IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

HELOMICS CORPORATION,	)	
	)	
Plaintiff,	)	Civil Action No. 15-1667
	)	
v.	)	Judge Cathy Bissoon
	)	
NOVITAS SOLUTIONS, INC,	)	
	)	
Defendant.	)	

MEMORANDUM OPINION

In an Order dated January 28, 2016 (Doc. 23), the Court granted Defendant's Motion to Dismiss (Doc. 13) for failure to exhaust, and denied as moot Plaintiff's motion for a preliminary injunction (Doc. 3). *See* Doc. 23. The reasons are stated below. Given that time in this case has been of the essence, the Court writes only for the benefit of the parties and their counsel.

In dismissing Plaintiff's case for want of exhaustion, the Court does not reach Plaintiff's request for injunctive relief. The Court thinks it important to note, however, that the circumstances surrounding Plaintiff's claims are less supportive than its counsel have suggested. Defendant's briefing reveals, for example, that the same non-coverage proposal was initiated in November 2012, and, in response to Plaintiff's request for additional time, Defendant placed the decision on hold for over two years. *See* Def.'s Br. (Doc. 14) at 11-12. Furthermore, Plaintiff's suggestion that another MAC, Palmetto, soon will be retained by Defendant to conduct a reassessment, and that Palmetto may or will act as Plaintiff's "white knight," is rather speculative, and seems a good bit of wishful thinking. *See id.* at 8 & n.9 (indicating that there is no evidence of an agreement between Defendant and Palmetto, and that Palmetto has a history of finding non-coverage for CSRA tests like Plaintiff's).

In light of the foregoing, the non-coverage LCD hardly can be viewed as having come as a surprise, nor is there a clear indication that a grant of Plaintiff's presumedly modest request for injunctive relief will result in a more favorable outcome. Under the circumstances, it seems reasonably likely to conclude that Plaintiff's business/litigation strategy is to avoid the non-coverage determination through whatever means, and for as long as is, possible. While Plaintiff cannot be faulted for this approach, given how important Medicare coverage is to its business, the Court believes that these considerations inevitably flavor both its request for injunctive relief, specifically, and its decision to initiate this federal lawsuit, more generally.

These observations notwithstanding, the Court restricts its rulings and legal analyses to Defendant's Motion to Dismiss, which is well taken. In the absence of directly applicable Third Circuit authority, the Court finds highly persuasive the decisions in Physician Hospitals of America v. Sebelius, 691 F.3d 649 (5th Cir. 2012), National Athletic Trainers' Association v. HHS, 455 F.3d 500 (5th Cir. 2006) and, particularly, Vertos Medical, Inc. v. Novitas Solutions, Inc., 2012 WL 5943542 (S.D. Tex. Nov. 27, 2012).[1] All of these decisions recognize that a party wishing to challenge a Medicare-related determination first must fulfill the "channeling requirement" discussed in *Illinois Council*. Although there is an exception allowing immediate federal-court review, it is a narrow one that applies only when administrative review "would mean no review at all." Physician Hospitals, 691 F.3d at 655 (references to cited and quoted sources now, and hereafter, omitted). Such a narrow reading is necessitated by the nature of the interests in balance:

[1] Vertos Medical presented materially similar circumstances and legal issues, and Plaintiff's efforts to distinguish it are unavailing. To the extent that either party would wish for a more full-throated discussion, the Court adopts and incorporates by reference the legal analyses in that decision.

> Insofar as § 405(h) . . . demands the 'channeling' of virtually all legal attacks through the agency, it assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts . . . . But this assurance comes at a price, namely, occasional individual, delay-related hardship. In the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts, paying this price [is] justified [in the eyes of Congress and the Supreme Court].

Illinois Council, 529 U.S. 1, 13 (2000).

It matters not whether Plaintiff has an individual right to further challenge the non-coverage LCD. So long as third parties have an aligned incentive, channeling is required. Physician Hospitals, 691 F.3d at 658-59; National Athletic Trainers, 507-508; Vertos Medical, 2012 WL 5943542 at *6 ("the possibility of review is not completely precluded as long as third parties, such as physicians or beneficiaries, have the ability and incentive to access . . . administrative review").[2]

Furthermore, any individual/financial hardship that Plaintiff may suffer, no matter how purportedly extreme, does not qualify. *See, e.g.*, Physician Hospitals (channeling required even where administrative review would require plaintiff to "knock down two commercial buildings, perfect financing, borrow tens of millions of dollars, finish the architectural and construction plans, pay a contractor, take two years to build a new hospital, treat a patient in the expansion,

[2] The availability of administrative review by proxy renders moot Plaintiff's grievances regarding the alleged mishandling of its request for reconsideration under the Medicare Program Integrity Manual ("MPIM"). *Cf.* Order dated Jan. 20, 2016 (Doc. 19) at 1 (soliciting Defendant's reply regarding consequences of its potentially having "conflat[ed] the concepts of a 'final' non-coverage LCD and the 'effective date' of a final non-coverage LCD"). Even assuming Defendant misapplied the MPIM, moreover, there is no indication that a substantively-based reconsideration should or must toll the implementation of Defendant's non-coverage LCD.

bill Medicare, appeal the denial of the payment administratively, receive a final denial of claim, and file a suit in federal court").

Plaintiff's attempts to distinguish the above-decisions are unconvincing. Although the Court is not entirely unsympathetic regarding Plaintiff's claim that implementation of the non-coverage LCD may result in the loss of over 100 local-jobs, the company's putative financial hardships are inadequate grounds for the Court to intervene. The "no review" exception applies a more categorical approach, and it requires the Court to examine hardship "as applied generally to those covered by a particular statutory provision," rather than "in an isolated, particular case." Physician Hospitals at 657. The outcome cannot properly turn on the particular levels of solvency, capitalization and/or diversification enjoyed by Plaintiff. Under the applicable legal standards, the result should not be different if Plaintiff was a richly funded multi-national conglomerate, as opposed to a small local company. Nor would the result properly differ if Plaintiff derived only nominal revenue from Medicare payments. The job and revenue-related matters raised by Plaintiff are insufficient, and the Court would be constrained from considering them even if it wanted to. *Cf., e.g.*, Physician Hospitals at 658 (highlighting plaintiff's failure to show absence of "physician-owned hospitals with a low enough Medicare . . . case mix" to financially sustain administrative challenge).

The proper question is, are there mechanisms for administrative review available to persons with similarly-aligned interests, and the answer undoubtedly is, yes. In addition to the substantial input that Plaintiff and its surrogates enjoyed in the rule-making process, including its successful delay of the non-coverage determination in 2012, its lawyers candidly admit that patient-beneficiaries successfully have challenged past denials of coverage. *See* Pl.'s Br. (Doc. 4) at 6. While Plaintiff attempts to distinguish Vertos Medical because in this case,

unlike there, the procedure involves the treatment of a life-threatening disease (cancer), Plaintiff has neither asserted nor shown the absence of individual patients who could pay for the test "out-of-pocket" until administrative review is completed, whether on a claim-specific or LCD-wide basis. Physician's Hospitals, 691 F.3d at 657 ("[t]here certainly have been attendant costs to the operation of Section 405(h) that have not caused courts to waive the requirement," such as where a patient might have to pay for "a desired surgery . . . out of pocket prior to bringing an administrative claim"). While the Court undeniably has sympathy for the plight of Plaintiff's patient-base, acting on those feelings, in the face of contrary applicable law, would equate to inappropriate judicial activism (not to mention, likely reversible error).[3]

Finally, for the same reasons explained in Vertos Medical, Plaintiff cannot cloak its requests for relief under the rubric of "mandamus" and achieve a different result. As there, "[t]he decision [Plaintiff] challenges -- whether to place [its] procedure in the non-coverage category of items and services -- is one that has divided MACs and provoked disagreement within the medical research community. It can hardly be described as a ministerial duty so

[3] An example where channeling was the "practical equivalent" of a total denial can be found in Council for Urological Interests v. Sebelius, 668 F.3d 704 (D.C. Cir. 2011) ("CUI"). There, the denial of coverage allowed the plaintiff's putative proxies, hospitals, to acquire expensive medical equipment at "fire-sale prices," and the court determined that the proxies had, for this and other reasons, "little incentive" to pursue plaintiff's non-coverage challenges. *Id.* at 713; *accord* Physician Hospitals, 691 F.3d at 657 (describing putative proxies in CUI as "categorically misaligned"). The instant case obviously is distinguishable, as was the CUI court's observation that history confirmed the plaintiff's assertions. *Compare* CUI, 668 F.3d at 713 ("[i]n the three years since the Secretary announced the regulations, not one of the 5,795 hospitals in the United States has brought an administrative challenge") *with* discuss in text, *supra* (noting Plaintiff's acknowledgement that patients successfully have challenged non-coverage determinations).

plainly prescribed as to be free from doubt, as required for mandamus to issue." *Id.*, 2012 WL 5943542 at *8.[4]

In conclusion, Plaintiff's attempted invocation of this Court's jurisdiction is materially indistinguishable from the plaintiff in Vertos Medical. Although the stakes of the patients here undoubtedly are higher, the Court finds insufficient grounds for deviating from this and other well-reasoned opinions. While the Court is not entirely unmoved by the plight of Plaintiff or its patients, Plaintiff and its financial-backers cannot have been naïve to the potential risks in their marketplace. In positioning itself to be so heavily reliant on Medicare funds, Plaintiff must accept the possibility that an adverse coverage determination one day may result. The existence and parameters of due-process rights notwithstanding, it seems wise to appreciate, on some level, that what the government giveth, it may well end up taking away.

For the reasons stated herein, Defendant's Motion to Dismiss (Doc. 13) has been granted, and Plaintiff's motion for a preliminary injunction (Doc. 3) has been denied as moot. Contemporaneously herewith, the Court will enter judgment under Federal Rule of Civil Procedure 58.

IT IS SO ORDERED.

February 1, 2016

s\Cathy Bissoon
Cathy Bissoon
United States District Judge

cc (via ECF email notification):

All Counsel of Record

[4] For the reasons explained in Defendant's reply brief (Doc. 22), the unavailability of mandamus relief extends to Plaintiff's grievances under the MPIM. *See id.* at 2-3; *see also generally* Vertos Medical at *7-8.