonableness and necessity of the prosthetic device that is the subject of the Medicare claim. Manual, ch. 5, § 5.7 (requiring the kind of medical information provided by a doctor); Local Coverage Determination for Lower

Limb Prostheses (LCD), Effective for Services Performed on or after January 1, 2011, at 3 (noting that "potential functional ability," a key determinant of medical necessity, is based on the "reasonable expectations of the prosthetist [ ] and treating physician.") (attached as Ex. 5); *see also* 42 U.S.C. § 1394u(p)(4) (contemplating physician corroboration). The local coverage determinations also had laid out the standards for determining "functional capabilities," including the scale with the five classification levels. LCD at 3. Finally, the Medicare statute already obligated doctors to provide suppliers with necessary information, 42 U.S.C. § 1395u(p)(4); indeed, the Letter contains relevant language from § 1395u(p)(4).

After reminding suppliers of the standards for documenting claims for prostheses, the contractors increased their auditing of such claims to root out waste, fraud, and abuse. "[R]eviewing these claims as recommended by the OIG" has "resulted in an increased number of prosthetic and orthotic claims [being] selected for medical review." Letter from Tavenner to Mills, May 9, 2013, at 1. AOPA, "a trade association whose stated mission includes working for the favorable treatment of the orthotic and prosthetic business in law, regulations, and services," Compl. ¶11, was displeased with the Letter and the increased auditing. It wrote letters to HHS on behalf of its members to try to secure more favorable treatment – *i.e.*, decreased scrutiny of its claims. *See, e.g.*, Letter from Mills to Tavenner, Dec. 14, 2012 (attached as Ex. 6). AOPA's primary gripe was that the "Dear Physician" letter supposedly established new standards for documenting claims. *Id.* at 1-2. But it also questioned the fact that HHS had yet to issue regulations implementing § 427 of the BIPA, which addressed the payment of claims for prosthetic devices and custom orthotics submitted by unqualified practitioners or suppliers. Letter

from Mills to Secretary Sebelius, April 15, 2013 at 2-3 (attached as Ex. 7). AOPA insists that its members are "qualified" and competitively harmed by unqualified non-members who receive Medicare payments, and that the fault for abusive practices in the industry rests with the "unqualified" providers. Compl. ¶ 47.

A letter writing campaign is not the process contemplated by the law for challenging Medicare-related actions. The Medicare statute and regulations afford a program beneficiary – or, a supplier (like an AOPA member) who receives an assignment of benefits, 42 U.S.C. § 1395u(b)(3)(B); 42 C.F.R. §§ 424.55 – extensive opportunities for review, including several levels of administrative review and, potentially, judicial review. 42 U.S.C. §§ 1395ff; 42 C.F.R. Part 405, Subpart I. If the supplier is dissatisfied with the contractor's initial determination of whether or to what extent the services are covered by Medicare, the claimant may seek a redetermination from the contractor. 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.904(a)(2), 405.940. If dissatisfied with the contractor's redetermination, the supplier may then request a reconsideration of the redetermination by a qualified independent contractor (also QIC). 42 U.S.C. § 1395ff(b), (c); 42 C.F.R. §§ 405.904(a)(2) and 405.960. When evaluating the redetermination, the QIC reviews the evidence upon which the initial determination and redetermination were based, and any additional evidence submitted by the parties or obtained by the QIC on its own. 42 C.F.R. § 405.968(a). A still dissatisfied supplier may appeal the decision of the QIC to an Administrative Law Judge (ALJ) for a hearing and decision if the amount-in-controversy requirements are met. 42 U.S.C. §§ 405(b), 1395ff(b)(1)(A), (E); 42 C.F.R. §§ 405.1000(a), 405.1002. The ALJ's hearing decision, in turn, may be reviewed by the

Medicare Appeals Council of the Departmental Appeals Board.[4] 42 U.S.C. § 1395ff(b)(1)(A), (d)(2); 42 C.F.R. § 405.1000, 405.1100, 405.1102, 405.1104, and 405.1110. The Council's decision is the final decision of the Secretary subject to judicial review if the amount-in-controversy requirements are met. 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A); 42 C.F.R. § 405.1136; *see also* 42 C.F.R. § 405.1130.[5] AOPA, in fact, alleges that a number of members have successfully used this carefully crafted process to challenge the denial of claims for artificial limbs. Compl. ¶ 81. Nonetheless, AOPA chose to try to raise its members concerns through a proxy letter-writing campaign.

When the letter-writing campaign did not accomplish its goal of ensuring more favorable treatment for AOPA's members, AOPA filed suit. The Complaint, which contains 110 numbered paragraph, encompasses six counts – and almost twice as many claims. Count I alleges that HHS violated the rulemaking requirements of the Medicare statute by (i) failing to provide notice and an opportunity to comment before issuing the August 2011 Letter and (ii) applying retroactively the supposedly new standards set out in the Letter. Compl.¶¶ 82-88. Count II maintains that HHS violated the Medicare statute by (i) failing to enforce the requirement, established by 42 U.S.C. § 1395u(p)(4), that doctors provide any necessary medical information, and (ii) requiring AOPA members to secure documents from physicians establishing the reasonableness and necessity of the item for which the AOPA members seeks Medicare payment. Compl. ¶¶ 89-92. Count III, echoing Counts I and II, contends that HHS transgressed the APA by

[4] Neither the ALJ nor the Appeals Council is bound by local coverage determinations or "CMS program guidance," but they will give "substantial deference to these policies if they are applicable to a particular case." 42 C.F.R. § 405.1062(a), (b).

[5] Given the cost of prostheses, *see* OIG Rpt. at 15 (table), these amount-in-controversy requirements would almost certainly be met with respect to claims by AOPA's members.

(i) failing to provide notice and an opportunity to comment before issuing the Letter and (ii) "refus[ing] to accept prosthetist notes as demonstrating [ ] medical necessity . . .[and] instead [requiring] that AOPA members secure from treating physicians the documentation set forth in the 'Dear Physician' letter," Compl. ¶ 97. Compl. ¶¶ 03-99. Count IV insists that HHS had an obligation to conduct a small-business impact analysis under the RFA. Compl. ¶¶ 100-105. Finally, in Count V, plaintiff seeks a writ of mandamus requiring HHS to issue supplier qualification rules implementing § 427 of the BIPA. Compl. ¶¶ 106-110.

STANDARD OF REVIEW

Plaintiffs bear the burden of establishing subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), and the Court must determine whether it has subject matter jurisdiction before addressing the merits of the complaint. *See Steel Co. v. Citizens for Better Env't*, 523 U.S. 83, 94-95 (1998). When deciding a motion to dismiss under Rule 12(b)(1), the Court may consider matters outside the pleadings. *Coal. for Underground Expansion v. Mineta*, 333 F.3d 193, 198 (D.C. Cir. 2003).

Under Rule 12(b)(6), "[t]o survive a motion to dismiss, a 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) (internal quotation marks omitted). In deciding a Rule 12(b)(6) motion, the Court may consider "the facts alleged in the complaint, any documents either attached to or incorporated in the complaint and matters of which [the Court] may take judicial notice." *E.E.O.C. v. St. Francis Xavier Parochial Sch.*, 117 F.3d 621, 624-625 (D.C. Cir. 1997).

ARGUMENT

I. The Court Should Dismiss the Complaint for Lack of Jurisdiction.

A. The Court Lacks Jurisdiction Because Plaintiff Has Not Alleged That Any Member Has Presented a Claim to HHS or Exhausted Its Remedies.

Judicial review of "any claim arising under" the Medicare statute may be obtained only as provided under the Act, 42 U.S.C. §§ 405(h), 1395*ii*; *see Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 10-12 (2000); a claim arises under the Medicare statute if the Act provides "both the standing and the substantive basis" for the claims, *see Weinberger v. Salfi*, 422 U.S. 749, 757-64 (1975). The Act provides that district courts have jurisdiction to conduct judicial review of Medicare claims only if the claimant has obtained a "final decision" from the Secretary. 42 U.S.C. §§ 405(g), 1395ff(b); *see also* 42 C.F.R. §§ 405.1130, 405.1136; *Illinois Council*, 529 U.S. at 5. Plaintiff bears the burden of establishing that the Court has jurisdiction under the Medicare statute. *Action Alliance of Senior Citizens v. Johnson*, 607 F.Supp.2d 33, 39 (D.D.C. 2009).

Under the Medicare statute and regulations, to obtain a final decision (*i.e.*, to exhaust administrative remedies), a beneficiary ordinarily must (1) present a claim to HHS – or more precisely, to a contractor who handles the first line of review for HHS – and receive an "initial determination," (2) request "redetermination" of the claim by the contractor, (3) request reconsideration of the claim by the Qualified Independent Contractor, (4) request a hearing from an administrative law judge (if the amount remaining in controversy and other requirements for an ALJ hearing are met), and (5) request that the Medicare Appeals Council review the case and issue a decision. 42 U.S.C. § 1395ff; 42 C.F.R. § 405.904(a)(2).

While a final decision ordinarily comprises these five elements, the final four elements may be waived by the Secretary or, in exceptional circumstances, a court. *Mathews v. Eldridge*, 424 U.S. 319, 328, 330 (1976). But the first element – the presentment requirement – is nonwaivable. *Ill. Council*, 529 U.S. at 15 ("[Section] 405(g) contains the nonwaivable and nonexcusable requirement that an individual present a claim to the agency before raising it in court."). And judicial review under the general federal question jurisdiction statute, 28 U.S.C. § 1331, which plaintiffs invoke, *see* Am. Compl. ¶ 10, is simply unavailable. *See* 42 U.S.C. §§ 405(h), 1395*ii*; *Ill. Council on Long Term Care*, 529 U.S. at 10-25.

The Supreme Court has characterized the § 405(h) bar to other avenues of review as "sweeping and direct," *see Salfi*, 422 U.S. at 757, and explained that it applies to "all 'claim[s] arising under' the Medicare statute," *Heckler v. Ringer*, 466 U.S. 602, 615 (1984), regardless of the nature of the particular claim, *Ill. Council on Long Term Care*, 529 U.S. at 14. *See also Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S. 449, 456 (1999) ("judicial review under the federal-question statute, 28 U.S.C. § 1331, is precluded by 42 U.S.C. § 405(h)"). So long as the claim arises under the Medicare statute, it must be channeled through the exhaustion and exclusive judicial review provisions of the Medicare statute.

The Supreme Court has repeatedly rejected efforts to read Section 405(h) narrowly. Thus, in *Heckler v. Ringer*, the Court held that an effort to enjoin a Medicare policy on constitutional due process and procedural rulemaking grounds must be channeled through the agency. 466 U.S. at 614-615. And in *Illinois Council*, the Court confirmed that it would not "accept a distinction that limits the scope of [Section] 405(h)

to claims for monetary benefits." 529 U.S. at 14. Accordingly, a claim arises under the Medicare statute when that statute "provides both the standing and the substantive basis for" the claim, regardless of whether the claims can be characterized as also arising under other statutes or Constitutional guarantees. *Ringer*, 466 U.S. at 615*; Salfi*, 422 U.S. at 760-761.[6]

Plaintiff's claims arise under the Medicare statute. With regard to the "standing" component of the arising-under inquiry, the injuries about which plaintiff complains – *i.e.*, that its members are being reimbursed for their Medicare claims too slowly or not at all, Compl. ¶¶ 64-65, or are losing Medicare reimbursement dollars to unqualified competitors as a result of HHS's failure to promulgate regulations under the BIPA, *id.* ¶47 – all arise from the Medicare statute because they ultimately relate to payments from the Medicare Trust Fund. *See Puerto Rican Ass'n of Physical Medicine and Rehab., Inc. v. United States*, 521 F.3d 46, 48 (1st Cir. 2008) (concluding that a suit arose under the Medicare statute because "it seeks at its heart the extension of Medicare benefits"). Similarly, the Medicare statute provides the substantive basis for the plaintiff's claims because all of the claims turn on what the Act or implementing standards say, Counts I-III, Compl. ¶¶ 82-99, might say if procedural rules had not allegedly been disregarded, Counts III, IV, or do not say, Count V, ¶¶ 106-110. *See Ill. Council*, 529 U.S. at 7, 11-15

[6] *See Salfi*, 422 U.S. at 760 ("It would, of course, be fruitless to contend that appellees' claim is one which does not arise under the Constitution, since their constitutional arguments are critical to their complaint. But it is just as fruitless to argue that this action does not also arise under the Social Security Act."); *Ringer*, 466 U.S. at 616, 621-22 ("Ringer's claim may well 'aris[e] under' the APA in the same sense that Salfi's claim arose under the Constitution, but we held in *Salfi* that the constitutional claim was nonetheless barred by § 405(h).").

(concluding that constitutional claims and procedural APA claims "arise under" the Medicare statute).

Plaintiff has not satisfied the presentment or exhaustion requirements. While Plaintiff has written generalized grievance letters to HHS, Compl. ¶¶ 74-81, it has not alleged, as it must, that any member on whose behalf it sues has "given the Secretary an opportunity to rule on a concrete claim for reimbursement . . . ." *Ringer*, 466 U.S. at 622; *Ill. Council*, 529 U.S. at 24 (indicating that an association suing on behalf of its members must satisfy presentment through its members). In other words, plaintiff has not alleged that any member on whose behalf it sues has presented a claim for benefits to the agency and received an adverse decision based on the August 2011 Letter. *See* 42 CFR § 405.904(a)(2). Thus, it has not satisfied the nonwaivable presentment requirement. *Ringer*, 466 U.S. at 622. Nor, relatedly, has plaintiff alleged that even one member (on whose behalf it is suing) has exhausted its administrative remedies – or that there is an "exceptional circumstance" that justifies waiving the exhaustion requirement. *UDC Chairs Chapter, Am. Ass'n of Univ. Professors v. Bd. of Trustees of Univ. of District of Columbia*, 56 F.3d 1469, 1475 (D.C. Cir. 1995); *Mathews*, 424 U.S. at 328, 330.

The Medicare statute provides a clear path for every prosthesis supplier dissatisfied with HHS's determination as to a Medicare claim to obtain relief in district court, following exhaustion of its administrative remedies. Plaintiff's attempt to leapfrog that requirement by filing as an association is of no avail. Congress and the Supreme Court have established the means by which participants in the Medicare program can obtain judicial review, and plaintiff can claim no greater rights than the members whom it

claims to represent. *See Ill. Council*, 529 U.S. at 24. The Court lacks jurisdiction over this suit.

B. Plaintiff Cannot Establish That Counts I-IV Are Redressable.

The Court should dismiss Counts I through IV of the complaint for lack of subject-matter jurisdiction because a decision in plaintiff's favor will not redress the injuries about which it complains. Plaintiff contends that the "new rules" contained in the "Dear Physician" letter result in delays processing and paying its members' claims for prostheses, or denials of such claims altogether. Compl. ¶¶ 2, 64-65. But the "Dear Physician" letter does not change the standards by which claims for payment are evaluated: The letter merely restates the existing standards contained in the statute, Program Integrity Manual, and common local coverage determinations. Thus, an order striking down the "Dear Physician" letter would not change the standards by which plaintiff's members claims are evaluated and, so, would not remedy the alleged injury underlying these four Counts.

To establish Article III standing, a plaintiff must demonstrate that it has suffered (or imminently will suffer) an (i) injury in fact, which is (ii) traceable to defendant's challenged conduct, and which likely will be (3) redressed by a favorable order from the court. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). "[S]tanding is not dispensed in gross." *Lewis v. Casey*, 518 U.S. 343, 358, n. 6 (1996). "A plaintiff must demonstrate standing for each claim he seeks to press." *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 352 (2006). And for an association, like AOPA, to press claims on behalf of its members, it must demonstrate (among other things) that at least one of its members would have Article III standing to sue in its own right. *Defenders of Wildlife v.*

Perciasepe, 714 F.3d 1317, 1323 (D.C. Cir. 2013). Courts have held that a plaintiff cannot establish that its alleged injury is redressable if an independent and unchallenged basis exists for the challenged action. *See, e.g., Cnty. of Delaware, Pa. v. Dep't of Transp.*, 554 F.3d 143, 150 (D.C. Cir. 2009); *St. John's United Church of Christ v. FAA*, 550 F.3d 1168, 1170 (D.C.Cir.2008); *Doe v. Va. Dep't of State Police*, 713 F.3d 745, 756 (4th Cir. 2013).

Plaintiff premises its standing to raise Counts I through IV on the supposed financial harm that the allegedly new documentation standards in the "Dear Physician" letter have caused – and will continue to cause – its members. Compl. ¶¶ 64, 65 (explaining purported financial harm). That is, plaintiff contends that the claims for which its members seek payment are being paid too slowly, or not at all, as a result of standards set out in the "Dear Physician" letter that did not previously exist.

But the standards set out in the "Dear Physician" letter are not new. They are restatements of standards set out in the Program Integrity Manual, the common local coverage determinations for lower limb prostheses, and statutory provisions. The Letter opens by noting that "in the event of an audit" the Medicare contractor "may request medical records to demonstrate that the prosthetic arm or leg was reasonable and necessary." Letter at 1. This is old hat. Before the Letter was issued, the Manual stated that "documentation in the patient's medical record does not have to be routinely sent" to the Medicare contractor, but the contractor "may request this information in selected cases," and the record "must contain sufficient documentation of the patient's medical condition to substantiate the necessity for the type and quantity of items ordered . . ." Manual § 5.7. (This manual provision flows naturally from the statute, which states that

coverage of items like prostheses and orthotic devices is limited to items that are "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).)

The same paragraph of the Letter continues by explaining that the "prosthetist's records must be corroborated by the information in your patient's medical record" and that it is the physician's records, "not the prosthetist's, which are used to justify payment." Letter at 1. The requirement for corroboration in the medical records simply restates the already quoted Manual provision requiring that the medical record contain documentation establishing the necessity of the item. Manual, ch. 5, § 5.7. As for the statement that the physician's records are used to justify payment, this merely repackages requirements in the Manual and the local coverage determinations. The Manual indicates that physician records are necessary, as it is implausible that a supplier could provide the kind of information, like the patient's prognosis, necessary to provide the medical substantiation for a claim. Manual, ch. 5, § 5.7. Also, the local coverage determinations, which existed prior to the Letter, explain that a "determination of medical necessity" is based on the "reasonable expectations of the prosthetist [ ] and [the] treating physician." LCD at 3. Since the prosthetist is submitting the claim, s/he necessarily believes that the item is necessary, and presumably his/her records will reflect that. The only real question, then – as the Letter recognizes – is whether the physician's records will support the finding of necessity.

In the next paragraph, the Letter discusses the importance of the "patient's functional capabilities . . . to establishing the medical necessity for a prosthetic device." Letter at 1. Included in this paragraph are discussions of the five classification levels of

functionality as well as the need to document functional potential. The Letter lifts the vast majority of this paragraph *word for word* from the common local coverage determinations on prostheses. *Compare* Letter at 1 *with* LCD at 3. For example, the description of each classification level in the Letter matches the description in the local coverage determinations to the jot and tittle. *Compare* Letter at 1 *with* LCD at 2. And the one or two passages that are not carbon copies of lines from the identical local coverage determinations do not contain any new substance; they simply use slightly different language to convey principles contained in the LCD. LCD at 3. (Indeed, plaintiff does not assert that any of these passages effected a change in the standards.)

The next paragraph of the Letter discusses the topics that should be addressed in constructing the medical history of the prospective prosthetic device recipient. Letter at 1. The bottom line, according to the Letter, is that the physician should "tailor the[ ] history and examination to the individual patient's condition," and "[t]he history should paint a picture of your patient's functional abilities and limitations on a typical day." *Id.* This standard is not meaningfully different from the one set out by the Manual, which explains that the medical record should include "the patient's diagnosis . . . prognosis, [and] nature and extent of functional limitations." Manual, ch. 5, § 5.7.

The Letter closes with a reminder to doctors that they have a legal obligation to provide the necessary information to suppliers and that, if they do not do so, their patients could end up "being financially responsible for all or part of the charges for the items/services received." Letter at 2. This paragraph certainly does not impose any obligation on AOPA's members, so they have no basis to complain about it. And in any

case, the principle expressed in the paragraph comes directly from 42 U.S.C. § 1395u(p)(4), which is block quoted.

Because the standards contained in the Letter are not new, "there exist[ ] [ ] unchallenged, independent rule[s], [or] polic[ies] . . . that would prevent relief even if the court were to render a favorable decision." *Doe*, 713 F.3d at 756. In other words, even if the letter were scuttled, HHS could handle claims for prostheses the same way because of the Medicare statute, Program Integrity Manual, and common local coverage determinations for lower limb prostheses. Striking down the letter, then, will boot plaintiff nothing.

Plaintiff contends that the difference between the pre-Letter and post-Letter payment standards is that, prior to the Letter, "CMS [ ] did not insist that physician notes corroborate prosthetist notes before the claims of AOPA members could be paid." Compl. ¶30. And as further evidence of a change in standards, plaintiff alleges that there has been an increase in claim denials. Compl. ¶ 76.

Regardless of whether contractors previously insisted on corroboration as a matter of practice, the written standards did insist on corroboration. The preexisting Manual provisions required medical information that a supplier could not realistically provide. Manual, ch. 5, § 5.7. And prior to the issuance of the the Letter, the common local coverage determinations premised "potential functional ability," a determinant of medical necessity, on the reasonable expectation of the "prosthetist [ ] *and* treating physician." LCD at 3 (emphasis added). Plaintiff recognizes that this language existed, *see* Compl. at 29, but treats the "and" as an "or," and therefore concludes that corroboration was not

necessary. This is wrong. "And" does not mean "or," so corroboration from a doctor was required under the local coverage determination prior to the issuance of the letter.

The discussion in this section highlights the fact that the true cause of any change in claims processing noticed by plaintiff's members resulted not from the issuance of new standards, but from increased enforcement of existing ones. In response to the HHS Inspector General's report, HHS vowed to "work to improve [its] oversight of lower limb prostheses in the future" by, in part, "strengthen[ing] monitoring of billing for lower limb prostheses." OIG Report, Appendix B, at 23-24. This resulted in "an increased number of prosthetic and orthotic claims [being] selected for medical review." Letter from Tavenner to Mills, May 9, 2013, at 1. That is, HHS altered its review and auditing priorities – and focused more resources on claims for prosthetic devices – to more effectively tamp down waste, fraud, and abuse; it did not change the standards that it enforces. And plaintiff does not allege that its members were harmed by increased enforcement of existing standards – and for good reason: Such a claim would run aground on the agency's unreviewable enforcement discretion. *See Heckler v. Chaney*, 470 U.S. 821, 831-32 (1985). The bottom line is this: Plaintiff lacks standing to raise Counts I through IV because its alleged injury will not be redressed by an order striking down the letter.

C. The Court Lacks Jurisdiction Because Plaintiff Has Not Specifically Identified a Member Who Has Standing to Sue.

AOPA sues on behalf of its members. Compl. ¶ 12. "When a [party] claims associational standing, it is not enough to aver that unidentified members have been injured. . . Rather, the petitioner must specifically identify members who have suffered the requisite harm." *Chamber of Commerce v. E.P.A.*, 642 F.3d 192, 200 (D.C. Cir.

2011) (internal quotation marks omitted); *W. Wood Preservers Inst. v. McHugh*, 2013 WL 692789, at *4 (D.D.C. Feb. 27, 2013). Plaintiff has not specifically identified a member who standing to sue. Thus, the Court should dismiss this suit for lack of subject matter jurisdiction.[7]

II. The Court Should Dismiss Plaintiff's Suit for Failure to State a Claim Upon Which Relief Can Be Granted[8]

A. The Letter Is Not A Reviewable Agency Action Because Contractors Cannot Issue Rules.

Counts I through IV of the Complaint depend on the Medicare statute, the RFA, and/or the APA. Compl. ¶¶ 82-105. All of these laws premise the ability to challenge an agency action on the action being final. The statutory review provisions of the Medicare statute, *see* 42 U.S.C. §§ 1395hh(a), (b)(1); *Fanning v. United States*, 346 F.3d 386, 401-02 (3d Cir. 2003), and the RFA, 5 U.S.C. § 611(a)(1), require that an agency action be

[7] Another standing defect lurks on the horizon. With respect to the BIPA-related mandamus claim, plaintiff asserts that members have been hurt in the following ways: (i) they have lost sales to "unqualified" purveyors of prosthetic devices, and (ii) the "overall image of the industry" has been damaged. Compl. ¶ 47. There is substantial doubt that plaintiff could marshal the facts needed to prove these claimed injuries.

[8] The Court can consider the "Dear Physician" letter, the Manual, and the local coverage determinations without converting the Rule 12(b)(6) motion into a motion for summary judgment. The "Dear Physician" letter is part of the pleadings because it was attached to the Complaint. *St. Francis Xavier Parochial Sch.*, 117 F.3d at 624-25. The Court can take judicial notice of the Manual as a publication by a government agency. *U.S. ex rel. Wall v. Vista Hospice Care, Inc.*, 778 F. Supp. 2d 709, 721 (N.D. Tex. 2011) (taking judicial notice of the Manual); *Seifert v. Winter*, 555 F.Supp.2d 3, 11 (D.D.C. 2008) (taking judicial notice of a manual produced by the U.S. Department of the Navy); *St. Francis Xavier Parochial School*, 117 F.3d at 625 (explaining that a court may consider, when deciding a Rule 12(b)(6) motion, documents of which it can take judicial notice). Similarly, the Court can take judicial notice of the local coverage determinations, which are available on a government website, http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx, because they are not "subject to reasonable dispute" and are "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned," Fed. R. Evid. 201(b). *See, e.g., Sears v. Magnolia Plumbing*, Inc., 778 F. Supp. 2d 80, 84 (D.D.C. 2011).

final to be reviewable. And the APA states that judicial review is available for two categories of agency actions: (1) "[a]gency action made reviewable by statute," and (2) "final agency action for which there is no other adequate remedy in a court." 5 U.S.C. § 704. Although only the second category contains an explicit reference to finality, the D.C. Circuit has also applied the finality requirement to "agency action made reviewable by statute." *Carter/Mondale Presidential Comm., Inc. v. FEC*, 711 F.2d 279, 285 n. 9 (D.C. Cir. 1983); *see also Am. Forest Res. Council v. Hall*, 533 F. Supp. 2d 84, 90 (D.D.C. 2008). Thus, even if the Medicare statute and the RFA did not address finality, the APA would limit suits brought under their statutory review provisions to those suits which challenged final agency action. *See Carter/Mondale Presidential Comm.*, 711 F.2d at 285 n. 9. In short, plaintiff cannot secure review of the "Dear Physician Letter," on which Counts I through IV are premised, Compl. ¶¶ 82-105, unless the Letter constitutes final agency action.

The Supreme Court has established a two part test for determining whether an agency action is final. *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). First, the action "must mark the consummation of the agency's decisionmaking process . . . ." *Id.* (quotation marks omitted). Second, "the action must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Id.* at 178 (quotation marks and citation omitted). Plaintiff contends that the "Dear Physician" letter announces "new rules." *See, e.g.*, Compl. ¶ 2. If it were true that the Letter announced rules, then it would satisfy the *Bennett* test. *See Ctr. for Auto Safety v. Nat'l Highway Traffic Safety Admin.*, 452 F.3d 798, 807 (D.C. Cir. 2006).

But the Letter does not announce rules that constitute final agency action. For an agency statement to constitute a rule, it must be promulgated by someone who has the authority to issue rules. *Devon Energy Corp. v. Kempthorne*, 551 F.3d 1030, 1039-40 (D.C. Cir. 2008); *Amoco Prod. Co. v. Watson*, 410 F.3d 722, 732 (D.C. Cir. 2005). The contractors who issued the "Dear Physician" letter, Medicare administrative contractors, do not have the authority to issue rules. A provision of the Medicare statute, 42 U.S.C. § 1395kk-1(a)(4), delineates the functions that the contractors are authorized to perform. The list of authorized functions does not include issuing rules. *Id.*; *see also Hays v. Sebelius*, 589 F.3d 1279, 1283 (D.C. Cir. 2009) (Randolph, concurring) (suggesting that these kinds of contractors do not have rulemaking authority).

Indeed, the "Dear Physician" letter resembles the "Dear Operator" letter that the D.C. Circuit concluded was unreviewable in *Devon Energy* and *Amoco*. Those cases involved a letter written by a Department of Interior official, the Minerals Management Service's Associate Director for Royalty Management, to "operators" that leased mineral rights from the government. *See Devon*, 551 F.3d at 1034-35, 39-40; *Amoco*, 410 F.3d at 732. The letter explained which costs could be deducted from lease payments owed to the government. *See Devon*, 551 F.3d at 1035; *Amoco*, 410 F.3d at 732. The plaintiff in each case alleged that the letter constituted a rule, and so needed to be preceded by notice and an opportunity for comment. *See Devon*, 551 F.3d at 1038; *Amoco*, 410 F.3d at 732. But in each case, the D.C. Circuit concluded that the "Dear Operator" letter did not constitute final agency action because the letter's author – *i.e.*, the Associate Director – did not have the authority to issue rules. *See Devon*, 551 F.3d at 1039-40; *Amoco*, 410 F.3d at 732. Just so here. The contractors do not have the authority to issue rules, so the

"Dear Physician" letter, like the "Dear Operator" letter, does not constitute final agency action – and is not reviewable. Counts I through IV should be dismissed.

B. The Letter Is Not a Reviewable Agency Action Because It Simply Restates the Existing Standards.

Even if the contractors have the authority to issue rules, the "Dear Physician" letter does not constitute final agency action because it does not contain any rules. Rather, it restates the existing standards for documenting claims for artificial limbs. Thus, the Court should dismiss Counts I through IV of the Complaint.

Plaintiff's first four counts hinge on its contention that the "Dear Physician" letter announces new rules for documenting claims for prosthetic devices. Compl. ¶ 2. Under the APA, a rule is "an agency statement of general or particular applicability and future effect designed to implement, interpret or prescribe law or policy . . . ." 5 U.S.C. § 551(4). Under the Medicare statute, a rule is a statement that "establishes or changes a substantive legal standard governing the scope of benefits, the payment for services, or the eligibility of individuals, entities, or organizations to furnish or receive services or benefits." 42 U.S.C. § 1395hh(a)(2). And under the RFA, "the term 'rule' means any rule for which the agency publishes a general notice of proposed rulemaking pursuant to section 553(b) of [Title 5], or any other law . . . ." 5 U.S.C. § 601. For an agency action to be reviewable, it "must be [an action] by which rights or obligations have been determined, or from which legal consequences will flow." *Bennett,* 520 U.S. at 178 (quotation marks and citation omitted).

The "Dear Physician" letter does not meet any of these definitions of rules and, by extension, does not amount to reviewable agency action. The letter does not satisfy the definition of rule under the APA because it simply restates existing standards; it

determines no rights or obligations, and no legal consequences flow from it. In *Independent Equipment Dealers Association v. Environmental Protection Agency*, the D.C. Circuit held that a letter from the EPA to the Dealers Association did not "constitute[ ] reviewable agency action" because it "neither announced a new interpretation of the regulations nor effected a changed in the regulations themselves." 372 F.3d 420, 427 (D.C. Cir. 2004). It simply "restat[ed] [the] established interpretation," leaving "the world just as it found it, and thus cannot be fairly described as implementing, interpreting, or prescribing law or policy." *Id.* at 428. The same analysis applies to the letter here. The Dear Physician letter also does not meet the definition of rule under the Medicare statute because, as explained in § I.B above, it does not "establish [ ] or change[ ] a substantive legal standard," 42 U.S.C. § 1395hh(a)(2). The letter simply synthesizes the existing standard. Accordingly, no obligations or legal consequences flow from it, and it does not constitute reviewable agency action.

Finally, the "Dear Physician" letter fails the definition of rule under the RFA because it was not a rule for which HHS "publish[ed] a general notice of proposed rulemaking under [§] 553(b) . . . or any other law." 5 U.S.C. § 601. But even if one assumes that the RFA encompasses rules for which a notice of proposed rulemaking should have been published, the "Dear Physician" letter does not fit the bill. Under § 553, no notice of proposed rulemaking was required because, under the APA, the Letter does not announce any rules. And no other "law" required publication of a notice of proposed rulemaking, as, under the Medicare statute, the "Dear Physician" letter did not establish or change a substantive legal standard. 42 U.S.C. § 1395hh(b)(1). Thus, the

issuance of the Letter is not an action that can be challenged under the RFA – or any other statute invoked by plaintiff.

D. Count I Also Fails Because the Letter Did Not Change Substantive Legal Standards.[9]

The Court should dismiss this Count for failure to state a claim upon which relief may be granted. Plaintiff contends the following in Count I: (i) the Medicare stature obligated HHS to issue the "Dear Physician" letter after notice and opportunity to comment; and (ii) HHS is improperly applying the "new" rules in the Letter retroactively. Compl. ¶¶ 82-88. With respect to (i), as explained in the discussion on the final agency action requirement, the Medicare statute did not obligate HHS to issue the Letter through notice and comment rulemaking because the Letter does not establish or change a substantive legal standard. 42 U.S.C. § 1395hh(b)(1); *see also* § II.B above. The Medicare statute's limitation on the retroactive application of "substantive changes" to various kinds of documents similarly does not apply because, and this should be familiar, the Letter did not effect a substantive change of the documentation standards for reimbursement. *See* 42 U.S.C. §1395hh(e).

E. Count II Lacks Merit Because Enforcement Decisions Are Committed to the Agency's Discretion and the Letter's Standards Are Consistent with § 1395u(p)(4).

Section 1395u(p)(4), which was mentioned earlier, obligates a "physician or practitioner" to provide "diagnostic or other medical information" necessary to justify payment for a prosthetic device to the supplier "at the time that the item or service is ordered by the physician or practitioner." 42 U.S.C. § 1395u(p)(4). Plaintiff alleges that HHS violated this provision by (i) "fail[ing] to take any steps to compel treating

[9] The following sections provide additional, claim-specific arguments.

physicians to honor their duty under [the provision] to provide [to suppliers] the documentation specified in the 'Dear Physician' letter" and (ii) requiring "AOPA members [to] secure the documentation identified in the 'Dear Physician' letter." Compl. ¶¶ 90-91.

These allegations lack merit. The first allegation attacks the manner in which HHS has chosen to enforce this provision. But "'an agency's decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency's absolute discretion' and therefore is presumptively unreviewable." *Jerome Stevens Pharm., Inc. v. FDA*, 402 F.3d 1249, 1257 (D.C. Cir. 2005) (quoting *Chaney*, 471 U.S. at 831.). This presumption may be overcome only in exceptional circumstances not present here. *See id.* The second allegation errs by treating complementary requirements as contradictory. What plaintiff labels the "requirement that AOPA members secure" the necessary documents, is simply the requirement that AOPA members supply to the contractor(s) the medical information necessary to justify payment under the standard established by statute, 42 U.S.C. §§ 1395y(a)(1)(A), 1395l(e), Manual Provision, § 5.7, and common local coverage determinations, LCD at 3. This obligation is consistent with § 1395u(p)(4). Section 1395u(p)(4) recognizes that the reason physicians should provide the information is so that it is available in case HHS needs it to authorize payment. In short, § 1395u(p)(4) permits the very thing – requiring the supplier to furnish the contractor with the information necessary to justify payment under Medicare – that plaintiff contends that it prohibits.

F. Count III Should Be Dismissed Because the APA's Notice and Comment Requirement Is Inapplicable and the Letter Is Consistent with Statutory Authority.

Count III contends that HHS has violated the APA by (i) failing to provide notice and an opportunity to comment before issuing the "Dear Physician" letter, *see* 5 U.S.C. § 553, and (ii) acting contrary to the dictates of the Medicare statute, the BIPA, and the Patient Protection and Affordable Care Act of 2010, Pub. L. No. 111–148, 124 Stat. 119 (2010). Compl. ¶¶ 93-99. Not so. The "Dear Physician" letter is not a final agency action to which the APA's notice and comment obligation attaches. And HHS's conduct conforms to the requirements established by the Medicare statute, the BIPA, and the Affordable Care Act.

The APA's notice and comment provision obligates an agency to provide notice and an opportunity to comment before issuing certain kinds of "legislative rules." *U.S. Telecom Ass'n v. FCC*, 400 F.3d 29, 34 (D.C. Cir. 2005); 5 U.S.C. § 553. But, as discussed above, the "Dear Physician" letter is not any kind or rule, because the contractors do not have the authority to issue rules and the letter simply restates the existing documentation standards. *See Devon*, 551 F.3d at 1039-40; *Indep. Equip. Dealers Ass'n*, 372 F.3d at 427. Thus, there was no obligation to provide notice and an opportunity to comment before issuing the "Dear Physician" letter. *Devon*, 551 F.3d at 1038-41; *Indep. Equip. Dealers Ass'n*, 372 F.3d at 425, 427-29. Even if the Letter were a rule, it would be an interpretative rule (interpreting 42 U.S.C. § 1395l(e) and 42 U.S.C. § 1395y(a)(1)(A)), *see Shalala v. Guernsey Mem'l Hosp.*, 514 U.S. 87, 101 (1995), and interpretative rules are not subject to notice and comment, 5 U.S.C. § 553(b). In addition, the portion of letter addressing the type of records necessary to document a claim would

constitute a procedural rule exempt from notice and comment requirements because it would not "alter the rights or interests of parties," but would address "the manner in which the parties present themselves or their viewpoints to the agency." *JEM Broadcasting Co. v. FCC*, 22 F.3d 320, 326 (D.C. Cir. 1994) (internal quotation marks omitted).[10]

Plaintiff contends that the "Dear Physician" letter violates the Medicare statute because under that statute the Secretary "lacks the authority" to "refuse to accept prosthetist notes as demonstrating the medical necessity of prosethetic devices" and to require instead that "AOPA members secure from treating physicians the documentation set forth in the 'Dear Physician' letter." Compl. ¶ 97. This contention does not hold up. The Medicare statute permits HHS to require that physician records establish the medical necessity for a particular prosthetic device. 42 U.S.C. §§ 1395kk-1(a)(4)(G) (permitting HHS to conduct medical audits), 1395u(p)(4) (recognizing that HHS can require medical records prior to authorizing payment), § 1395l(e) (stating that no payment may be made until "there has been furnished such information as may be necessary in order to determine the amounts due").[11]

Plaintiff also maintains that the BIPA and the Affordable Care Act demonstrate Congress' intention that "implementation of supplier qualifications, rather than physician documentation, be the means of deterring waste and abuse in the supplying of prosthetic

[10] As courts generally interpret 42 U.S.C. § 1395hh to impose "no standards greater than those established by the APA," *Baptist Health v. Thompson*, 458 F.3d 768, 776 n. 8 (8th Cir. 2006), the arguments that the Letter is, if a rule at all, an interpretative and procedural rule apply to Count I too.

[11] Plaintiff also alleges that HHS's actions are arbitrary and capricious. Compl. ¶ 99. But its actions accord with statutory authority, and plaintiff does not specify any basis for challenging HHS's actions other than that they contradict the law. *See Id.* ¶¶ 93-99.

devices." Compl. ¶ 98. Plaintiff misunderstands the scope and intent of these laws. Congress may have intended for supplier qualifications to be one means for deterring waste and abuse, but that does not mean Congress intended for the qualification requirements to be the only available deterrent, and thereby immunize "qualified suppliers" from the review or auditing of Medicare claims. How do we know that? For one thing, Congress did not explicitly repeal HHS's ability to require physician documentation, and the Supreme Court has established a strong presumption against implied repeals, *Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 662–63 (2007) ; *cf. Mackenzie Med. Supply, Inc. v. Leavitt*, 506 F.3d 341, 347-48 (4th Cir. 2007) (declining to infer that a provision of the Medicare statute provided the "exclusive" means of accomplishing a task in the absence of explicit words of exclusivity). For the presumption to be overcome, the later statute must be irreconcilable with the first, or clearly meant to replace it. *Nat'l Ass'n of Home Builders*, 551 U.S. at 662–63. Neither criterion is met here. The documentation and provider qualification requirements can clearly coexist. And no language of the BIPA or Affordable Care Act demonstrates that the supplier qualification requirement is meant to supplant the physician documentation requirements. Moreover, it would be odd for Congress to ask HHS to rely solely on qualification requirements to deter waste and abuse, because those requirements would not stop "qualified" suppliers from engaging in waste and abuse. The Court should not interpret provisions meant to strengthen protections against waste, fraud, and abuse to eviscerate those protections.

G. Count IV Lacks Merit Because the Letter Did Not Regulate AOPA Members.

Plaintiff alleges that HHS violated the RFA by failing to analyze the impact of the "Dear Physician" letter on small businesses. Compl. ¶¶ 101-104. This claim fails for one reason, in addition to those already articulated: The RFA requires an agency to conduct a regulatory impact analysis with respect only to those entities "subject to the requirements of the [challenged] rule." *Mid–Tex Electric Coop. v. FERC*, 773 F.2d 327, 342 (D.C. Cir. 1985); *Cement Kiln Recycling Coal. v. EPA*, 255 F.3d 855, 868–69 (D.C. Cir. 2001). But the "Dear Physician" letter is directed to doctors, not prosthetic device suppliers. Letter at 1. Thus, even if the "Dear Physician" letter qualified as a rule under the RFA, HHS was not obligated to conduct an analysis of the impact it would have on small business that supply prosthetic devices because the letter does not impose any responsibilities directly on suppliers.

H. Count V Should Be Dismissed

Plaintiff seeks a writ of mandamus (under 28 U.S.C. § 1361) requiring HHS to issue regulations implementing § 427 of the BIPA. Compl. ¶¶ 106-110. This Count should be dismissed for lack of jurisdiction, as explained earlier in the memorandum. But if this Count should somehow survive dismissal, at the next stage of the proceedings, the Court will have to consider a number of factors, including "the effect of expediting [any] delayed action on agency activities of a higher or competing priority . . . and the nature and extent of the interests prejudiced by delay," before deciding whether to order the extraordinary remedy of mandamus. *In re United Mine Workers of America Intern. Union*, 190 F.3d 545, 549 (D.C. Cir. 1999).

CONCLUSION

For the reasons stated above, the Court should dismiss the Complaint for lack of subject matter jurisdiction, or dismiss Counts I through IV for failure to state a claim upon which relief can be granted.

DATED: July 19, 2013

Respectfully submitted,

STUART F. DELERY
Acting Assistant Attorney General

RONALD C. MACHEN JR
United States Attorney

SHEILA LIEBER
Deputy Director, Federal Programs Branch, Civil Division

/s/ Justin M. Sandberg
JUSTIN M. SANDBERG
(Ill. Bar No. 6278377)
Trial Attorney
U.S. Dept. of Justice, Civil Division,
Federal Programs Branch
20 Mass. Ave., NW, Rm. 7302
Washington, DC 20001
(202) 514-5838 phone
(202) 616-8202 fax
justin.sandberg@usdoj.gov

Attorneys for Defendant