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., Civ. Action No. 17-0797 (EGS/RMM)

Defendants.

MEMORANDUM OPINION AND ORDER

I. Introduction

Mr. Michael Greenwald ("Mr. Greenwald" or "Plaintiff") brings this action against the Secretary of the United States Department of Health and Human Services ("HHS" or the "agency") and the Administrator of the Centers for Medicare and Medicaid Services ("CMS"), both in their official capacities (collectively, "Defendants"). *See* First Am. Compl. ("Compl."), ECF No. 26.¹ He challenges the validity of Local Coverage Determination ("LCD") L33829-the application of which resulted in the denial of his claim for Medicare coverage for a pneumatic

¹ When citing electronic filings throughout this Opinion, the Court refers to the ECF page numbers, not the page numbers of the filed documents.

compression device ("PCD") that his physician prescribed to treat his lymphedema. See id. ¶¶ 55, 58-80.

Defendants moved to dismiss the Complaint for lack of subject matter jurisdiction and failure to state a claim. See Defs.' Mem. of P. & A. Supp. Mot. Dismiss ("Defs.' Mot. Dismiss"), ECF No. 27-1. Following referral of the case, see Minute Order (July 11, 2018); Magistrate Judge Robin M. Meriweather issued a Report and Recommendation ("R. & R.") recommending that the Court grant Defendants' Motion to Dismiss, see R. & R., ECF No. 47 at 17; and Mr. Greenwald objected, see Pl. Michael Greenwald's Objs. Nov. 8, 2021 R. & R. Regarding Defs.' Mot. Dismiss Compl. ("Pl.'s Objs."), ECF No. 49. The Court thereafter issued a Memorandum Opinion and Order denying Defendants' Motion to Dismiss the Complaint. See Greenwald v. Becerra, No. CV 17-797(EGS/RMM), 2022 WL 2046108, at *9 (D.D.C. June 7, 2022).

Pending before the Court is Mr. Greenwald's Motion for Clarification of that Memorandum Opinion and Order. See Pl.'s Mot. Clarification Ct.'s June 7, 2022 Mem. Op. & Order ("Pl.'s Mot."), ECF No. 56. Upon careful consideration of the motion, opposition, and reply thereto; the applicable law; and the entire record herein, the Court hereby the Court hereby **DENIES** Mr. Greenwald's motion.

II. Background

A. Factual

The Court assumes the parties' familiarity with the facts of the case as set forth in its June 7, 2022 Memorandum Opinion and Order. See Greenwald, 2022 WL 2046108, at *1-3. As before, for the purposes of the Motion to Dismiss, the Court assumes the following facts alleged in the Amended Complaint to be true and construes them in Mr. Greenwald's favor. See Baird v. Gotbaum, 792 F.3d 166, 169 n.2 (D.C. Cir. 2015) (citation omitted).

In short, this case concerns the treatment of Mr. Greenwald's lymphedema. See Compl., ECF No. 26 ¶¶ 1, 13, 48. Following his 2014 diagnosis, his physician attempted to treat the condition with compression stockings, exercise, and limb elevation. See id. ¶¶ 13-14, 48-49. These treatments were ineffective, so in 2016, his physician prescribed him a pneumatic compression device ("PCD"). See id. ¶¶ 14, 52.

Because Mr. Greenwald is eligible for Medicare benefits, he expected his PCD prescription to be covered under Medicare Part B. See id. ¶¶ 13, 18, 24, 54. His coverage claim was denied, though, as was his appeal for a redetermination. See id. ¶¶ 55-56. He therefore has paid the full cost of his prescribed PCD out of pocket. See id. ¶¶ 47, 63.

Mr. Greenwald's PCD is subject to a National Coverage Determination ("NCD") and Local Coverage Determination ("LCD").

Id. ¶¶ 31, 33-34, 40-45; see also CMS, Nat'l Coverage
Determination for Pneumatic Compression Devices, Pub. No. 100-3
\$ 280.6 (eff. Jan. 14, 2002) ("NCD 280.6"); Ex. A, ECF No. 26-1
at 1 ("LCD L33829"). 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."). Mr. Greenwald argues that NCD 280.6 and LCD L33829
conflict, see Compl., ECF No. 26 ¶¶ 5, 6; such that his claimdenied under application of LCD L33829-might have been approved
under NCD 280.6, see id. ¶¶ 54-55, 57.

B. Procedural

Mr. Greenwald filed this Motion for Clarification on September 23, 2022. See Pl.'s Mot., ECF No. 56. Defendants submitted their brief in opposition on October 7, 2022, see Defs.' Resp. Pl.'s Mot. Clarification of Ct.'s June 7, 2022 Mem. Op. & Order ("Defs.' Opp'n"), ECF No. 57; and Mr. Greenwald replied on October 14, 2022, see Pl.'s Reply Mem. Law Supp. Mot. Clarification of Ct.'s June 7, 2022 Mem. Op. & Order ("Pl.'s Reply"), ECF No. 58. The motion is now ripe and ready for adjudication.

III. Legal Standard

No Federal Rule of Civil Procedure specifically governs "motions for clarification." United States v. Philip Morris USA Inc., 793 F. Supp. 2d 164, 168 (D.D.C. 2011). Nevertheless, federal courts generally recognize and allow these motions. Barnes v. Dist. of Columbia, 289 F.R.D. 1, 13 n.6 (D.D.C. 2012). "The general purpose of a classic motion for clarification is to explain or clarify something ambiguous or vague." Id. (internal quotation marks omitted) (quoting Resol. Tr. Corp. v. KPMG Peat Marwick, et al., No. 92-1373, 1993 WL 211555, *2 (E.D. Pa. June 8, 1993)). Parties may file motions for clarification "when they are uncertain about the scope of a ruling." United States v. All Assets Held at Bank Julius, Baer & Co., Ltd., 315 F. Supp. 3d 90, 99 (D.D.C. 2018) (citing United States v. Volvo Powertrain Corp., 758 F.3d 330, 344 (D.C. Cir. 2014); Barnes v. Dist. of Columbia, 289 F.R.D. 1, 12-13 (D.D.C. 2012)). However, these motions "cannot open the door to 're-litigat[ing] a matter that the court has considered and decided."" Id. (quoting SAI v. Transp. Sec. Admin., No. 14-403, 2015 U.S. Dist. LEXIS 192323 (D.D.C. Aug. 19, 2015)).

III. Analysis

Mr. Greenwald moves the Court to clarify that its June 7, 2022 Memorandum Opinion and Order invalidated LCD L33829 "in its entirety" such that the Secretary cannot apply the LCD "in any

way." Pl.'s Mot., ECF No. 56 at 9. He presents three arguments to reach this conclusion. First, he argues that the language the Court used in its Memorandum Opinion and Order plainly means that LCD L33829 "is invalid in its entirety." *Id.* at 6. Second, he contends that the Court invalidated LCD L33829 completely because he had previously argued that each provision of the LCD is invalid in the Complaint and his Motion for Summary Judgment. *See id.* at 6-7. Third, he asserts that LCDs are not severable, so the Court cannot invalidate only one part of LCD L33829. *See id.* at 7-8. The Court addresses each argument in turn and, for the reasons that follow, **DENIES** Mr. Greenwald's Motion for Clarification.

A. The Plain Meaning of "Invalid" Does Not Resolve Mr. Greenwald's Motion

Mr. Greenwald first argues that the Court must have invalidated LCD L33829 in its entirety based on the language in the June 7, 2022 Memorandum Opinion and Order. See Pl.'s Mot., ECF No. 56 at 6. There, "[t]he Court conclude[d] that the LCD and NCD impermissibly conflict, rendering LCD L33829 invalid and providing this Court with jurisdiction under § 1395ff(f)." *Greenwald*, 2022 WL 2046108, at *7. He reasons that because "[t]he plain meaning of the word 'invalid' is something that is 'not legally binding' or 'without basis in fact,'" LCD L33829

"is void in its entirety." Pl.'s Mot., ECF No. 56 at 6 (quoting Black's Law Dictionary 900 (9th ed. 2009)).

Defendants do not respond to this argument. See generally Defs.' Opp'n, ECF No. 57. In his reply brief, though, Mr. Greenwald again emphasizes that "the plain meaning of the word 'invalid' should control." Pl.'s Reply, ECF No. 58 at 2-3 (collecting cases). He also points out that Section 1395ff(f) does not define "invalid" or otherwise indicate that the term "ha[s] any meaning other than its ordinary meaning." Id. at 3 (citing H. Conf. Rep. 106-1033 at 896 (2000)).

The Court is not persuaded by Mr. Greenwald's argument. Despite his statements to the contrary, the parties agree that the Court held that at least part of LCD L33829 is invalid-that is, "not legally binding"-in its June 7, 2022 Memorandum Opinion and Order. See generally Pl.'s Mot., ECF No. 56; Defs.' Opp'n, ECF No. 57. Stated differently, they agree that the word "invalid" should be given its plain meaning in this context. They dispute, however, whether the Court held LCD L33829 invalid in part or in whole. See generally Pl.'s Mot., ECF No. 56; Defs.' Opp'n, ECF No. 57. The meaning of the word "invalid" therefore does not help explain precisely what is now "void."

B. The Court Previously Considered and Decided Only One Ground for Subject Matter Jurisdiction

Mr. Greenwald next argues that the Court's June 7, 2022 Memorandum Opinion and Order must have invalidated LCD L33829 in its entirety because his "pleadings . . . make it clear that the LCD [i]s completely invalid." Pl.'s Mot., ECF No. 56 at 6. He states that, in the Complaint and in his Motion for Summary Judgment, he set forth the following points where the LCD conflicts with the NCD:

> (i) The LCDs include a definition of the severity of lymphedema symptoms that qualify for Medicare coverage;

> (ii) When a trial period of conservative therapy is a prerequisite for PCD coverage, the LCDs impose a lengthier trial period than that stated in the NCD even when the patient's treating physician determines that significant symptoms remain after the trial;

> (iii) The LCDs contain additional prerequisites for coverage for lymphedema treatment;

(iv) The LCDs add new prerequisites for coverage for chronic venous insufficiency with venous stasis ulcers;

(v) The LCDs add new prerequisites for coverage requiring that the lymphedema extend into the chest, trunk, or abdomen; and

(vi)The LCDs add a new exclusion from Medicare coverage for PCDs when used for peripheral artery disease or for deep venous thrombosis prophylaxis. Id. (quoting Compl., ECF No. 1 ¶ 43; see Pl.'s Mot. Summ. J., ECF No. 29 at 15-16, 32). He concedes that the Court's Memorandum Opinion and Order discussed only the second point. Id. Nevertheless, he argues that "the additional five points demonstrate that the LCD is invalid for exactly the same reason." Id.

Defendants oppose this characterization of the proceedings. See Defs.' Opp'n, ECF No. 57 at 2-5. They argue instead that the Court resolved the only issue before it: whether the LCD's conservative therapy trial requirements conflict with the NCD such that the Court has subject matter jurisdiction under Section 1395ff(f)(3). See id. They recount that Mr. Greenwald raised several potential conflicts between the LCD and the NCD as grounds for subject matter jurisdiction in his consolidated Motion for Summary Judgment and Opposition to Defendants' Motion to Dismiss. Id. at 3 (citing Mem. P. & A. Supp. Pl.'s Mot. Summ. J. & Opp'n Def.'s Mot. Dismiss, ECF No. 30 at 22-23, 39-40). Defendants concede that Magistrate Judge Meriweather considered each potential conflict Mr. Greenwald raised as a possible basis for subject matter jurisdiction. See id. at 4 (citing R. & R., ECF No. 47 at 12-17). They explain, however, that in objecting to the R. & R., Mr. Greenwald "addresse[d] only the conservative therapy trial requirements" to establish subject matter jurisdiction under Section 1395ff(f)(3). Id. (quoting Pl.'s

Objs., ECF No. 49 at 4-5). Further, they argue that the Court's Memorandum Opinion and Order "only discusses the conservative therapy trial requirements"; "does not identify any other conflict between the [NCD and LCD]"; and rejects the R. & R.'s conclusion that the Court lacks subject matter jurisdiction under Section 1395ff(f)(3). *Id.* (quoting Mem. Op. & Order, ECF No. 52 at 22-24, 29).

The Court agrees with Defendants that it decided only that it has subject matter jurisdiction because the LCD's conservative therapy trial requirements conflict with the NCD. In its Memorandum Opinion and Order, the Court stated: "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." *Greenwald*, 2022 WL 2046108, at *7. The Court discussed only this potential conflict for the purpose of determining jurisdiction. *See id*. Moreover, upon concluding that "[t]his conflict is evident in the plain language of the text," the Court stated that it "need not reach any additional argument as to jurisdiction." *Id*.

Because of this clear language, the Court does not need to review documents preceding the June 7, 2022 Memorandum Opinion and Order. Mr. Greenwald's earlier arguments that other

conflicts support jurisdiction—and Defendants' arguments against those other conflicts—cannot change the scope of the Court's ruling. Likewise, the R. & R. cannot alter the Court's decision particularly since the Court held that it rejected "[t]he portion of the R. &. R . . . finding that there is no jurisdiction under 42 U.S.C. § 1395ff(f)(3)." *Greenwald*, 2022 WL 2046108, at *9.

In reply, Mr. Greenwald contends that Defendants have "misconstru[ed]" the Memorandum Opinion and Order. Pl.'s Reply, ECF No. 58 at 4. Specifically, he contends that "this action did not dismiss [his] allegations that the LCD is inconsistent with the NCD or render them abandoned." *Id.* Defendants do not suggest this outcome in their briefing. *See* Defs.' Opp'n, ECF No. 57 at 2-5. Rather, they admit-as they must-that Mr. Greenwald's Motion for Summary Judgment raises multiple conflicts between the NCD and LCD and that the Motion has not yet been decided. *See id.* at 3. Nevertheless, the Court clarifies that it held only that it has subject matter jurisdiction because of the conflict regarding the conservative therapy trial requirements in its June 7, 2022 Memorandum Opinion and Order. *See Greenwald*, 2022 WL 2046108, at *6-7, 9. The Court did not decide whether there are other conflicts. *See id.*

C. LCD L33829 is Severable

Finally, Mr. Greenwald asserts that the entire LCD must be invalid because one portion is invalid. See Pl.'s Mot., ECF No. 56 at 7-8. He contends that courts may not invalidate "selected portions of LCDs" for two reasons: (1) courts may not amend Section 1395ff(f) by inference, *id*. (citing *Hollingsworth v*. *Duff*, 444 F. Supp. 2d 61, 65 (D.D.C. 2006)); and (2) LCDs are not severable, *id*. at 8 (citing *United States v*. *Mead Corp.*, 533 U.S. 218 (2001); *Scenic America, Inc. v*. *U.S. Dep't of Transp.*, 49 F. Supp. 3d 53, 60 (D.D.C. 2014); 42 C.F.R. § 405.1062). He suggests instead that the Court adopt "the procedure when a court finds that a regulation violates the Administrative Procedure Act and is vacated by a court." *Id*. (citing *Nat'1 Mining Ass'n v*. *U.S. Army Corps of Eng'rs*, 145 F.3d 1399, 1409 (D.C. Cir. 1998)).

As to Mr. Greenwald's argument against amendment by inference, Defendants respond that the caselaw is "irrelevant" because those cases concern situations where one statute repeals another statute by implication. Defs.' Opp'n, ECF No. 57 at 9 (citing *Hollingsworth*, 444 F. Supp. 2d at 65). The Court agrees with Defendants on this point. In *Hollingsworth*, the district court considered whether the AOUSC Personnel Act repealed and modified the Rehabilitation Act by implication. *See Hollingsworth*, 444 F. Supp. 2d at 65. By contrast, the instant

case concerns the severability of a single LCD, not a conflict between two statutes.

As to Mr. Greenwald's argument against severability, Defendants insist that the severability doctrine applies to LCDs. See Defs.' Opp'n, ECF No. 57 at 5-9. They suggest that the Court treat LCDs like other agency determinations and apply binding precedent governing the severability of those determinations. See id. at 6. Mr. Greenwald contests this proposal, stating that "[t]he LCD is not a statute, but a policy published by a private contractor" such that "[i]t does not qualify for deference and may be disregarded by Administrative Law Judges." Pl.'s Reply, ECF No. 58 at 5. This argument understates the significance of LCDs. As Defendants explain, LCDs "are only issued after [MACs] follow detailed procedures, including engaging in a comment-and-notice period, soliciting feedback and recommendations from the medical community, and presenting the policy in meetings of stakeholders." Defs.' Opp'n, ECF No. 57 at 6 (citation omitted). Further, the agency has promulgated regulations for administrative challenges to LCDs that closely track regulations for administrative challenges to NCDs, which are agency rules. See 42 C.F.R. Part 426 (implementing 42 U.S.C. §§ 1395ff(f)(1),(2)); Defs.' Opp'n, ECF No. 57 at 7. Because the agency treats LCDs like administrative rules, the Court is persuaded that it should

treat LCDs like other agency determinations to decide the severability question.

This question is governed by binding precedent from the Court of Appeals for the District of Columbia Circuit ("D.C. Circuit"). Accordingly, "[w]hether the offending portion of [the LCD] is severable depends upon the intent of the agency and upon whether the remainder of the [LCD] could function sensibly without the stricken provision." MD/DC/DE Broadcasters Ass'n v. F.C.C., 236 F.3d 13, 22 (D.C. Cir. 2001) (citing K Mart Corp. v. Cartier, Inc., 486 U.S. 281, 294 (1988)). To aid its inquiry, the Court must consider whether the provisions of the LCD are "intertwined" or instead "operate entirely independently of one another." Davis Cnty. Solid Waste Mgmt. v. EPA, 108 F.3d 1454, 1459 (D.C. Cir. 1997) (per curiam).

The parties agree that the agency has not stated whether LCDs are severable. See Defs.' Opp'n, ECF No. 57 at 7; Pl.'s Reply, ECF No. 58 at 5. Even so, Defendants argue that the agency must have intended LCDs to be severable because: (1) requiring the issuance of a new LCD in every instance "would create an unnecessary burden"; and (2) regulations permit Administrative Law Judges to sever provisions of LCDs when parties challenge those provisions in administrative proceedings. Defs.' Opp'n, ECF No. 57 at 6-8. Mr. Greenwald challenges both of these arguments. See Pl.'s Reply, ECF No. 58

at 5-7. He contends that invalidation of LCD L33829 as a whole would not be burdensome because: the Secretary compensates MACs for developing LCDs; the MAC here need only make the LCD conform with the relevant NCD; and the MAC could reinstate the previous LCD regarding pneumatic compression devices. *See id.* at 6. The Court is not persuaded, as this argument ignores the comprehensive process MACs must follow to set new LCDs. *See* Medicare Program Integrity Manual § 13.7.4.

Mr. Greenwald also challenges Defendants' reliance on regulations set pursuant to Section 1395ff(f)(2), which discusses the administrative appeals process for challenges to LCDs. See Pl.'s Reply, ECF No. 38 at 5-6. Citing Supreme Court authority, he argues that Section 1395ff(f)(3) must not be severable because "Section 1395ff(f)(2) may allow for severability under the Secretary's regulations," but "Congress did not include any provision for severability in Section 1395ff(f)(3)." Id. at 6 (citing Keene Corp. v. United States, 508 U.S. 200, 208 (1993) ("[W]here Congress includes particular language in one section of a statute but omits it in another . . . , it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (quoting Russello v. United States, 464 U.S. 16, 23 (1983))). This argument is unpersuasive. Congress did not specify that LCDs are severable in Section 1395ff(f)(2); rather, the Secretary

promulgated regulations setting forth procedures for administrative procedures and making it clear that LCDs are severable in these proceedings, see 42 C.F.R. § 426.400. Mr. Greenwald does not explain why LCDs may be severable in administrative proceedings but not in federal court, and the Court declines to formulate a reason now. The Court therefore agrees with Defendants that the regulatory scheme suggests that the agency intended for federal courts to treat LCDs as severable.

This conclusion is further supported by the text of LCD L33829. In addition to the conservative therapy trial requirements, the LCD addresses the following topics under separate headings:

• Requirements for prescriptions for pneumatic compression devices;

• Definitions of edema, primary lymphedema, secondary lymphedema, chronic venous insufficiency, and peripheral artery disease;

• Coding for pneumatic compression devices;

• Requirements for coverage of pneumatic compression devices for lymphedema;

• Coverage for chronic venous insufficiency with venous stasis ulcers;

• Various requirements for coverage where lymphedema extends onto the chest, trunk, and/or abdomen;

• Coverage for peripheral artery disease;

- Coverage for deep venous thrombosis prevention;
- Coverage for pneumatic compression device related accessories;
- Pneumatic compression device coding selection;
- Requirements for physician orders; and
- Various documentation requirements.

See LCD L33829. The Court therefore concludes that the conservative therapy trial requirements are not intertwined with the other provisions of the LCD and concludes that those requirements may be severed from the remainder of the LCD.²

IV. Conclusion and Order

For the reasons explained above, it is **HEREBY ORDERED** that Mr. Greenwald's Motion for Clarification of the Court's June 7, 2022 Memorandum Opinion and Order, *see* ECF No. 56, is **DENIED**.

SO ORDERED.

Signed: Emmet G. Sullivan United States District Judge May 24, 2023

² The Court will not address Defendants' argument that compliance with the June 7, 2022 Memorandum Opinion and Order would fully resolve this action. See Defs.' Opp'n, ECF No. 57 at 9-11. This argument ignores the fact that the Court has not reached the merits of Mr. Greenwald's claims or decided his summary judgment motion. See Greenwald, 2022 WL 2046108, at *9; Docket for Civ. Action No. 17-797.