UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

ROW 1 INC., D/B/A REGENATIVE LABS,	)	
Plaintiff,	)	
v.	)	
	)	**Case No. 22-cv-0718 (APM)**
XAVIER BECERRA, *et al.*, *Secretary of Health and Human Services*,	)	
Defendants.	)	

MEMORANDUM OPINION

I.

This action raises many of the same background facts as *StimLabs, LLC. v. Becerra*, 22-cv-1988 (APM), a case recently resolved by this court. The court does not repeat those facts here but simply incorporates them by reference and recites only the additional allegations specific to this case.

Plaintiff Row 1 Inc. d/b/a/ Regenative Labs ("Regenative") is a company that manufactures, markets, and distributes medical products containing human cells, tissues, or cellular or tissue-based products ("HCT/Ps"). As relevant here, Regenative distributes two products, Coretext and Protext, which consist of minimally manipulated Wharton's Jelly tissue—a connective tissue found in the umbilical cord. Regenative brings this action to challenge policies that allegedly bar reimbursement for use of Coretext and Protext under the Medicare program. Just as the plaintiffs did in *StimLabs*, Plaintiff here alleges that the Secretary of Health and Human Services (the "Secretary") unlawfully bypassed the notice-and-comment rulemaking requirement for policies that change a substantive legal standard governing Medicare coverage and payment,

and that the Secretary's decision to stop covering Coretext and Protext is arbitrary and capricious under the Administrative Procedure Act.

Plaintiff brings claims against the Secretary in his official capacity, the Department of Health and Human Services, the Administrator of the Center for Medicare and Medicaid Services ("CMS") in her official capacity, CMS, and several Medicare Administrative Contractors[1] ("MACs") (together, "Defendants"). Before the court is Defendants' motion to dismiss. *See* Defs.' Mot. to Dismiss, ECF No. 23 [hereinafter Defs.' Mot.]. The court concludes that, because Plaintiff failed to exhaust administrative remedies before filing suit, the court lacks subject matter jurisdiction over this action. Accordingly, Defendants' motion to dismiss is granted.

II.

Federal Question Jurisdiction. As in *StimLabs,* the "primary jurisdictional dispute centers on whether the court lacks general federal question jurisdiction to hear this action." *StimLabs, LLC., v. Becerra*, No. 22-cv-01988-APM, 2022 WL 13840218, at *4 (D.D.C. Oct. 21, 2022); Memorandum Opinion and Order, *StimLabs, LLC., v. Becerra*, No. 22-cv-01988-APM (D.D.C.), ECF No. 32. Section 405(h), a Social Security Act provision incorporated into the Medicare Act, "channels most, if not all, Medicare claims through [the agency] review system." *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 8 (2000). Generally speaking, only after exhausting agency review procedures can claimants "seek judicial review [in federal court] pursuant to the Medicare Act." *Council for Urological Interests v. Sebelius*, 668 F.3d 704, 706 (D.C. Cir. 2011). In *Illinois Council*, the Court recognized an exception to the channeling requirement in cases "where application of § 405(h) would not simply channel review through the agency, but would

[1] Plaintiff brings claims against the following MACs: Noridian Healthcare Solutions, LLC., Wisconsin Physicians Service Insurance Corporation, Novitas Solutions, Inc., National Government Services Inc., CGS Administrators, LLC., Palmetto GBA, LLC., and First Coast Service Options Inc.

mean *no review at all*." *Ill. Council*, 529 U.S. at 19 (emphasis added). In other words, for claims arising under the Medicare Act, if the channeling requirement leads to a "*complete* preclusion of judicial review," a party need not present and exhaust its claims before coming to federal court. *Id.* at 23. The *Illinois Council* exception is a narrow one—it 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*, 668 F.3d at 711.

Courts conduct a "three-step analysis" when determining "whether a court has subject matter jurisdiction to hear a claim related to Medicare." *Sensory Neurostimulation, Inc. v. Azar*, 977 F.3d 969, 976 (9th Cir. 2020). First, the court must determine whether the claim "arises under" the Medicare Act. *Id.* If it does, the court next "must decide whether the plaintiff has satisfied the channeling requirements by properly presenting the claim and exhausting the appropriate administrative channel." *Id.* Finally, if plaintiff has not satisfied the channeling requirement, the court must inquire whether the "no review at all" exception applies. *Id.* "If it [does], the plaintiff may proceed in court under 28 U.S.C. § 1331 or some other jurisdictional predicate. If not, the plaintiff's claim cannot proceed and must be dismissed for lack of subject matter jurisdiction." *Id.*

Plaintiff here concedes that it has not satisfied the second step of the analysis—the channeling requirement. It nevertheless contends that the court has subject matter jurisdiction because it prevails at the first and third steps of the analysis. The court disagrees.

A.

Plaintiff first contends that its claim does not "arise under" § 405(h), rendering the channeling requirement inapplicable. According to Plaintiff, its "claims for relief here are purely procedural and are not within the scope of Section 405(h)." Pl.'s Opp'n to Defs.' Mot., ECF No. 25 [hereinafter Pl.'s Opp'n], at 13. Plaintiff continues, its "cause of action is not to recover

unpaid Medicare claims; rather it challenges CMS's failure to follow required rulemaking procedures and CMS's actions in excess of its statutory authority in improperly adopting policies." *Id.*

The Supreme Court in *Illinois Council* expressly rejected the distinctions Plaintiff makes here to avoid the channeling requirement. The Court observed that § 405(h)'s channeling requirement "assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts applying 'ripeness' and 'exhaustion' exceptions case by case. But this assurance comes at a price, namely, occasional individual, delay-related hardship." *Ill. Council*, 529 U.S. at 13. It further stated that the channeling requirement does not vary based on how a claim is characterized: "distinction[s] that limit[] the scope of § 405(h)" "based upon the 'potential future' versus 'actual present' nature of the claim, the 'general legal' versus the 'fact-specific' nature of the challenge, the 'collateral' versus the 'noncollateral' nature of the issues, or the 'declaratory' versus 'injunctive' nature of the relief sought" cannot be sustained. *Id.* at 13–14. Nor would the Court "accept a distinction that limits the scope of § 405(h) to claims for monetary benefits." *Id.* at 14.

> Claims for money, claims for other benefits, claims of program eligibility, and claims that contest a sanction or remedy may all similarly rest upon individual fact-related circumstances, may all similarly dispute agency policy determinations, or may all similarly involve the application, interpretation, or constitutionality of interrelated regulations or statutory provisions. There is no reason to distinguish among them in terms of the language or in terms of the purposes of § 405(h).

Id.; *see also Heckler v. Ringer*, 466 U.S. 602, 614–15 (1984) ("Thus, to be true to the language of the statute, the inquiry in determining whether § 405(h) bars federal-question jurisdiction must be whether the claim 'arises under' the Act, not whether it lends itself to a 'substantive' rather than a 'procedural' label."). Accordingly, just as the court held in *StimLabs*, the fact that Plaintiff "is

unable to assert a claim directly, is challenging a policy and not an individual claim, and is seeking only procedural relief does not excuse it from the channeling requirement." 2022 WL 13840218, at *5.

Plaintiff's citation to *American Clinical Laboratory Association v. Azar*, 931 F.3d 1195, 1206 (D.C. Cir. 2019), is perplexing. *See* Pl.'s Opp'n at 13. That case concerned a jurisdiction-stripping provision under a different statute altogether—the Protecting Access to Medicare Act—that eliminated administrative and judicial review of "establishment of payment amounts" for reimbursement rates of laboratory tests, 42 U.S.C. § 1395m-1(h)(1). *American Clinical* has nothing to do with understanding the scope of § 405(h).

B.

The court now turns to Plaintiff's contention at the third step that they are not required to satisfy the channeling requirement because the "no review at all" exception applies. *See* Pl.'s Opp'n at 15 ("Regenative is a manufacturer and not subject to these channeling requirements."). Plaintiff does not fall within the exception.

For the "no review at all" exception to apply, it is not enough for a plaintiff to claim it cannot itself file a claim. A plaintiff "must show that there is not an 'adequate proxy' that could raise claims on its behalf." *StimLabs*, 2022 WL 13840218, at *5. Plaintiff argues that "there is no adequate proxy for Regenative" because "MACs now require providers to submit impossible-to-obtain documentation" when submitting claims for Coretext or Protext, and that "it is impossible for providers to [submit reimbursement claims], as the required documentation does not exist and is not required under Section 361," "which does not require FDA Approval or a Clearance Letter." Pl.'s Opp'n at 16 (internal quotation marks omitted).

Plaintiff's argument misses the point. Even if Medicare approval of its products now requires "impossible-to-obtain documentation," the proper inquiry is not whether the Secretary has established insuperable requirements to secure reimbursement. Rather, it is whether a potential proxy is "highly unlikely" to pursue administrative review to challenge those requirements, thereby creating a "'practical roadblock' to judicial review." *Council for Urological*, 668 F.3d at 712. Plaintiff does not meet this high bar.

Plaintiff has not, for example, pleaded or produced facts showing that there are no existing providers of its products that have pending claims before CMS. *See RICU LLC v. U.S. Dep't of Health & Hum. Servs.*, 22 F.4th 1031, 1038–39 (D.C. Cir. 2022) (holding that the "client hospitals" of a telehealth medicine company were an adequate proxy to seek reimbursement for incurred physicians' costs). In *StimLabs*, for instance, there were providers whose incentives aligned with the plaintiff-manufacturer that could assert the very challenge that Plaintiff brings here to the alleged unwritten denial policy. 2022 WL 13840218, at *5. Plaintiff has not shown that similarly situated providers with respect to its products do not exist. Nor has Plaintiff established that it has attempted but cannot secure a provider to designate them as a "appointed representative" under 42 C.F.R. § 405.910 (2019) to pursue administrative review of a claim. That regulation provides: "An appointed representative may act on behalf of an individual or entity in exercising his or her right to an initial determination or appeal. Appointed representatives do not have party status and may take action only on behalf of the individual or entity that they represent." Because Plaintiff has not shown that adequate proxies do not exist, the "no review at all" exception does not apply.[2]

[2] Plaintiff's opposition brief cites *Baxter Healthcare v. Weeks*, 643 F. Supp. 2d 111 (D.D.C. 2009), and *Akebia Therapeutics, Inc. v. Becerra*, 548 F. Supp. 3d 274 (D. Mass. 2021). *See* Pl.'s Opp'n at 17. The court explained in *StimLabs* why those cases are inapposite and adopts that reasoning here. *See StimLabs*, 2022 WL 13840218, at *5–6.

III.

Mandamus Jurisdiction. Plaintiff also invokes the court's jurisdiction pursuant to the Mandamus Act, 28 U.S.C. § 1361. Pl.'s Opp'n at 18. Such relief is available in the Medicare Act context only "to review otherwise unreviewable procedural issues" that are "unrelated to the merits." *Randall D. Wolcott, M.D., P.A. v. Sebelius*, 635 F.3d 757, 765– 66 (5th Cir. 2011). For the reasons set forth in *StimLabs*, Plaintiff's procedural claims rest on Plaintiff's merits contention that CMS in fact has changed its coverage policy. *StimLabs*, 2022 WL 13840218, at *8. "For that reason alone, the exercise of mandamus jurisdiction is not appropriate." *Id.*

Additionally, mandamus relief is available only if: "(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." *Council of & for the Blind of Del. Cnty. Valley, Inc. v. Regan*, 709 F.2d 1521, 1533 (D.C. Cir. 1983). Even if all jurisdictional requirements are met, "a court may grant relief only when it finds compelling equitable grounds." *Am. Hosp. Ass'n v. Burwell*, 812 F.3d 183, 189 (D.C. Cir. 2016) (citation omitted). Here, Plaintiff has not shown that the administrative appeals process is not an adequate remedy, which by itself bars mandamus jurisdiction. *See Monmouth Med. Ctr. v. Thompson,* 257 F.3d 807, 810 (D.C. Cir. 2001) ("[W]e must first examine all other possible avenues of relief to ensure that the hospitals have fully exhausted those which were available."); *id.* at 813 (stating that mandamus is available only when the claimant has exhausted administrative remedies). Moreover, as explained in *StimLabs*, mandamus relief is unavailable because there is no clear, "ministerial" duty to act. 2022 WL 13840218, at *9. In short, Plaintiff has not plausibly established that this is the type of "extraordinary" case in which the "drastic" remedy of mandamus would be proper. *California Clinical Lab'y Ass'n v. Sec'y of Health & Hum. Servs.*, 104 F. Supp. 3d 66, 83 (D.D.C. 2015).

III.

For the foregoing reasons, Defendants' Motion to Dismiss, ECF No. 23, is granted. Plaintiff's Motion for Oral Hearing on Defendants' Motion to Dismiss, ECF No. 34, is denied as moot. A final, appealable order accompanies this Memorandum Opinion.

Dated: January 12, 2023

Amit P. Mehta
United States District Court Judge