UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

COUNCIL FOR UROLOGICAL INTERESTS,

Plaintiff,

v.

KATHLEEN SEBELIUS, in her official capacity as Secretary of the Department of Health and Human Services,

and

UNITED STATES OF AMERICA,

Defendants.

Civil Action 09-00546 (HHK)

MEMORANDUM OPINION

Plaintiff Council for Urological Interests ("CUI") brings this action against the United States and Kathleen Sebelius, in her official capacity as Secretary of the Department of Health and Human Services, under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701–706, and the Regulatory Flexibility Act ("RFA"), 5 U.S.C. §§ 601–612. CUI alleges that the Centers for Medicare and Medicaid Services ("CMS"), acting under the Secretary's authority, has promulgated regulations that exceed its statutory powers under the Stark Act, 42 U.S.C. § 1395nn. CUI bring this suit for declaratory and injunctive relief, arguing that these regulations wrongly prevent joint ventures, through which urologists purchase medical equipment, from providing laser treatment to Medicare patients. Before the Court is defendants' motion to dismiss for lack of subject matter jurisdiction [#7]. Upon consideration of the motion, the

opposition thereto, and the record of this case, the Court concludes that the motion must be granted.

I. BACKGROUND

A. Urologist Joint Ventures and Medicare

In recent years, physicians have discovered that certain types of lasers are capable of performing surgical procedures that would in the past have required traditional invasive surgery and a lengthy recovery period. These laser surgery procedures require no hospital stay and are less likely than traditional surgery to create complications. Compl. ¶¶ 7–8. Because, however, hospitals have been reluctant to invest in the expensive equipment required, many urologists have formed joint ventures to purchase the lasers and provide various treatments. Compl. ¶¶ 11–12. Under CMS regulations, however, these joint ventures may not be directly reimbursed for their technical costs under Medicare, which covers over 75% of the patients who receive laser surgery. Compl. ¶¶ 16, 18. As a result, many urologist joint ventures entered into contractual relationships with hospitals through which the hospitals acted as billing agents for Medicare, transferring fees to the joint ventures on a per-procedure ("per-click") basis and retaining some portion of each payment. Compl. ¶ 19. Entities providing treatment for hospitals in this fashion are referred to as operating "under arrangement" with those hospitals.

B. The Stark Act and the Challenged Regulations

In 1989, Congress passed legislation, commonly known as "Stark I," that was designed 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). In 1993, "Stark II" followed, expanding the reach of Stark I to include physician self-referrals for eleven "designated health services" ("DHS"), including urological laser procedures performed under contract with hospitals.[1] *Id.* at 26–27. Under Stark II, physicians may not refer patients for any of these treatments to entities with which they have either an ownership or compensation arrangement. *Id.* at 27. Exceptions are made, however, for certain compensation arrangements that set payment rates in advance, comport with fair market value, and do not take into account the volume or value of referrals. Compl. ¶ 27. Accordingly, CMS promulgated regulations in 2001 that allowed physician joint ventures to be paid "under arrangement" with hospitals on a per-procedure basis, as described above. Under those regulations, only the hospital was considered to "furnish" the DHS, so referrals to the joint ventures did not run afoul of Stark's ban on "referral[s] . . . for the furnishing of designated health services" to entities with which physicians have financial relationships. 42 U.S.C. § 1395nn(a)(1)(A).

Subsequently, however, CMS reinterpreted the Stark II exceptions, expanding the class of entities considered to "furnish" health services, and concluding that per-procedure payments should be banned. Compl. ¶¶ 30–33, 47–52. CUI alleges that this round of revisions, which

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[1] The designated services are: "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 inpatient and outpatient health services." *Am. Lithotripsy*, 215 F. Supp. 2d at 26–27. CMS considers urological laser surgery performed under contract with a hospital to fall into the last category. Compl. ¶ 53.

took effect on October 1, 2009, has the effect of precluding physician-owned joint ventures from providing urological laser treatments and vitiating the contracts with hospitals under which they have done so in the past. Specifically, CUI asserts that physician joint ventures now fall within the definition of entities that "furnish" DHS, creating a prohibited financial relationship. Compl. ¶¶ 56–57. Further, CUI avers that these revisions treat physicians who own joint ventures that operate "under arrangement" with hospitals as having prohibited indirect financial relationships with the hospitals themselves. CUI asserts that these changes are contrary to the language of the statute and the intent of Congress. Compl. ¶¶ 30–46.

CUI brought this suit to enjoin the enforcement of these regulations and defendants moved to dismiss for lack of subject-matter jurisdiction.

II. LEGAL STANDARD

Under Federal Rule of Civil Procedure 12(b)(1), a defendant may move to dismiss a complaint, or any portion thereof, for lack of subject-matter jurisdiction. FED. R. CIV. P. 12(b)(1); *see Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) ("Federal courts are courts of limited jurisdiction. . . . It is to be presumed that a cause lies outside this limited jurisdiction . . . ."). In response to such a motion, the plaintiff must establish that the court has subject-matter jurisdiction over the claims in the complaint. *Hunter v. Bd. of Real Prop. Tax Assessment & Appeals*, 2010 WL 3275529, at *1 n.3 (D.D.C. Aug. 19, 2010) (citing *Moms Against Mercury v. FDA*, 483 F.3d 824, 828 (D.C. Cir. 2007)). If the plaintiff is unable to do so, the Court must dismiss the action. *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 94 (1998) (citing *Ex parte McCardle*, 7 Wall. 506, 514 (1868)). When resolving a motion made

under Rule 12(b)(1), a court may consider material beyond the allegations in the plaintiff's complaint. *Jerome Stevens Pharm., Inc. v. FDA*, 402 F.3d 1249, 1253–54 (D.C. Cir. 2005).

III. ANALYSIS

Defendants argue that this Court lacks jurisdiction over CUI's claims because they are subject to the jurisdictional bar of 42 U.S.C. § 405(h), which precludes federal question jurisdiction over any claims arising under the Medicare Act that were not first channeled through CMS's administrative claims process.[2] Defs.' Mot. to Dismiss ("Defs.' Mot.") at 8. CUI acknowledges that its claims arise under the Medicare Act, but argues that its claims are exempt from § 405(h) because it cannot present its claims directly to CMS[3] and there is no feasible alternative means for it to seek administrative and judicial review. Pl.'s Opp'n to Defs.' Mot. ("Pl.'s Opp'n") at 10. Thus, CUI argues, its claims fall within the exception to § 405(h) recognized by the Supreme Court in *Shalala v. Illinois Council on Long Term Care*, 529 U.S. 1 (2000). There, the Court explained that where the Medicare Act's administrative channeling rule would "amount to the 'practical equivalent of a total denial of judicial review,'" the rule does not apply and general federal question jurisdiction lies under 42 U.S.C. § 1331. *Ill. Council*, 529

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[2] § 405(h) provides in relevant part: "No findings of fact or decision of the Commissioner of Social Security shall be reviewed by any person, tribunal, or governmental agency except as herein provided. No action against the United States, the Commissioner of Social Security, or any officer or employee thereof shall be brought under section 1331 or 1346 of Title 28 to recover on any claim arising under this subchapter." 42 U.S.C. § 405(h). This provision is applied to the Medicare Act and the Secretary of Health and Human Services by 42 U.S.C. § 1395ii.

[3] CUI's members are unable to present their claims directly to CMS because that option is restricted to Medicare providers and suppliers, which they are not.

U.S. at 20 (quoting *McNary v. Haitian Refugee Ctr., Inc.*, 498 U.S. 479, 497 (1991)). Defendants respond that although CUI's members cannot themselves present their claims to CMS, those claims can nevertheless be heard through the hospitals with which CUI's members contract, rendering the *Illinois Council* exception inapplicable.

At bottom, the parties agree that the pivotal question here is whether CUI's members could have their claims heard administratively through a proxy or intermediary, but disagree sharply as to the application of the *Illinois Council* exception to their case.[4] In particular, they dispute: (i) whether the *Illinois Council* inquiry focuses on the plaintiffs themselves, or considers the whole range of parties subject to the regulations; (ii) whether the inquiry should take into account not just the means but also the incentives for a would-be proxy to actually present the claim administratively; and (iii) whether, incentives aside, an adequate mechanism for CUI's claims to be heard is present here. The Court addresses each of these issues in turn.

A. The Scope of the *Illinois Council* Inquiry

Defendants argue that under *Illinois Council*, the "Court's analysis should focus not on the particular circumstances of CUI here, but on whether those parties allowed to pursue administrative claims under the statute . . . in this case, the hospitals themselves . . . are precluded from obtaining judicial review." Defs.' Reply to Pl.'s Opp'n ("Def.'s Reply") at 2. In support of this argument, they point to the following language from the Supreme Court's *Illinois Council* opinion: "the question is whether, as applied generally to those covered by a particular statutory

[4] It is uncontested that, if an adequate proxy exists, the fact that neither the CUI itself nor its members can present their claims directly to CMS is insufficient to trigger the *Illinois Council* exception. *See Am. Chiropractic Ass'n, Inc. v. Leavitt*, 431 F.3d 812, 816–18 (D.C. Cir. 2005).

provision, hardship likely found in many cases turns what appears to be simply a channeling requirement into *complete* preclusion of judicial review." *Ill. Council*, 529 U.S. at 22–23. CUI responds that the *Illinois Council* inquiry is a pragmatic one, and thus necessarily requires consideration of a plaintiff's particular circumstances. Pl.'s Opp'n at 12–14. On this point, CUI has the better argument.

There are two problems with defendants' interpretation. First, the portion of the *Illinois Council* opinion upon which defendants rely was not discussing whether the plaintiffs there had access to judicial review, or how to determine whether that was the case. Rather, the Court was discussing the circumstances under which plaintiffs who unquestionably *did* have access to judicial review could nevertheless avoid the administrative process by showing that hardship caused by the delay of judicial review could effectively prevent review altogether.[5] The Court did not have occasion to consider whether the exception turned either on a particular plaintiff's ability to access the administrative process or on the ability of the balance of parties subject to the regulation to do so. *See Ill. Council*, 529 U.S. at 22–23.

Second, defendants' interpretation does not align with the approach taken by the D.C. Circuit in *American Chiropractic Association, Inc. v. Leavitt*, 431 F.3d 812 (D.C. Cir. 2005). The *American Chiropractic* court framed the question under *Illinois Council* as "whether the [plaintiff association] could *get its claims heard* administratively and whether *it* could receive judicial review after administrative channeling." *Id.* at 816 (emphasis added). This language implies some amount of agency on the part of the plaintiffs; the court asked whether the plaintiff

[5] The Court concluded that "potentially isolated instances of the inconveniences sometimes associated with the postponement of judicial review" were insufficient to establish that review was precluded as a practical matter. *Ill. Council*, 529 U.S. at 23.

could "get its claims heard," not whether anyone else could independently raise equivalent claims. Indeed, in answering its own question, the *American Chiropractic* court specifically discussed methods by which the plaintiffs in that case, acting together with third parties, might obtain administrative and then judicial review. *See id.* at 816–18 (suggesting that the plaintiff chiropractors could become the assignees of their patients' claims against HMOs that declined to cover their treatments). Thus, it is clear that in this circuit the *Illinois Council* inquiry focuses specifically on a plaintiff's circumstances, and does not simply ask whether the balance of other affected parties could obtain review of similar claims. *Cf. Colo. Heart Inst. v. Johnson*, 609 F. Supp. 2d 30, 36 (D.D.C. 2009) (finding that the plaintiffs in that case "could have their claim heard indirectly through a hospital with which they contract.").[6]

B. *Illinois Council* Does Not Require Consideration of a Proxy's Incentives

The parties bitterly dispute the extent to which the Court may consider whether a potential proxy who could present plaintiff's claims to CMS actually has the incentive to do so. CUI argues that because *Illinois Council* emphasized the "practical" effect of the channeling requirement, the incentives of a putative administrative proxy are necessarily part of the inquiry. Pl.'s Opp'n at 11–12. Defendants reply that the D.C. Circuit made no consideration of third-party incentives in *American Chiropractic*, and point to *Colorado Heart Institute v. Johnson*, 609 F. Supp. 2d 30, in which Judge Collyer concluded that after *American Chiropractic*, an analysis

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[6] Further, even if defendants were, in the abstract, correct about the scope of the *Illinois Council* inquiry, here CUI's members' particular circumstances would still need to be considered. As is explained below, a referral from one of CUI's members or an equivalently situated doctor is necessary for a challenge to the regulations to proceed; without such a referral, the hospitals would unable to test the validity of the regulations. Thus, the inquiry conducted in Section III.C, *infra*, would be substantially the same.

of a would-be proxy's incentives "does not appear to be the law in this Circuit." *Id.* at 37. Here, defendants are correct.

The opinion in *Colorado Heart* is instructive. The *Colorado Heart* plaintiffs mounted a challenge to the same regulations that are at issue here. There, as here, it was undisputed that although the plaintiffs could not themselves bring an administrative challenge, the hospitals with which they contracted could do so. *Id.* at 35. Looking to the circuit's opinion in *American Chiropractic*, Judge Collyer concluded that § 405(h)'s jurisdictional bar applied to the plaintiffs' claims, even absent evidence that their putative proxies had sufficient incentive to present the plaintiffs' claims on their behalf.[7] *See id.* at 37. She contrasted *American Chiropractic* with this Court's prior opinion in *American Lithotripsy Society*[8] and the Fifth Circuit's opinion in *National Athletic Trainers' Association, Inc. v. HHS*, 455 F.3d 500 (5th Cir. 2006), emphasizing that in *American Chiropractic*, the D.C. Circuit "[t]ellingly . . . did not analyze whether the patients were adequate proxies . . . . There was no discussion of the patients' incentive to bring an administrative claim." *Colo. Heart Inst.*, 609 F. Supp. 2d at 37.

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[7] As the parties both observe, Judge Collyer also found that even if the incentive of the ostensible proxy were a consideration, the hospitals in that case had the necessary incentive to bring the claims. *Colorado Heart Inst.*, 609 F. Supp. 2d at 37. This additional finding by Judge Collyer does not diminish the persuasiveness of the analysis that lead her to conclude that the incentives of a would-be proxy are not a consideration in determining whether the *Illinois Council* exception applies.

[8] This Court's decision in *American Lithotripsy*, which declined to apply § 405(h)'s jurisdictional bar in a very similar situation, emphasized the plaintiffs' lack of standing to directly challenge the regulations at issue and the lack of incentive for any other parties to do so. 215 F. Supp. 2d at 30. As Judge Collyer noted in *Colorado Heart*, however, *American Lithotripsy* predated the D.C. Circuit's decision in *American Chiropractic*, and relied on the reasoning of the district court that was reversed in *American Chiropractic*. *Id.* at 29–30.

CUI suggests that *Colorado Heart* misreads *American Chiropractic* by over-emphasizing *American Chiropractic*'s omission of any discussion of incentives. Pl.'s Opp'n at 12. *Colorado Heart*'s reliance on that omission is entirely sensible, however, particularly in light of the fact that the district court that was reversed in *American Chiropractic* had emphasized the importance of a would-be proxy's incentives. *See Am. Chiropractic Ass'n, Inc. v. Shalala*, 131 F. Supp. 2d 174, 177 (D.D.C. 2001) ("Because enrollees have no incentive to pursue a claim [equivalent to the plaintiffs'], they do not provide a vehicle for presenting Counts II, III, or V for administrative and, ultimately, judicial review."). Indeed, the analysis in *Colorado Heart* closely parallels that of the *American Chiropractic* court. CUI criticizes *Colorado Heart* for making "no finding as to the likelihood of an appeal by a hospital, and offer[ing] no guidance as to how long the plaintiffs . . . were expected to wait before they would be allowed to bring their case." Pl.'s Opp'n at 12. These same observations, however, could be made about the circuit's opinion in *American Chiropractic*.[9]

In sum, Judge Collyer's opinion in *Colorado Heart* is persuasive, and reflects the better reading of *American Chiropractic*. Accordingly, the motivation of the hospitals to present CUI's claims to CMS is not a factor in establishing whether the *Illinois Council* exception applies.[10] Thus, as in *Colorado Heart*, the ultimate issue is, incentives aside, "whether the hospitals' ability

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[9] CUI also appears to read *Colorado Heart* as eschewing the need to consider both the proxy's incentives and its *means* to bring the claim. *See* Pl.'s Opp'n at 12. This reading is plainly incorrect. *Colorado Heart* did precisely what *American Chiropractic* did: consider the proxy's means but not its incentives. *See Colorado Heart*, 609 F. Supp. 2d at 36–37; *see also id.* at 37 (contrasting the D.C. Circuit's means-only approach with the Fifth Circuit's means-and-incentives analysis).

[10] The same analysis applies to the hospitals' potential incentives to pursue the judicial review that would follow the administrative process. *See* Pl.'s Opp'n at 13.

to get administrative and judicial review of CMS's [new regulations] ousts the Court of jurisdiction over Plaintiff['s] claim." *Colo. Heart Inst.*, 609 F. Supp. 2d at 35. To that question the Court now turns.

C. The Feasibility of Hospitals Presenting CUI's Claims to CMS

In order for the hospitals with which CUI's members contract to present CUI's claims to CMS, two steps must occur. First, a doctor must refer a patient to an entity in which she has a financial interest for a treatment that constitutes a designated health service. Next, a hospital must submit a claim for reimbursement for that service to CMS. CUI argues that this scenario is effectively impossible, because both the hospital and the referring physician would be subject to severe sanctions under Stark, including significant monetary penalties and disbarment from Medicare.[11] Defendants respond that CMS provides a "no payment" option whereby Medicare providers can, for the purpose of commencing the administrative review process, submit claims that do not seek payment. This is accomplished by attaching a particular administrative code to the claim when it is submitted. Thus, defendants argue, the doctor and hospital would not be subject to Stark's penalties for the submission of Medicare claims for services that the claimant knows are excluded from coverage. Defendants' arguments have merit.

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[11] Stark provides that "[a]ny person [who] presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made" under the referral prohibitions "shall be subject to a civil money penalty of not more than $15,000 for each such service." 42 U.S.C. 1395nn(g)(3). The same provision also incorporates 42 U.S.C. § 1320a-7a, which allows "the Secretary [to] make a determination . . . to exclude the person from participation in the Federal health care programs." *Id.* § 1320a-7a(a). This Court has previously found these same sanctions to be sufficiently "draconian" to avoid administrative review where plaintiffs would otherwise be forced to expose themselves to the sanctions in order to challenge a rule. *See Am. Lithotripsy*, 215 F. Supp. 2d at 29.

The relevant statutory section provides for penalties for any person who "presents or causes to be presented a bill or a claim for a service that such person knows or should know is for a service for which payment may not be made" under Stark's substantive provisions. 42 U.S.C. § 1395nn(g)(3). Defendants argue that this language does not reach claims submitted under the "no payment" option, "because the claim would be submitted solely for the purposes of administrative exhaustion." Although their analysis is not thoroughly articulated, *see* Defs.' Reply at 11–12, defendants clearly believe that the "no payment" option prevents liability because a claim that does not request payment is not "a bill or a claim" in the meaning of § 1395nn(g)(3).[12] Other courts, following the example of the *Illinois Council* Court, have credited CMS's explanation that the "no payment" option enables hospitals to make "administrative challenge[s] without the risk of incurring sanctions." *Colo. Heart Inst.*, 609 F. Supp. 2d at 35 n.6; *see also Atl. Urological Assocs. v. Leavitt*, 549 F. Supp. 2d 20, 31–32 (D.D.C. 2008); *cf. Nat'l Athletic Trainers' Ass'n, Inc. v. HHS*, 455 F.3d 500, 506–07 (5th Cir. 2006). Here, as in those cases, CUI "gives [the Court] no convincing reason to doubt the Secretary's description of the agency's general practice" with regard to "no payment" claims. *Ill. Council*, 529 U.S. at 22. Accordingly, the Court finds that the Stark sanctions present no bar to the submission to CMS of a "no payment" test claim by a hospital.

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[12] Although not inevitable from the face of the statute, this reading accords with the provision's purpose (to penalize attempted and actual Medicare fraud) and its text. *See St. Agnes Med. Ctr. v. Dogali,* 2010 WL 307916, at *4 (E.D. Cal. January 19, 2010) (observing that "[t]he purpose of the Stark Law is to protect the government from Medicare fraud"); THE OXFORD ENGLISH DICTIONARY ONLINE (3d ed. 2010) (defining "bill" as "[a] note of *charges* for goods delivered or services rendered . . ." (emphasis added)); *id.* (defining "claim" as "[a] *demand* for something as due; an assertion of a right to something" (emphasis added)).

CUI argues, however, that even if the "no payment" option insulates hospitals from liability, it does not provide the same benefit to referring physicians. This is the case, CUI asserts, because Stark prohibits not only the submission of a claim based on a disallowed referral, but also the act of the referral itself. CUI is correct that both acts are proscribed. *See* 42 U.S.C. § 1395nn(a)(1)(A) (prohibiting certain types of referrals); *id.* § 1395nn(a)(1)(B) (proscribing claims based on the prohibited referrals). The *sanctions* for both, however, flow from the statutory section discussed above, 42 U.S.C. § 1395nn(g)(3), which makes no separate discussion of referrals. Thus, if a "no payment" claim does not constitute "a bill or a claim" for the purposes of the submitting hospital — which this Court joins others in concluding to be the case — the same is true as to the doctor who caused the hospital to submit the claim. Indeed, defendants assert as much, and as with the hospitals, CUI provides no reason for the Court to doubt their explanation. Thus, the Court concludes that a doctor who provided a referral that served as the basis for a "no payment" claim would not be exposed to these sanctions.[13]

CUI further contends, however, that because the new regulations "extend Stark to the entire relationship between physician and hospital, the net effect will be to prohibit all referrals from CUI's members to hospitals they have contracted with through their joint ventures." Pl.'s Opp'n at 17. Thus, even though test cases are permissible, CUI's members would be prohibited from making any *other* referrals to the hospitals for the duration of their "under arrangement" contracts, even for non-designated treatments, because those referrals *would* seek payment and

[13] Because the Court concludes that a test case can be brought without risk of Stark sanctions, it does not reach defendants' argument that these sanctions would not be severe enough to effectively bar judicial review. *See* Defs.' Reply at 12 n.7.

thus be subject to sanctions under Stark.[14] Similarly, CUI argues that, in order to avoid this broad impact of the new regulations, its members will be forced to terminate their "under arrangement" contracts, which would in turn result in the dissolution of their joint ventures, because they would be unable to treat the Medicare patients who receive the lion's share of the urological treatments at issue. Defendants respond that these arguments at most demonstrate hardship resulting from a *delay* of judicial review, and do not establish an effective denial of review. Defendants are correct.

As the Supreme Court explained in *Illinois Council*, the Medicare Act's near-absolute channeling requirement "comes at a price, namely, occasional individual, delay-related hardship," which Congress considered to be justified. *Ill. Council*, 529 U.S. at 13. Accordingly, in rejecting the plaintiffs' hardship-from-delay argument, the *Illinois Council* Court stated that "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." *Ill. Council*, 529 U.S. at 22–23.

In light of the high bar set by *Illinois Council*, other courts have distinguished between situations where a plaintiff is "required to violate a regulation . . . in order to challenge the regulation" and those where, as here, the plaintiff argues that review will be "costly and time-

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[14] Although CUI does not point to a specific portion of the new regulations that has this effect, they appear to refer to 42 C.F.R. § 411.354(c), which states: "An "under arrangements" contract between a hospital and an entity providing DHS "under arrangements" to the hospital creates a compensation arrangement for purposes of these regulations." 42 C.F.R. § 411.354(c). In turn, compensation relationships constitute financial relationships, and Stark prohibits all referrals by "physician[s] who ha[ve] a direct or indirect financial relationship with an entity . . . to that entity." *Id.* § 411.353(a). Thus, CUI's understanding of the scope of the Stark referral prohibition appears to be correct.

consuming." *Atl. Urological Assocs.*, 549 F. Supp. 2d at 31–32; *accord*. *Triad at Jeffersonville, LLC v. Leavitt*, 563 F. Supp. 2d 1, 14 (D.D.C. 2008). This is so even where, as here, plaintiffs have alleged that waiting for an administrative challenge would "drive them out of . . . business." *Atl. Urological Assocs.*, 549 F. Supp. 2d at 31. Here, some of CUI's members may incur costs, but they are not faced with the Hobson's choice that the Supreme Court saw as justifying the *Illinois Council* exception.

CUI argues, however, that the termination of its members' "under arrangement" contracts would result in not only hardship, but also an effective denial of review, because without the contracts, there would be no way for CUI's members to make a test case referral challenging the changed status of those very contracts. If Stark actually imposed penalties on the existence of "under arrangement" contracts, CUI would likely be correct. As explained above, however, Stark only penalizes payment-seeking referrals made pursuant to such contracts, not the contracts themselves. Thus, the contracts can continue, allowing a "no payment" test case to be brought, and CUI's members are not forced to choose between "abandoning legitimate challenges to agency regulations [and] violating the regulations and incurring draconian sanctions," *Triad*, 563 F. Supp. 2d at 14. Accordingly, they cannot evade the channeling requirement on these grounds.

In sum, because CUI has failed to demonstrate that its members would be forced to expose themselves to the Stark sanctions in order to challenge the new regulations, the Court finds that it has failed to establish that those sanctions create an effective denial of judicial

review. Accordingly, the *Illinois Council* exception is inapplicable and § 405(h) removes the Court's jurisdiction over CUI's claims.[15]

IV. CONCLUSION

For the foregoing reasons, defendants' motion to dismiss must be granted. An appropriate order accompanies this memorandum opinion.

Henry H. Kennedy, Jr.
United States District Judge

[15] CUI fails to respond to defendants' argument that if the Court lacks jurisdiction over CUI's APA claim, it likewise lacks jurisdiction to hear CUI's RFA claim. *See* Defs.' Mot. at 20–21; Pl.'s Opp'n at 18–20 (responding to only part of defendants' argument regarding the RFA claim). Accordingly, the court treats that argument as conceded and dismisses both claims. *See Buggs v. Powell*, 293 F. Supp. 2d 135, 141 (D.D.C. 2003) ("It is understood in this Circuit that when a plaintiff files an opposition to a dispositive motion and addresses only certain arguments raised by the defendant, a court may treat those arguments that the plaintiff failed to address as conceded." (citing *FDIC v. Bender*, 127 F.3d 58, 67–68 (D.C. Cir. 1997))); *accord*. *Stephenson v. Cox*, 223 F. Supp. 2d 119, 121 (D.D.C. 2002)).