No. 13-144

In the Supreme Court of the United States

SOUTHWEST PHARMACY SOLUTIONS, INCORPORATED,
PETITIONER

v.

CENTERS FOR MEDICARE AND MEDICAID SERVICES,
ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

BRIEF FOR THE RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether a particular person who does not have direct access to the administrative process, but whose claim may be brought by other parties through that process (and by the particular person in a representative capacity), may challenge a Medicare regulation in district court even though 42 U.S.C. 405(h) and 1395ii expressly preclude federal question jurisdiction over such claims.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1-23) is reported at 718 F.3d 436. The order of the district court (Pet. App. 24-43) is not reported but is available at 2011 WL 6033038.

JURISDICTION

The judgment of the court of appeals was entered on May 1, 2013. The petition for a writ of certiorari was filed on July 30, 2013. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. Part D of the Medicare statute (Part D), established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-

173, 117 Stat. 2066, provides subsidized prescription drug insurance for Medicare enrollees. 42 U.S.C. 1395w-101 *et seq.* Under Part D, prescription drug coverage is provided through prescription drug plans sponsored by private insurers. 42 U.S.C. 1395w-101(a). Plans are required to permit enrollees to fill prescriptions at "any willing pharmacy," *i.e.*, "any pharmacy that meets the terms and conditions under the plan." 42 U.S.C. 1395w-104(b)(1)(A). Medicare regulations, however, permit plans to contract with pharmacies to provide drugs at lower costs and to pass those savings along to their customers by charging lower copayments or coinsurance for drugs purchased at these "preferred pharmacies." 42 C.F.R. 423.120(a)(9). That "preferred pharmacy" regulation has been challenged in this case.

The Medicare statute generally makes federal jurisdiction over all claims arising under the statute, including under Part D, contingent on presentment of a claim to the Secretary of Health and Human Services (Secretary) and exhaustion of statutorily prescribed administrative remedies. See 42 U.S.C. 405(g), 1395ii. Under Section 405(h), which is incorporated by reference into the Medicare statute (see 42 U.S.C. 1395ii), "[n]o action against the United States, the [Secretary], 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). And "[n]o findings of fact or decision of the [Secretary] shall be reviewed by any person, tribunal, or governmental agency except as" provided in the Medicare statute. *Ibid.*; see 42 U.S.C. 1395ii.

2. Petitioner, a coalition of independent pharmacies, filed suit in federal district court invoking federal question jurisdiction under 28 U.S.C. 1331, and challenging the preferred pharmacy regulation. Pet. App. 25. Petitioner alleged that the regulation was inconsistent with Part D's requirement that a plan permit enrollees to fill prescriptions at "any willing pharmacy." *Ibid.* (quoting 42 U.S.C. 1395w-104(b)(1)(A)).

Respondents filed a motion to dismiss for lack of subject matter jurisdiction. Pet. App. 24-25. Petitioner acknowledged that it had not channeled (or attempted to channel) its claim through the administrative review process but, instead, had brought suit in federal court in the first instance. Petitioner argued that the district court nevertheless had jurisdiction because the Medicare statute did not provide an avenue for administrative or judicial review of its claim. *Id.* at 4-5 (citing *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1 (2000) (*Illinois Council*)). The district court disagreed and granted the motion to dismiss. *Id.* at 24-43.

3. The court of appeals affirmed in a unanimous decision. Pet. App. 1-23.

The court of appeals explained that Section 405(h), as incorporated into the Medicare statute, "severely restricts the authority of federal courts by requiring [that] virtually all legal attacks under the Act be brought through the agency." Pet. App. 5 (citations and internal quotation marks omitted; brackets in original). The purpose of that channeling requirement, the court continued, is to ensure that the Secretary has an "opportunity to apply, interpret or revise policies, regulations, or statutes without possibly premature interference by different individual

courts." *Id.* at 6 (citations and internal quotation marks omitted). The court of appeals explained that, in *Illinois Council*, this Court had recognized an exception to that general rule when "application of [Section] 405(h) would not simply channel review through the agency, but would mean no review at all." *Ibid.* (quoting *Illinois Council*, 529 U.S. at 19). The court accordingly examined whether applying Section 405(h)'s jurisdictional bar would result in a "*complete* preclusion of judicial review." *Ibid.* (quoting *Illinois Council*, 529 U.S. at 22-23).

The court of appeals concluded that, in this case, it would not. Pet. App. 6. The court explained that petitioner's challenge to the preferred pharmacy regulation could be raised through the administrative process and subject to judicial review as a "coverage determination." *Id.* at 8-13. The court acknowledged that petitioner (and its members) are not entitled "to bring coverage determination claims"; but, it explained, enrollees in preferred pharmacy plans can bring such claims and have a "financial" incentive to do so. *Id.* at 13, 15-16. The court also explained that the Part D regulations "allow for an enrollee to appoint a representative to navigate the appeals process on his behalf" and that "a provider" pharmacy could "seek to be appointed as the representative of an enrollee." *Id.* at 13 (citing 42 C.F.R. 423.566(c)(2)). And, the court continued, "enrollees may request judicial review" of a final adverse administrative determination. *Ibid.* (citing 42 C.F.R. 423.562(b)(4)(vi)). After considering and rejecting petitioner's arguments as to "why channeling its claims through the administrative process would effectively result in a

total loss of judicial review," the court held that the district court lacked jurisdiction. *Id.* at 7, 8-22.

ARGUMENT

Petitioner contends that this Court's precedents allow a person to circumvent the administrative process and bring claims arising under the Medicare statute directly in federal court if that person does not have personal access to the statute's administrative and judicial review procedures. Petitioner did not specifically press that argument below, and the court of appeals correctly rejected the case-specific arguments made by petitioner. That decision does not conflict with any decision of this Court or any other court of appeals. Further review is not warranted.

1. Section 405(h) provides that "[n]o action against the United States, the [Secretary], 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); see 42 U.S.C. 1395ii. As the court of appeals held, on the facts of this case, applying Section 405(h) according to its terms would not amount to a complete preclusion of judicial review.

a. Any claim arising under the Medicare statute, including challenges to a Medicare regulation, must first be presented to the Secretary through the available administrative review procedures. See 42 U.S.C. 405(g) and (h), 1395ii. Only final decisions of the Secretary are subject to judicial review in federal court. *Ibid.* That bar is "sweeping and direct," *Weinberger* v. *Salfi*, 422 U.S. 749, 757 (1975), and it applies to "all 'claim[s] arising under' the Medicare Act," *Heckler* v. *Ringer*, 466 U.S. 602, 615 (1984). By "'channeling' * * * virtually all legal attacks through the agency,

[Section 405(h)] assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts." *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000). And while a strict application of Section 405(h) may lead to hardship in individual cases, "[i]n the context of a massive, complex health and safety program such as Medicare, embodied in hundreds of pages of statutes and thousands of pages of often interrelated regulations, any of which may become the subject of a legal challenge in any of several different courts," Congress determined that "paying this price" was "justified." *Ibid.*

The Court in *Illinois Council* recognized a limited exception to that general rule. If "application" of Section 405(h) "would not simply channel review through the agency, but would mean no review at all," then it should not be applied to bar a claim arising under the Medicare statute. 529 U.S. at 19. But a party cannot "circumvent [Section] 1395ii's channeling requirement simply because the party shows that postponement would mean added inconvenience or cost." *Id.* at 22. "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." *Id.* at 22-23.

b. Applying the Court's precedents to the circumstances of this case, the court of appeals concluded that petitioner failed to demonstrate that adhering to the administrative channeling requirement would

result in a "*complete* preclusion of judicial review." *Illinois Council*, 529 U.S. at 23.

Although petitioner and its pharmacy members cannot personally seek administrative review, enrollees in a preferred pharmacy plan indisputably can. Pet. App. 8-13; see 42 U.S.C. 1395w-104(h)(1); 42 C.F.R. 423.566(b)(5), 423.568(a); Ctrs. for Medicare & Medicaid Servs., *Prescription Drug Benefit Manual*, Ch. 18, § 30.3 (June 22, 2006), http://www.cms.gov/MedPrescriptDrugApplGriev/downloads/partdmanualchapter18.pdf. An enrollee who purchases medication at a non-preferred pharmacy can initiate administrative review of the preferred pharmacy regulation by challenging his plan's refusal to accept copayment at the "preferred" rate. Enrollees have a financial incentive to seek such review in the hope of reducing future copayments or coinsurance; and they may also have a non-financial interest in continuing to use independent pharmacies (as petitioner alleged in its complaint). See Pet. App. 16.

Moreover, any individual (including an individual associated with a non-preferred pharmacy) may act as an enrollee's appointed representative in those proceedings. See 42 C.F.R. 423.566(c)(2) (coverage determinations can be requested by "enrollee's appointed representative"); 42 C.F.R. 423.560 (defining "appointed representative"). In that representative capacity, petitioner could further incentivize enrollees by "shoulder[ing] the administrative and financial burdens of bringing an administrative claim." Pet. App. 17. Finally, judicial review of the Secretary's decision is available, so long as the amount-in-controversy requirement is satisfied. See 42 C.F.R. 423.562(b)(4)(vi), 423.1976(a); 77 Fed. Reg. 59,619

(Sept. 28, 2012) (setting amount-in-controversy threshold for judicial review in 2013 at $1400); see also Pet. App. 18-19 (explaining aggregation rules).

2. Petitioner contends (Pet. 10-23) that the court of appeals misapplied this Court's decision in *Illinois Council* because the "*Illinois Council* exception" applies whenever the particular plaintiffs "themselves" cannot "be parties to an administrative appeal." That argument was not specifically pressed below;[1] it is without merit; and there is no conflict among the courts of appeals. Further review is not warranted.

a. In the court of appeals, petitioner primarily argued that "neither [petitioner], its members[,] *nor any other proxy* has available to it an administrative channel that would lead to judicial review." Pet. C.A. Br. 54 (emphasis added). Petitioner acknowledged that cases in the Fifth and D.C. Circuits looked to whether other parties had access to (and the incentive to seek) administrative and judicial review of the plaintiff's claim. It sought to distinguish the cases finding no jurisdiction, while embracing those that found the asserted "proxy" insufficient. See *id.* at 15, 47-48, 52. But petitioner never argued that any of the Fifth or D.C. Circuit cases were wrongly decided.

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[1] The closest petitioner came to raising that argument was in an introductory discussion of Section 405(h) and the *Illinois Council* exception. See Pet. C.A. Br. 18-19. Immediately following that general discussion, petitioner identified four reasons why an enrollee's ability to pursue an administrative challenge (followed by judicial review) is insufficient in this particular context. *Id.* at 21. Petitioner did not specifically argue that an enrollee's ability to access the administrative and judicial review process is entirely irrelevant to the analysis because all that matters is whether petitioner itself (or its members) can personally seek judicial review.

And while the panel in this case was bound by circuit precedent, petitioner did not seek rehearing en banc to argue that the prior Fifth Circuit decision should be "overturned" (Pet. 22-23).

Petitioner's argument is, in any event, without merit. As the court of appeals held, judicial review is "*complete[ly]* preclu[ded]" only in a narrow class of cases in which the plaintiff has no remedy under the statute and where there is no party with the ability and incentive to bring the same claim on its own or at the plaintiff's behest. See *Illinois Council*, 529 U.S. at 22-23; *ibid.* ("[T]he 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."). Parties that have a more indirect relationship to the Medicare program and, for that reason, do not have any remedies under the statute, should not be afforded a fast-track avenue of judicial review outside Medicare's jurisdictional scheme. Cf. *Block* v. *Community Nutrition Inst.*, 467 U.S. 340, 349 (1984) ("[W]hen 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."). If the same substantive claim can effectively be brought by some other party, judicial review of the issue has not been completely precluded and the administrative process should not be circumvented.

b. More than a decade has passed since this Court's decision in *Illinois Council*. In the ensuing years, only two courts of appeals have directly considered the question presented here. See *National Ath-*

letic Trainers' Ass'n, Inc. v. *U.S. Dep't of Health & Human Servs.*, 455 F.3d 500 (5th Cir. 2006) (*National Athletic Trainers*); *American Chiropractic Ass'n* v. *Leavitt*, 431 F.3d 812 (D.C. Cir. 2005). They both agree: the relevant question is whether the plaintiff's *claim* can be subject to judicial review after administrative channeling, not whether the particular plaintiff before the court *itself* has direct access to such review. Cf. *Puerto Rico Ass'n of Physical Med. & Rehab., Inc.* v. *United States*, 521 F.3d 46, 49 (1st Cir. 2008) ("What does matter is whether [the plaintiff] can, at some point, using some process, obtain judicial review of its claims.") (citing *American Chiropractic Ass'n*, 431 F.3d at 816).[2]

In *American Chiropractic Ass'n*, the D.C. Circuit held that the district court lacked jurisdiction over a suit filed by a chiropractic organization challenging a regulation promulgated by the Secretary. 431 F.3d at 814-815. The court of appeals explained that the exception recognized in *Illinois Council* did not apply

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[2] Petitioner suggests (Pet. 15 n.3) that the Second Circuit "reached a different result" in *Furlong* v. *Shalala*, 238 F.3d 227 (2001), but (as petitioner later acknowledges, *ibid.*) the court did not directly address the question presented here. See also, *e.g.*, *Bartlett Mem'l Med. Ctr., Inc.* v. *Thompson*, 347 F.3d 828, 842-844 (10th Cir. 2003) (finding that *Illinois Council* exception applied without considering question presented here). In any event, there may well be circumstances in which no one with an interest in challenging a particular regulation has access to the administrative process. In those circumstances, the exception recognized in *Illinois Council* may apply because judicial review of the claim would be unavailable. See, *e.g.*, *Council for Urological Interests* v. *Sebelius*, 668 F.3d 704, 713-714 (D.C. Cir. 2011) (concluding that no other party had both access to, and the incentive to pursue, the administrative review procedures and, thus, application of Section 405(h) would result in no judicial review at all).

because the plaintiff "could receive an administrative decision" on the "issue[s] presented" if an enrollee (or one of the plaintiff's members as the enrollee's assignee) brought the "claim[s]" in "administrative proceedings leading to judicial review." *Id.* at 816-818. In *National Athletic Trainers*, the Fifth Circuit agreed. 455 F.3d at 504-505. In that case, an athletic trainers' association similarly filed suit in federal court challenging a regulation promulgated by the Secretary. *Id.* at 502. The court of appeals held that the *Illinois Council* exception did not apply because a third party (a physician) could bring the same claim through administrative channels and that claim would then be subject to judicial review. *Id.* at 504-507. The court below simply applied those decisions (which were not challenged) to the facts of this case.

3. Petitioner also suggests (Pet. 10-11, 16-17, 20-22) that, in this case, *no* party has access to an administrative channel that would lead to judicial review. That claim is not fairly included within the question presented, which asks only the general question "whether a claimant must * * * prove that it cannot recruit proxies to pursue the challenge on the claimant's behalf" and does not seek review of the court of appeals' specific holding that adequate proxies are available here. Pet. i; see Sup. Ct. R. 14(1)(a). In any event, the court of appeals correctly concluded otherwise and that case-specific determination does not warrant the Court's review.

Petitioner contends (Pet. 16-17) that enrollees are not suitable proxies because "Medicare Part D regulations do not provide for assignment of enrollee claims to providers." But petitioner does not dispute that the regulations allow an enrollee to appoint an individual

(such as a non-preferred pharmacy employee) to act as his representative. The "only meaningful distinction" that petitioner identifies "between appointment as a representative and assignment is that an appointment can be revoked." Pet. App. 14; see Pet. 16 ("[U]nlike an assignment, an appointment as a representative can be revoked by the enrollee."). As the court of appeals explained, the fact "[t]hat a representative's appointment can be revoked is not relevant to whether a representative whose appointment has not been revoked can vindicate its claim in the courts." Pet. App. 14. And, even if there was a meaningful distinction between assignee status and representative status for present purposes, petitioner also failed to demonstrate that "enrollees would be ineffective or unwilling proxies" on their own. *Id.* at 15; see *American Chiropractic Ass'n*, 431 F.3d at 816-817 (noting that enrollees could bring claim on their own).

Petitioner intimates (Pet. 10, 20-21) that judicial review would require "four or more Medicare Part D patients, each taking the same expensive medicine, and each seeking a coverage determination that they should be required to pay less at their non-preferred pharmacy." That assertion appears to be based on the amount-in-controversy requirement for judicial review and the rules governing the aggregation of claims. See 42 C.F.R. 423.562(b)(4)(vi), 423.1976(a); 77 Fed. Reg. at 59,619 (setting amount-in-controversy threshold for judicial review in 2013 at $1400); see also Pet. App. 18-19 (explaining aggregation rules). On that issue, the court of appeals simply held that petitioner had not met its burden and declined to allow circumvention of the administrative process based on "hypothetical, unconfirmed difficulties" and pure "specula-

tion." *Id.* at 21, 22; see *id.* at 21 n.8 (noting that petitioner had made no "attempt[] to recruit enrollees"). If judicial review proves to be "impossible" (as petitioner contends), rather than simply postponed, the court of appeals' decision leaves open the possibility that petitioner may then be able to satisfy its burden on a more developed record. See *id.* at 20-22.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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