UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

MICHAEL GREENWALD Plaintiff, v. XAVIER BECERRA, Secretary of the United States Department of Health and Human Services *et al.*, Defendants.[1]	Civ. Action No. 17-797(EGS/RMM)

MEMORANDUM OPINION AND ORDER

Plaintiff Michael Greenwald ("Mr. Greenwald"), a Medicare beneficiary, brings this suit to challenge the validity of a Local Coverage Determination ("LCD") cited when he was denied Medicare coverage for a pneumatic compression device prescribed by his physician. *See generally* First Am. Compl. ("Compl."), ECF No. 26. He names as defendants the Secretary of the United States Department of Health and Human Services ("HHS")[1] and the Administrator of the Centers for Medicare and Medicaid Services ("CMS"), both in their official capacities (collectively "Defendants"). Defendants move to dismiss Mr. Greenwald's claims for lack of subject matter jurisdiction and failure to state a

[1] Pursuant to Federal Rule of Civil Procedure 25(d), the Court substitutes as defendant Mr. Xavier Becerra, in place of former Secretary Alex Azar.

claim. *See* Defs.' Mem. of P. & A. Supp. Mot. Dismiss ("Mot. to Dismiss"), ECF No. 27-1. On March 30, 2018, the Court referred the case to a Magistrate Judge for full case management, including a Report and Recommendation ("R. & R.") on the pending Motion to Dismiss, and the case was randomly referred to Magistrate Judge Robin M. Meriweather. *See generally*, Docket for Civ. Act. No. 17-797. Pending before the Court is Defendants' Motion to Dismiss, *see* ECF No. 17. Magistrate Judge Meriweather issued a R. & R. recommending that this Court grant Defendants' motion since this Court lacks subject matter jurisdiction over Mr. Greenwald's claims. *See* R. & R., ECF No. 47 at 1-2. Plaintiff objects to Magistrate Judge Meriweather's R. & R. *See generally* Plaintiff Michael Greenwald's Objections to the November 8, 2021 Report and Recommendations Regarding Defendants' Motion to Dismiss the Complaint ("Pl.'s Objs."), ECF No. 49.

Upon careful consideration of the R. & R., the objections of both parties and opposition thereto, the applicable law, and the entire record herein, the Court hereby **ADOPTS IN PART and REJECTS IN PART** the R. & R., *see* ECF No. 49; and **GRANTS IN PART and DENIES IN PART** Defendants' Motion to Dismiss, *see* ECF No. 27.

I. Background[2]

A. Factual Background

Accepting the factual allegations in the complaint as true, as is required at this stage of proceedings, *see Jerome Stevens Pharms., Inc. v. Food & Drug Admin.*, 402 F.3d 1249, 1253–54 (D.C. Cir. 2005); this case stems from Mr. Greenwald's lymphedema—a chronic medical condition that results in the accumulation of fluid in the subcutaneous tissues of his legs. *See* Compl., ECF No. 26 ¶¶ 1, 13, 48. Mr. Greenwald was first diagnosed with lymphedema in 2014. *See id.* ¶¶ 13–14, 48. His physician attempted to treat the condition with compression stockings, exercise, and limb elevation. *See id.* ¶¶ 14, 48–49. In 2016, the physician determined these treatments had been ineffective in alleviating Mr. Greenwald's symptoms and prescribed him a pneumatic compression device ("PCD"). *See id.* ¶¶ 14, 52. PCDs are items of durable medical equipment designed to treat patients suffering from a range of circulatory conditions, including lymphedema. *See id.* at ¶ 30. They do so by intermittently inflating a garment with compressed air to

[2] In the interest of judicial efficiency, the Background section is adopted from Magistrate Judge Meriweather's R. & R. *See* ECF No. 49.

stimulate fluid circulation in affected parts of the body. *See id.* ¶ 31.

Mr. Greenwald is eligible for Medicare benefits and expected his PCD prescription to be covered under Medicare Part B. *See id.* ¶¶ 13, 18, 24, 54. Mr. Greenwald's coverage claim was denied, however. *See id.* ¶ 55. His appeal for a redetermination was also unsuccessful. *See id.* ¶ 56. As a result, Mr. Greenwald has paid the full cost of his prescribed PCD out-of-pocket. *See id.* ¶¶ 47, 63. The following description of the Medicare system provides necessary context for understanding why Mr. Greenwald's coverage claim was denied and the nature of his suit against the Defendants.

B. The Medicare Program

Congress established the Medicare program in 1965 to provide health benefits to persons aged sixty-five and older who are eligible for Social Security benefits or retirement benefits under the railroad retirement system. *Cal. Clinical Lab'y Ass'n v. Sec'y Health & Hum. Servs.*, 104 F. Supp. 3d 66, 70 (D.D.C. 2015) (citing Pub. L. No. 89-97, 79 Stat. 291 (July 30, 1965) (codified at 42 U.S.C. §§ 1395 *et seq.*)). Part A of the program covers institutional healthcare services. *See* 42 U.S.C. § 1395d. Part B of the program is voluntary, providing enrollees with coverage for medical professional services, outpatient and

homecare services, and durable medical equipment that is not furnished in an inpatient setting or otherwise covered by Part A. *See id.* § 1395k. Part C of the program, also enrollment based, provides benefits to individuals who elect to receive coverage through private health insurance companies. *See id.* §§ 1395w-21 to 1395w-28. Both Parts B and C of the Medicare program cover durable medical equipment, including PCDs, in appropriate circumstances. *See* Compl., ECF No. 26 ¶ 46; *see also* 42 C.F.R. §§ 410.38, 414.202.

Those appropriate circumstances are defined in part by the Medicare Act. Relevant here, Medicare does not cover "expenses incurred for items or services which . . . are not 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 HHS Secretary implements this rule through CMS—the agency that administers Medicare more generally. *See id.* § 1395b-9. CMS in turn delegates some of its responsibilities to private Medicare Administrative Contractors ("MACs"). *See id.* §§ 1395(u), 1395kk-1. Under this scheme, a healthcare provider who seeks payment for an item or service provided to a Medicare beneficiary submits a claim for reimbursement to the MAC authorized in the provider's region. *See id.* § 1395kk-1(a). The MAC then assesses

whether the item or service is covered by Medicare, including whether the item or service is "reasonable and necessary" under § 1395y.

The Secretary has significant control over these MAC coverage determinations. He may promulgate binding regulations regarding which items or services are covered by Medicare. *See id.* §§ 1395hh, 1395ff(a)(1). He may also issue binding national coverage determinations, or "NCDs," that reflect his determination that an item or service is covered under designated medical circumstances on a nationwide basis. *See id.* § 1395ff(f)(1)(B); 42 C.F.R. § 405.1060(a)(4). Additionally, if coverage is initially denied by a MAC, a Medicare beneficiary may appeal the MAC determination to an administrative law judge ("ALJ") housed within the Secretary's Office of Medicare Hearings and Appeals. *See id.* § 1395ff(b)(1)(E), (d)(1)(A); *see also Am. Hosp. Ass'n v. Burwell*, 76 F. Supp. 3d 43, 46 (D.D.C. 2014), *rev'd on other grounds*, 812 F.3d 183 (D.C. Cir. 2016) (describing this process).

The MACs may also develop their own guidelines for coverage determinations, known as local coverage determinations ("LCDs"). *See* 42 U.S.C. § 1395ff(f)(2)(B). LCDs are limited in scope, applying only on an "intermediary- or carrier-wide basis." *Id.* They are meant to guide MAC administrators in determining

whether an item or service is "covered . . . in accordance with § 1395y(a)(1)(A)"—in other words, that an item or service is "reasonable and necessary" as required for Medicare coverage—within the MAC's designated service area. *Id.* §§ 1395y(a)(1)(A); 1395ff(f)(2)(B). Individuals who believe their claim was wrongly denied pursuant to an LCD can appeal their individual coverage determination to an ALJ, and if that appeal is unsuccessful, to the HHS Departmental Appeals Board ("DAB"). *Id.* at § 1395ff(b)– (e); 42 C.F.R. §§ 405.900 *et seq*. Neither the ALJ nor the DAB is bound by the LCD, but they cannot invalidate or set aside the LCD in its entirety. *See* 42 C.F.R. §§ 405.1062(a), (c); *see also Cal. Clinical Lab'y*, 104 F. Supp. 3d at 72. To challenge the validity of the LCD itself, a Medicare beneficiary must utilize a different complaint process, appealing to an ALJ and the DAB via 42 U.S.C. § 1395ff(f)(2). If there are "no material issues of fact in dispute" and the "only issue of law" is the validity of the LCD, the Medicare recipient may also side-step the usual administrative review process and file a complaint directly with "a court of competent jurisdiction." *Id.* § 1395ff(f)(3).

C. Local and National Coverage Determinations for Pneumatic Compression Devices, and Their Application to Mr. Greenwald's Claim

The PCD prescribed by Mr. Greenwald's physician is subject to both a NCD and a LCD. The relevant NCD is published in CMS's Medicare Coverage Database. *See* Compl., ECF No. 26 ¶ 31; *see also* CMS, Nat'l Coverage Determination for Pneumatic Compression Devices, Pub. No. 100-3 § 280.6 (eff. Jan. 14, 2002) ("NCD 280.6"). The relevant LCD is also available on CMS' website, and is used by MACs serving most of the United States and its territories. *See* Compl. ECF No. 26 ¶¶ 33–34, 40–45; Ex. A, ECF No. 26-1 at 1 ("LCD L33829") (listing the names and jurisdictions of MACs using the LCD); *see also* Compl., ECF No. 26 ¶ 46 (asserting that the LCD is also used by private health insurers under Medicare Part C, "even though these LCDs are not binding on Medicare Advantage plans"). Both NCD 280.6 and LCD L33829 purport to interpret the "reasonable and necessary" requirement for Medicare coverage for PCDs. *See* 42 U.S.C. §§ 1395ff(f)(1)(B), (f)(2)(B); LCD L33829 at 1 ("The purpose of [this LCD] is to provide information regarding 'reasonable and necessary' criteria[.]"). The problem, according to Mr. Greenwald, is that NCD 280.6 and LCD L33829 conflict. *See* Compl., ECF No. 26 ¶¶ 5, 6; Mem. of P. & A. in Supp. of Mot. for Summ. J. and in Opp'n to Defs.' Mot. to Dismiss ("Pl.'s Opp'n"),

ECF No. 29 at 29. Mr. Greenwald alleges the LCD "introduced new legal standards for determining Medicare coverage that were not included or mentioned in [the] NCD." *Id.* at 24. These standards are substantive, he says, because they add additional requirements for coverage for a PCD instead of merely interpreting the guidance in the NCD. *See id.* at 36; Surreply, ECF No. 48 at 6. For this reason, when a MAC applied LCD L33829 to Mr. Greenwald's claim for coverage for his PCD, the claim was denied even though Mr. Greenwald insists it might have been approved under the less restrictive NCD 280.6. *See* Compl., ECF No. 26 ¶¶ 54–55, 57; Pl.'s Opp'n, ECF No. 29 at 26. That initial determination was upheld at the redetermination stage, also based on LCD L33829. *See* Compl., ECF No. 26 ¶ 56; *see also* Compl. Ex. C, ECF No. 26-3 at 3.

D. Procedural Background

Mr. Greenwald did not request reconsideration of his coverage redetermination. *See* Compl., ECF No. 26 ¶¶ 55–57; Mot. to Dismiss, ECF No. 27-1 at 8–9. He instead brought this civil action to challenge the overarching validity of LCD L33829. *See generally* Compl., ECF No. 26. The suit is not an appeal of Mr. Greenwald's individual coverage determination, but a claim that LCD L33829 is invalid as a general matter, whether applied to Mr. Greenwald or to another. *See id.* at Prayer for Relief. Mr.

Greenwald's theory is that, because LCD L33829 imposed new substantive requirements for Medicare coverage for PCDs, the Defendants were required to follow rulemaking procedures in the Administrative Procedure Act and Social Security statutes. *See* Pl.'s Opp'n, ECF No. 29 at 29; Surreply, ECF No. 48 at 6. Mr. Greenwald asks this Court to conclude that LCD L33829 is invalid as a matter of law because these procedures were not followed. *See id.* Mr. Greenwald's complaint was filed in April 2017. *See* Compl., ECF No. 1. After several extensions of their time to respond, Defendants filed a Rule 12 motion to dismiss Mr. Greenwald's complaint. *See* Mot. to Dismiss, ECF No. 20. Mr. Greenwald amended his complaint soon thereafter.[3] *See* Compl., ECF No. 26. This Court then dismissed the Defendants' motion to dismiss as moot, *see* Min. Order (Mar. 12, 2018); and Defendants filed a renewed motion to dismiss Mr. Greenwald's amended complaint for lack of subject matter jurisdiction and failure to state a claim. *See* Mot. to Dismiss, ECF No. 27-1. Mr. Greenwald responded to the Defendants' motion and moved for entry of summary judgment. *See* Pl.'s Opp'n, ECF No. 29. The Court stayed Mr. Greenwald's summary judgment motion pending resolution of

[3] Additional defendants named in Mr. Greenwald's first complaint were dismissed by stipulation in August 2017. *See* ECF No. 16.

the Defendants' renewed motion to dismiss and directed Defendants to file their reply specifically for the motion to dismiss. *See* Min. Order (Feb. 12, 2018). After Defendants filed their reply, *see* Defs.' Reply, ECF No.33; Mr. Greenwald requested leave to file a sur-reply in further opposition to Defendants' motion to dismiss, *see* Mot. for Leave to File a Sur-reply, ECF No. 34; which Defendants opposed, *see* Defs.' Response to Pl.'s Mot. for Leave to File Sur-Reply, ECF No. 35. This case was referred to a Magistrate Judge for full case management, up to but excluding trial, pursuant to Local Civil Rule 72.2. *See* Min. Order (Mar. 30, 2018). Following the assignment of the case to Magistrate Judge Meriweather, *see* Min. Entry (Mar. 30, 2018), the parties filed two notices of supplemental authority and a response thereto. *See* ECF Nos. 37, 38, 40. After reviewing these initial briefs, Magistrate Judge Meriweather requested supplemental briefing on an issue raised by the parties' memoranda. *See* ECF No. 42. The parties' responsive briefs were filed in December 2020. *See* ECF Nos. 43, 44. On November 8, 2021, Magistrate Judge Meriweather entered an order granting Mr. Greenwald's motion for leave to fire a sur-reply. *See* Min. Order (Nov. 8, 2021). Magistrate Judge Meriweather also issued a R. & R. recommending that this Court grant Defendants' motion to dismiss for lack of subject matter jurisdiction. *See* ECF No. 49.

Mr. Greenwald objected to this conclusion, *see* Pl.'s Objs. ECF No. 49; and Defendants filed a response thereto, *see* Defs.' Resp. to Pl.'s Objs. to the Nov. 8, 2021 R. & R. ("Defs.' Resp."), ECF No. 51. The motion is ripe and ready for adjudication.

II. Legal Standard

A. Objections to a Magistrate Judge's Report and Recommendation

Pursuant to Federal Rule of Civil Procedure 72(b), a party may file specific written objections once a magistrate judge has entered a recommended disposition. Fed. R. Civ. P. 72(b)(1)-(2). A district court "may accept, reject or modify the recommended disposition." Fed. R. Civ. P. 72(b)(3); *see also* 28 U.S.C. § 636(b)(1) ("A judge of the court may accept, reject, or modify, in whole or in part, the findings or recommendations made by the magistrate judge."). A district court "must determine de novo any part of the magistrate judge's disposition that has been properly objected to." Fed. R. Civ. P. 72(b)(3). "If, however, the party makes only conclusory or general objections, or simply reiterates his original arguments, the Court reviews the [R. & R.] only for clear error." *Houlahan v. Brown*, 979 F. Supp. 2d 86, 88 (D.D.C. 2013) (citation omitted). "Under the clearly erroneous standard, the magistrate judge's decision is entitled to great deference" and "is clearly erroneous only if on the

entire evidence the court is left with the definite and firm conviction that a mistake has been committed." *Buie v. D.C.*, No. CV 16-1920 (CKK), 2019 WL 4345712, at *3 (D.D.C. Sept. 12, 2019) (citing *Graham v. Mukasey*, 608 F. Supp. 2d 50, 52 (D.D.C. 2009)) (internal quotation marks omitted).

Objections must "specifically identify the portions of the proposed findings and recommendations to which objection is made and the basis for objection." LCvR 72.3(b). "[O]bjections which merely rehash an argument presented to and considered by the magistrate judge are not 'properly objected to' and are therefore not entitled to de novo review." *Shurtleff v. EPA*, 991 F. Supp. 2d 1, 8 (D.D.C. 2013) (quoting *Morgan v. Astrue*, No. 08-2133, 2009 WL 3541001, at *3 (E.D. Pa. Oct. 30, 2009)).

B. Subject Matter Jurisdiction

Federal district courts are courts of limited jurisdiction and "possess only that power conferred by [Article III of the] Constitution and [by] statute." *Logan v. Dep't of Veterans Affairs*, 357 F. Supp. 2d 149, 152 (D.D.C. 2004) (*quoting Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377, 114 S. Ct. 1673, 128 L. Ed. 2d 391 (1994)). "There is a presumption against federal court jurisdiction and the burden is on the party asserting the jurisdiction, the plaintiff in this case, to establish that the Court has subject matter

jurisdiction over the action." *Id.* at 153 (citing *McNutt v. Gen. Motors Acceptance Corp. of Ind.*, 298 U.S. 178, 182–83, 56 S. Ct. 780, 80 L. Ed. 1135 (1936)).

The requirement of "standing is an essential and unchanging part of the case-or-controversy requirement of Article III." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560, 112 S. Ct. 2130 (1992). "[T]he defect of standing is a defect in subject matter jurisdiction." *Haase v. Sessions*, 835 F.2d 902, 906 (D.C. Cir. 1987). There are three requirements for standing:

> First, the plaintiff must have suffered an "injury in fact"—an invasion of a legally protected interest which is (a) concrete and particularized, and (b) "actual or imminent, not 'conjectural' or 'hypothetical.'" Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be "fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court." Third, it must be "likely," as opposed to merely "speculative," that the injury will be "redressed by a favorable decision."

Lujan, 504 U.S. at 560–61 (citation omitted).

In assessing whether a complaint sufficiently alleges subject matter jurisdiction, the Court accepts as true the allegations of the complaint, *see Ashcroft v. Iqbal*, 556 U.S. 662, 678, 129 S. Ct. 1937 (2009); and liberally construes the pleadings such that the plaintiff benefits from all inferences

derived from the facts alleged, *Barr. v. Clinton,* 370 F. 3d 1196, 1199 (D.C. Cir. 2004).

However, "[a] pleading that offers labels and conclusions or a formulaic recitation of the elements of a cause of action will not do. Nor does a complaint suffice if it tenders naked assertions devoid of further factual enhancement." *Iqbal,* 556 U.S. at 678 (citations, quotation marks and brackets omitted). Consequently, "[a] claim invoking federal-question jurisdiction under 28 U.S.C. § 1331 ... may be dismissed for want of subject matter jurisdiction if it is not colorable, *i.e.,* if it is immaterial and made solely for the purpose of obtaining jurisdiction or it is wholly insubstantial and frivolous." *Arbaugh,* 546 U.S. 500, 513 n.10, 126 S. Ct. 1235 (2006) (citation omitted); *accord Tooley v. Napolitano,* 586 F.3d 1006, 1009 (D.C. Cir. 2009) (citation omitted).

C. Rule 12(b)(6) Motion to Dismiss

A motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of a complaint. *Browning v. Clinton*, 292 F.3d 235, 242 (D.C. Cir. 2002). A complaint must contain "a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the ... claim is and the grounds upon which it rests." *Bell At. Corp. v. Twombly*, 550

U.S. 544, 555, 127 S. Ct. 1955 (2007). While detailed factual allegations are not required, a complaint must contain "sufficient factual matter ... to state a claim to relief that is plausible on its face." *Iqbal*, 556 U.S. at 678 (quoting *Twombly*, 550 U.S. at 570). When ruling on a Rule 12(b)(6) motion, the Court "may consider only the facts alleged in the complaint, any documents either attached to or incorporated in the complaint and matters of which we may take judicial notice." *EEOC v. St. Francis Xavier Parochial Sch.*, 117 F. 3d 621, 624 (D.C. Cir. 1997). In so doing, the court must give the plaintiff the "benefit of all inferences that can be derived from the facts alleged." *Kowal v. MCI Commc'ns Corp.*, 16 F.3d 1271, 1276 (D.C. Cir. 1994). "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements" are not sufficient to state a claim. *Iqbal*, 556 U.S. at 678. The plaintiff must "give the defendant fair notice of what the . . . claim is and the grounds upon which it rests." *Erickson v. Pardus*, 551 U.S. 89, 93 (2007) (quoting *Twombly*, 550 U.S. at 555).

III. Analysis

Mr. Greenwald argues that this Court has subject matter jurisdiction over this matter under 28 U.S.C. § 1331 (federal question jurisdiction) and 28 U.S.C. § 1346 (United States as

defendant), because it involves an agency of the United States as a defendant, and because it involves the interpretation and application of the laws of the United States, including the Administrative Procedure Act and Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 et seq. *See* Compl., ECF No. 26 ¶ 10. He also asserts jurisdiction pursuant to 42 U.S.C. § 1395ff(f)(3), which authorizes judicial review of an LCD without prior exhaustion of administrative remedies where there are no material issues of fact in dispute. *Id.* ¶ 11. Defendants respond that Mr. Greenwald is no longer seeking the relief that his denied claim be reversed and covered under Medicare Part B, and therefore has no stake in the outcome of this matter, rendering federal question jurisdiction absent. *See* Defs.' MTD, ECF No. 27-1 at 13. Defendants also assert that this Court lacks jurisdiction because Mr. Greenwald has not exhausted his administrative remedies. *Id.* at 15.

Magistrate Judge Meriweather finds that Mr. Greenwald cannot rely on 28 U.S.C. §§ 1331 and 1346, because Section 405(h) of the Social Security Act (as incorporated into the Medicare Act through 42 U.S.C. § 1395ii) channels "most, if not all, Medicare claims through agency review provisions," unless doing so would result in "*complete* preclusion of judicial review," which is not the case here, where the Medicare statutes

provide explicitly for judicial review of the agency's final determinations on both the issue of Mr. Greenwald's individual claim determination and the overarching validity of LCD L33829. R. & R., ECF No. 47 at 10 (citation and quotation marks omitted). As to jurisdiction under 42 U.S.C. § 1395ff(f)(3), Magistrate Judge Meriweather finds that Mr. Greenwald has not carried his burden of demonstrating that this case falls within the limited jurisdictional grant of the statute, because the "undisputed facts are insufficient to demonstrate whether NCD 280.6 and LCD L33829 conflict as a matter of law," a conflict which would render LCD L33829 invalid. *Id.* at 11. Mr. Greenwald raises objections only as to Magistrate Judge Meriweather's findings on jurisdiction under 42 U.S.C. § 1395ff(f)(3).

A. Magistrate Judge Meriweather Erred In Concluding That This Court Lacks Jurisdiction Under 42 U.S.C. § 1395ff(f)(3)

Section 1395ff(f) provides for facial review of NCDs and LCDs. *See id.* § 1395ff(f)(1), (2). Challenges brought under § 1395ff(f) are ordinarily reviewed by an ALJ, whose decision is appealable to the DAB. *Id.* § 1395ff(2)(A)(i)–(ii). The DAB's decision constitutes final agency action subject to judicial review. *Id.* § 1395ff(2)(A)(iv). But an aggrieved individual may avoid the ordinary administrative review process and proceed directly to a "court of competent jurisdiction" if "the moving

party alleges that (A) there are no material issues of fact in dispute, and (B) the only issue of law is . . . that a regulation, determination, or ruling by the Secretary is invalid." *Id.* § 1395ff(f)(3); *see also Bailey v. Mut. of Omaha Ins. Co.*, 534 F. Supp. 2d 43, 51 (D.D.C. 2008).

Here, the parties agree that the LCD at issue would be invalid if it conflicts with the Medicare NCD for pneumatic compression devices. R. & R., ECF No. 47 at 11. The relevant NCD excludes coverage for a pneumatic compression device if conservative treatment is shown to be effective, and states in relevant part:

> Pneumatic compression devices are covered in the home setting for the treatment of lymphedema if the patient has undergone a four-week trial of conservative therapy and the treating physician determines that there has been no significant improvement or if significant symptoms remain after the trial. The trial of conservative therapy must include use of an appropriate compression bandage system or compression garment, exercise, and elevation of the limb.

NCD 280.6, ECF No. 27-4. As Defendants acknowledge, "if a trial of a compression bandage or garment leads to significant improvement and relief of significant symptoms, there is no Medicare coverage for pneumatic compression devices." Defs.' Resp., ECF No. 51 at 4.

The relevant LCD states as follows:

> At the end of the four-week trial, if there has been improvement, then reimbursement for a [pneumatic compression device] is not justified. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessment at intervals at least a week apart. Only when no significant improvement has occurred in the most recent four weeks and the coverage criteria above are still met, may the lymphedema be considered unresponsive to conservative therapy, and coverage for a [pneumatic compression device] considered. CMS' NCD for [pneumatic compression device] (280.6) instructs: "The determination by the physician of the medical necessity of a pneumatic compression device must include...symptoms and objective findings, including measurements which establish the severity of the condition."
>
> At a minimum, re-assessments conducted for a trial must include detailed measurements, obtained in the same manner and with reference to the same anatomic landmarks, prior to and at the conclusion of the various trials and therapy, with bilateral comparisons where appropriate.

LCD L33829, ECF No. 27-5. Explaining the LCD, Defendants state that "if there has been improvement, but a patient is still symptomatic, then the patient must continue the trial of conservative therapy." Defs.' Resp., ECF No. 51 at 5. Magistrate Judge Meriweather observes that "[t]he parties appear to agree that LCD L33829 would be invalid if it is inconsistent with or narrows NCD 280.6." R. & R., ECF No. 47 at 11. However, "[t]hey disagree on whether this Court can determine if the LCD and NCD

conflict without considering additional facts or expert opinions." *Id.* at 12. Magistrate Judge Meriweather concludes that the Court requires additional facts to determine whether NCD 280.6 and LCD L33829 conflict. *Id.* Specifically, Magistrate Judge Meriweather states that:

> [T]he Court is not equipped to assess the merits of [Plaintiff's] theory without additional facts or expert opinions. The record in this case is too sparse to determine whether the coverage pathway required by the LCD conflicts with, or merely restates and interprets, the pre-coverage treatment requirements of the NCD. The parties have not provided the Court with adequate information about which symptoms associated with lymphedema and similar circulatory conditions are 'significant,' how their significance is measured, how improvement is documented and weighted, or whether any individuals would meet the conservative trial requirements of NCD 280.6 but not LCD L33829. Without that information, the undersigned cannot determine whether LCD conflicts with or is a substantive interpretation of NCD 280.6, and so recommends this Court dismiss Mr. Greenwald's case, as it cannot exercise subject-matter jurisdiction under § 1395ff(f)(3).

R. & R., ECF No. 47 at 15-16. In response, Mr. Greenwald objects that the question of whether the MACs lacked the legal authority to impose new legal obligations or conditions for Medicare coverage and payment through the LCD is purely a question of law within the authority of this Court. Pl.'s Objs., ECF No. 49 at 3. The Court reviews the R. & R. only for clear error since Mr.

Greenwald's argument is repeated from his filing in opposition to the Motion to Dismiss. *See* Pl.'s Opp'n, ECF No. 29 at 28; *see also Houlahan*, 979 F. Supp. 2d at 88 ("If, however, the party makes only conclusory or general objections, or simply reiterates his original arguments, the Court reviews the [R. & R.] only for clear error.") (Internal citation omitted). The Court finds clear error here.

The critical question for the Court for the purposes of subject matter jurisdiction is whether additional facts are needed to determine if the LCD and NCD at issue conflict. The potential conflict arises when a conservative therapy trial leads to improvement, but significant symptoms remain. *See* Pl.'s Objs., ECF No. 49 at 5; Defs.' Resp., ECF No. 51 at 4. The Medicare NCD clearly states two pathways to coverage: pneumatic compression devices are covered if the treating physician determines there has been no significant improvement *or* if significant symptoms remain after the trial. NCD 280.6, ECF No. 27-4. As Mr. Greenwald points out, the LCD however, eliminates the second phrase, by instead requiring that "[o]nly when no significant improvement has occurred in the most recent four weeks and the coverage criteria above are still met, may the lymphedema be considered unresponsive to conservative therapy, and coverage for a [pneumatic compression device] considered."

LCD L33829. Thus, while the NCD ensures coverage for people who continue to have significant symptoms after the trial, *regardless of improvement*, the LCD restricts that coverage only to people who have seen no significant improvement in the most recent four weeks. This conflict is evident in the plain language of the text, and additional facts or expert opinions would not eliminate the conflict. As the R. & R. acknowledges, "[t]he national rule requires on its face only one four-week trial; the local rule might require several, potentially prolonging a patient's discomfort and health complications considerably before the patient can obtain a PCD covered by Medicare." R. & R., ECF No. 47 at 15. The Court disagrees with Magistrate Judge Meriweather that it needs to know "which symptoms associated with lymphedema and similar circulatory conditions are 'significant,' how their significance is measured, how improvement is documented and weighted." *Id.* at 15-16. The text makes amply clear that individuals who would meet the conservative trial requirements of NCD 280.6 may not satisfy LCD L33829 if they have had improvements in their condition within the past four weeks. Any other conclusion would make the plain language of NCD 280.6 surplusage and fail to give it meaning, violating the fundamental tools of interpretation. *See, e.g., Bailey v. United States*, 516 U.S. 137, 146 (1995)

("We assume that Congress used two terms because it intended each term to have a particular, nonsuperfluous meaning."); *see also Colautti v. Franklin*, 439 U.S. 379, 392 (1979) ("Appellants' argument . . . would make either the first or the second condition redundant or largely superfluous, in violation of the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative."); *Yates v. United States*, 135 S. Ct. 1074, 1085 (2015) (declining to read statute so as to "significantly overlap" with a distinct statute, resisting a reading that would "render superfluous an entire provision passed in proximity as part of the same Act"). The Court concludes that the LCD and NCD impermissibly conflict, rendering LCD L33829 invalid and providing this Court with jurisdiction under § 1395ff(f). The Court need not reach any additional argument as to jurisdiction.

B. Mr. Greenwald Has Standing to Bring This Case

Because Magistrate Judge Meriweather determines that this Court does not have subject matter jurisdiction, she does not reach the issue of standing raised by Defendants in their Motion to Dismiss. The Court therefore addresses it *de novo*. Defendants argue that Mr. Greenwald lacks standing to bring this case because he has failed to satisfy the redressability requirement of standing. Defs.' Reply, ECF No. 33 at 2. Specifically,

Defendants assert that even if the LCD were invalidated as Mr. Greenwald requests, his sole injury, paying out of pocket for the PCD, would not be redressed. *Id.* at 3. Defendants argue that Mr. Greenwald's ability to file future claims based on the NCD rather than the LCD is too conjectural to be the basis of redressability and add that even if the LCD and NCD conflict, Mr. Greenwald "does not qualify for the pneumatic compression device under the terms of the NCD," and therefore has no concrete stake in this lawsuit. *Id.* at 4-5. Mr. Greenwald responds that he meets the statutory standing requirements in 42 U.S.C. § 1395ff(f)(5), which are only that he (1) be a Medicare beneficiary who is (2) in need of the items or services that are the subject of the coverage determination. Surreply, ECF No. 48 at 2. He further argues that he meets the *Lujan* standing requirements since he suffered a concrete injury – the denial of coverage for a pneumatic compression device through a LCD that created new rules without the requisite process – and his injury was caused solely and directly by the Secretary, who authorized the publication of the LCD. *Id.* at 3. Mr. Greenwald adds that he has a procedural right to challenge the LCD which comes with a relaxed redressability standard. *Id.* Defendants reply that Mr. Greenwald's procedural right to file under section 1395ff(f)(5) does not suffice for Article III standing, which requires a

concrete injury even in the context of a statutory violation. Defs.' Suppl. Brief, ECF No. 44 at 6-7. The Court concludes that Mr. Greenwald has standing.

To demonstrate standing, a litigant must show that they have suffered a concrete and particularized injury that is either actual or imminent, that the injury is fairly traceable to the defendant, and that it is likely that a favorable decision will redress that injury. *Massachusetts v. E.P.A.*, 549 U.S. 497, 127 S. Ct. 1438 (2007). However, when a litigant is vested with a procedural right – here the right of Medicare beneficiaries to directly challenge LCDs in a District Court under 42 U.S.C. § 1395ff(f)(3) – that litigant has standing if there is some possibility that the requested relief will prompt the injury-causing party to reconsider the decision that allegedly harmed the litigant. *Id.* Article III standing requires a concrete injury even in the context of a statutory violation. *Thole v. U. S. Bank N.A*, 140 S. Ct. 1615, 1619-20 (2020).

Defendants do not dispute that Mr. Greenwald has a procedural right to challenge the LCD; they argue instead that "Plaintiff's procedural right to file under section 1395ff(f)(5) does not suffice for Article III standing." Defs.' Suppl. Brief, ECF No. 44 at 7. Defendants suggest that the reason Plaintiff's procedural right is insufficient is the lack of a concrete

injury, *see id.*; but it is indisputable that Plaintiff was injured by having to pay for the PCD out of pocket. This case is therefore distinct from *Spokeo v. Robins*, 136 S. Ct. 1540, 1549 (2016), where the Supreme Court held that plaintiff "could not, for example, allege a bare procedural violation, divorced from any concrete harm, and satisfy the injury-in-fact requirement of Article III."

It is also not the case, contrary to Defendants' suggestions, that Mr. Greenwald lacks a concrete interest in the case because he will not be compensated for his PCD if he prevails. First, a favorable decision by the Court will redress Mr. Greenwald's past injury of having to pay out of pocket by ensuring he is not in the future denied a PCD for his ongoing chronic lymphedema because of an invalid LCD. Second, "[a litigant] who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show that the procedural step was connected to the substantive result." *Sugar Cane Growers Cooperative of Fla. v. Veneman*, 289 F.3d 89, 94-95 (D.C. Cir. 2002). Accordingly, Mr. Greenwald does not have to show that he would receive Medicare coverage without an invalid LCD, and "the Secretary's contention that under the Medicare National

Coverage Determination for pneumatic compression devices Mr. Greenwald would not qualify for Medicare coverage is pure speculation and irrelevant to this case." Surreply, ECF No. 48 at 5. This is especially true given that the record does not reflect that any MAC relied on the NCD for any determination affecting Mr. Greenwald. Additionally, the Court is cognizant Defendants cannot "defeat standing merely by asserting that [] [they] will come to the same conclusion once the procedures are satisfied on remand." *ADX Communications of Pensacola v. FCC*, 794 F.3d 74, 82 (D.C. Cir. 2015) (citations omitted). Finally, standing is supported by the fact that Mr. Greenwald continues to suffer from lymphedema, such that the LCD represents an ongoing harm. *See, e.g., Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC)*, Inc., 528 U.S. 167, 184-86 (2000). The Court concludes that Mr. Greenwald has standing to bring this case.

Mr. Greenwald does not, however, have standing to bring Count IV of his complaint, which alleges that the Secretary violated the non-discretionary duty imposed by 42 U.S.C. § 1395ff(1). *See* Compl., ECF No. 26 at 21. Defendants raise several arguments as to why Mr. Greenwald lacks standing for this Count, none of which are addressed by Mr. Greenwald. *See generally* Pl.'s Opp'n, ECF No. 29. The Court therefore

treats these arguments as conceded. *See Bancoult v. McNamara*, 227 F. Supp. 2d 144, 149 (D.D.C. 2002) ("[I]f the opposing party files a responsive memorandum, but fails to address certain arguments made by the moving party, the court may treat those arguments as conceded, even when the result is dismissal of the entire case.").

IV. Conclusion and Order

For the foregoing reasons, the Court

ADOPTS IN PART and REJECTS IN PART Magistrate Judge Meriweather's R. & R., *see* ECF No. 49. The portion of the R. &. R that is rejected is Magistrate Judge Meriweather's finding that there is no jurisdiction under 42 U.S.C. § 1395ff(f)(3); and further

GRANTS IN PART and DENIES IN PART Defendants' Motion to Dismiss, *see* ECF No. 27. The Motion is granted only as to Count IV of the Complaint.

SO ORDERED.

Signed: Emmet G. Sullivan
United States District Judge
June 7, 2021