UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

JAMES HENRY, et al.,

Plaintiffs,

v.

ALEX M. AZAR II
Secretary of Health and Human Services,

Defendant.

Civil Action No. 20-1144 (CKK)

MEMORANDUM OPINION
(February 8, 2021)

This case involves a dispute over the appropriate reimbursement payment for a medical device called Relizorb under Part B of the Medicare Act. *See* 42 U.S.C. § 1395k(a)(2)(B). Plaintiff Alcresta Therapeutics, Inc. ("Alcresta") is the manufacturer of Relizorb, and Plaintiff James Henry is a Medicare beneficiary who uses Relizorb to improve his lung function and address his malnourishment. *See* Compl. ¶¶ 5–6. Together, Alcresta and Mr. Henry (collectively, "Plaintiffs"), have filed a motion for summary judgment against the Secretary of Health and Human Services ("HHS"), asking the Court to invalidate the agency's Medicare payment determination for Relizorb. *See* ECF No. 8. In turn, the Secretary has filed a motion to dismiss Plaintiffs' claims for lack of subject-matter jurisdiction, as well as a cross-motion for summary judgment. *See* ECF No. 13.

Upon consideration of the briefing, the relevant authorities, and the record as a whole,[1] the Court concludes that it does not possess subject-matter jurisdiction over Plaintiffs' claims. Accordingly, it will **GRANT** the Secretary's motion and **DISMISS** Plaintiffs' claims **WITHOUT PREJUDICE**. Because this Court lack's subject-matter jurisdiction, it will also **DENY** Plaintiffs' motion for summary judgment **WITHOUT PREJUDICE**.

I. BACKGROUND

Plaintiff Alcresta is the exclusive manufacturer of Relizorb, which "is a small, single use cartridge that connects in-line between the feeding pump and the patient as part of the enteral feeding pump tubing set-up." Compl. ¶ 33. Relizorb "mimics normal pancreatic function by breaking down fats in formula used for enteral tube feeding—*i.e.*, delivery of nourishment directly to a patient's gastrointestinal tract—by exposing the formula to a special digestive enzyme immediately before it enters the body." *Id.* In this way, Relizorb "facilitates absorption of essential fats in patients suffering from severe fat malabsorption resulting from pancreatic insufficiency associated with cystic fibrosis and other serious pancreatic conditions." *Id.* ¶ 32. Alcresta maintains that there is no comparable "product currently available that breaks down fats

[1] The Court's consideration has focused on the following briefing and material submitted by the parties:

- Compl., ECF No. 1;
- Pls.' Mem. of P. & A. in Supp. of Mot. for Summ. J. ("Pls.' Mot."), ECF No. 8;
- Gov't Mem. In. Supp. of Mot. to Dismiss and Remand and Cross-Mot. for Summ. J. ("Gov't Mot."), ECF No. 13-1;
- Pls.' Reply in Supp. of Pls. Mot. for Summ. J. ("Pls. Reply"), ECF No. 17;
- Pls.' Opp'n to Gov't Mot. to Dismiss and Remand and to its Alt. Cross-Mot. for Summ. J. (Pls.' Opp'n"), ECF No. 18;
- Gov't Reply in Supp. of Mot. to Dismiss and Remand and Alt. Cross-Mot. for Summ. J. ("Gov't Reply"), ECF No. 19; and,
- Joint App'x of Admin. Record ("AR"), ECF No. 20.

In an exercise of its discretion, the Court finds that holding oral argument in this action would not be of assistance in rendering a decision. *See* LCvR 7(f).

throughout a full enteral feeding session." *Id.* ¶ 34. The Food and Drug Administration ("FDA") cleared Relizorb for prescription use in 2015. *See id.* ¶¶ 31, 34.

Medicare Part B offers coverage for prosthetic devices used for enteral nutrition therapy, such as Alcresta, where they are medically necessary for enrolled beneficiaries. *See* 42 U.S.C. §§ 1395k(a)(2)(B), 1395k(a)(2)(I); 42 C.F.R. § 421.210(b)(2); disc. *infra* at 10. Accordingly, after Relizorb's FDA clearance in 2015, Alcresta applied with the Centers for Medicare & Medicaid Services ("CMS") for a unique Medicare billing code for Relizorb. *See* Compl. ¶ 35. Initially, CMS determined that Relizorb did not require a separate Medicare billing code, because preexisting codes for other enteral nutrition supply kits adequately covered Relizorb. *See id.* ¶ 36. But Alcresta disputed this determination, *see id.* ¶¶ 35–50, and in December 2018, CMS ultimately issued a unique Medicare billing code for Relizorb, *see id.* ¶ 51. At this point, Relizorb became a newly-coded product that was not yet on Medicare's national fee schedule for enteral nutrition therapy. *See id.* ¶ 52; Pub. L. No. 105-33 § 4315. As such, CMS directed Medicare contractors processing payment claims for the newly-coded Relizorb to determine reimbursement payments "'in accordance with the gap-filling methodology in section 60.3 of Chapter 23 of the Medicare Claims Processing Manual.'" Compl. ¶ 52 (quoting Technical Direction Letter (TDL-190132) at 2 (Dec. 20, 2018)).

Plaintiff James Henry is a cystic fibrosis patient enrolled under Medicare Part B, who uses Medicare coverage of Relizorb to obtain the device for his medical treatment. Compl. ¶ 53. In 2019, Mr. Henry's Medicare supplier submitted a Medicare claim on his behalf for 60 cartridges of Relizorb that had been prescribed by Mr. Henry's physician. *See id.* ¶ 54. In this Medicare claim, Mr. Henry sought a total reimbursement of $9,898.20 for the 60 cartridges of Relizorb, a rate of $164.97 per cartridge. *Id.* On October 31, 2019, however, the first-level Medicare

contractor approved a payment of $2,025.07 for the 60 Relizorb cartridges, a rate of only $33.75 per cartridge. *See id.* ¶ 55: AR at 314. Mr. Henry requested a redetermination from the Medicare contractor, arguing that the contractor's payment determination for Relizorb rested on an erroneous application of the Medicare gap-filling methodology. *See* Compl. ¶ 56; AR at 92, 105–14. On January 7, 2020, however, the contractor upheld its original payment determination. *See* AR at 308–09.

Pursuant to the Medicare administrative appeals process, *see* 42 U.S.C. § 1395ff(c), Mr. Henry then requested that a "qualified independent contractor" ("QIC") reconsider the payment determination for Relizorb made by the first-level Medicare contractor, *see* AR at 305–06. But on February 18, 2020, the QIC dismissed Mr. Henry's claim, concluding that the first-level contractor's payment determination for Relizorb was not an "initial determination" under the Medicare Act and, therefore, could not be appealed. AR at 69 (citing 42 C.F.R. § 405.926(c)). Mr. Henry subsequently requested that an administrative law judge ("ALJ") within HHS review the QIC's dismissal. *See* AR at 2–4. The ALJ, however, dismissed Mr. Henry's request to review the QIC's dismissal order on March 30, 2020, also concluding that the contractor's payment determination was not an "initial determination." *See* AR at 4. Following the ALJ's dismissal, Mr. Henry and Alcresta jointly filed a complaint before this Court on May 1, 2020. *See generally* Compl., ECF No. 1.

In their complaint, Mr. Henry and Alcresta assert four claims, each aimed at invalidating the Medicare contractor's payment determination for Relizorb. *See id.* ¶ 2. In Count I, Plaintiffs allege that the Relizorb payment determination was "contrary to law" and specifically violated the Medicare gap-filling requirements applicable to newly-coded products like Relizorb. *See id.* ¶¶ 82–89. In Count II, Plaintiffs similarly allege that the Medicare contractor's payment

determination for Relizorb was "arbitrary and capricious because it started from an unreasonable assessment of reasonable charges and approached gap-filling payment[s] for Relizorb differently than for other products, and without explanation for the departure." *Id.* ¶ 91 (citing 5 U.S.C. § 706(2)(A). In Count III, Plaintiffs argue that the contractor's "payment determination is also unsupported by substantial evidence and should be set aside as unlawful" for that separate reason. Compl. ¶ 98. Finally, in Count IV, Plaintiffs allege that the contractor's underpayment for Relizorb constituted an "amendment" to a preexisting Medicare standard, known as a "national coverage determination" ("NCD"), which requires Medicare coverage for enteral nutrition therapy. *See id.* ¶ 102. Specifically, Plaintiffs allege that this functional NCD "amendment" was invalid because the agency failed to adhere to the requisite notice and comment procedures applicable to such a regulatory change. *See id.* ¶ 102–03; *Azar v. Allina*, 139 S. Ct. 1804, 1808–09 (2019). For relief, Mr. Henry and Alcresta ask the Court to "set aside the invalid payment determination and direct the agency to require its contractor to apply properly the gap-filling methodology set forth in the Medicare statute and rules." Compl., Relief Requested, at ¶ (d).

Plaintiffs have now filed for summary judgment, relying upon the administrative record and requesting relief from the agency's Relizorb payment determination as a matter of law. *See* Pls.' Mot. at 1–2. In response, however, the Secretary has filed a cross-motion for summary judgment and a motion to dismiss Plaintiffs' claims for lack of subject matter jurisdiction. *See* Gov't Mot. at 15–24. The parties have now fully briefed these motions and filed the administrative record before the Court. *See* LCvR 7(n). Consequently, the parties' pending motions are ripe for the Court's review.

II. LEGAL STANDARD

A court must dismiss a case pursuant to Federal Rule of Civil Procedure 12(b)(1) when it lacks subject-matter jurisdiction. In determining whether there is jurisdiction, the Court may "consider the complaint supplemented by undisputed facts evidenced in the record, or the complaint supplemented by undisputed facts plus the court's resolution of disputed facts." *Coal. for Underground Expansion v. Mineta*, 333 F.3d 193, 198 (D.C. Cir. 2003) (internal quotation marks omitted) (quoting *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992)); *see also Jerome Stevens Pharm., Inc. v. Food & Drug Admin.*, 402 F.3d 1249, 1253 (D.C. Cir. 2005) ("[T]he district court may consider materials outside the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction.")

In reviewing a motion to dismiss pursuant to Rule 12(b)(1), courts must accept as true all factual allegations in the complaint and construe the complaint liberally, granting plaintiff the benefit of all inferences that can be drawn from the facts alleged. *See Settles v. U.S. Parole Comm'n*, 429 F.3d 1098, 1106 (D.C. Cir. 2005) ("At the motion to dismiss stage, counseled complaints as well as *pro se* complaints, are to be construed with sufficient liberality to afford all possible inferences favorable to the pleader on allegations of fact."); *Leatherman v. Tarrant Cty. Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164 (1993) ("We review here a decision granting a motion to dismiss, and therefore must accept as true all the factual allegations in the complaint."); *Koutny v. Martin*, 530 F. Supp. 2d 84, 87 (D.D.C. 2007) ("[A] court accepts as true all of the factual allegations contained in the complaint and may also consider 'undisputed facts evidenced in the record.'" (internal citations omitted) (quoting *Mineta*, 333 F.3d at 198)).

Despite the favorable inferences that a plaintiff receives on a motion to dismiss, it remains the plaintiff's burden to prove subject-matter jurisdiction by a preponderance of the evidence. *Am.*

Farm Bureau v. United States Envtl. Prot. Agency, 121 F. Supp. 2d 84, 90 (D.D.C. 2000). "Although a court must accept as true all factual allegations contained in the complaint when reviewing a motion to dismiss pursuant to Rule 12(b)(1), [a] plaintiff['s] factual allegations in the complaint . . . will bear closer scrutiny in resolving a 12(b)(1) motion than in resolving a 12(b)(6) motion for failure to state a claim." *Wright v. Foreign Serv. Grievance Bd.*, 503 F. Supp. 2d 163, 170 (D.D.C. 2007) (internal citations and quotation marks omitted) (quoting *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13–14 (D.D.C. 2001)), *aff'd*, 2008 WL 4068606 (D.C. Cir. Mar. 17, 2008). A court need not accept as true "a legal conclusion couched as a factual allegation" or an inference "unsupported by the facts set out in the complaint." *Trudeau v. Fed. Trade Comm'n*, 456 F.3d 178, 193 (D.C. Cir. 2006) (internal quotation marks omitted) (quoting *Papasam v. Allain*, 478 U.S. 265, 286 (1986)).

III. DISCUSSION

"Federal courts are courts of limited jurisdiction," and "[t]hey possess only that power authorized by Constitution and statute." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994). Here, Plaintiffs have not established that this Court has the requisite authority to adjudicate their claims. In their complaint and briefing, Plaintiffs assert two separate bases for subject-matter jurisdiction: 42 U.S.C. § 1395ff(f) and 28 U.S.C. § 1331. *See* Compl. ¶ 3. But for the reasons set forth below, the Court concludes that neither statute confers this Court with jurisdiction over Plaintiffs' Medicare claims. Accordingly, the Court must **DISMISS** Plaintiffs' complaint in its entirety for lack of subject-matter jurisdiction. *See* Fed. R. Civ. P. 12(b)(1).

A. Plaintiffs' Claims Arise Under the Medicare Act

The first jurisdictional inquiry in a Medicare case such as this, is to determine whether the claims at issue "arise under" the Medicare Act and are, therefore, subject to the unique

jurisdictional requirements embedded in that statute. *See Porzecanski v. Azar*, 943 F.3d 472, 480 (D.C. Cir. 2019). "In determining whether a particular claim 'arises under' the . . . Medicare Act, the Supreme Court has construed the phrase 'quite broadly to include any claims in which both the standing and the substantive basis for the presentation of the claims is the Social Security Act,'" which includes the Medicare Act itself. *Integrity Soc. Work Servs., LCSW, LLC v. Azar*, No. 20-CV-118 (BAH), 2020 WL 3103913, at *4 (D.D.C. June 11, 2020) (quoting *Heckler v. Ringer*, 466 U.S. 602, 615 (1984)).

In this case, Plaintiffs' claims each arise under the Medicare Act. As set forth above, Plaintiffs claims in Counts I, II, and III derive from the October 31, 2019 payment determination made by a Medicare contractor for Mr. Henry's Relizorb cartridges, which Plaintiffs allege was improper under the Medicare "gap-filling" rules. *See* Pls.' Mot. at 21 (citing 42 U.S.C. §§ 1395u(a), (s); 42 C.F.R.§ 405.502); Compl. ¶¶ 82–100. Similarly, Plaintiffs' Count IV asserts that the contractor's payment determination for Relizorb improperly "amended" the existing Medicare NCD for enteral nutrition therapy. *See* Compl. ¶ 102. These claims derive directly from the substance of the Medicare Act and, therefore, Plaintiffs' standing and the substantive basis for their claims arise from that statute as well. *See Heckler*, 466 U.S. at 615. Indeed, Plaintiffs do not dispute that their claims arise under the Medicare Act. *See Am. Med. Techs. v. Johnson*, 598 F. Supp. 2d 78, 81 n.4 (D.D.C. 2009).

The conclusion that Plaintiffs' claims arise under the Medicare Act restricts this Court's authority. It is well established that "[f]ederal jurisdiction is extremely limited for claims arising under the Medicare Act." *Porzecanski*, 943 F.3d at 480. Thereunder, "42 U.S.C. § 1395ii—part of the Medicare Act—incorporates the judicial review scheme set forth in 42 U.S.C. § 405(h)." *Id.* Section "405(h) divests the district courts of federal question jurisdiction on any claim arising

under" the Medicare Act, except as provided in 42 U.S.C. § 405(g). *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825 (D.C. Cir. 2018). "In pertinent part, [§ 405(g)] permits any person to file a civil action, after any final decision of the [Secretary of Health and Human Services] made after a hearing to which he was a party, to obtain a review of such decision' in federal district court." *Id.* (internal quotations omitted); *see also* 42 U.S.C. § 1395ff(b)(1)(A).

In practice then, § 405(g) "demands the 'channeling' of virtually all legal attacks through the agency." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). There are, however, narrow exceptions to these channeling and exhaustion requirements, which derive from the Medicare Act itself, *see* 42 U.S.C. § 1395ff(f)(3), as well as from the Supreme Court precedent, *see Ill. Council*, 529 U.S. at 19. It is upon these exceptions that Plaintiffs rest their jurisdictional arguments in this case.

B. Jurisdiction Under 42 U.S.C. § 1395ff(f)

Plaintiffs first argue that this Court possesses jurisdiction under 42 U.S.C. § 1395ff(f). *See* Compl. ¶ 3. Section 1395ff(f)(3) supplies a "limited exception" to the presentment and exhaustion requirements of the Medicare Act. *Hays v. Leavitt*, 583 F. Supp. 2d 62, 66 (D.D.C. 2008), *aff'd sub nom. Hays v. Sebelius*, 589 F.3d 1279 (D.C. Cir. 2009). Under this provision, a party "may seek" judicial review of a "national coverage determination" or "local coverage determination" "without otherwise exhausting other administrative remedies," so long as "there are no material issues of fact in dispute" and "the only issue of law is . . . that a regulation, determination, or ruling by the Secretary is invalid." 42 U.S.C. § 1395ff(f)(3). Relevant here, the Medicare Act defines an NCD as "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this subchapter." *Id.* § 1395ff(f)(1)(B).

Plaintiffs contend that § 1395ff(f)(3) allows them to seek judicial review directly in this case, because the Secretary has effectively "amended" the existing NCD pertaining to Relizorb through its unreasonably low reimbursement payment for the device. *See* Compl. ¶ 3; Pls.' Opp'n at 17–22. As to Plaintiff Alcresta, however, this position is facially untenable on standing grounds. Section 1395ff(f)(5) makes clear that "[a]n action under [§ 1395ff(f)(3)] seeking review of a national coverage determination . . . may be initiated only by individuals entitled to benefits under part A, or enrolled under part B, or both, who are in need of the items or services that are the subject of the coverage determination." 42 U.S.C. § 1395ff(f)(5). Alcresta, however, is the manufacturer of Relizorb, *see* Compl. ¶ 6, and therefore does not have standing as a beneficiary to challenge an NCD under § 1395ff(f)(3), *see Hays*, 583 F. Supp. 2d at 67. The plain language of § 1395ff(f)(5) limiting expedited judicial review of NCDs to Medicare beneficiaries must control. *See Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 349 (1984) (holding that specific Congressional language overrides the presumption favoring judicial review). As such, Alcresta cannot rely upon § 1395ff(f)(3) as a basis for subject-matter jurisdiction in this case.

Mr. Henry, however, is a Medicare beneficiary and, therefore, does have standing to challenge an NCD under § 1395ff(f)(3). *See* Compl. ¶ 5. Unfortunately, Mr. Henry encounters another problem: he has not challenged an NCD. As noted above, an NCD is "a determination by the Secretary with respect to whether or not a particular item or service is covered nationally" by Medicare. 42 U.S.C. § 1395ff(f)(1)(B); *see also* Pls.' Mot. at 2. In 1984, for example, the Secretary adopted an NCD for "Enteral and Parenteral Nutritional Therapy," stating that: "Enteral nutrition is considered reasonable and necessary for a patient with a functioning gastrointestinal tract who, due to pathology to, or non-function of, the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general

condition." *See* National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (180.2) (July 11, 1984). Pursuant to that 1984 NCD, Medicare now covers enteral nutritional therapy, as well as related supplies and equipment, such as Relizorb. *See* Gov't Mot. at 4; Pls.' Mot. at 24.

Mr. Henry now argues that the Medicare contractor's underpayment for his Relizorb cartridges effectively "amended" the existing NCD coverage for Relizorb. *See* Pls.' Opp'n at 17–22. Mr. Henry's argument on this point, while novel, is not without merit. In October 2019, Mr. Henry's Medicare supplier submitted a reimbursement claim for 60 cartridges of Relizorb provided to Mr. Henry for his medical use. *See* Compl. ¶ 54. The Medicare supplier sought reimbursement for this Relizorb at a rate of $164.97 per cartridge. *See id.* The Medicare contractor, however, approved a reimbursement of only $33.75 per cartridge of Relizorb. *See id.* ¶ 55. On this point, Plaintiffs allege that the reimbursement rate of $33.75 per cartridge is *below* even the supplier's own acquisition cost for Relizorb, *see id.* ¶ 68, and that "[b]y reimbursing Relizorb below the supplier's cost of acquiring the product, the agency creates an unsustainable revenue loss for Medicare suppliers that effectively removes Relizorb as a covered item for Medicare beneficiaries," Pls.' Opp'n at 6.

On its face, Mr. Henry's theory of an effective NCD "amendment" rests on sound logic. A Medicare reimbursement rate set below the supplier's own cost of acquisition forces that supplier to transact at a loss. In this way, a Medicare reimbursement rate set below acquisition cost could suffocate the market for Medicare suppliers of a given drug or medical device. There are no clear incentives for a Medicare supplier to sell such a product at a price lower than his own rate of purchase. Under these conditions, one would eventually expect all Medicare suppliers to

discontinue the sale of that product which, by definition, would be unprofitable. This is the gravamen of Mr. Henry's effective NCD amendment theory. *See* Pls.' Opp'n at 6.

Unfortunately, Mr. Henry's theory runs headlong into the plain language of the Medicare Act. In defining an NCD, § 1395ff(f)(1)(B) expressly states that an NCD "*does not include . . . a determination with respect to the amount of payment* made for a particular item or service so covered." 42 U.S.C. § 1395ff(f)(1)(B) (emphasis added). Yet, Mr. Henry's claims in this case clearly arise from a dispute over "a determination with respect to the amount of payment made" for his Relizorb cartridges. *Id.* Mr. Henry sought a reimbursement in the amount of $164.97 per cartridge of Relizorb, *see* Compl. ¶ 54, but the Medicare contractor determined that Medicare would only cover $33.75 per cartridge, *see id.* ¶ 55. Mr. Henry now disputes the amount of that payment determination. Congress expressly excluded such "amount of payment" disputes from the definition of an NCD and did not create any exceptions for this rule. 42 U.S.C. § 1395ff(f)(1)(B). Instead, the Medicare Act provides an alternative channel for beneficiaries to raise payment claims when dissatisfied with the amount of a Medicare reimbursement. *See, e.g.*, 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.904(a)(2). While the Court is sympathetic to the functional argument Mr. Henry presents, *see* Pls.' Opp'n at 18 (citing *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1812 (2019)), it must adhere to this plain language in the Medicare Act, *see Block*, 467 U.S. at 349. For these reasons, the Court concludes that Mr. Henry has not challenged an NCD in this case and, therefore, may not seek judicial review under § 1395ff(f)(3).

C. Jurisdiction Under 28 U.S.C. § 1331

Plaintiffs also attempt to assert their Medicare claims under traditional federal question jurisdiction. *See* Compl. ¶ 3 (citing 28 U.S.C. § 1331). As a general matter, 42 U.S.C. § 405(h), as incorporated into the Medicare Act by 42 U.S.C. § 1395ii, "divests the district courts of federal question jurisdiction" for all Medicare claims. *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825 (D.C.

Cir. 2018). Instead, as described above, claimants must "channel" their Medicare claims through the Medicare Act itself, seeking judicial review only as provided therein. *See id.*; 42 U.S.C. § 1395ff(b)(1)(A). In this case, however, Plaintiffs attempt to circumvent the Medicare "channeling" rule by relying on a narrow exception addressed by the Supreme Court in *Illinois Council*. *See* Pls.' Opp'n at 10–17; *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986).

Under *Illinois Council*, parties may invoke traditional federal question jurisdiction for Medicare claims, "where [the] application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Ill. Council*, 529 U.S. at 19. This *Illinois Council* exception "applies not only when administrative regulations foreclose judicial review, but also when roadblocks practically cut off any avenue to federal court." *Am. Chiropractic Ass'n v. Leavitt*, 431 F.3d 812, 816 (D.C. Cir. 2005). Nonetheless, a party seeking to invoke the *Illinois Council* exception must do more than merely show "that postponement of judicial review would mean added inconvenience or cost in an isolated, particular case." *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 708 (D.C. Cir. 2011). Rather, federal question jurisdiction for Medicare claims is appropriate only where the "difficulties [are] severe enough to render judicial review unavailable as a practical matter." *Am. Chiropractic Ass'n*, 431 F.3d at 816.

1. Alcresta

The Court first considers whether Plaintiff Alcresta may assert its Medicare claims under 28 U.S.C. § 1331, as permitted by *Illinois Council*. Here, the parties agree that Alcresta is the *manufacturer* of Relizorb and, therefore, does not have access to the administrative appeals process set forth in the Medicare Act. *See* Pls.' Opp'n at 14. The Court concurs with this assessment. Alcresta's present Medicare claims turn on Mr. Henry's payment claim regarding his Relizorb

supply in September 2019, *see* Compl. ¶¶ 82–111, but as the manufacturer of Relizorb, Alcresta was not a "party" to the initial determination on Mr. Henry's reimbursement claim, *see* 42 C.F.R. § 405.906; 42 U.S.C. § 1395ff(b)(1)(A). Consequently, Alcresta possesses "no direct means of channeling its claims through the agency before seeking judicial review under the Medicare Act." *Council for Urological Interests*, 668 F.3d at 707.

It does not inexorably follow, however, that Alcresta may now invoke federal question jurisdiction under *Illinois Council*. To the contrary, "the *Illinois Council* exception is not intended to allow section 1331 federal question jurisdiction in every case where section 405(h) would prevent a particular individual or entity from seeking judicial review." *Council for Urological Interests*, 668 F.3d at 711. Instead, the Medicare Act "channeling" requirement still applies so long as an "adequate proxy" could pursue the Medicare claim in question for Alcresta. *See id.* at 712; *Am. Chiropractic Ass'n*, 431 F.3d at 816. In identifying an "adequate proxy," the D.C. Circuit has considered whether a potential third party exists to assert the Medicare claim at issue and whether any "lack of incentive" or "misalignment of interests" would prevent that party from adequately pursuing the claim. *Council for Urological Interests*, 668 F.3d at 712. "In cases where the only entities able to invoke Medicare Act review are highly unlikely to do so, their unwillingness to pursue a Medicare Act claim poses a serious 'practical roadblock' to judicial review," sufficient to trigger the *Illinois Council* exception. *Id.*

The D.C. Circuit's decisions in *American Chiropractic* and *Council for Urological Interests* define the contours of the "adequate proxy" doctrine. In *American Chiropractic*, the D.C. Circuit considered a challenge by the American Chiropractic Association (the "Association") to a Medicare rule allowing HMOs to require that patients procure a referral from a non-chiropractor before seeking chiropractic services. *Am. Chiropractic Ass'n*, 431 F.3d at 814–15. The

Association opposed this chiropractor-referral rule, but it did not have access to an administrative channel to challenge the rule through the Medicare Act. *See id.* Nonetheless, the D.C. Circuit concluded that the Association could instead rely upon a beneficiary to challenge the rule through the Medicare Act. Specifically, a Medicare "beneficiary could receive chiropractic services without a referral, have his or her claim for benefits denied by his or her HMO, and then proceed through the administrative process." *Sensory Neurostimulation, Inc. v. Azar*, 977 F.3d 969, 983 (9th Cir. 2020) (citing *Am. Chiropractic Ass'n*, 431 F.3d at 816–17). The possibility of such review through the administrative channels of the Medicare Act was sufficiently plausible and rendered the *Illinois Council* exception inapplicable to the Association's claim. *See Am. Chiropractic Ass'n*, 431 F.3d at 816–18.

In *Council for Urological Interests*, the D.C. Circuit reached a different conclusion. There, the plaintiff-appellant was the Council for Urological Interests (the "Council"), a group of "physician-owned joint ventures formed to purchase specialized equipment for urologic laser surgery." 668 F.3d at 706. "These joint ventures typically operate[d] 'under arrangement' with hospitals," wherein "the urologist-owned venture provide[d] the laser equipment and related services, while the hospital provide[d] space for the procedure." *Id.* In turn, Medicare would "pay[] full 'technical fees' for [the] equipment and nonprofessional services" rendered by the joint-venture during a procedure, but would make those payments "only to hospitals." *Id.* Therefore, "in a typical joint venture arrangement, the hospital bill[ed] Medicare for the technical fee for each surgical procedure performed and then passe[d] on a pre-negotiated portion of that fee to the joint venture on a per-procedure basis." *Id.* In 2008, however, HHS promulgated new regulations providing that "urologists who have a financial interest in a joint venture may no longer refer patients to the venture for laser services, even if the services are provided under arrangement with

a hospital." *Id.* As such, the new 2008 HHS regulations governing patient referrals directly impacted the Council and its financial interests.

But like the Association in *American Chiropractic*, neither the Council nor its members had standing to raise an administrative challenge through the Medicare Act. *See id.* at 707, 714. In *Council for Urological Interests*, however, the D.C. Circuit found that the Council could instead resort to federal question jurisdiction under the *Illinois Council* exception. In reaching this conclusion, the D.C Circuit acknowledged that only *hospitals* could challenge the 2008 HHS regulations through the channeling provisions of the Medicare Act. *See id.* at 707. Yet, these hospitals had little incentive to do so. The hospitals "resented" physicians exercising control over the equipment used in medical procedures and viewed the new HHS regulations as an opportunity "to reassert control over the procurement of lasers and other urological medical equipment." *Id.* at 713. Moreover, "the regulations also allowed hospitals to purchase expensive laser equipment from urologist joint ventures at 'fire-sale prices.'" *Id.* Consequently, at the time of the appeal in *Council for Urological Interests*, "not one of the 5,795 hospitals in the United States ha[d] brought an administrative challenge to th[e] regulations" at issue. *Id.* Under these circumstances, the D.C. Circuit found that federal question jurisdiction under *Illinois Council* was appropriate: the Council could not pursue its own claim through the Medicare Act and the only parties that could do so had no interest in pursuing such a claim. *See id.* Without § 1331, the application of the Medicare Act's "channeling" requirement would have meant no judicial review at all of the 2008 HHS regulations.

In this case, Plaintiffs rely on *Council for Urological Interests* to argue that Alcresta qualifies for the *Illinois Council* exception. *See* Pls.' Opp'n at 15–17. The Court, however, disagrees. Here, there are Medicare beneficiaries using Relizorb who could challenge reimbursement rates for the medical device, in place of Alcresta. *See* 42 C.F.R. § 405.904(a)(2).

And importantly, the relationship between Alcresta and these Medicare beneficiaries is not structurally adverse, as was the unique relationship between the Council and its partner hospitals in *Council for Urological Interests*. Conversely, "Relizorb users can present and exhaust [payment] claims" through the Medicare Act, and, in doing so, "their interests align with those of Alcresta." *Alcresta Therapeutics, Inc. v. Azar*, 755 F. App'x 1, 7 (D.C. Cir. 2018) (Katsas, J., dissenting). In this very case, for example, Mr. Henry stands as a co-plaintiff with Alcresta challenging the adequacy of the payment determination for Relizorb as a Medicare beneficiary. *See* Compl. ¶ 53. Mr. Henry's presence in this case directly undercuts the argument that no party exists to raise a reimbursement challenge for Relizorb through the Medicare Act—Mr. Henry has already done just that. Consequently, Alcresta is more closely analogous to the chiropractic association in *American Chiropractic*, which could rely on Medicare beneficiaries to assert Medicare claims on its behalf and could not, therefore, circumvent the channeling requirements of the Medicare Act. *See Am. Chiropractic Ass'n*, 431 F.3d at 814–15. For these reasons, the Court concludes that the *Illinois Council* exception does not apply to Alcresta and, therefore, Alcresta may not assert its Medicare claims under 28 U.S.C. § 1331.

2. Mr. Henry

Finally, the Court considers whether Mr. Henry may rely upon the *Illinois Council* exception and bring his Medicare claims under 28 U.S.C. § 1331. For the reasons below, the Court concludes that the *Illinois Council* exception is also inapplicable to Mr. Henry. Consequently, he may not assert his Medicare claims under § 1331.

To begin, Mr. Henry did attempt to channel his Relizorb payment determination claim through the administrative appeals process. In October 2019, Mr. Henry received an initial payment determination for his Relizorb cartridges from a Medicare contractor. *See* Compl. ¶ 54.

Dissatisfied with that contractor's payment determination, Mr. Henry requested a "redetermination" from that same contractor. *See* Compl. ¶ 56; 42 U.S.C. § 1395ff(a)(3)(A). After receiving another negative result, Mr. Henry requested reconsideration of the contractor's decision by a qualified independent contractor ("QIC"). *See* Compl. ¶ 58. The QIC, however, dismissed this request for reconsideration on procedural grounds, concluding that under 42 C.F.R. § 405.926(c), the contractor's payment determination for Relizorb did not constitute an "initial determination" subject to appeal. *See* Compl. ¶ 58; AR at 69. Mr. Henry then appealed the QIC's dismissal order to an HHS ALJ, *see* Compl. ¶ 59, but on March 30, 2020, the ALJ upheld the QIC's determination that Mr. Henry's reimbursement claim was not an "initial determination" subject to review, *see* AR at 2–4.

At this point in the Medicare appeals process, an aggrieved beneficiary can generally appeal an adverse order from an ALJ to the Medicare Appeals Council, the final layer of agency review. *See* 42 C.F.R. § 405.1130. The Medicare Act would then permit judicial review of that final decision from the Medicare Appeals Council. *See id.*; 42 U.S.C. § 1395ff(b)(1)(A). Here, however, Mr. Henry argues that the ALJ's March 30, 2020 dismissal order precluded him from reaching the Medicare Appeals Council. Instead, he contends that under 42 C.F.R. § 405.1054(b), an ALJ's "dismissal of a request for review of a QIC dismissal of a request for reconsideration is binding and not subject to further review" by the Medicare Appeals Council. *See* Pls.' Opp'n at 12–14. On these grounds, Mr. Henry maintains that following the ALJ's March 30, 2020 dismissal order, *see* AR at 2, he had "no further avenue of administrative proceedings available" and his "only option to obtain further review of his claim was to bring an action before this court" under federal question jurisdiction, Pls.' Opp'n at 13.

On its face, the "binding" effect of the ALJ's March 30, 2020 dismissal order might seem like an adequate trigger for the *Illinois Council* exception permitting federal question jurisdiction. There are two complicating factors, however, that impede Mr. Henry's jurisdictional argument. First, the parties now *agree* that the ALJ's March 30, 2020 dismissal order was erroneous. Citing to 42 C.F.R. § 405.924(b)(11), the Secretary concedes in his briefs before the Court that Mr. Henry did, in fact, "receive[] an initial determination on a specific Medicare claim," and that "the agency adjudicators improperly dismissed [his] administrative appeal" under 42 C.F.R. § 405.926(c). Gov't Mot. at 22, 24.

This *post hoc* admission of error from the government creates something of a legal conundrum. As described above, Mr. Henry claims that federal question jurisdiction is necessary because the ALJ's March 30, 2020 procedural dismissal precluded him from obtaining a final agency action that could have triggered judicial review through the Medicare Act. *See* 42 C.F.R. § 405.1054(b). But now, the parties before the Court agree that this should not have been the case. Instead, the parties agree that Mr. Henry did receive an "initial determination" on his Relizorb payment claim, properly subject to administrative appeals and ultimately judicial review through the Medicare Act following a final agency decision by the Secretary. *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.904(a)(2). Unsurprisingly, Mr. Henry provides no authority demonstrating the applicability of *Illinois Council* in a case where the "roadblock" to an otherwise accessible administrative channel through the Medicare Act was an agency decision that all parties agree was erroneous.

There is also a second factor that impacts Mr. Henry's jurisdictional argument. Mr. Henry argues that the ALJ's March 30, 2020 dismissal order left him "[w]ith no further avenue of administrative proceedings available," such that his "only option to obtain further review of his

claim was to bring an action before this court" under § 1331. Pls.' Opp'n at 13. But upon a closer review of the administrative record, this is not clearly the case. In her March 30, 2020 order, the ALJ dismissed Mr. Henry's "request for review of a QIC dismissal of a request for reconsideration." 42 C.F.R. § 405.1054(b); *see also* AR at 4. Under § 405.1054(b) of the Medicare regulations, such an order "is binding and not subject to further review *unless it is vacated by the ALJ or attorney adjudicator under § 405.1052(e).*" 42 C.F.R. § 405.1054(b) (emphasis added). To that end, the agency notified Mr. Henry on March 30, 2020, that he could request vacatur from the ALJ, and if "good and sufficient cause is established, the adjudicator may vacate the dismissal." AR at 2. Mr. Henry does not address whether he requested that the ALJ vacate her March 30, 2020 order, and there is nothing in the administrative record to suggest that he ever availed himself of this option.

Considering these unique factors, the Court does not find the Medicare Act's channeling requirement "would result in 'complete preclusion of judicial review'" for Mr. Henry's Relizorb payment claim. *Calif. Clinical Lab. Ass'n v. Sec'y of Health & Human Servs.*, 104 F. Supp. 3d 66, 81 (D.D.C. 2015) (Jackson, J.) (quoting *Illinois Council*, 529 U.S. at23). First, Mr. Henry now has an administrative channel through which he may challenge the agency's reimbursement determination for Relizorb. *See* 42 U.S.C. § 1395ff(b)(1)(A); 42 C.F.R. § 405.904(a)(2). As a Medicare beneficiary, Mr. Henry can challenge the Relizorb coverage determination up to the Medicare Appeals Council and then "seek[] judicial review under section 1395ff(b)(1)(A) after the Secretary has rendered a final decision with respect to the initial coverage determination." *Calif. Clinical Lab. Ass'n,* 104 F. Supp. 3d at 81. The practical roadblock that previously stalled this administrative channel was an erroneous determination from an HHS ALJ that the Relizorb payment determination that Mr. Henry challenged was not an "initial determination" subject to

further appeal under the Medicare Act. *See* AR at 4. The Secretary now acknowledges, however, that Mr. Henry's Relizorb coverage claim does, in fact, challenge an "initial determination" from the agency and, therefore, may proceed through the administrative appeals process. *See* Gov't Mot. at 22 (citing 42 C.F.R. § 405.926). While the administrative errors in Mr. Henry's case have caused unfortunate delay, such added "inconvenience or cost in an isolated, particular case" does not trigger the *Illinois Council* exception, particularly where the Secretary concedes that the payment claim in question can be channeled through the Medicare Act. *Council for Urological Interests*, 668 F.3d at 708.[2]

Furthermore, the Court disagrees with Mr. Henry's assertion that following the ALJ's March 30, 2020 dismissal order, he had "no further avenue of administrative proceedings available" and his "only option to obtain further review of his claim was to bring an action before this court" under § 1331. Pls.' Opp'n at 13. To support this proposition, Mr. Henry relies on 42 C.F.R. § 405.1054(b), which provides that such an ALJ order "is binding and not subject to further review." *See* Pls.' Opp'n at 13. But, as explained above, § 405.1054(b) goes on to state that such an administrative order "is binding and not subject to further review *unless it is vacated by the ALJ or attorney adjudicator under § 405.1052(e)*." 42 C.F.R. § 405.1054(b)(emphasis added). Mr. Henry does not address this administrative provision for vacatur, but the Court finds it relevant to his jurisdictional argument under *Illinois Council*.

The administrative record does not show that Mr. Henry ever requested vacatur of the March 30, 2020 dismissal order, even though the agency notified Mr. Henry that he could "request that the adjudicator who issued the dismissal vacate the dismissal by sending a letter explaining

[2] Going forward, the Court anticipates that agency adjudicators will adhere to the Secretary's concession in this case that the payment determination made for Mr. Henry's Relizorb cartridges was an "initial determination" subject to further agency appeal. *See* Gov't Mot. at 22 (citing 42 C.F.R. § 405.926).

why . . . the dismissal should be vacated." AR at 2. Moreover, the Medicare regulations permit an ALJ to "vacate his or her dismissal of a request for hearing or review within 180 calendar days of the date of the notice of dismissal" if "good and sufficient cause is established." 42 C.F.R. § 405.1052(e). It is significant that Mr. Henry did not avail himself of the opportunity to vacate the ALJ's March 30, 2020 order. The parties now agree that the ALJ's order was erroneous. *See* Gov't Mot. at 22. If Mr. Henry had established "good and sufficient cause" for the ALJ to vacate that erroneous order during his administrative appeal, Mr. Henry would not have been bound by 42 C.F.R. § 405.1054(b), as he now claims. Instead of resorting to § 1331 for jurisdiction, Mr. Henry could have continued to pursue his Relizorb payment claim through a final decision by the Medicare Appeals Council, ultimately subject to judicial review under the Medicare Act itself. *See* 42 U.S.C. § 1395ff(b)(1)(A); Pls.' Opp'n at 11. Mr. Henry's failure to pursue this administrative channel places his case even further outside the contours of the *Illinois Council* exception.

For these reasons, the Court concludes that the *Illinois Council* exception does not apply to Mr. Henry's Medicare claims challenging the agency's payment determination for Relizorb. Consequently, Mr. Henry may not pursue those claims under traditional federal question jurisdiction. *See* 28 U.S.C. § 1331; *Am. Hosp. Ass'n*, 895 F.3d at 825.

IV. CONCLUSION

For the reasons set forth in this Memorandum Opinion, the Court concludes that it lacks subject-matter jurisdiction over Plaintiffs' Medicare claims. Accordingly, it will **GRANT** the Secretary's motion and **DISMISS** Plaintiffs' claims **WITHOUT PREJUDICE**. Because this Court lack's subject-matter jurisdiction, it will also **DENY** Plaintiffs' motion for summary judgment **WITHOUT PREJUDICE**.

An appropriate Order accompanies this Memorandum Opinion.

Dated: February 8, 2021

/s/
COLLEEN KOLLAR-KOTELLY
United States District Judge