UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GREGG POPKIN, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 16-141 (RMC)**
SYLVIA M. BURWELL,	)	
Defendant.	)	

OPINION

The Department of Health and Human Services, through the Centers for Medicare and Medicaid Services, deemed Dr. Gregg Popkin and his clinic, Atlantic Medical, Inc., to be at high risk for fraud and abuse and placed Atlantic Medical on pre-payment review. When the vast majority of claims for payment were denied, Atlantic Medical went out of business. Plaintiffs Dr. Popkin and Atlantic Medical sue the Secretary of the Department of Health and Human Services, alleging claims under the Administrative Procedure Act, 5 U.S.C. § 701 *et seq*., the Fifth Amendment Due Process Clause, and the First Amendment. They seek a preliminary injunction terminating pre-payment review and requiring the Secretary to remit all payments. The Secretary opposes. Because Plaintiffs failed to exhaust their administrative remedies, the case must be dismissed for lack of jurisdiction and the motion for a preliminary injunction will be denied.

I. FACTS

A. Medicare Act and the Administrative Process

The Medicare Act, 42 U.S.C. § 1395 *et seq*., establishes a health insurance program for disabled and elderly individuals. Part A covers inpatient hospital stays, other institutional care, and home health care. 42 U.S.C. § 1395d. Part B covers physician and other medical services. *Id*. § 1395k. The Secretary of the Department of Health and Human Services administers the Medicare program through the Centers for Medicare and Medicaid Services, which contracts with Medicare Administrative Contractors to manage enrollment of health care providers and to process payments. *Id*. §§ 1395kk-1395kk-1(a). Under this system, a Medicare health care provider submits its claim for payment directly to the Medicare Administrative Contractor for its geographic region, and the Medicare Administrative Contractor issues an initial payment determination. *Id*. §§ 1395kk-1(a), 1395ff(a)(1)-(2); 42 C.F.R. § 405.904(a)(2).

When a Medicare Administrative Contractor denies or limits payment on a claim on initial determination, there is a four-level appeal process. 42 U.S.C. § 1395ff. At the first level, a provider may seek redetermination from an individual at the Medicare Administrative Contractor who was not involved in the initial decision. *Id*. § 1395ff(a)(3); 42 C.F.R. §§ 405.904(a)(2), .948. At the second level, a provider may seek reconsideration by a Qualified Independent Contractor.[1] 42 U.S.C. § 1395ff(b)-(c), (g); 42 C.F.R. § 405.904(a)(2). If the Qualified Independent Contractor does not make a decision within 60 days, a provider can bypass such review and appeal to the third level. 42 U.S.C. § 1395ff(c)(3)(C)(ii); 42 C.F.R. § 405.970.

[1] A Qualified Independent Contractor is an entity that contracts with the Secretary to decide requests for reconsideration. 42 C.F.R. §§ 405.902.

Where the amount in controversy is over $100, a third level of review is available—a hearing before an administrative law judge (ALJ). 42 U.S.C. §§ 1395ff(b)(1)(E), (d)(1). The Medicare Act requires the ALJ to conclude a hearing and render a decision on the appeal of a decision of a Qualified Independent Contractor within 90 days after the request for hearing. *Id*. § 1395ff(d)(1)(A); 42 C.F.R. § 405.1016. A claimant can appeal the decision of the ALJ to the fourth level, the Medicare Appeals Council, *see id*. § 1395ff(d)(2), or if the ALJ fails to render a decision in 90 days, a claimant can "escalate" his appeal to the Medicare Appeals Council. *Id*. § 1395ff(d)(3)(A). The regulations describe the process for requesting that an appeal be escalated to the next level:

> (a) Requesting escalation. An appellant who files a timely request for hearing before an ALJ and whose appeal continues to be pending before the ALJ at the end of the applicable ALJ adjudication period under § 405.1016 may request [Medicare Appeals Council] review if—
>
> > (1) The appellant files a written request with the ALJ to escalate the appeal to the MAC after the adjudication period has expired; and
> >
> > (2) The ALJ does not issue a decision, dismissal order, or remand order within the later of 5 calendar days of receiving the request for escalation or 5 calendar days from the end of the applicable adjudication period set forth in § 405.1016.
>
> (b) Escalation.
>
> > (1) If the ALJ is not able to issue a decision, dismissal order, or remand order within the time period set forth in paragraph (a)(2) of this section, he or she sends notice to the appellant.
> >
> > (2) The notice acknowledges receipt of the request for escalation, and confirms that the ALJ is not able to issue a decision, dismissal order, or remand order within the statutory timeframe.
> >
> > (3) If the ALJ does not act on a request for escalation within the time period set forth in paragraph (a)(2) of this section or

> does not send the required notice to the appellant, the QIC decision becomes the decision that is subject to MAC review consistent with § 405.1102(a).
>
> (c) No escalation. If the ALJ's adjudication period set forth in § 405.1016 expires, the case remains with the ALJ until a decision, dismissal order, or remand order is issued or the appellant requests escalation to the MAC.

42 C.F.R. § 405.1104.

The Medicare Appeals Council conducts a de novo review of the ALJ decision. 42 U.S.C. § 1395ff(d)(2). On appeal from an ALJ decision, the Medicare Appeals Council must make a decision or remand within 90 days. *See id*.; *see also* 42 C.F.R. § 405.1100(d) (in cases where there was no ALJ decision and the appeal was escalated to the Council from the ALJ level, the Council must render a decision or remand within 180 days). If the Medicare Appeals Council fails to render a timely decision, the claimant can file suit in federal district court. 42 U.S.C. § 1395ff(d)(3)(B). The Medicare regulations also describe the process for taking a claim to federal court when the Medicare Appeals Council has not issued a decision within the allotted time for adjudication:

> (a) If the MAC [*i.e*., the Medicare Appeals Council] does not issue a decision or dismissal or remand the case to an ALJ within the adjudication period specified in § 405.1100, or as extended as provided in this subpart, the appellant may request that the appeal, other than an appeal of an ALJ dismissal, be escalated to Federal district court. Upon receipt of a request for escalation, the MAC may—
>
> > (1) Issue a decision or dismissal or remand the case to an ALJ, if that action is issued within the latter of 5 calendar days of receipt of the request for escalation or 5 calendar days from the end of the applicable adjudication time period set forth in § 405.1100; or
> >
> > (2) If the MAC is not able to issue a decision or dismissal or remand as set forth in paragraph (a)(1) of this section, it will send a notice to the appellant acknowledging receipt of the request for escalation and confirming that it is not able to

> issue a decision, dismissal or remand order within the statutory time frame.
>
> (b) A party may file an action in a Federal district court within 60 calendar days after the date it receives the MAC's notice that the MAC is not able to issue a final decision, dismissal order, or remand order unless the party is appealing an ALJ dismissal.

42 C.F.R. § 405.1132.

Most of the work done by Medicare Administrative Contractors consists of audits on providers *after* payments have been made to them. "Most of the millions of Medicare claims are reviewed on a post payment 'honor system.' The carrier pays the claim upon receipt of a minimum set of information and later audits the physician's or supplier's underlying documentation of medical necessity and other such requirements." *Bertschland Family Practice Clinic, P.C. v. Thompson*, No. IP01-562-CHF, 2002 WL 1364155, at *2 (S.D. Ind. June 4, 2002). If a Medicare Administrative Contractor denies a claim during post-payment review and the claimant appeals, the Secretary can recoup the payment if the payment denial is affirmed at the first two appeal levels. 42 U.S.C. § 1395ddd(f)(2). If the claimant subsequently prevails, the Secretary is required to repay the funds to the claimant.

However, to ensure that the Medicare program pays only legitimate claims, Medicare Administrative Contractors also are authorized to conduct pre-payment review of Medicare claims submitted by providers deemed to be at high risk for fraud and abuse. *See Farkas v. Blue Cross & Blue Shield of Mich.*, 24 F.3d 853, 854 n.1 (6th Cir. 1994) ("The use of [pre-payment review] finds statutory support at 42 U.S.C. § 1395*l*e, which provides that '[n]o payment shall be made to any provider of services . . . unless there has been furnished such information as may be necessary in order to determine the amounts due such provider . . . .'"). When a provider is placed on pre-payment review, the provider is required to submit substantive documentation to support some or all of its claims before such claims can be paid. The Medicare

Administrative Contractor examines such material to determine the sufficiency of the documentation and whether the medical services or supplies were medically necessary, reasonable, and otherwise payable under Medicare law. *See* 42 U.S.C. § 1395u(b)(3); 42 C.F.R. § 405.501 *et seq*.; *Isaacs v. Bowen*, 865 F.2d 468, 470 (2d Cir. 1989).

Whether pre-payment review or post-payment review is utilized, an initial denial of a Medicare claim can be appealed through the four-level process described above. After exhausting administrative remedies and obtaining a final agency decision, either from the Medicare Appeals Council or, if the Council fails to render a timely decision, by utilizing the escalation process, a claimant may seek judicial review in federal district court. 42 U.S.C. §§ 405(g), (h) (made applicable to the Medicare Act via 42 U.S.C. §§ 1395ff(b)(1)(A), 1395ii).

B. Placement of Atlantic Medical on Pre-Payment Review and Denial of Claims

Dr. Gregg Popkin is a chiropractor who owned and operated a primary medical care clinic, Atlantic Medical, Inc., from July 2013 to August 2014. Compl. [Dkt.1] ¶ 9. While the clinic provided a variety of medical services, it specialized in treating osteoarthritis of the knee and other joints through the injection of hyaluronic acid, a gel-like fluid that acts as a lubricant. *Id*. ¶ 25. In March 2014, Dr. Popkin moved Atlantic Medical from Ft. Lauderdale to Miami, Florida. *Id*. ¶¶ 89, 94. As part of the move, Dr. Popkin submitted an application for Atlantic Medical to serve as a Medicare supplier in Miami. *Id*. ¶ 98. First Coast Service Options, Inc. was assigned as the Medicare Assistance Contractor to process Atlantic Medical's application. Compl. ¶¶ 92, 97; Gallion Decl. [Dkt. 11-1] ¶ 4.[2]

[2] Yvette Gallion is the Project Manager of the South Florida Enrollment Project at First Coast. Gallion Decl. ¶ 1.

First Coast sent an inspector to conduct a site verification of Atlantic Medical's Miami location on June 3, 2014. Compl. ¶ 99, 101. With information from the site verification and from other sources, on June 17, 2014, First Coast determined that Atlantic Medical was at high risk for fraud and abuse. Gallion Decl. ¶ 6. First Coast based its determination on a history of aberrant billing practices by one Atlantic Medical employee and a pending investigation of another employee. *Id*. ¶ 7.

Because Atlantic Medical was deemed high risk, on June 23, 2014, First Coast placed Atlantic Medical on pre-payment review for claims over a certain dollar amount, which required Atlantic Medical to submit substantiating documentation for each claim before it could receive payment. Compl. ¶ 120; Gallion Decl. ¶ 9. First Coast notified Atlantic Medical of such placement by letter; the letter also notified Atlantic Medical that educational materials regarding the type of documentation required to substantiate claims for payment were available on First Coast's website. Compl. ¶ 120; Gallion Decl. ¶ 13. Between June 23, 2014 and April 30, 2015, First Coast denied 97% of Atlantic Medical's requests for payment. Of the payment denials that Atlantic Medical appealed through the administrative process, 87% were upheld. Gallion Decl. ¶ 11. Because of the high rates of denial and affirmance, on April 30, 2015, First Coast required that *all* of Atlantic Medical's Medicare claims be submitted for pre-payment review. *Id*. ¶ 12. Due to lack of Medicare income, Atlantic Medical closed in August 2015. Compl. ¶¶ 9, 170-83.

Dr. Popkin and Atlantic Medical brought this suit against the Department of Health and Human Services and its Secretary, Sylvia Burwell, in her official capacity (collectively, the Secretary). Plaintiffs allege that the Secretary acted arbitrarily and capriciously, in violation of the Administrative Procedure Act (APA), 5 U.S.C. § 701 *et seq*., when it placed Atlantic Medical on pre-payment review. Compl. ¶¶ 289-297. Further, Plaintiffs

claim that the Secretary violated their First Amendment right to freedom of association, contending that the Secretary required pre-payment review because Atlantic Medical employed Dr. Gary Jett part-time. *Id*. ¶¶ 280-288.[3] Plaintiffs also contend that they were deprived of property and liberty interests in violation of procedural due process. *Id*. ¶¶ 184-279. They seek a preliminary injunction, asking the Court to order the Secretary to (1) terminate pre-payment review; (2) return/remit to Atlantic Medical all withheld and/or recouped monies; (3) direct the Secretary to continue reimbursement to Atlantic Medical for medical services rendered until Atlantic Medical "can have effective administrative procedures afforded to it"; and (4) order First Coast to "cease and desist any further harassment of Plaintiffs." Mot. for Preliminary Inj. [Dkt. 3] at 2; *see also* Mem. in Support of Preliminary Inj. (Pl. Mem.) [Dkt. 3-1]; Reply [Dkt. 13]. The Secretary opposes. Opp'n [Dkt. 11]. Because Plaintiffs failed to exhaust their administrative remedies, the case must be dismissed for lack of jurisdiction and the motion for preliminary injunction will be denied.

II. LEGAL STANDARD

> Plaintiffs who seek preliminary injunction must establish that:
>
> (a) they are likely to succeed on the merits;
>
> (b) they are likely to suffer irreparable harm in the absence of preliminary relief;
>
> (c) the balance of equities tips in their favor; and

[3] Plaintiffs allege that Dr. Jett was working at Atlantic Medical on the day First Coast came to do the site inspection, that he was associated with two high risk clinics at the time, *see* Compl. ¶¶ 111, 115, and that Dr. Popkin and other employees sensed that "something was wrong" based on the how the reviewer "spoke and acted toward Gregg Popkin after seeing Dr. Jett," *see id*. ¶ 116. The Secretary denies that its placement of Atlantic Medical on pre-payment review was based on Plaintiffs' affiliation with Dr. Jett. Gallion Decl. ¶¶ 8, 10. This dispute is not material, since the case must be dismissed for lack of jurisdiction.

(d) an injunction is in the public interest.

Winter v. NRDC, Inc., 555 U.S. 7, 20 (2008). "[T]he movant has the burden to show that all four factors . . . weigh in favor of the injunction." *Davis v. Pension Benefit Guar. Corp.*, 571 F.3d 1288, 1292 (D.C. Cir. 2009).

However, a plaintiff cannot show any likelihood of success on the merits if a court lacks subject matter jurisdiction. Plaintiffs bear the burden of demonstrating subject matter jurisdiction. *See Khadr v. United States*, 529 F.3d 1112, 1115 (D.C. Cir. 2008); *see also Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) (noting that federal courts are courts of limited jurisdiction and "[i]t is to be presumed that a cause lies outside this limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction") (internal citations omitted); *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003) (no action of the parties can confer subject matter jurisdiction on a federal court because subject matter jurisdiction is both a statutory requirement and an Article III requirement). A court may consider materials outside the pleadings to determine its jurisdiction. *Settles v. U.S. Parole Comm'n*, 429 F.3d 1098, 1107 (D.C. Cir. 2005). If a court determines at any time that it lacks subject matter jurisdiction, the court must dismiss the action. Fed. R. Civ. P. 12(h(3); *see also Jerez v. Republic of Cuba*, 777 F. Supp. 2d 6, 15 (D.D.C. 2011). Resolving a merits issue while jurisdiction is in doubt "carries the courts beyond the bounds of authorized judicial action." *Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 94 (1998).

III. ANALYSIS

The Court lacks jurisdiction because Plaintiffs failed to exhaust their administrative remedies, as they acknowledge. The Medicare Act provides that only an individual aggrieved by a "final decision of the [Secretary] made after a hearing to which he was

a party" may obtain judicial review in federal district court. *See* 42 U.S.C. § 405(g) (incorporated into the Medicare Act by 42 U.S.C. §§ 1395ff(b)(1)(A), 1395ii.). The exhaustion requirement is more expansive under the Medicare Act than in other administrative settings. First, Congress expressly precluded federal question jurisdiction under 28 U.S.C. § 1331 over claims "arising under" the Medicare Act. *See* 42 U.S.C. § 405(h) (incorporated into the Medicare Act by 42 U.S.C. §§ 1395ff(b)(1)(A), 1395ii) ("[n]o action against ... the [Secretary] shall be brought under Section 1331 . . . of title 28 to recover on any claim arising under [the Medicare Act]"). A claim "arises under" the Medicare Act when both the plaintiff's standing and the basis for the claim are dependent on the Act. *Your Home Visiting Servs., Inc. v. Shalala*, 525 U.S. 449, 456 (1999). This language is construed "quite broadly." *Heckler v. Ringer*, 466 U.S. 602, 615 (1984). Second, § 405(h) also provides that no agency decisions "shall be reviewed by any person, tribunal, or governmental agency except as herein provided." 42 U.S.C. § 405(h). The Supreme Court has interpreted § 405(h) to mandate the "channeling" of "virtually all legal attacks through the agency." *See Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12-13 (2000). This channeling requirement extends beyond ordinary principles of ripeness and exhaustion of administrative remedies where exceptions may apply. *Id*. at 12.

It is well established that channeling is required for APA claims as well as constitutional claims. *Ringer*, 466 U.S. at 614-15 (APA claim under the Medicare Act must be channeled through the agency); *Ill. Council*, 529 U.S. at 6-7 (due process challenge to Medicare regulations is subject to § 405(h) channeling); *Weinberger v. Salfi*, 422 U.S. 749, 762 (1975) (constitutional claims must be brought in conformity with the same standards that apply to nonconstitutional claims arising under the Medicare Act); *Calif. Clinical Laboratory Ass'n v.*

HHS, 104 F. Supp. 3d 66, 73, 80-82 (D.D.C. 2015) (claims under the Medicare Act, the APA, and the U.S. Constitution must be channeled first through the agency).

Plaintiffs' claims arise under the Medicare Act, as the statute provides both standing and the substantive basis for their claims. First Coast was responsible for reviewing, auditing, and investigating claims for payment submitted by providers such as Plaintiffs. The Complaint challenges the placement of Atlantic Medical on pre-payment review and the denial of Medicare payments through claims asserting violations of the Fifth Amendment Due Process Clause, the First Amendment, and the APA. For example, Plaintiffs' claim for deprivation of property in violation of due process alleges that Plaintiffs "gained various appeal and procedural and other rights and privileges as in[-]Network providers of the Medicare program" and Plaintiffs "had a legitimate expectation of continued payment pursuant to the Medicare Program." Compl. ¶¶ 188, 190. Similarly, the claim for deprivation of liberty without due process also reveals that the claim is based on alleged rights afforded by the Medicare Act. *Id.* ¶ 240 (Plaintiffs "had a protected liberty interest and a protected property interest in their Medicare Provider Agreement . . . ."); *see also id.* ¶ 285 (alleging that Atlantic Medical was placed on pre-payment review in retaliation for Plaintiffs' association with Dr. Jett); *id.* ¶ 290 (Plaintiffs were adversely affected by actions of the Secretary in violation of the APA). Plaintiffs' claims arise under the Medicare Act and thus federal question jurisdiction is precluded at this time. *See* 42 U.S.C. § 405(h). Plaintiffs must channel their claims through the agency, and they can only obtain judicial review upon a final decision of the Secretary. *See id.* §§ 405(g), (h).

Plaintiffs' claim of hardship caused by the delay inherent in the channeling requirement is insufficient to avoid the duty to exhaust. The Supreme Court recognized that delay due to channeling was inevitable:

> [Channeling] 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. 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 may seem justified.

Ill. Council, 529 U.S. at 13. The only exception to the channeling requirement is where the administrative process would result in the complete preclusion of judicial review. *Id*. at 22-23. "[W]e do not hold that an individual party could circumvent [the Medicare Act's] channeling requirement simply because that party shows that postponement would mean added inconvenience or cost in an isolated, particular case. Rather, the question is whether, as applied generally to those covered by a particular statutory provision, hardship likely found in many cases turns what appears to be simple channeling requirement into *complete* preclusion of judicial review." *Id*. (emphasis in original). Plaintiffs' contention that administrative review will be time-consuming does not demonstrate complete preclusion of court review. They are not exempt from the channeling requirement.

Plaintiffs further contend that the delay inherent in seeking administrative review violates their right to due process, especially because of the large backlog currently pending in the third level of appeal at the Office of Medicare Hearings and Appeals. Compl. ¶¶ 73-86. In December 2013, it was estimated that the average wait time for a hearing before an ALJ in the Office of Medicare Hearings and Appeals was 16 months, as there were over 460,000 claims

pending. Compl. ¶ 74. Plaintiffs allege that there are now approximately 800,000 claims pending. *Id*. ¶¶ 79, 83. The Secretary acknowledges that administrative appeals have risen to "unprecedented levels" and that the "magnitude of the increase exceeds the ALJs' current capacity to keep up with the incoming appeals." *See* Opp'n at 5. However, the Medicare statute itself contains a remedy—it permits a claimant to escalate his appeal to the fourth level when an ALJ fails to render a decision in 90 days. 42 U.S.C. § 1395ff(d)(3)(A); *see also* 42 C.F.R. § 405.1104. At the fourth level, on an appeal from an ALJ decision the Medicare Appeals Council must make a decision or remand within 90 days. *See* 42 U.S.C. § 1395ff(d)(2); *see also id*. § 405.1100(d) (for cases escalated from the ALJ level with no ALJ decision, Council must decide within 180 days). If a timely decision is not rendered, the claimant can file suit in federal district court. 42 U.S.C. § 1395ff(d)(3)(B); 42 C.F.R. § 405.1132. Plaintiffs acknowledge that they have not exhausted these administrative remedies on any of their claims for payment, noting that they "seek to exhaust their 405(g) administrative remedies in the future . . . ." *See* Pl. Mem. at 35. Further, Plaintiffs have not utilized the escalation provisions. *See id.* at 2 (Plaintiffs seek reimbursement until Plaintiffs "can have effective administrative procedures afforded to it, in the normal course of processing of all Medicare Part B claims in the [Secretary's] queue. . . Plaintiffs do not assert a right to accelerate to the head of the line.").

The Secretary can waive the exhaustion requirement at any stage of the administrative process if she determines that "no further review is warranted either because the internal needs of the agency are fulfilled or because the relief that is sought is beyond [her] power to confer." *Mathews v. Eldridge*, 424 U.S. 319, 329 (1976). The Secretary has not waived exhaustion in this case. Further, a court may waive exhaustion under § 405(g) if the issue raised is entirely collateral to a claim for payment, plaintiffs would be irreparably injured if

exhaustion were required, and exhaustion would be futile. *See Hall v. Sebelius*, 689 F. Supp. 2d 10, 18 (D.D.C. 2009). The Court declines to waive exhaustion because Plaintiffs fail to meet the very first factor of this test—the issues raised here are not collateral and instead are inextricably intertwined with Plaintiffs' claims for payment.

Because Plaintiffs have failed to exhaust their administrative remedies, this Court lacks subject matter jurisdiction. Accordingly, this case will be dismissed without prejudice.

IV. CONCLUSION

For the reasons set forth above, the motion for a preliminary injunction [Dkt. 3] will be denied. Since Plaintiffs' have not exhausted their administrative remedies, the case will be dismissed without prejudice for lack of jurisdiction. A memorializing Order accompanies this Opinion.

Date: March 24, 2016

/s/
ROSEMARY M. COLLYER
United States District Judge