FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

SENSORY NEUROSTIMULATION, INC., a California corporation, *Plaintiff-Appellant*, and FRED BURBANK, MD, CEO, President, Board Chairman, and stock holder, *Plaintiff*, v. ALEX M. AZAR II, in his official capacity as Secretary of the United States Department of Health and Human Services; U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; CENTERS FOR MEDICARE & MEDICAID SERVICES, *Defendants-Appellees*, and SEEMA VERMA, Administrator Centers for Medicare and Medicaid Services; DEMETRIOS KOUZOUKAS, Principal Deputy Administrator Centers for Medicare and Medicaid	No. 19-55036 D.C. No. 8:18-cv-00180-CJC-JDE OPINION

Services; LAURENCE WILSON, Centers for Medicare and Medicaid Services; PETER J. GURK, MD, Medical Director, DME MAC, Jurisdiction D; ROBERT D. HOOVER, JR., MD, MPH, FACP, Medical Director, DME MAC, Jurisdiction C; STACEY V. BRENNAN, M.D., FAAFP, Medical Director, DME MAC, Jurisdiction B; WILFRED MAMUYA, MD, PHD Medical Director, DME MAC, Jurisdiction A,

Defendants.

Appeal from the United States District Court
for the Central District of California
Cormac J. Carney, District Judge, Presiding

Argued and Submitted May 13, 2020
Pasadena, California

Filed October 16, 2020

Before: Mary M. Schroeder and Daniel P. Collins, Circuit Judges, and Michael M. Baylson,[*] District Judge.

Opinion by Judge Baylson

[*] The Honorable Michael M. Baylson, United States District Judge for the Eastern District of Pennsylvania, sitting by designation.

SUMMARY[**]

Medicare

The panel affirmed the district court's dismissal for lack of jurisdiction of a lawsuit brought by a medical device supplier seeking to have Medicare "cover" the supplier's product.

Medical devices classified as "durable medical equipment" may be eligible for Medicare reimbursement. 42 U.S.C. § 1395m(a)(2). Devices considered "personal comfort items" are categorically not covered. 42 U.S.C. § 1395y(a)(6). A nationwide determination by the Centers for Medicare and Medicaid Services ("CMS") as to whether Medicare will reimburse beneficiaries for the purchase of the device is a "national coverage determination" ("NCD"). The Medicare statute eliminates federal question jurisdiction over lawsuits brought to "recover on any claim arising under" Medicare. 42 U.S.C. § 405(h). This "channeling requirement" forces plaintiffs to exhaust pertinent administrative channels. The channeling requirement does not apply where its application would mean no review at all.

Plaintiff-appellant Sensory NeuroStimulation, Inc. sells a prescription leg massager called "Relaxis," and it is seeking a favorable NCD that Medicare will reimburse beneficiaries for the purchase of Relaxis. Sensory applied to CMS for an NCD, which determined that Relaxis was a personal comfort item but did not make a formal NCD.

[**] This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

Sensory filed this action, and the district court granted the government's motion to dismiss based on its finding that Medicare's channeling requirement applied and had not been met.

The panel held that this lawsuit arose under Medicare such that the administrative channeling requirements applied. The panel also held that Sensory was not entitled to a waiver of the statute's exhaustion requirement. The panel further held that applying the exhaustion requirement would not mean "no review at all." Finally, the panel held that the exception to the exhaustion requirement articulated in *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986), did not apply because another party – medical device suppliers – could bring the same claim through the existing administrative channel, and therefore some review was available. The panel concluded that § 405(h)'s administrative channeling requirement applied, and therefore there was no subject matter jurisdiction to hear Sensory's claim.

COUNSEL

Linda T. Coberly (argued), Winston & Strawn LLP, Chicago, Illinois; Diana Leiden and Saul S. Rostamian, Winston & Strawn LLP, Los Angeles, California; Lauren Gailey, Winston & Strawn LLP, Washington, D.C.; for Plaintiff-Appellant.

Karen Y. Paik (argued), Assistant United States Attorney; David M. Harris, Chief, Civil Division; Nicola T. Hanna, United States Attorney; United States Attorney's Office, Los Angeles, California; for Defendants-Appellees.

OPINION

BAYLSON, District Judge:

I. Introduction

The issue in this case is whether the district court correctly decided it lacked subject matter jurisdiction over a lawsuit brought by a medical device supplier seeking to have Medicare "cover" the supplier's product. We conclude that the lawsuit is subject to Medicare's administrative channeling requirements, that Plaintiff-Appellant Sensory NeuroStimulation, Inc. ("Sensory") has not met those requirements, that there exists a way to satisfy those requirements, and that these conclusions do not completely preclude judicial review so as to trigger a key exception to the channeling requirements. We therefore affirm the district court.

II. Background

A. Statutory Background

Medicare is a half-century-old federal health insurance program for elderly and disabled Americans. Social Security Amendments of 1965, Pub. L. 89-97, 79 Stat. 286. As of 2019, it insured 61.2 million people. *2020 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds* 6 (2020). These federal insureds are known generally as Medicare "beneficiaries." The program is administered by the Centers for Medicare and Medicaid Services ("CMS"), an agency housed in the United States Department of Health and Human Services ("HHS"). Medicare administrative contractors ("MACs") help CMS

administer Medicare benefits in specific geographic regions. *See* 42 U.S.C. § 1395u.

Medicare is governed by an intricate statutory scheme, codified at 42 U.S.C. §§ 1395–1395*lll*. This case involves two parts of the statutory scheme: (1) provisions addressing how medical devices become covered, and (2) provisions defining the availability of judicial review.

1. *Medicare's Coverage for Medical Devices*

Medicare covers a limited universe of medical devices. Relevant here, devices classified as "durable medical equipment" *may* be eligible for Medicare reimbursement, subject to an exception that does not apply here. 42 U.S.C. § 1395m(a)(2). Devices considered "personal comfort items," on the other hand, are categorically not covered. *Id.* § 1395y(a)(6). Durable medical equipment is equipment that "[c]an withstand repeated use," "has an expected life of at least 3 years," "[i]s primarily and customarily used to serve a medical purpose," "[g]enerally is not useful to an individual in the absence of an illness or injury," and "[i]s appropriate for use in the home." 42 C.F.R. § 414.202.

Devices may be covered nationally, regionally, or on a case-by-case basis. A nationwide determination by CMS as to whether Medicare will reimburse beneficiaries for the purchase of the device is a "national coverage determination" ("NCD"). *See* 42 U.S.C. § 1395y(*l*)(6)(A). NCDs may be favorable or unfavorable.[1] *Id.* NCDs bind

[1] The Medicare statute sometimes distinguishes "national coverage determinations," which mandate nationwide coverage, from "national noncoverage determinations," which bar coverage nationwide. *See* 42 U.S.C. § 1395ff(f)(4)(A) (discussing the issuance of "national coverage or noncoverage determination[s]"). Other times, it combines

MACs. *See id.* § 1395ff(c)(3)(B)(ii)(I); 42 C.F.R. § 405.1060(a)(4). In the absence of an NCD, MACs may also issue "local" coverage determinations that apply to their own subsequent decisions. *See* 42 U.S.C. § 1395ff(f)(2)(B). In the absence of a national or local coverage determination, MACs deciding whether to reimburse particular claims make case-by-case decisions "based on applicable information, including clinical experience and medical, technical, and scientific evidence." *Id.* § 1395ff(c)(3)(B)(ii)(III).

There are several pathways for CMS to initiate an NCD evaluation process. CMS may initiate an NCD process on its own initiative. Medicare Program; Revised Process for Making National Coverage Determinations, 78 Fed. Reg. 48164, 48167 (Aug. 7, 2013). Alternatively, beneficiaries, medical professional societies, businesses such as medical device manufacturers, and others can request CMS initiate an NCD process through a written, "formal" request. *Id.* at 41166.

When there is no NCD for particular medical services or devices, individual beneficiaries "in need of the items or services" can request that CMS initiate a coverage determination process and are ordinarily entitled to receive a decision within ninety days. 42 U.S.C. § 1395ff(f)(4)–(5). Such beneficiaries in need are known as "aggrieved parties." *Id.* If the aggrieved party finds CMS's decision

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both under the label "national coverage determinations." *Id.* § 1395ff(f)(1)(B) ("For purposes of this section, the term 'national coverage determination' means a determination . . . with respect to whether or not a particular item . . . is covered nationally under" Medicare.). Here, we refer to national coverage and noncoverage determinations together as NCDs. Where the distinction matters, we refer to "favorable" or "unfavorable" NCDs.

unsatisfactory—*i.e.*, if CMS ultimately decides not to issue an NCD or issues an unfavorable NCD—the aggrieved party may appeal to the Departmental Appeals Board of HHS. *Id.* § 1395ff(f)(1)(A). The result of that appeal is a final agency action subject to judicial review. *Id.* § 1395ff(f)(1)(A)(v). No NCD requestors other than aggrieved parties have the same or even similar statutory rights to a decision and appeal, and aggrieved parties may not assign their rights. *Id.* § 1395ff(f)(1)(A)(iii); 42 C.F.R. § 426.320.

The heart of this case is about what, if any, rights to appeal are available to NCD requestors like Sensory who are not Medicare beneficiaries.

2. *Medicare's Limitation on Judicial Review: The "Channeling" Requirement*

The Medicare statute eliminates federal question jurisdiction over lawsuits brought "to recover on any claim arising under" Medicare. *See* 42 U.S.C. § 405(h) ("No action against the United States . . . 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."); *id.* § 1395ii (incorporating § 405(h) into the Medicare statute). This is known as § 405(h)'s "channeling requirement" because it forces plaintiffs to exhaust pertinent administrative channels. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 19 (2000). In practice, the channeling requirement "assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts." *Id.* at 13.

The Medicare statute creates administrative channels specifically designed for Medicare. As discussed earlier, under 42 U.S.C. § 1395ff(f)(1)(A)(iii), when an aggrieved

party is unhappy with the agency's NCD, that aggrieved party may appeal that decision to the Departmental Appeals Board of HHS, and that Appeals Board's decision "constitutes a final agency action and is subject to judicial review." 42 U.S.C. § 1395ff(f)(1)(A)(v). Some of the administrative channels are adapted from other statutory schemes. For example, beneficiaries' challenges to adverse benefits determinations "shall be entitled to reconsideration of the determination, and . . . a hearing thereon by the Secretary to the same extent as is provided in" 42 U.S.C. § 405(b). *Id.* § 1395ff(b)(1)(A).

When a claim arises under Medicare, § 405(h) eliminates federal question jurisdiction and the plaintiffs must first exhaust the appropriate administrative channels before seeking judicial review. The Supreme Court has held that a wide range of claims "arise under" Medicare. *See Weinberger v. Salfi*, 422 U.S. 749 (1975); *Ill. Council*, 529 U.S. at 13–14. Of course, § 405(h)'s channeling requirement applies in "a typical Social Security or Medicare benefits case, where an individual seeks a monetary benefit from the agency (say, a disability payment, or payment for some medical procedure), the agency denies the benefit, and the individual challenges the lawfulness of that denial." *Ill. Council*, 529 U.S. at 10. § 405(h) also requires that plaintiffs channel claims that advance "general legal" arguments just as much as claims that advance "fact-specific" arguments; claims that are "collateral" to a benefits determination just as much as claims that are not; claims based on a "potential future" just as much as claims rooted in the "actual present"; and claims for declaratory, injunctive, or monetary relief. *Id.* at 13–14.

There is an important exception to the broad channeling requirement, however. The channeling requirement does not

apply where its "application . . . would mean no review at all." *Id.* at 19 (interpreting *Bowen v. Mich. Acad. of Fam. Physicians*, 476 U.S. 667 (1986)) (known as the "*Michigan Academy* exception"). In *Michigan Academy*, a group of physicians brought statutory and constitutional challenges to a regulation promulgated under Part B of the Medicare statute. 476 U.S. at 668–69. That regulation determined rates at which physicians could recover for certain services. *See* 42 C.F.R. § 405.504(b) (1985). The Court explained that, because plaintiffs could not bring their challenges through any administrative channel, applying § 405(h)'s channeling requirement would have meant the plaintiffs could not obtain judicial review of their claims at all. *Mich. Acad.*, 476 U.S. at 681. The Court, applying the "'strong presumption that Congress did not mean to prohibit all judicial review' of executive action," thus concluded that § 405(h) did not divest the federal courts of jurisdiction. *Id.* at 680–81 (quoting *Dunlop v. Bachowksi*, 421 U.S. 560, 567 (1975)).

In assessing whether requiring channeling would result in "no review at all," *id.* at 680, "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 (citing *McNary v. Haitian Refugee Ctr.*, 498 U.S. 479, 496–97 (1991)).

Taking these statutory provisions and cases together, it becomes clear that assessing whether a court has subject matter jurisdiction to hear a claim related to Medicare requires a three-step analysis.

1. In the first step, the court must decide whether the claim "arises under" Medicare such that

§ 405(h)'s administrative channeling requirement applies. If it does not, the plaintiff may proceed in court. If it does, the court moves on to the second step.

2. In the second step, the court must decide whether the plaintiff has satisfied the channeling requirements by properly presenting the claim and exhausting the appropriate administrative channel. If the plaintiff has done so, or alternatively, has satisfied the requirements for judicial waiver of the exhaustion requirement, the plaintiff may proceed in court. If the plaintiff has not, the court moves on to the third and final step.

3. In this last step, the court must decide whether the administrative channeling requirement would mean that there would be "no review at all" of the plaintiff's claim. If it would, the plaintiff may proceed in court under 28 U.S.C. § 1331 or some other jurisdictional predicate. If not, the plaintiff's claim cannot proceed and must be dismissed for lack of subject matter jurisdiction.

As explained below, this case implicates all three of the above steps.

B. Factual Background

Appellant Sensory Neurostimulation, Inc. sells a prescription leg massager called "Relaxis" specifically designed to treat Restless Leg Syndrome ("RLS"). The company's founder, Dr. Fred Burbank, is an RLS sufferer and Medicare beneficiary. Sensory is ultimately seeking a favorable NCD—that is, a binding nationwide determination

that Medicare will reimburse beneficiaries for the purchase of Relaxis.

In November of 2015, Sensory asked CMS to make an informal "benefit category determination" ("BCD") for Relaxis—in other words, to decide whether Relaxis is durable medical equipment eligible to be covered by Medicare. A CMS employee decided that Relaxis is a personal comfort item, categorically ineligible for coverage, on the grounds that it could serve a non-medical purpose. The employee then suggested that Relaxis ask Noridian, the California MAC, for a "local" BCD. A few months later, Noridian also decided that Relaxis is a personal comfort item.

In June of 2016, Sensory formally applied to CMS for an NCD. CMS informed Sensory by letter dated March 20, 2017 that it had determined that Relaxis is a personal comfort item. The determination was not a formal NCD, so it did not bind the MACs. A few months later, Sensory met with Dr. Demetrios L. Kouzoukas, Principal Deputy Administrator of CMS and Director for the Center of Medicare, to try to persuade him otherwise. CMS took no action for six months, at which point Dr. Burbank sued HHS in his own name. On February 16, 2018, Dr. Kouzoukas sent Sensory a brief letter affirming the March 20, 2017 letter. Sensory filed the First Amended Complaint, which substituted Sensory for Dr. Burbank as plaintiff, on September 28, 2018.

C. District Court Proceedings

The Government moved under Federal Rule of Civil Procedure 12(b)(1) to dismiss the First Amended Complaint on October 25, 2018. The Government argued that the District Court lacked subject matter jurisdiction because

Sensory's lawsuit arose under Medicare such that § 405(h)'s channeling requirement applied and Sensory had not gone through the appropriate administrative channels. In its response brief, Sensory argued that it was entitled to judicial review because there was no further appropriate channel that it was required to follow. Either the channeling requirement did not apply, Sensory argued, or Sensory had satisfied it.

The district court agreed with the Government. It found that Medicare's channeling requirement applied and had not been met. Consequently, it dismissed the case without prejudice, and without leave to amend.

First, the district court decided that there was "little question that Sensory's claim substantively 'ar[o]se under' the Medicare statute." "[An NCD] merely codifies the Secretary's position on whether Medicare will approve individual claims for that item or service. Accordingly . . . Sensory's claims [are] 'inextricably intertwined with a claim for benefits . . . .'" (quoting *Heckler v. Ringer*, 466 U.S. 602, 614–15 (1984)). Thus, the channeling requirement applied.

Next, the district court considered whether the channeling requirement would effectively result in "no review at all" such that the channeling requirement should be ignored. The court concluded that Sensory could still pursue its interests by either accepting assignments of beneficiaries' claims to benefits or by recruiting an aggrieved party to file a request for an NCD determination pursuant to 42 U.S.C. § 1395ff(f)(1)(A). The court held it irrelevant that Sensory could not receive an NCD by accepting assignments of individuals' claims, because it is "action[s]," not "particular contention[s]," that must be channeled through the agency. (quoting *Ill. Council*, 529 U.S. at 23) (internal quotation marks omitted).

Finally, the district court considered whether it could waive the need for Sensory to exhaust possible administrative remedies. It concluded that Sensory's lawsuit met none of the three requirements for waiver. The lawsuit was not "collateral" to a claim of entitlement under Medicare, as it arose under Medicare; any harm was not "irreparable," because harm could be remedied with money damages; and administrative procedures were not "futile," because further proceedings would serve the purposes of exhaustion by enabling the agency to fulfill its role "without possibly premature interference." (quoting *Ill. Council*, 529 U.S. at 13) (internal quotation marks omitted).

The district court dismissed the suit without prejudice and denied leave to amend on grounds of futility.

D. The Parties' Arguments on Appeal

The parties dispute three issues in this appeal. First, whether the lawsuit "arises under" Medicare such that the channeling requirement of 42 U.S.C. § 405(h) applies. Second, whether Sensory has met the requirements to sue under 42 U.S.C. § 405(g). And third, whether, if the lawsuit arises under Medicare and there is no jurisdiction under 42 U.S.C. § 405(g), that means that there is "no review at all" such that Sensory may bypass § 405(h)'s channeling requirement altogether.

For the reasons stated below, we agree with the Government that this lawsuit arises under Medicare, that Sensory is not entitled to waiver of the statute's exhaustion requirement, and that applying the exhaustion requirement here would not mean "no review at all."

III. Standard of Review

Our review of questions of subject matter jurisdiction is de novo. *Do Sung Uhm v. Humana, Inc.*, 620 F.3d 1134, 1140 (9th Cir. 2010) (citing *Sommatino v. United States*, 255 F.3d 704, 707 (9th Cir. 2001)).

IV. Discussion

A. Section 405(h)'s channeling requirement applies.

Section 405(h)'s channeling requirement eliminates federal question jurisdiction for lawsuits "arising under" the Medicare statute. Because Sensory's lawsuit arises under Medicare, it applies here.

In interpreting the phrase "arising under," we are not writing on a "blank slate." *P.R. Ass'n of Physical Med. & Rehab., Inc. v. United States*, 521 F.3d 46, 48 (1st Cir. 2008). The Supreme Court has provided considerable guidance in this area. We briefly review three key cases below.

Weinberger v. Salfi, a Social Security case, interpreted the scope of § 405(h)'s administrative channeling requirement. In *Salfi*, a widow and her child had been denied survivorship benefits on the grounds that the widow's marriage to her late husband was too brief. 422 U.S. at 753–54. They brought a § 1331 (federal question) suit seeking monetary, declaratory, and injunctive relief against the Social Security Administration on behalf of themselves and a putative class of others similarly situated. *Id.* at 755. The Supreme Court held that § 405(h)'s administrative channeling requirement applied to the suit, barring § 1331 jurisdiction, notwithstanding the fact that the plaintiffs' claims were constitutional rather than statutory. *Id.* at 760–61. The Court explained that, "not only is it Social Security

benefits which appellees seek to recover, it is the Social Security Act which provides both the standing and the substantive basis for the presentation of their constitutional contentions." *Id.* Ultimately, the Supreme Court held that because the complaint did not allege that the putative class members had even sought administrative remedies, the class allegations should have been dismissed for failure to exhaust administrative remedies. *Id.* at 764. In contrast, the named plaintiffs had exhausted their remedies and were allowed to proceed to the merits. *Id.* at 764–67. Although *Salfi* dealt with the Social Security Act, "*Salfi*'s interpretation of § 405(h) is directly applicable to conflicts arising under the Medicare Act and the courts have applied *Salfi* to a broad variety of disputes arising under the Medicare Act." *Drennan v. Harris*, 606 F.2d 846, 850 (9th Cir. 1979).

After *Salfi* came the important 1984 case of *Heckler v. Ringer*. In *Heckler*, four Medicare beneficiaries sued the Government under *inter alia* § 1331 to obtain coverage for a particular surgical procedure. 466 U.S. at 604–05. The beneficiaries sought declaratory and injunctive relief only. *Id.* at 615, 620. Despite the beneficiaries' choice not to seek monetary relief, the Supreme Court held that the suit arose under Medicare and that § 405(h)'s administrative channeling requirement applied. *Id.* at 615–16, 621–22. The channeling requirement even applied to the claim for declaratory relief brought by one beneficiary who had not yet undergone the procedure and so could not have had a claim for reimbursement pending at the time of the suit. *Id.* at 621–22.

Finally, the Supreme Court further clarified the scope of the administrative channeling requirement in *Illinois Council*. There, the Court considered how § 405(h) affected § 1331 lawsuits brought by plaintiffs "who *might* later seek

money or some other benefit from (or contest the imposition of a penalty by) the agency[,] challeng[ing] in advance . . . the lawfulness of a policy, regulation, or statute that *might* later bar recovery of that benefit (or authorize the imposition of the penalty)[.]" 529 U.S. at 10. After reviewing *Heckler* and *Salfi*, the Court concluded:

> Those cases themselves foreclose distinctions based upon the "potential future" versus the "actual present" nature of the claim, the "general legal" versus the "fact-specific" nature of the challenge, the "collateral" versus "noncollateral" nature of the issues, or the "declaratory" versus "injunctive" nature of the relief sought. Nor can we accept a distinction that limits the scope of § 405(h) to claims for monetary benefits . . . . There is no reason to distinguish among them in terms of the language or in terms of the purposes of § 405(h).

Id. at 13–14.

As *Illinois Council* makes clear, Sensory's lawsuit arises under Medicare. Sensory contends that it is seeking to create an entitlement to benefits for others, but not for itself. In other words, its argument is that its suit is "collateral," addresses "general legal" issues, is aimed at "potential future" outcomes, seeks no particular monetary benefits, and is third-party. But *Illinois Council* held that a lawsuit's "collateral," "general legal," or "potential future" nature, as well as the fact that the plaintiff is not seeking damages, are all immaterial to the "arising under" analysis. *Id.* That leaves only one way in which this case can be distinguished

from one in which channeling can be required under *Illinois Council*: that Sensory, as a medical device supplier, is a third party to the relationship between Medicare beneficiaries and the government. We are unpersuaded that this distinction matters for two reasons.

First, stating that Sensory is a third party simply restates two of the other four immaterial distinctions. Its lawsuit is collateral to claims for benefits and seeks no particular monetary benefits precisely because Sensory is a third party—specifically, a medical device supplier. Given that the prior two derivative distinctions are immaterial, the distinction that that the lawsuit is brought by a third party must be as well.

Second, allowing Sensory to proceed because it is a third party would enable plaintiffs to circumvent Medicare's administrative channeling scheme. Such circumvention is disfavored. *See Heckler*, 466 U.S. at 621–22. One of the *Heckler* plaintiffs had not yet undergone the surgery at issue and so sought prospective relief. *Id.* at 620. This distinguished him from his co-plaintiffs, who had undergone the surgery and sought retroactive relief. *Id.* at 613. The Supreme Court held that he could not proceed in court without first exhausting his claim before the agency, because it would "invit[e] [beneficiaries] to bypass the exhaustion requirements of the Medicare Act by simply bringing declaratory judgment actions in federal court before they undergo the medical procedure in question." *Id.* at 621 (citing *Att'y Registration & Disciplinary Comm'n v. Schweiker*, 715 F.2d 282, 287 (7th Cir. 1983)). Similarly, allowing providers or device suppliers to sue where beneficiaries cannot could enable beneficiaries to bypass § 405(h)'s administrative channeling requirement by having third-party providers or suppliers bring declaratory

judgment actions in federal court before the beneficiaries undergo the medical procedure or obtain the device in question.

The role the *Heckler* beneficiaries' physician played in their case demonstrates that such circumvention is a real possibility. In *Heckler*, all the beneficiaries were treated by the same physician, a specialist in the surgery in question, who also served as a co-plaintiff representing the beneficiaries. *Id.* at 609 & n.6. As the Court noted, the physician brought no individual claims; he merely served as a representative of his patients, who were the actual claimants. *Id*. at 609 n.6. The physician was therefore a third party in all but name. The Court concluded that because there was no jurisdiction as to the patients, there necessarily was no jurisdiction as to the physician. *Id*.

To summarize: *Illinois Council*, *Salfi*, and *Heckler* dictate that Sensory's lawsuit arises under Medicare even though the lawsuit may be third-party or otherwise distinguishable from a typical benefits appeal. Because Sensory's lawsuit arises under Medicare, § 405(h)'s administrative channeling requirement applies. Unless Sensory has exhausted an appropriate administrative channel or can show that applying the administrative channeling requirements would mean "no review at all," it cannot proceed.

Before discussing those issues, we note that the First Circuit came to the same conclusion in 2008 when faced with a lawsuit much like this one. An association of physical therapists had sued to overturn a regulation prohibiting Medicare reimbursements for services provided by physical therapists who did not meet certain educational and training requirements. *P.R. Ass'n*, 521 F.3d at 47–48. Applying

Illinois Council, the First Circuit concluded the lawsuit arose under Medicare:

> Although [the association's] suit challenges a regulation and does not directly request payment for a specific service, it seeks at its heart the extension of Medicare benefits; accordingly, it would appear barred by section 405(h) as construed by the Supreme Court. The regulation being challenged is simply a limitation on the claims that Medicare will pay and so foreshadows the denial of such claims.

Id. at 48. Like Sensory, the plaintiff in *Puerto Rican Ass'n* was a third party suing to create coverage for medical care that it could provide. The First Circuit held that that lawsuit arose under Medicare. We hold the same as to Sensory's.

B. Section 405(g) does not provide an alternative basis for jurisdiction.

Sensory contends that, even if federal question jurisdiction is unavailable, it has met the requirements to bring suit under 42 U.S.C. § 405(g), which provides for judicial review of final agency actions that have been presented to the Secretary of HHS. We disagree.

Even assuming *arguendo* that the Medicare statute incorporated § 405(g) for claims like Sensory's, Sensory could not proceed under § 405(g) in this case. Parties proceeding under § 405(g) must obtain a "final decision" from the Secretary. 42 U.S.C. § 405(g); *Johnson v. Shalala*, 2 F.3d 918, 921 (9th Cir. 1993). Sensory has not done so.

There are two components to a final decision under § 405(g): "the presentment of a claim to the Secretary and the exhaustion of administrative remedies." *Johnson*, 2 F.3d at 921. Of these elements, only the exhaustion requirement is judicially waivable. *See Haro v. Sebelius*, 747 F.3d 1099, 1112 (9th Cir. 2014) ("Exhaustion is waivable, presentment is not." (citing *Kaiser v. Blue Cross of Cal.*, 347 F.3d 1107, 1115 (9th Cir. 2003))). Sensory has not exhausted administrative remedies, so § 405(g) only provides jurisdiction if the exhaustion requirement in this case can be judicially waived.

Waiver is warranted if the claim is "(1) collateral to a substantive claim of entitlement (collaterality); (2) colorable in its showing that denial of relief will cause irreparable harm (irreparability); and (3) one whose resolution would not serve the purposes of exhaustion (futility)." *Johnson*, 2 F.3d at 921 (citing *Briggs v. Sullivan*, 886 F.2d 1132, 1139 (9th Cir. 1989)). The third of these elements—futility—has not been satisfied, so we cannot waive the exhaustion requirement.

Futility is established if exhausting administrative remedies "would not serve the policies underlying exhaustion." *Cassim v. Bowen*, 824 F.2d 791, 795 (9th Cir. 1987). "In most cases, the exhaustion requirement allows the agency to compile a detailed factual record and apply agency expertise in administering its own regulations. The requirement also conserves judicial resources. The agency will correct its own errors through administrative review." *Johnson*, 2 F.3d at 922.

Requiring Sensory to seek administrative review of CMS's decision that Relaxis is a personal comfort item would serve all these policies. There are at least two ways for Sensory to seek administrative review. Sensory can

either accept assignment of an individual claim for benefits and pursue that claim or recruit an aggrieved party to file a request for an NCD then challenge an adverse decision through the HHS appeals process. Either of these proceedings might result in the agency changing its mind and providing coverage for Relaxis, so further proceedings would serve the policy of allowing the agency to "correct its own errors through administrative review." *Id.* And either of these proceedings might result in an administrative record that could assist in any subsequent judicial review. This is simply not a case where "there [i]s nothing to be gained from permitting the compilation of a detailed factual record, or from agency expertise." *Bowen v. City of New York*, 476 U.S. 467, 485 (1986) (citing *McKart v. United States*, 395 U.S. 185, 200 (1969)). For these reasons, further administrative proceedings would not be futile.

Because further administrative proceedings would not be futile, exhaustion should not be waived. And because exhaustion should not be waived, Sensory has not obtained a "final decision" within the meaning of § 405(g). As a result, even if claims like Sensory's could proceed under § 405(g) in theory, Sensory could not proceed under § 405(g) in this case.

C. Applying § 405(h)'s channeling requirement will not result in "no review at all," so the *Michigan Academy* exception does not apply.

There is an important exception to § 405(h)'s administrative channeling requirement. Sensory contends that it applies here.

As explained above, the Supreme Court first articulated this exception in *Bowen v. Michigan Academy of Family Physicians*. In that case, applying § 405(h)'s channeling

requirement would have meant the plaintiff could obtain "no [judicial] review at all of substantial statutory and constitutional challenges to the Secretary's administration of Part B of the Medicare program." 476 U.S. at 680. The Court, applying the "'strong presumption that Congress did not mean to prohibit all judicial review' of executive action," concluded that § 405(h) did not apply. *Id.* at 680–81 (quoting *Dunlop v. Bachowksi*, 421 U.S. 560, 567 (1975)).

The Court later clarified the sweep of the *Michigan Academy* exception in *Illinois Council*. There, an association representing nursing homes challenged a Medicare regulation that dictated what agencies were to do when they found that a nursing home was violating substantive standards. 529 U.S. at 6. The association argued that the Medicare statute only allowed review when the Secretary terminated a nursing home agreement, but not when the Secretary imposed a lesser sanction. *Id*. at 20. Relying on the Secretary's assurances that nursing homes could obtain review of most decisions by incurring a minor penalty, the Court concluded that channeling was required and that § 405(h) barred review. *Id*. at 22. The Court explained that in deciding whether channeling "mean[s] no review at all," "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 19, 22–23 (citing *Haitian Refugee Ctr.*, 498 U.S. at 496–97). If such *complete* preclusion of judicial review occurs, § 405(h)'s channeling requirement does not apply. *Id.* at 22–23.

The Supreme Court has not revisited the *Michigan Academy* exception since *Illinois Council*. This Circuit has rarely encountered it, but we did find that the exception

applied in *Haro v. Sebelius*, 747 F.3d 1099, 1115 (9th Cir. 2014). In *Haro*, an attorney for a Medicare beneficiary sued to overturn a Medicare policy that distinctly affected attorneys for Medicare beneficiaries. *Id.* at 1104. The panel observed that the attorney could not follow the administrative channels open to beneficiaries, that it was "unaware of any other path to administrative review of the policy that [the attorney] challenge[d], and [that] the parties cite[d] none." *Id.* at 1115. Because there was no administrative channel through which the attorney (or anyone else) could bring his claim, the panel concluded that "the claim falls within the very narrow *Michigan Academy* exception, and the district court had federal question jurisdiction under § 1331 to adjudicate it." *Id.* (citation omitted).

The Fifth and D.C. Circuits have both considered the exception at greater length. Both have ruled that the *Michigan Academy* exception does not apply where another party is able to pursue the same claim through an appropriate administrative channel and is incentivized to do so. *See Fam. Rehab., Inc. v. Azar*, 886 F.3d 496, 505 (5th Cir. 2018) ("[W]e have required channeling so long as 'there potentially were other parties with an interest and a right to seek administrative review.'") (quoting *Physician Hosps. of Am. v. Sebelius*, 691 F.3d 649, 657 (5th Cir. 2012)); *Am. Chiropractic Ass'n v. Leavitt*, 431 F.3d 812, 816–17 (D.C. Cir. 2005) (holding *Michigan Academy* exception did not apply because chiropractors' association, although unable to proceed in its own name, could recruit enrollee to proceed through administrative channels); *cf. Council for Urological Interests v. Sebelius*, 668 F.3d 704, 712 (D.C. Cir. 2011) ("Although we agree that the [*Michigan Academy*] 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."); *P.R. Ass'n*, 521 F.3d at 49–50 (holding *Michigan Academy* exception did not apply because "doctors and therapists certainly have ample economic incentive to frame and support a test case"). *American Chiropractic*, for example, concerned the American Chiropractic Association's attack on a Medicare rule allowing HMOs to require that patients receive a referral from a non-chiropractor before seeking chiropractic services. 431 F.3d at 814–15. Although there was no administrative channel through which the Association could attack the rule, the D.C. Circuit concluded that applying the channeling requirement would not mean "no review at all" because a *beneficiary* could receive chiropractic services without a referral, have his or her claim for benefits denied by his or her HMO, and then proceed through the administrative process. *Id.* at 816–17.

These out-of-circuit cases address the basic question here: does the *Michigan Academy* exception apply when an administrative channel exists for review of a certain category of claims, but is closed to the particular plaintiff bringing the lawsuit? They conclude that if another party can bring the same claim through the existing administrative channel, and is sufficiently incentivized to do so, then some review is available, and the *Michigan Academy* exception does not apply. We agree, and we reach the same conclusion here.

In this case, an administrative channel for review exists.[2] Indisputably, 42 U.S.C. § 1395ff(f) provides an administrative channel for "aggrieved parties" to request

[2] This feature distinguishes this case from *Haro*, where no appropriate administrative channel existed. 747 F.3d at 1115.

NCDs and challenge unsatisfactory results. The difficulty for Sensory (and similarly situated suppliers) is that it is not an "aggrieved party" within the meaning of the statute. Because it is not an "aggrieved party," it cannot directly avail itself of this administrative channel. However, Sensory (or a similarly situated supplier) could indirectly avail itself of this channel. That is enough to take this case out of the *Michigan Academy* exception.

It may not be easy for a particular supplier to find an agreeable proxy, but particular suppliers' difficulties do not affect the analysis. Whether there would be "no review at all" is an objective inquiry. *See Ill. Council*, 529 U.S. at 22–23 ("[T]he question is whether, *as applied generally* . . . hardship *likely found in many cases* turns what appears to be simply a channeling requirement into *complete* preclusion of judicial review." (first and second emphasis added)). A particular supplier's difficulty finding a proxy does not amount to "hardship *likely* found in many cases . . . [causing] *complete* preclusion of judicial review." *Id.* (first emphasis added).

Although the government contends otherwise, the fact that Dr. Burbank is an RLS sufferer and Medicare beneficiary does not inform the "no review at all" inquiry either. Again, the *Michigan Academy* inquiry is objective. *Id.* Circumstances that make recruiting proxies easier for particular medical device suppliers are no more pertinent to that inquiry than circumstances that make recruiting proxies more difficult for others. This case's unusual feature—that Sensory's CEO, President, Board Chairman, and stockholder is himself capable of becoming "aggrieved"—is simply not "likely found in many cases," *id.*, and cannot relieve Sensory from the channeling requirements.

Ultimately, because medical device suppliers seeking NCDs can be expected to recruit proxies to exhaust the administrative channel provided in 42 U.S.C. § 1395ff(f), they can effectively obtain judicial review. Because medical device suppliers can effectively obtain judicial review, the *Michigan Academy* exception does not apply in this suit. And because the *Michigan Academy* exception does not apply, the district court correctly dismissed this lawsuit for lack of subject matter jurisdiction.

V. Conclusion

The district court correctly held that § 405(h)'s administrative channeling requirement applied and that it therefore had no subject matter jurisdiction to hear Sensory's claims. **AFFIRMED.**