

United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued October 14, 2011

Decided December 23, 2011

No. 11-5030

COUNCIL FOR UROLOGICAL INTERESTS,
APPELLANT

v.

KATHLEEN SEBELIUS, IN HER OFFICIAL CAPACITY AS
SECRETARY OF THE DEPARTMENT OF HEALTH AND HUMAN
SERVICES, AND UNITED STATES OF AMERICA,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:09-cv-00546)

Elizabeth Petrela Papez argued the cause for appellant. With her on the briefs were *Thomas L. Mills* and *Michael T. Morley*.

Jeffrey Clair, Attorney, U.S. Department of Justice, argued the cause for appellee. With him on the brief were *Tony West*, Assistant Attorney General, *Ronald C. Machen Jr.*, U.S. Attorney, and *Michael S. Raab*, Attorney. *R. Craig Lawrence*, Assistant U.S. Attorney, entered an appearance.

Before: SENTELLE, *Chief Judge*, TATEL and BROWN, *Circuit Judges*.

Opinion for the Court filed by *Circuit Judge* TATEL.

TATEL, *Circuit Judge*: Although the Medicare Act provides for judicial review of reimbursement decisions, it requires that claimants first exhaust their administrative remedies. In *Shalala v. Illinois Council on Long Term Care, Inc.*, the Supreme Court recognized an exception to this requirement for cases where its application “would not lead to a channeling of review through the agency, but would mean no review at all.” 529 U.S. 1, 17 (2000). In this case, an association of doctor-owned equipment providers challenges regulations issued by the Secretary of Health and Human Services (HHS) that effectively prevent its members from obtaining Medicare reimbursement for their services. For the reasons set forth in this opinion, we conclude that under the particular circumstances of this case, the *Illinois Council* exception applies and the association may invoke the district court’s general federal question jurisdiction without first seeking administrative review under the Medicare Act.

I.

The HHS Secretary issued the challenged regulations under a statute known as the Stark law, 42 U.S.C. § 1395nn. Congress enacted that statute to address perceived overutilization of services by physicians who stood to profit by referring patients to facilities or entities in which they had a financial interest. *United States ex rel. Kosenske v. Carlisle HMA, Inc.*, 554 F.3d 88, 95 (3d Cir. 2009). In its current form, the Stark law provides that if a physician has a financial relationship with an entity that “furnish[es]” certain “designated health services,” the physician “may not make a referral to the entity for the furnishing of designated health

services for which payment otherwise may be made” under the Medicare Act, and the entity “may not present or cause to be presented a claim . . . or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to” such a referral. 42 U.S.C. § 1395nn(a)(1).

The Stark law directly affects the members of appellant Council for Urological Interests—physician-owned joint ventures formed to purchase specialized equipment for urologic laser surgery. These joint ventures typically operate “under arrangement” with hospitals, that is, under a contract in which the urologist-owned venture provides the laser equipment and related services, while the hospital provides space for the procedure and compensates the venture for the equipment and services provided. Although Medicare reimburses urologists directly for their professional services, it pays full “technical fees” for equipment and non-professional services only to hospitals. Appellant’s Br. 7. So in a typical joint venture arrangement, the hospital bills Medicare for the technical fee for each surgical procedure performed and then passes on a pre-negotiated portion of that fee to the joint venture on a per-procedure basis.

The Secretary initially approved these arrangements as consistent with the Stark law. In 2008, however, the Secretary reconsidered the issue and promulgated new regulations prohibiting most such arrangements. Under the 2008 regulations, urologists who have a financial interest in a joint venture may no longer refer patients to the venture for laser services, even if the services are provided under arrangement with a hospital. *See* 42 C.F.R. § 411.351 (defining an entity “furnishing [designated health services]” to include “the person or entity that has performed services that are billed as [designated health services]”); 42 U.S.C. § 1395nn(a)(1)(A) (prohibiting referrals by physicians who have a financial

relationship with the entity “furnishing” the designated health services). The regulations also prohibit per-procedure leases with physician-owned equipment suppliers. 42 C.F.R. § 411.357(b)(4)(ii)(B).

After the new regulations were issued but before they became effective, the Council filed suit in the United States District Court for the District of Columbia, invoking the court’s general federal question jurisdiction pursuant to 28 U.S.C. § 1331, and alleging that the 2008 regulations exceeded the Secretary’s statutory authority. The government moved to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(1) for lack of subject matter jurisdiction, arguing that section 405(h) of the Social Security Act, incorporated into the Medicare Act through 42 U.S.C. § 1395ii, precluded federal question jurisdiction over the Council’s claims. Under section 405(h), “[n]o action against the United States, the [Secretary of Health and Human Services], or any officer or employee thereof shall be brought under section 1331 . . . of title 28 to recover on any claim arising under” the Medicare Act. 42 U.S.C. § 405(h); *see also* 42 U.S.C. § 1395ii. Instead, such claims must be “channeled” through the agency’s administrative procedures. *Ill. Council*, 529 U.S. at 12. After exhausting those procedures, the claimant can seek judicial review pursuant to the Medicare Act, which contains its own jurisdictional provision separate from section 1331’s grant of general federal question jurisdiction. *See* 42 U.S.C. § 1395ff(a)(1)(C), (b), (d); 42 U.S.C. § 405(b), (g)–(h).

Responding to the government’s motion, the Council acknowledged that direct judicial review is normally unavailable for Medicare Act challenges, but claimed that it had no choice but to seek immediate judicial review pursuant to section 1331. Specifically, because only Medicare “providers” may seek administrative review of the

reimbursement decision at issue in this case, and because neither the Council nor its members qualify as “providers,” the Council argued—and the government agreed—that it had no direct means of channeling its claims through the agency before seeking judicial review under the Medicare Act. Compl. ¶ 80. Thus barred from seeking Medicare Act review, the Council argued that section 405(h) could not likewise bar section 1331 jurisdiction; otherwise, the Council would have no judicial remedy at all. The district court disagreed. Although recognizing that the Council and its members lacked access to Medicare Act review, the court concluded that no exception to the channeling requirement applied because the hospitals with which Council members had contracted, as Medicare “providers,” could challenge the 2008 regulation through the administrative process. *See Council for Urological Interests v. Sebelius*, 754 F. Supp. 2d 78, 83–88 (D.D.C. 2010). Accordingly, the district court dismissed the complaint for lack of subject matter jurisdiction—a decision we now review *de novo*. *Nat’l Air Traffic Controllers Ass’n v. Fed. Serv. Impasses Panel*, 606 F.3d 780, 786 (D.C. Cir. 2010) (“We review *de novo* the district court’s grant of a motion to dismiss for lack of subject matter jurisdiction.” (internal quotation marks omitted)).

II.

The Supreme Court has long understood section 405(h) as a “channeling” requirement that “reaches beyond ordinary administrative law principles of ‘ripeness’ and ‘exhaustion of administrative remedies.’” *Ill. Council*, 529 U.S. at 12–13 (citing *Weinberger v. Salfi*, 422 U.S. 749, 757 (1975)). Because section 405(h), as incorporated by section 1395ii, applies to any case in which the Medicare Act supplies “both the standing and the substantive basis” for the claim, it has the effect of “‘channeling’ . . . virtually all legal attacks through the agency.” *Id.*

That said, the Supreme Court has also held that section 405(h)'s "channeling requirement" is not absolute. In *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), the Court considered a challenge, brought under section 1331, to regulations governing the method for calculating benefits under Medicare Part B. Because at that time the Medicare Act provided no avenue, either administrative or judicial, for challenging the validity of Part B regulations, applying section 405(h) would have meant "no review at all of substantial statutory and constitutional challenges" to those regulations. *Id.* at 680. Proceeding from "the strong presumption that Congress intends judicial review of administrative action," *id.* at 670, the Court found it "implausible to think [that Congress] intended that there be *no* forum to adjudicate statutory and constitutional challenges to regulations promulgated by the Secretary," *id.* at 678. Accordingly, finding no "clear and convincing evidence" to overcome the strong presumption favoring judicial review, *id.* at 681 (internal quotation marks omitted), the Court rejected the government's view that "whatever specific procedures [Congress] provided for judicial review of final action by the Secretary were exclusive," *id.* at 679, and held the challenge to the Secretary's regulations cognizable under section 1331, *id.* at 680.

The Supreme Court fleshed out the scope of the *Michigan Academy* exception in *Illinois Council*. Emphasizing that section 405(h) is intended to postpone judicial review, not totally preclude it, 529 U.S. at 19, the Court read *Michigan Academy* as holding section 405(h) inapplicable to Medicare Act claims "where its application to a particular category of cases . . . would not lead to a channeling of review through the agency, but would mean no review at all." *Ill. Council*, 529 U.S. at 17. The Court cautioned, however, that a party may not circumvent the channeling requirement by showing

merely that “postponement [of judicial review] would mean added inconvenience or cost in an isolated, particular case.” *Id.* at 22. Rather, in determining whether the *Illinois Council* exception to section 405(h) applies, “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.” *Id.* at 22–23.

This Circuit’s approach to the *Illinois Council* inquiry is best illustrated by *American Chiropractic Association, Inc. v. Leavitt*, 431 F.3d 812 (D.C. Cir. 2005). In that case, an association of chiropractors brought suit under section 1331 to challenge Medicare reimbursement regulations. In order to determine whether section 405(h) applied, and guided by the Supreme Court’s warning that mere inconvenience is no reason for invoking the *Illinois Council* exception, we carefully considered the various ways through which the association’s claim could be brought before the agency. Ultimately, because we determined that at least some chiropractors—though not all—could obtain administrative review of the challenged regulations, we found the *Illinois Council* exception inapplicable. *Id.* at 817–18.

The case before us presents a somewhat different situation, one not clearly addressed by existing case law. *Illinois Council* and *Michigan Academy* make clear that section 405(h) is inapplicable where the Medicare Act offers no avenue for review of a particular category of statutory or constitutional claims. But here other parties—specifically, the hospitals with which the Council’s members had contracted—could challenge the 2008 regulations through Medicare Act channels. *American Chiropractic*, in turn, suggests that section 405(h) applies so long as Medicare Act review of a claim is available to some, though perhaps not all, of a class

of affected parties. But here, as the government acknowledges, a whole category of affected parties—that is, joint ventures providing laser surgery equipment and services—has no way to obtain review through Medicare Act channels. This case, then, presents the following question: How does section 405(h) apply when the Medicare Act provides an avenue for administrative and judicial review of a particular claim (the challenge to the 2008 regulations), but not by the category of affected parties who wish to bring it (the Council)? Before addressing that question, however, we must consider an antecedent matter, namely, the government’s argument that the failure of anything in the Medicare Act to provide administrative remedies for non-Medicare providers, such as the Council and its members, reflects congressional intent to limit the right of judicial review to Medicare providers, i.e., hospitals.

III.

As directed by the Supreme Court in *Michigan Academy*, “[w]e begin with the strong presumption that Congress intends judicial review of administrative action” and that “judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress.” *Mich. Acad.*, 476 U.S. at 670 (internal quotation marks omitted). To overcome this presumption, the government bears a “heavy burden.” *Id.* at 672 (internal quotation marks omitted). Pursuant to *Block v. Community Nutrition Institute*, the government may attempt to satisfy its burden in several ways: by pointing to “specific language or specific legislative history that is a reliable indicator of congressional intent”; by demonstrating “congressional acquiescence” to a “contemporaneous judicial construction barring review”; or by drawing “inferences of intent . . . from the statutory scheme as a whole,” such as when the statute provides a

“detailed mechanism for judicial consideration of particular issues at the behest of particular persons,” but not at the behest of others. 467 U.S. 340, 349 (1984). Seeking to overcome the presumption via the last route, the government argues that by prohibiting review of HHS decisions except as provided in the Medicare Act and by barring claims brought under section 1331, section 405(h) “unambiguously limits judicial review to those parties who can invoke Medicare’s administrative remedies”—that is, hospitals, not the Council or its members. Appellees’ Br. 43. We disagree.

Critical to our analysis, the Supreme Court has understood section 405(h) as having only channeling force, not, as the government would have it, foreclosing force. *See Ill. Council*, 529 U.S. at 19 (characterizing section 405(h) as “a channeling requirement, not a foreclosure provision—of ‘amount determinations’ or anything else,” and drawing a distinction “between a total preclusion of review and postponement of review” (emphasis added)); *Mich. Acad.*, 476 U.S. at 680 (finding no evidence of congressional intent to foreclose statutory and constitutional challenges to Medicare regulations). Indeed, in *Michigan Academy*, the Court rejected an implied preclusion argument very similar to the one the government makes here—that “by failing to authorize [review of Medicare Part B determinations] while simultaneously authorizing administrative and judicial review [of Part A determinations]” and by “expressly preclud[ing] all administrative or judicial review not otherwise provided in that statute,” the Medicare Act foreclosed review of the challenged regulation. 476 U.S. at 673. Invoking the strong presumption favoring judicial review, the Court declined to interpret the statute’s “total silence about review” of Part B regulations, coupled with section 405(h)’s jurisdictional bar, as an implied preclusion of judicial review. *See Ill. Council*,

529 U.S. at 16–17 (describing *Michigan Academy*); *Mich. Acad.*, 476 U.S. at 675–76, 678–81.

The government argues that this case differs from *Michigan Academy* where “limiting appeal rights to those conferred by Medicare’s remedial scheme would result in ‘no forum to adjudicate statutory and constitutional challenges to regulations promulgated by the Secretary.’” Appellees’ Br. 45 (quoting *Mich. Acad.*, 476 U.S. at 678). According to the government, “[t]hat is not the case here. Hospitals, the parties directly affected by Stark law limitations on hospital reimbursement, indisputably have the right to challenge the pertinent regulations through Medicare’s jurisdictional scheme, thereby providing the administrative and judicial fora deemed lacking in *Michigan Academy*.” Appellees’ Br. 45. In support of its argument, the government relies on *Block*, in which the Supreme Court recognized that “when a statute provides a detailed mechanism for judicial consideration of particular issues at the behest of particular persons, judicial review of those issues at the behest of other persons may be found to be impliedly precluded.” 467 U.S. at 349.

In our view, however, this case is different from *Block*. There, ordinary consumers possessing only a general interest in a reliable, low-cost supply of milk sought section 1331 review of milk market orders regulating payments between dairy producers and processors, *see id.* at 344, 352 & n.3. Here, Council members, unlike the consumers in *Block*, are directly targeted by the regulations they challenge. The 2008 regulations redefine the status of urologist-owned joint ventures, *see* 42 C.F.R. § 411.351 (providing a new definition of entities “furnishing DHS” that includes any “entity that has performed services that are billed as DHS”), in such a way that the joint ventures can no longer either receive referrals from their urologist-owners or bill for services furnished

pursuant to such referrals, 42 U.S.C § 1395nn(a)(1). The regulations also bar physician-owned ventures from charging per procedure, while imposing no similar bar on the non-physician-owned ventures with which Council members compete. *See* 42 C.F.R. § 411.357(b)(4)(ii)(B) (prohibiting per-unit charges “to the extent that such charges reflect services provided to patients referred by the lessor to the lessee”). That Council members are not “providers” who can bill Medicare and receive reimbursements directly hardly makes their interest in the 2008 regulations “tangential” or “indirect,” as the government argues. Appellees’ Br. 46–47. Quite to the contrary, because over seventy-five percent of patients who undergo urologic laser surgery are insured by Medicare, Appellant’s Br. 7, the regulations’ impact on urologist-owned joint ventures is not only direct, but substantial, a fact that distinguishes the ventures from the ordinary consumers who *Block* held were precluded from judicial review.

In *Block*, moreover, the statute at issue “contemplate[d] a cooperative venture among the Secretary [of Agriculture], handlers, and producers,” and nowhere provided for participation by consumers. 467 U.S. at 346. The milk market orders set minimum prices that handlers (dairy product processors) were required to pay to producers for milk products, *id.* at 341–42, and the statute provided a mechanism for handlers and producers, but not ordinary consumers, to participate in the adoption of market orders, to enter into agreements with each other and the Secretary, and to obtain administrative and judicial review of the Secretary’s orders, *id.* at 346. Here, the statute is not so exclusive. Although the Council and its members may not bill Medicare directly, they are free to participate in rulemakings, and the Act contemplates their participation in the Medicare system (although now, of course, the challenged regulations largely

forbid such participation). Indeed, under those regulations, Council members are deemed to “furnish[]” designated health services, 42 C.F.R. § 411.351, leaving little distinction between urologist-owned joint ventures and Medicare “suppliers” who have access to Medicare Act channels for administrative and judicial review, at least for some claims. *See* 42 U.S.C. § 1395x(d) (defining “supplier” to mean “a physician or other practitioner, a facility, or other entity . . . that furnishes items or services”).

True, the Supreme Court has described the Medicare Act’s review provisions as “precisely drawn.” *United States v. Erika, Inc.*, 456 U.S. 201, 208 (1982). But the Court has found implied preclusion in the Medicare Act’s review scheme only where Congress’s failure to authorize review is “[c]onspicuous[]” and suggests “deliberate[] inten[t]” to foreclose judicial review. *Compare id.* at 208–11 (finding intent to preclude judicial review of amount determinations where the statute expressly authorized judicial review of eligibility determinations, but provided only for limited insurance carrier-review of amount determinations and “[c]onspicuously . . . fail[ed] to authorize further review” of those determinations, and where the legislative history “unambiguously support[ed] [this] reading of the statutory language”), *with Mich. Acad.*, 476 U.S. at 675–76 (refusing to read Congress’s silence as intent to preclude review, despite the Medicare Act’s “carefully detail[ed]” review scheme). Particularly considering the Supreme Court’s characterization of section 405(h) as “a channeling requirement, not a foreclosure provision,” *Ill. Council*, 529 U.S. at 19, we see no “clear and convincing evidence,” *Mich. Acad.*, 476 U.S. at 671 (internal quotation marks omitted), in the statute’s language or structure indicating that Congress deliberately intended to completely bar non-providers from seeking review of regulations that target them directly.

In reaching this conclusion, we acknowledge that it may seem anomalous to require providers to go through administrative review channels while permitting non-providers to seek immediate review in federal court. But that is a consequence of the fundamental principle lying at the heart of this case—that “judicial review of a final agency action by an aggrieved person will not be cut off unless there is persuasive reason to believe that such was the purpose of Congress.” *Id.* at 670 (internal quotation marks omitted). In any event, this “two-tiered system” of review is not as “nonsensical” as the government would have us believe, Appellees’ Br. 46–47. As the government itself points out, *id.* at 33 n.6, a provider bringing a pure legal challenge to the validity of a regulation may invoke the Medicare Act’s provisions for expedited judicial review, in which case a provider may also obtain prompt access to the federal courts. *See* 42 U.S.C. § 1395ff(b)(2). That providers must take the extra step of presenting their claim to the agency for an initial determination is, in our view, insufficient to justify precluding entities who “furnish” services for purposes of the Medicare Act, *see* 42 C.F.R. § 411.351, from obtaining judicial review of regulations that directly and substantially affect them.

IV.

Having determined that the Medicare Act imposes no absolute bar to the Council’s challenge, we return to the issue identified at the outset—whether section 405(h)’s channeling requirement applies to the Council’s claims.

We start from the premise that, as emphasized in *American Chiropractic*, the *Illinois Council* exception is not intended to allow section 1331 federal question jurisdiction in every case where section 405(h) would prevent a particular individual or entity from seeking judicial review. *See Ill. Council*, 529 U.S. at 23–24 (“[W]e do not hold that an

individual party could circumvent § 1395ii's channeling requirement simply because that party shows . . . 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 simply a channeling requirement into *complete* preclusion of judicial review.”); *Am. Chiropractic*, 431 F.3d at 817–18 (applying section 405(h) to the association's claims because some, though not all, of its members could access administrative review). The Council nowhere disagrees with this basic premise. Making clear that its “quarrel is not with administrative exhaustion by proxy,” Appellant's Reply Br. 21, the Council concedes that there are some situations—like the one in *American Chiropractic*—in which a particular plaintiff is unable to exhaust its claims, but the channeling provision nonetheless applies because an adequate proxy could raise the plaintiff's claims in its stead. In those situations, however, the Council insists that courts must have some assurance that the proxy's interests align with the plaintiff's, such that the proxy can be expected to bring and diligently pursue the plaintiff's claims through Medicare Act channels. The Council proposes two possible means of assuring such an alignment of interests. First, courts could require a legal relationship between the plaintiff and the proxy that presupposes a strong alignment of interests, such as the relationship between an association, which generally has standing only to seek redress of its members' injuries, and those very members, *see Ill. Council*, 529 U.S. at 24, or the relationship between a patient who has assigned her claim to a physician and that very physician, *cf. Am. Chiropractic*, 431 F.3d at 817 (noting that a chiropractor could obtain review by becoming the patient's assignee). Second, and apart from any legal relationship, courts could require a showing that the proxy “has adequate incentive to initiate and diligently pursue a timely administrative

proceeding on the claims the litigant wishes to raise in federal court.” Appellant’s Br. 29–30. According to the Council, neither condition exists here.

For its part, the government contends that our precedent requires no showing that a third party capable of exhausting the plaintiff’s claims has adequate incentive to do so or has any specific legal relationship to that plaintiff. According to the government, because “the *Illinois Council* exception turns solely on whether a *claim* can be heard, not whether a particular *party* can be heard,” Appellees’ Br. 23, our inquiry ends—and section 405(h) applies—once we determine that some party, somewhere, could bring the Council’s claims before HHS. As the government sees it, we need not, indeed may not, consider whether that party is likely to do so as a practical matter.

Although we agree that the *Illinois Council* exception is primarily concerned with whether a particular *claim* can be heard through Medicare Act channels, we see nothing in the case law requiring us to disregard factors that speak to a potential proxy’s willingness and ability to pursue the plaintiff’s claim. To the contrary, the *Illinois Council* inquiry is fundamentally a practical one. The exception applies “not only when administrative regulations foreclose judicial review, but also when roadblocks practically cut off any avenue to federal court.” *Am. Chiropractic*, 431 F.3d at 816; *see also Ill. Council*, 529 U.S. at 21–22 (suggesting that section 405(h) does not apply in cases where “as applied generally to those covered by a particular statutory provision, hardship likely found in many cases” amounts to the “practical equivalent of a total denial of judicial review” (internal quotation marks omitted)). In cases where the only entities able to invoke Medicare Act review are highly unlikely to do so, their unwillingness to pursue a Medicare

Act claim poses a serious “practical roadblock” to judicial review.

In this case, however, we have no need to determine precisely at what point a third party’s lack of incentive or misalignment of interests triggers the *Illinois Council* exception. Wherever that point lies, we think it clear that given the particular circumstances of this case, the *Illinois Council* exception applies: invoking section 405(h) would result not merely in “added inconvenience or cost in an isolated, particular case,” but in the “*complete* preclusion of judicial review.” *Ill. Council*, 529 U.S. at 22–23.

This conclusion flows from several unique characteristics of the hospitals’ relationship to the Council and to the challenged regulations. To begin with, the Council alleged in its complaint that the hospitals had no incentive to challenge the 2008 regulations. Compl. ¶ 82. Hospitals, the Council contended, “resent[ed] the notion of doctors having control over the purchase of medical equipment, which they view as a hospital prerogative,” *id.* ¶ 22, and the regulations presented an opportunity “for hospitals to reassert control over the procurement of lasers and other urological medical equipment,” *id.* ¶ 82. According to the Council, the regulations also allowed hospitals to purchase expensive laser equipment from urologist joint ventures at “fire-sale prices,” *id.* ¶ 75, while hospitals choosing not to acquire their own equipment could simply contract with non-urologist-owned ventures instead, thus suffering no material financial harm, *id.* ¶¶ 72, 82. Although the government points to allegations in the complaint that might indicate different incentives, such as the suggestion that only urologist-owned ventures have been willing to invest in new technology, *see, e.g.*, Compl. ¶¶ 78–79, it has failed to counter the Council’s allegations with, for instance, affidavits from hospitals attesting to their incentives

or intent to pursue an administrative challenge. *See Coal. for Underground Expansion v. Mineta*, 333 F.3d 193, 198 (D.C. Cir. 2003) (noting that courts may consider materials outside the pleadings in ruling on a 12(b)(1) motion to dismiss for lack of subject matter jurisdiction). Taking the Council's allegations as true and drawing all reasonable inferences in its favor, as we must at this stage, *City of Harper Woods Emps.' Retirement Sys. v. Olver*, 589 F.3d 1292, 1298 (D.C. Cir. 2009), we believe that the complaint demonstrates, at the very least, that hospitals have little incentive to pursue the Council's challenge to the regulations. Indeed, history confirms the Council's contentions. In 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 to those regulations. Appellant's Reply Br. 23 (citing Am. Hosp. Ass'n, Fast Facts on US Hospitals (2010), available at <http://www.aha.org/aha/resource-center/Statistics-and-Studies/fast-facts.html>). Finally, unlike the chiropractors in *American Chiropractic*, who could "mount an administrative challenge" by becoming assignees of their patients' claims, 431 F.3d at 817, here all parties agree that Council members have no way of becoming the assignee of a hospital's claim. Nor do they possess some other relationship with the hospitals that would assure us that the hospitals share their interest in challenging the 2008 regulations. Although the joint ventures have a contractual relationship with hospitals, this in itself provides no assurance of shared interests, for many hospitals have terminated their contracts with Council members and, pursuant to their contracts, have done so without penalty. Compl. ¶ 74; Appellant's Br. 48.

Taken together, the allegations in the Council's complaint, the fact that not one hospital has challenged the regulations despite having had three years to do so, and the absence of any relationship between Council members and the

hospitals that would ensure an alignment of interests demonstrate that invoking section 405(h) in this case would have the practical effect of “turn[ing] what appears to be simply a channeling requirement into *complete* preclusion of judicial review.” *Ill. Council*, 529 U.S. at 22–23. We therefore conclude that, under the specific facts of this case, the *Illinois Council* exception applies and the Council may therefore pursue its claim in district court pursuant to section 1331 general federal question jurisdiction.

V.

We reverse the district court’s dismissal for lack of subject matter jurisdiction and remand for further proceedings consistent with this opinion.

So ordered.