UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

INOGEN, INC., *Plaintiff*, v. XAVIER BECERRA, Secretary of Health and Human Services, et al., *Defendants*.	Civil Action No. 1:20-cv-02675 (CJN)

MEMORANDUM OPINION

Inogen, Inc., challenges the Department of Health and Human Services's decision to retract a billing code for its medical device. *See generally* Compl., ECF No. 8. Pending before the Court are Inogen's Motion for a Preliminary Injunction, ECF No. 20, and Defendants' Motion to Dismiss, ECF No. 29. Because the Medicare Act forecloses judicial review of Inogen's claims at this time, the Court must dismiss this action.

I. Background

Inogen manufactures durable medical equipment for long-term, at-home patient use. Compl. ¶¶ 9–10. One of its products is the Sidekick Tidal Assist Ventilator ("Sidekick"), a device that helps deliver oxygen to patients needing respiratory assistance. *Id.* ¶ 11. Inogen's claims relate to the Healthcare Common Procedure Coding System ("HCPCS") code assigned to the Sidekick. *Id.* ¶¶ 15, 29–30.

Medicare Part B beneficiaries may purchase or rent durable medical equipment using their Part B benefits. Pl.'s Mem. Supp. Appl. for Prelim. Inj. at 8 ("Pl.'s Prelim. Inj."), ECF No. 21 (citing 42 U.S.C. § 1395m *et seq.*). The HCPCS coding system categories medical items, including

durable medical equipment, for billing purposes. *Id.* at 1. A product's HCPCS code largely determines whether (and to what extent) private and public insurers will reimburse a supplier of such equipment. Compl. ¶¶ 17, 26.

The Centers for Medicare & Medicaid Services ("CMS") is the HHS component responsible for administering the Medicare program and oversees the HCPCS coding system. Suppliers of durable medical equipment may seek an HCPCS code assignment for their products in two ways: they may file applications to assign, modify, add, or delete HCPCS codes with an entity called the CMS Workgroup, which conducts a HCPCS coding review on a biannual cycle, Defs.' Mem. Supp. Mot. to Dismiss and Opp'n to Pl.'s Mot. for Prelim. Inj. at 2 ("Defs.' Mot."), ECF No. 31-1; or they may request that a Pricing, Data Analysis, and Coding ("PDAC") contractor assign an already-existing code to their product, Pl.'s Prelim. Inj. at 8; Defs.' Mot. at 3. If a supplier is dissatisfied with the PDAC contractor's determination, it may file a reconsideration request with the PDAC contractor or a request for evaluation during the CMS Workgroup's biannual coding review. Defs.' Mot. at 3.

In August 2019, Inogen submitted a Code Verification Request to confirm that it could bill the Sidekick as a noninvasive ventilator (code E0466). Compl. ¶ 36. Palmetto—the PDAC contractor involved in this case—initially verified the Sidekick for that code. *Id.* ¶ 36. But Palmetto retracted that determination two weeks later because, in its view, the Sidekick "does not have the full range of controls and gas delivery that would allow it to be accurately classified as a ventilator." Compl. Ex. E at 3, ECF No. 8-5. Palmetto determined that the Sidekick should instead be classified as an oxygen accessory (code E1352) and oxygen concentrator (code E1390). *Id.* at 2. Inogen submitted a reconsideration request on October 18, which Palmetto denied on January

16, 2020. Pl.'s Opp'n to Defs.' Mot. and Reply to Defs.' Opp'n to Pl.'s Mot. for Prelim. Inj. at 4 ("Pl.'s Reply"), ECF No. 32; Compl. ¶ 43. Palmetto's denial stated:

> Upon discussion with [CMS], it was concluded that the decision made by CMS stands and that your product would stay as E1352 and E1390. We do not have the authority to change this decision. To change your coding assignment you would need to submit to the CMS [HCPCS] Workgroup and request a change with relevant rationale. As you sent a request to us end-dating your product. No updates will be made to our Product Classification List (PCL).

Compl. Ex. F, ECF No. 8-6.

Inogen also employed other strategies in an attempt to persuade CMS to change the Sidekick's HCPCS code. On September 20, 2019—one week after Palmetto's retraction but before the reconsideration denial—Inogen sent a letter to the CMS Administrator. Pl.'s Reply at 4. Inogen also met with an HHS/CMS attorney and had its congressional representative send a letter to the Administrator. *Id.* at 5. None of these communications resulted in a coding reassignment. *Id.* at 9–10. Inogen never applied to the HCPCS Workgroup for a new code or code modification. *Id.*

Inogen filed this suit on September 21, 2020, *see generally* Compl., asserting violations of the Administrative Procedure Act, 5 U.S.C. § 706(2), the Medicare Act, 42 U.S.C. § 1395hh(a)(2), and its due process rights, and seeking an order of mandamus establishing procedural requirements for HCPCS code verification and review. Compl. ¶¶ 53–95. Shortly thereafter, it moved for a preliminary injunction, seeking to enjoin Defendants from retracting the E0466 code. Pl.'s Prelim. Inj. at 1. Defendants opposed and moved to dismiss for lack of subject matter jurisdiction. *See generally* Defs.' Mot.

II. Legal Standard

"Because Article III courts are courts of limited jurisdiction, we must examine our authority to hear a case before we can determine the merits." *Khadr v. United States*, 529 F.3d

1112, 1115 (D.C. Cir. 2008) (quoting *United States v. British Am. Tobacco Austl. Servs.*, 437 F.3d 1235, 1239 (D.C. Cir. 2006)). When contemplating a motion to dismiss pursuant to Rule 12(b)(1), the Court may consider materials outside the pleadings "to assure itself of its own subject matter jurisdiction," *Settles v. U.S. Parole Comm'n*, 429 F.3d 1098, 1107 (D.C. Cir. 2005) (quoting *Haase v. Sessions*, 835 F.2d 902, 908 (D.C. Cir. 1987)), and must construe the complaint liberally to afford all possible inferences favorable to the pleader on allegations of fact, *id.* at 1106. But the Court need not "assume the truth of legal conclusions" nor "accept inferences that are unsupported by the facts set out in the complaint." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 913 (D.C. Cir. 2015) (quoting *Arpaio v. Obama*, 797 F.3d 11, 19 (D.C. Cir. 2015)). In all events, the plaintiff bears the burden of establishing that the court has subject matter jurisdiction by a preponderance of the evidence. *Freedom Watch, Inc. v. McAleenan*, 442 F. Supp. 3d 180, 185 (D.D.C. 2020) (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992)).

III. Analysis

Three statutes govern the scheme for obtaining judicial review of Medicare claims. 42 U.S.C. § 405(h) bars federal question jurisdiction over "any claim arising under" Title II of the Social Security Act and prohibits judicial review of any "decision of the Commissioner of Social Security . . . except as herein provided." *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825 (D.C. Cir. 2018). 42 U.S.C. § 405(g), in turn, permits judicial review of Social Security Act claims following "any final decision of the Commissioner of Social Security made after a hearing to which he was a party." *Id.* And 42 U.S.C. § 1395ii provides that certain provisions in Section 405 "shall also apply with respect to [the Medicare Act] to the same extent as they are applicable with respect to" Title II, with any reference to the "Commissioner of Social Security" considered as a reference to the Secretary of HHS. *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 7–9 (2000);

Heckler v. Ringer, 466 U.S. 602, 614–15 (1984); *Nat'l Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1130–31 (D.C. Cir. 1992).[1] The Supreme Court has interpreted these provisions to impose two prerequisites for judicial review of a claim "arising under" the Medicare Act. First, "a claim for benefits shall have been presented to the Secretary." *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976). Second, "the plaintiff must fully exhaust all available administrative remedies, though this more demanding requirement is waivable." *Am. Hosp. Ass'n*, 895 F.3d at 826 (citing *Mathews*, 424 U.S. at 328).

As a result, the Medicare Act "demands the channeling of virtually all legal attacks through the agency." *Shalala*, 529 U.S. at 13 (quotation marks omitted). Channeling extends "beyond ordinary administrative law principles of ripeness and exhaustion of administrative remedies" in order to "assure[] the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts." *Id.* at 12–13 (quotation marks omitted).

There is one exception: judicial review is available "where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Shalala*, 529 U.S. at 19; *see also Am. Hosp. Ass'n*, 895 F.3d at 825 ("[F]ederal-question jurisdiction remains available where necessary to preserve an opportunity for judicial review."). This 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). But the "difficulties must be severe enough to render judicial review unavailable as a practical matter," *id.*; it is not enough to show "merely that postponement

[1] "Although § 1395ii does not specifically enumerate § 405(g) as one of the incorporated Title II provisions, these decisions treat it as such, presumably on the theory that expressly incorporating the judicial-review bar in § 405(h) also effectively incorporates the exception 'herein provided' in § 405(g)." *Am. Hosp. Ass'n*, 895 F.3d at 825 (quoting *United States v. Blue Cross & Blue Shield of Ala., Inc.*, 156 F.3d 1098, 1103 (11th Cir. 1998)).

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) (quotation marks, brackets, and citation omitted).

Defendants argue that Inogen's claims "arise under" the Medicare Act and that Inogen is required (but has failed) to present its claims through the agency. Defs.' Mot. at 10–24.

A. Inogen's Claims

The Court must first determine whether Inogen's claims "arise under" the Medicare Act, a question that turns on whether the Act provides both the standing and the substantive basis for Inogen's claims. *Your Home Visiting Nurse Servs., Inc. v. Shalala*, 525 U.S. 449, 456 (1999). Inogen does not dispute that its claims arise under the Medicare Act, Pl.'s Reply at 6–7, and for good reason. After all, Inogen's position is that CMS has improperly refused to assign it a billing code that would reimburse the Sidekick at Inogen's desired rate. *See generally* Compl. As for relief, Inogen asks the Court to (1) invalidate the PDAC's retraction of its initial code determination; (2) order Defendants to assign the Sidekick code E0466 (thereby increasing the level at which Medicare would reimburse Inogen); and (3) require Defendants to develop guidelines governing HCPCS code verification. *Id.* ¶ 69. And all of the harms alleged in Inogen's Motion for a Preliminary Injunction stem from the level of reimbursement Inogen receives for the Sidekick. *See* Pl.'s Prelim. Inj. at 33–36. There is no serious dispute that the Medicare Act provides the "standing and substantive basis" for Inogen's claims.

B. Availability of Review

Even though Inogen's claims arise under the Medicare Act, the Court would have jurisdiction if this action were the only way Inogen could seek judicial review. *Shalala*, 529 U.S. at 19. Inogen argues that is in fact the case; because its reconsideration request was denied, Inogen

argues, "there is no further appeal process or administrative review available . . . [n]or is there any mechanism for a reimbursement claim appeal to address the issues of HCPCS code assignment." Pl.'s Reply at 7.

This argument, however, misapprehends Inogen's options. As a Medicare-enrolled supplier, Inogen may submit a Part B benefit claim and, if unsatisfied with the decision on the claim, appeal the reimbursement determination or "[a]ny other initial determination with respect to a claim for benefits." 42 U.S.C. § 1395ff(a)–(b); 42 C.F.R. § 405.924(b)(11) (appealable initial determinations include contractor determinations with respect to "[a]ny other issue[] having a present or potential effect on the amount of benefits to be paid" under Part B). To start the review process, Inogen must request a "redetermination" of the initial decision by the same contractor that made the initial determination, 42 U.S.C. § 1395ff(a)(3); 42 C.F.R. §§ 405.904(a)(2), 405.940, and then seek "reconsideration" by a "qualified independent contractor," 42 U.S.C. § 1395ff(b)(1)(A), (c); 42 C.F.R. §§ 405.904(a)(2), 405.960. Assuming it disagrees with those decisions, Inogen may thereafter request a hearing before an administrative law judge, 42 U.S.C. §§ 1395ff(b)(1)(A)–(E), (d)(1); 42 C.F.R. §§ 405.1000–405.1058, and the ALJ's decision may be reviewed by the Medicare Appeals Council, 42 U.S.C. § 1395ff(d)(2); 42 C.F.R. §§ 405.1100–405.1140. At that point, Inogen may seek judicial review in an appropriate district court of the Council's decision (assuming a statutory amount-in-controversy requirement is met). 42 U.S.C. §§ 405(g), 1395ff(b)(1)(A), (E); 42 C.F.R. §§ 405.1130, 405.1136. Inogen therefore has a well-worn path to judicial review of the HCPCS coding assignment, *see, e.g.*, *Gentiva Healthcare Corp. v. Sebelius*, 723 F.3d 292, 294–95 (D.C. Cir. 2013); Section 405(h) thus applies and Inogen must pursue its claims through this process.

Inogen nevertheless argues that it has presented its claim because "officials at the highest levels of CMS reviewed Inogen's reconsideration request . . ., as well as Inogen's follow-up requests for re-coding, and rejected them all." Pl.'s Reply at 8. It contends that it "presented" its claim when it filed a reconsideration request with Palmetto, "sent an additional letter to CMS, had its [c]ongressional representative send a letter to [the] CMS Administrator . . ., and met [an] HHS/CMS attorney." *Id.* at 9.

But the fact that Inogen has made certain components of CMS aware of its dissatisfaction is not enough. The Court of Appeals has repeatedly required that determinations impacting the amount of benefits available to suppliers, including "methodology disputes[,] . . . [be] fed through the administrative-judicial system as parts of disputes over actual amounts." *Nat'l Kidney Patients Ass'n*, 958 F.2d at 1133–34. Inogen attempts to justify its failure to submit a reimbursement claim by arguing that such a claim would not include an opportunity to challenge the Sidekick's coding assignments, Pl.'s Reply at 7–8, that the "actual amount" requirement is outdated, *id.*, and that it cannot submit a claim for reimbursement without facing potential liability under the False Claims Act, Pl.'s Prelim. Inj. at 15. But Inogen is wrong on all counts. As previously discussed, there *is* an avenue for review of the coding decision in this case, and the Court of Appeals has been clear that parties must feed methodology challenges—such as challenges to coding assignments—through the administrative-judicial review system for disputes over actual amounts. *See, e.g.*, *Am. Hosp. Ass'n*, 895 F.3d at 826 (challenge to reimbursement regulation required specific administrative claim for payment); *Three Lower Cntys. Cmty. Health Servs, Inc. v. U.S. Dep't of Health & Human Servs.*, 317 Fed. App'x 1, 3 (D.C. Cir. 2009) ("The Medicare Act . . . requires that parties present all such challenges to the agency in the context of a fiscal year reimbursement claim."). And Inogen need not expose itself to False Claims Act liability to submit a claim for

reimbursement—it may submit its claim under the code currently assigned to the Sidekick and then raise its challenge to the code assignment on appeal. *See* 42 U.S.C. § 1395ff(a)(1)(C); 42 C.F.R. § 405.924(b)(11).

As for Inogen's arguments that it has already presented its challenge through other channels, such informal efforts cannot satisfy the presentment requirement. *Cf. Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 109 n.1 (D.D.C. 2015) (presentment not satisfied by plaintiffs' "comments to the agency and . . . meeting with agency officials to voice disagreement with [a particular] rule"); *Am. Orthotic & Prosthetic Ass'n, Inc.*, 62 F. Supp. 3d 114, 123 (D.D.C. 2014) ("Because [plaintiff's letters] were not tied to any concrete claims, [plaintiffs]'s self-described 'detailed critiques of the [agency action] . . . [were] insufficient to establish presentment.'"). Inogen's reconsideration request and informal communications are not enough; it must bring its challenge to the coding retraction as part of a claim for reimbursement.[2]

That is enough to end the matter, but the Court also notes that Inogen has failed to exhaust. In ordinary challenges to agency action, the exhaustion requirement "may be waived only in the most exceptional circumstances." *UDC Chairs Chapter, Am. Ass'n of Univ. Professors v. Bd. of Trs. of UDC*, 56 F.3d 1469, 1475 (D.C. Cir. 1995) (citation omitted). Courts often waive exhaustion upon a finding that agency review would be futile; but that requires certainty—not just

[2] Although the Parties do not discuss the decision in their briefs, the Court notes that the decision in *Alcresta Therapeutics, Inc. v. Azar*, 755 Fed. App'x 1 (D.C. Cir. 2018) (per curiam), does not require a different result. As an initial matter, *Alcresta* is an unpublished decision, and the majority opinion did not discuss the question here—whether the plaintiffs were required to pursue their claims through the agency rather than suing in district court. *See Ticor Title Ins. Co. v. FTC*, 814 F.2d 731, 749 (D.C. Cir. 1987) ("[I]t is well settled that cases in which jurisdiction is assumed *sub silentio* are not binding authority for the proposition that jurisdiction exists." (citing *Pennhurst State Sch. & Hosp. v. Halderman*, 465 U.S. 89, 119 (1984))). Moreover, the manufacturer plaintiffs in that case could not bring a reimbursement claim themselves, *see id.* at 5; the "encumbered" HCPCS code in that case acted as "an absolute barrier to meaningful reimbursement," *id.;* and the plaintiffs *had* presented their coding challenge in the form of an application to the Workgroup, *id.* at 2. Inogen, in contrast, remains free to submit a claim for reimbursement and raise the coding assignment issue through the process discussed *supra*, and it also has not applied to the Workgroup for relief.

a probability—that the agency will deny the claim. *Id.* The bar is higher here, where "§ 405(h) reaches beyond ordinary administrative law principles [such as] exhaustion of administrative remedies" and "demands the channeling of virtually all legal attacks through the agency." *Shalala,* 529 U.S. at 12–13 (citations omitted); *see also Tataranowicz v. Sullivan,* 959 F.2d 268, 274 (D.C. Cir. 1992) (noting that the Act's requirement of a final decision is "more than simply a codification of the judicially developed doctrine of exhaustion, and may not be dispensed with merely by a judicial conclusion of futility" (citation omitted)).

Inogen has failed to avail itself of two clear avenues for relief: the reimbursement claim appeals process discussed above, as well as an application to the Workgroup. Inogen's informal communications with CMS can hardly constitute exhaustion (or demonstrate futility) with respect to the comprehensive administrative-judicial review scheme available through reimbursement claims.[3] And the relief sought here by Inogen—invalidation of the code retraction and assignment of a different code—could be provided by the Workgroup through a modification of code E0466 such that the code, as modified, would be assigned to the Sidekick. Inogen has not pursued either administrative process nor has it demonstrated any "exceptional circumstances" justifying waiver of the exhaustion requirement.

C. Mandamus Jurisdiction

Inogen also argues that the Court may exercise mandamus jurisdiction.[4] The Court of Appeals has held that Section 405(h) does not preclude mandamus jurisdiction. *Monmouth Med.*

[3] Inogen argues that appealing a reimbursement claim would be futile because ALJs do not have the authority to review Medicare Administrative Contractor's coding determinations. Pl.'s Reply at 11–12. But even if Inogen is correct in asserting that an ALJ could not review the contractor's code determination—a question the Court declines to answer at this time—the ALJ's authority has no bearing on the fact that Inogen has an opportunity for the relief it seeks in the steps before ALJ review (i.e., during the Medicare Administrative Contractor's redetermination of a reimbursement claim or on reconsideration by a qualified independent contractor). *See* 42 U.S.C. § 1395ff(b)(1)(A) & (c); 42 C.F.R. §§ 405.940, 405.960.

[4] Contrary to Inogen's arguments, *see* Compl. ¶¶ 6–7, neither the APA nor the Declaratory Judgment Act provides an independent basis for jurisdiction. *See Califano v. Sanders*, 430 U.S. 99, 107 (1977); *Colo. Heart Inst., LLC v.*

Ctr. v. Thompson, 257 F.3d 807, 813 (D.C. Cir. 2001). But mandamus relief is only available when "(1) the plaintiff has a clear right to relief; (2) the defendant has a clear duty to act; and (3) there is no other adequate remedy available to [the] plaintiff." *Power v. Barnhart*, 292 F.3d 781, 784 (D.C. Cir. 2002) (citation omitted). The party seeking mandamus must establish each element for relief, *see In re Cheney*, 406 F.3d 723, 729 (D.C. Cir. 2005) (en banc) ("[T]hose invoking the court's mandamus jurisdiction must have a clear and indisputable right to relief." (quotation marks omitted)), and "mandamus will issue only where the duty to be performed is ministerial and the obligation to act peremptory, and clearly defined," *13th Reg'l Corp. v. U.S. Dep't of Interior*, 654 F.2d 758, 760 (D.C. Cir. 1980) (quoting *United States ex rel. McLennan v. Wilbur*, 283 U.S. 414, 420 (1931)). "The law must not only authorize the demanded action, but require it; the duty must be clear and indisputable." *Id.* Even then, "a court may grant relief only when it finds 'compelling . . . equitable grounds.'" *In re Medicare Reimbursement Litig.*, 414 F.3d 7, 10 (D.C. Cir. 2005) (quoting *13th Reg'l Corp.*, 654 F.2d at 760).

Inogen argues that Defendants owe durable medical equipment manufacturers duties (1) "to submit proposed rules to be considered by the interested public for comments;" (2) to provide notice and comment opportunity prior to "changing policies affecting HCPCS code verification procedures and definitions;" and (3) to "afford DME manufacturers due process when retracting previously verified HCPCS codes." Pl.'s Prelim. Inj. at 32 (citing 5 U.S.C. § 553(b); 42 U.S.C. § 1395hh(a)). But there is no clear policy change at issue here; Inogen's challenge is to a coding determination, not a rule or policy. And, perhaps most tellingly, Inogen does not point to

Johnson, 609 F. Supp. 2d. 30, 34 (D.D.C. 2009) (APA does not provide independent basis for jurisdiction in action brought under Medicare Act.); *Lovitky v. Trump*, 918 F.3d 160, 161 (D.C. Cir. 2019) (Declaratory Judgment Act is not an independent source of federal jurisdiction.).

any law or regulation imposing any of these claimed duties. *See id.* at 32–33. Inogen therefore falls far short of establishing that mandamus relief is appropriate.

IV. Conclusion

Inogen's challenge to the Sidekick's HCPCS code arises under the Medicare Act and it was required to present its claim to the agency and exhaust its administrative remedies, which it has failed to do. Inogen also has failed to demonstrate that mandamus relief is warranted. The Court therefore denies Inogen's Motion for a Preliminary Injunction and dismisses the Complaint. An Order will be entered contemporaneously with this Memorandum Opinion.

DATE: June 17, 2021

CARL J. NICHOLS
United States District Judge