UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COLORADO HEART INSTITUTE, LLC, *et al.*,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 08-1626 (RMC)**
CHARLES E. JOHNSON,[1] Acting Secretary, U.S. Department of Health and Human Services,	)	
Defendant.	)	

MEMORANDUM OPINION

The Stark Law, 42 U.S.C. § 1395nn, generally prohibits a physician from referring Medicare patients to an "entity for the furnishing of designated health services" ("DHS") where a financial relationship exists between the physician and the entity. The Centers for Medicare & Medicaid Services ("CMS") currently interprets this statutory language to refer only to the entity that directly bills Medicare for DHS. However, effective October 1, 2009, CMS will interpret this language to also include a second entity that provides DHS to the first entity that directly bills Medicare. Plaintiffs are physicians and physician-owned entities that provide DHS under contract with hospitals in Colorado. Under CMS's current interpretation, only the hospital – the billing entity – is considered to be furnishing DHS and, therefore, the individual physician Plaintiffs can lawfully

[1] Pursuant to Federal Rule of Civil Procedure 25(d), Charles E. Johnson is substituted as Acting Secretary for his predecessor, Michael O. Leavitt, Secretary of the U.S. Department of Health and Human Services.

refer their Medicare patients to the entities they own. But under CMS's new interpretation, the physician-owned entities that provide DHS under contract with the hospitals also will be considered to be furnishing DHS. Consequently, absent an applicable exception, the Stark Law will prohibit the individual physician Plaintiffs from referring their Medicare patients to their own entities. Plaintiffs seek a declaration that CMS's new interpretation of entities furnishing DHS is unlawful, and move for summary judgment. Defendant moves to dismiss or, in the alternative, for summary judgment. This Court lacks subject matter jurisdiction. Accordingly, it will grant Defendant's motion to dismiss and deny Plaintiffs' motion for summary judgment.

I. BACKGROUND

Medicare is a federally funded program that subsidizes health insurance for the elderly and disabled. *See* 42 U.S.C. § 1395 *et seq*. The Stark Law was enacted "to address the strain placed on the Medicare Trust fund by the overutilization of certain medical services by physicians who, for their own financial gain rather than their patients' medical need, referred patients to entities in which the physicians held a financial interest." *Am. Lithotripsy Soc'y v. Thompson*, 215 F. Supp. 2d 23, 26 (D.D.C. 2002). To prevent such financial conflicts of interest from influencing medical decision-making, the Stark Law sets out explicit prohibitions intended to restrict the ability of physicians to profit from their own referrals. Specifically, the statute generally prohibits physicians from making a referral to an "entity for the furnishing of designated health services"[2] that will be paid by Medicare

[2] In addition to inpatient and outpatient hospital services at issue here, the other categories of DHS are clinical laboratory services; physical therapy services; occupational therapy services; radiology services, including magnetic resonance imaging, computerized axial tomography scans, and ultrasound services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and outpatient speech-language pathology services. *See* 42 U.S.C. § 1395nn(h)(6).

if the physician, or an immediate family member of the physician, has a "financial relationship"[3] with the entity.[4] 42 U.S.C. § 1395nn(a)(1)(A). In addition to the general prohibition on referrals, the Stark Law provides that an "entity may not present or cause to be presented a claim" for Medicare reimbursement of DHS referred in violation of the statute. *Id.* § 1395nn(a)(1)(B). The statute further provides that no Medicare payments may be made for such services, and any amounts collected for such services must be refunded. *Id.* § 1395nn(g)(1) & (2). An entity that knowingly presents or causes to be presented a prohibited claim, or knowingly enters into a prohibited arrangement or scheme, is subject to civil monetary penalties and liability under the False Claims Act, 31 U.S.C. § 3729 *et seq.* *Id.* § 1395nn(g)(3) & (4).[5]

Plaintiffs in this case include: (i) three entities that provide diagnostic and therapeutic cardiac catheterization and related services ("Cath Labs"); (ii) cardiologists and vascular surgeons who perform and refer catheterization services in the Cath Labs and who have an ownership or investment interest in one or more of the Cath Labs; (iii) a cardiology practice that is part owner of the Cath Labs; and (iv) a company and its owner that provide management services to two of the Cath Labs. *See* Am. Compl. ¶¶ 1-36. Under Medicare's billing rules, only a hospital may bill for

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[3] A "financial relationship" is defined broadly to encompass either a "compensation arrangement" or an "ownership or investment interest." *Id.* § 1395nn(a)(2). A "compensation arrangement" generally means "any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity . . . ." *Id.* § 1395nn(h)(1)(A). An "ownership or investment interest" includes an interest "through equity, debt, or other means and includes an interest in an entity that holds an ownership or investment interest in any entity providing the designated health service." *Id.* § 1395nn(a)(2).

[4] Specific statutory exceptions permit referrals even where an ownership or compensation arrangement exists. *See id.* § 1395nn(b)-(e).

[5] Criminal penalties may also apply under the "anti-kickback statute." *See* 42 U.S.C. § 1320a-7b(b).

the cardiac catheterization services performed by the Cath Labs. *See* Medicare Provider Reimbursement Manual, Part I, Ch. 21, § 2118.1. As a result, the Cath Labs provide their services to hospitals "under arrangements" in which the hospitals contract with the Cath Labs to provide "nursing and technical personnel, equipment, drugs, and medical supplies" for the cardiac catheterization services. Am. Compl. ¶¶ 42, 60. Each of the hospitals that has contracted with a Cath Lab "establishes its own prices, negotiates reimbursement amounts with third-party payors, and bills such payors including Medicare and Medicaid for all hospital services including those provided under arrangement." *Id.* ¶ 53. The hospitals then pay the Cath Labs a "flat fee for each service provided." *Id.* ¶ 52. The Cath Labs, in turn, distribute the earnings from the fees paid by the hospitals "to the physician investors according to their ownership interests." *Id.* ¶ 64. Due to efficiencies, the Cath Labs can provide the cardiac catheterization services "at a lower cost than could be provided by the hospitals." *Id.* ¶ 54. "Accordingly, the hospitals profit by having these services under arrangement." *Id.* And because Medicare only reimburses hospitals for such services, "only a very small percentage" of the Cath Labs' revenues "are generated from services that could be performed and billed from an independent outpatient facility." *Id.* ¶ 43.

The Secretary of Health and Human Services ("HHS") has authority to promulgate regulations implementing the Medicare program, including the Stark Law, *see* 42 U.S.C. §§ 1395hh(a)(1) & 1395nn(b)(4), and has delegated his authority to CMS. Because the Stark Law does not define when an entity furnishes DHS, it has been left to CMS to do so by regulation. Under CMS's current regulations, "[a] person or entity is considered to be furnishing DHS if it is the person or entity to which CMS makes payment for the DHS, directly or upon assignment on the patient's behalf." 42 C.F.R. § 411.351 (definition of "entity"). Accordingly, presently in an "under

arrangements" transaction, only the hospital is considered to be an entity furnishing DHS; the entities supplying DHS to the hospital, such as the Cath Labs, are not considered to be entities furnishing DHS. Therefore, the Stark Law does not currently prohibit the individual physician Plaintiffs from making referrals to the Cath Labs in which they have a financial interest.

This will all change on October 1, 2009, when CMS's final rule that Plaintiffs challenge here takes effect. That rule provides that "[a] person or entity is considered to be furnishing DHS if it is the person or entity that has performed services that are billed as DHS" or it "is the person or entity that has presented a claim to Medicare for the DHS . . . ." Changes to Physician Self-Referral Rules, 73 Fed. Reg. 48,434, at 48,751 (Aug. 19, 2008) (to be codified at 42 C.F.R. § 411.351 (definition of "entity")). Thus, effective October 1, 2009, both the hospital and the entities supplying DHS to the hospital, such as the Cath Labs, will be considered to be entities furnishing DHS in an "under arrangements" transaction. Consequently, absent an applicable exception, the Stark Law will prohibit the individual physician Plaintiffs from making referrals to their own Cath Labs.

Plaintiffs sue the Secretary of HHS in his official capacity seeking a declaration that CMS's broadened definition of an entity furnishing DHS "is contrary to clear congressional intent, based on an impermissible construction of the Stark Law, arbitrary and capricious, and exceeds the agency's authority," in contravention of the Administrative Procedure Act ("APA"), 5 U.S.C. § 551 *et seq.* Am. Compl. at 4-5 (Introduction). Plaintiffs assert that the Court has jurisdiction under Section 702 of the APA, 5 U.S.C. § 702, and the general federal question statute, 28 U.S.C. § 1331. *Id.* ¶ 38. They move for summary judgment. Defendant moves to dismiss for lack of subject matter jurisdiction, or in the alternative, for summary judgment.

II. LEGAL STANDARD

Federal courts are courts of limited jurisdiction and the law presumes that "a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *St. Paul Mercury Indem. Co. v. Red Cab Co.*, 303 U.S. 283, 288-89 (1938). Because "subject-matter jurisdiction is an 'Art. III as well as a statutory requirement[,] no action of the parties can confer subject-matter jurisdiction upon a federal court.'" *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003) (quoting *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxite de Guinea*, 456 U.S. 694, 702 (1982)). On a motion to dismiss for lack of subject-matter jurisdiction pursuant to Rule 12(b)(1), the plaintiff bears the burden of establishing that the court has subject-matter jurisdiction. *Kokkonen*, 511 U.S. at 377.

Because subject-matter jurisdiction focuses on the court's power to hear the claim, however, the court must give the plaintiff's factual allegations closer scrutiny when resolving a Rule 12(b)(1) motion than would be required for a Rule 12(b)(6) motion for failure to state a claim. *Macharia v. United States*, 334 F.3d 61, 64, 69 (D.C. Cir. 2003); *Grand Lodge of Fraternal Order of Police v. Ashcroft*, 185 F. Supp. 2d 9, 13 (D.D.C. 2001). Moreover, the court is not limited to the allegations contained in the complaint. *Hohri v. United States*, 782 F.2d 227, 241 (D.C. Cir. 1986), *vacated on other grounds*, 482 U.S. 64 (1987). Instead, to determine whether it has jurisdiction over the claim, the court may consider materials outside the pleadings. *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992).

III. ANALYSIS

Plaintiffs assert that the Court has jurisdiction under Section 702 of the APA, 5 U.S.C. § 702, and the general federal question statute, 28 U.S.C. § 1331. Am. Compl. ¶ 38. However, Section 702 of the APA does not provide an independent basis for jurisdiction. *See Califano v. Sanders*, 430 U.S. 99, 107-07 (1977) (concluding that the "APA does not afford an implied grant of subject-matter jurisdiction permitting federal judicial review of agency action"). Thus, jurisdiction lies, if at all, under 28 U.S.C. § 1331. *See Robbins v. Reagan*, 780 F.2d 37, 42-43 (D.C. Cir. 1985).

Section 405(h) of the Social Security Act, made applicable to the Medicare Act by 42 U.S.C. § 1395ii, provides:

> No action against the United States, the [Secretary of Health and Human Services], or any officer or employee thereof shall be brought under section 1331, or 1346 of title 28 to recover on any claim arising under [the Medicare Act].

42 U.S.C. § 405(h). "This bar against § 1331 actions applies to all claims that have their 'standing and substantive basis' in the Medicare Act." *Am. Chiropractic Ass'n, Inc. v. Leavitt*, 431 F.3d 812, 816 (D.C. Cir. 2005) (quoting *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 11 (2000)). As this Court recently explained, in *Illinois Council* the Supreme Court held that "Section 405(h) of the Medicare Act precluded review under the general federal question jurisdiction of Section 1331 and required that the claim be exhausted through HHS's administrative claims process before it could be heard in federal court." *Atl. Urological Assocs., P.A. v. Leavitt*, 549 F. Supp. 2d 20, 29 (D.D.C. 2008). "In other words, Section 405(h) mandates the ''channeling' of virtually all legal attacks through the agency.'" *Id*. (quoting *Ill. Council*, 529 U.S. at 13).

"Although § 1395ii, which incorporates § 405(h), would appear to preclude all Medicare suits founded on general federal question jurisdiction, the Supreme Court has recognized an exception: if the claimant can obtain judicial review only in a federal question suit, § 1395ii will not bar the suit." *Am. Chiropractic*, 431 F.3d at 816 (citing *Ill. Council*, 529 U.S. at 10-13). "The question therefore is whether [Plaintiffs] could get [their] claim[] heard administratively and whether [they] could receive judicial review after administrative channeling." *Id.*

It is undisputed that Plaintiffs could not themselves bring an administrative challenge before HHS because they cannot directly bill or receive payments from Medicare for DHS. *See* Am. Compl. ¶ 100; Def.'s Mot. to Dismiss & Cross Mot. for Summ. J. at 14. It also is undisputed that the hospitals with which the Cath Labs contract – the entities that directly bill and receive payments from Medicare for DHS – could, if they so chose, bring an administrative challenge before HHS and get judicial review of HHS's determination. *See* 42 C.F.R. Part 405, Subpart I; 42 U.S.C. § 1395ff(b).[6] The issue, then, is whether the hospitals' ability to get administrative and judicial review of CMS's expanded interpretation of entities furnishing DHS ousts the Court of jurisdiction over Plaintiffs' claim.

In *American Chiropractic*, an association of chiropractors sought to challenge a Medicare regulation that permitted HMOs to require patients to obtain a referral from a doctor or osteopath in order to receive covered chiropractic services. In finding that the district court lacked

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[6] In cases involving a facial challenge to the validity of a regulation or statutory provision, the hospitals may request expedited judicial review so that the legal challenge may be decided more quickly. *See* 42 U.S.C. § 1395ff(b)(2); 42 C.F.R. § 405.990. Moreover, Defendant has assured the Court that the hospitals will be able to bring an administrative challenge without risk of incurring sanctions. *See* Defs.'Mot. to Dismiss & Cross Mot. for Summ. J. at 16-17. Plaintiffs have given the Court "no convincing reason to doubt the Secretary's description of the agency's general practice." *Ill. Council*, 529 U.S. at 22.

Section 1331 jurisdiction over that claim, the D.C. Circuit noted that one way the chiropractors could get their claim heard administratively was indirectly through a patient filing a grievance with the HMO claiming that the referral requirement was illegal. 431 F.3d at 816. If a patient were to do so, then the patient's filing "would trigger the administrative process" and the chiropractors' claim could get heard indirectly through the patient's filing. *Id.* at 817. The association of chiropractors also sought to challenge a Medicare regulation that permitted medical doctors and osteopaths, in addition to chiropractors, to perform a specific covered service. The court held that the district court lacked Section 1331 jurisdiction over that claim as well because the chiropractors could get their claim heard administratively if (1) an HMO provided that only medical doctors and osteopaths could perform the service; (2) a patient in such an HMO enlisted the services of a chiropractor; (3) the patient (or the chiropractor as the patient's assignee) filed an administrative claim arguing that the HMO must cover the service (or reimburse the chiropractor); and (4) the HMO defended on the ground that another Medicare regulation entitles it to restrict the type of practitioners who may provide a service. *See id*. The court held that under that chain of events:

> [t]he HMO's invocation of this provision would squarely present the question whether medical doctors and osteopaths, as well as chiropractors, are "qualified to furnish" the service . . . . It follows that chiropractors could receive an administrative decision on the issue presented . . . and that under *Illinois Council* the district court had no jurisdiction to decide that claim.

Id. at 817-18. The court reached that conclusion despite acknowledging that just 22 percent of HMOs required the service to be performed by medical doctors or osteopaths only, and that chiropractors with patients in the remaining 78 percent of HMOs would have no means of getting their claim heard administratively or judicially. *See id.* at 817.

Against this backdrop, the Court finds that it lacks jurisdiction over Plaintiffs' claim. Any one of the hospitals "under arrangement" with a Cath Lab could get administrative and judicial review of CMS's expanded interpretation of entities furnishing DHS, the issue presented by Plaintiffs' claim here. Like the chiropractors in *American Chiropractic* whose claims could be heard indirectly through their patients, the physicians and physician-owned Cath Labs here could have their claim heard indirectly through a hospital with which they contract. Because Plaintiffs could get their claim heard administratively and could get judicial review after administrative channeling, the Court has no Section 1331 jurisdiction over Plaintiffs' claim.

Plaintiffs argue that *American Chiropractic* is distinguishable because "the court found that the plaintiff association of chiropractors could 'get its claim heard' because its members had direct access to administrative review as the assignee of their patients." Pls.' Opp'n to Def.'s Mot. to Dismiss at 10. While it is true that the court noted that the chiropractors could also get their claim heard directly by waiving any right to payment from the patient and becoming the patient's assignee, *see* 431 F.3d at 817, there would have been no reason for the court to discuss how the chiropractors could get their claim heard indirectly through the patient if the only relevant inquiry was whether the chiropractors themselves could challenge the referral requirement directly. *See Nat'l Athletic Trainers' Ass'n, Inc. v. HHS*, 455 F.3d 500, 504 (5th Cir. 2006) ("Unlike the chiropractors in *American Chiropractic*, the athletic trainers here are not service providers, therefore they cannot become assignees of the patients. Nevertheless, the *American Chiropractic* court considered both the patient's and the chiropractor's rights to pursue administrative review."). Plaintiffs' lack of a direct avenue to administrative review through an assignment does not mean that they could not get their *claim* heard. As the Fifth Circuit has explained:

> We are not persuaded that the inability to acquire the physician or beneficiary's right to administrative review ends our inquiry; "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 simply a channeling requirement into *complete* preclusion of judicial review." Accordingly, in deciding whether the *Illinois Council* exception applies, we must consider whether the claim may ultimately be subject to review after proceeding through administrative channels.

Id. at 504-05 (citations omitted) (emphasis in original).

Plaintiffs argue that the hospitals are not adequate proxies because they have no incentive to channel the claim administratively and because they face their own roadblocks to the administrative review process. In support of their argument that the Court has jurisdiction absent an adequate proxy for their claim, Plaintiffs cite *American Lithotripsy Society v. Thompson*, 215 F. Supp. 2d 23 (D.D.C. 2002). But that decision issued before the D.C. Circuit's decision in *American Chiropractic*. The *American Lithotripsy* court specifically relied on the reasoning of the district court in *American Chiropractic* in finding jurisdiction because there was an inadequate proxy, *see* 215 F. Supp. 2d at 29-30, reasoning that the D.C. Circuit omitted when it reversed the district court in *American Chiropractic*. *See* 431 F.3d at 817-18. Tellingly, in finding that the district court lacked Section 1331 jurisdiction over the chiropractors' claims in *American Chiropractic*, the D.C. Circuit did not analyze whether the patients were adequate proxies for the chiropractors' claims. There was no discussion of the patients' incentive to bring an administrative claim or the chiropractors' roadblocks to obtaining administrative review. It was enough "that chiropractors *could* receive an administrative decision on the issue presented " *if* an HMO disallowed chiropractors to perform the service (only 22 percent did), a patient in such an HMO enlisted the services of a chiropractor, and the patient (or the chiropractor as assignee) filed a claim *Id.* at 817 (emphasis added).

The Court recognizes that the Fifth Circuit has looked to see not only whether a plaintiff's claim could be heard administratively but also whether the third party with the means to bring the claim before the agency has the necessary incentive to do so. *See Nat'l Athletic*, 455 F.3d at 505-08. However, the Fifth Circuit relied on *American Lithotripsy*. *See id.* at 505. As discussed above, *American Lithotripsy* relied on the reasoning of the district court in *American Chiropractic* that the D.C. Circuit omitted when it reversed the district court. Accordingly, while Fifth Circuit law might require a third party to have both the means and the incentive to file an administrative claim, that does not appear to be the law in this Circuit. But even if it were, the Court finds that the hospitals have the necessary incentive to file an administrative claim here because the Cath Labs provide the cardiac catheterization services "at a lower cost than could be provided by the hospitals" and "the hospitals profit by having these services under arrangement." Am. Compl. ¶ 54. Assuming Plaintiffs' allegations to be true, then the hospitals have sufficient incentive to challenge CMS's expanded interpretation of entities furnishing DHS.

IV. CONCLUSION

For the foregoing reasons, this Court lacks jurisdiction. Accordingly, the Court will grant Defendant's motion to dismiss [Dkt. # 17], deny Plaintiffs' motion for summary judgment [Dkt. # 13], and deny as moot Defendant's motion for summary judgment [Dkt. # 16]. A memorializing Order accompanies this Memorandum Opinion.

Date: April 20, 2009

/s/
ROSEMARY M. COLLYER
United States District Judge