FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ROBERT H. ODELL, JR.; ROBERT ODELL, M.D., PH.D. MEDICAL ENTERPRISES, A Nevada Corporation, *Plaintiffs-Appellees*, v. U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES; XAVIER BECERRA, *Defendants-Appellants.*	No. 19-15262 D.C. No. 2:15-cv-01793-RFB-GWF OPINION

Appeal from the United States District Court
for the District of Nevada
Richard F. Boulware II, District Judge, Presiding

Argued and Submitted June 10, 2020
San Francisco, California

Filed April 27, 2021

Before: Eric D. Miller and Danielle J. Hunsaker, Circuit Judges, and Douglas L. Rayes,* District Judge.

Opinion by Judge Miller

SUMMARY**

Medicare

The panel vacated a preliminary injunction and remanded to the district court with instructions to dismiss the complaint for lack of jurisdiction in an action brought by a Nevada physician against a Medicare contractor who allegedly wrongly denied his claims for reimbursement.

The panel held that the Medicare statute permits a court to review only claims that have been presented to the agency. The panel held that the physician here had not satisfied the presentment requirement for any of his claims. Because this case did not involve a claim that was presented to the agency, the district court lacked subject matter jurisdiction.

* The Honorable Douglas L. Rayes, United States District Judge for the District of Arizona, sitting by designation.

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

COUNSEL

Sarah Carroll (argued), Michael S. Raab, and Abby C. Wright, Appellate Staff; Nicholas A. Trutanich, United States Attorney; Civil Division, United States Department of Justice, Washington, D.C.; Janice L. Hoffman, Associate General Counsel; Susan Maxson Lyons, Deputy Associate General Counsel for Litigation; Brett Bierer, Attorney; United States Department of Health & Human Services, Washington, D.C.; for Defendants-Appellants.

George K. Brew (argued), Law Office of George Brew PLLC, Jacksonville, Florida, for Plaintiffs-Appellees.

OPINION

MILLER, Circuit Judge:

Dr. Robert H. Odell, Jr., is a Nevada physician who treats patients covered by Medicare. For several years, Odell has been engaged in a dispute with the contractor that administers Medicare in his region. Believing that the contractor was improperly applying an "unwritten rule" that led to the denial of his claims for reimbursement, Odell sought an injunction compelling the contractor to change its method of evaluating his claims. The district court granted the injunction. The Medicare statute, however, permits a court to review only claims that have been presented to the agency. Because this case does not involve a claim that was presented to the agency, the district court lacked subject-matter jurisdiction. We therefore vacate the preliminary injunction and remand to the district court with instructions to dismiss the complaint for lack of jurisdiction.

I

A

Medicare is a federally subsidized medical insurance program for the elderly and disabled. *See* 42 U.S.C. § 1395 *et seq.*; *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 506 (1994). The Centers for Medicare & Medicaid Services (CMS), an agency within the Department of Health and Human Services, oversees the Medicare program. CMS contracts with private entities to administer Medicare. *See* 42 U.S.C. §§ 1395u(a), 1395kk-1(a); 42 C.F.R. § 421.5(c). Each contractor is responsible for a particular region of the country. 42 C.F.R. § 421.404(b)(1), (c)(1).

Medicare pays only for services that are "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A). The Medicare contractor determines initially whether a service is covered. *Id.* § 1395ff(a)(1); 42 C.F.R. § 405.920. In making that determination, the contractor can rely on several sources of guidance.

Sometimes, the agency issues a regulation or a "national coverage determination" specifying "whether or not a particular item or service is covered." 42 U.S.C. § 1395ff(f)(1)(B); *see id.* § 1395hh. Both regulations and national coverage determinations are binding on Medicare contractors. *See Erringer v. Thompson*, 371 F.3d 625, 628 (9th Cir. 2004).

In other cases, a Medicare contractor can issue a "local coverage determination" (LCD) specifying whether a particular item or service will be covered within its jurisdiction. 42 U.S.C. § 1395ff(f)(2)(B); *see Erringer*, 371 F.3d at 628. Before adopting an LCD, a contractor must solicit public comment and hold an open meeting. *See*

Medicare Program Integrity Manual § 13.2.4 (rev. 863, Oct. 3, 2018). Once a contractor has adopted an LCD, any interested party may request that the contractor reconsider it. *Id.* § 13.3.2. And Medicare patients—but not doctors or hospitals—may challenge an LCD through an administrative process and, ultimately, in court. 42 U.S.C. § 1395ff(f)(2), (5).

Absent a regulation, a national coverage determination, or an LCD, the Medicare contractor proceeds on a case-by-case basis to determine whether a service is reasonable and necessary. 42 U.S.C. § 1395y(a)(1)(A).

If the contractor determines that a service is covered, it pays the claim. 42 U.S.C. § 1395*l*(a). Otherwise, it denies the claim. A party seeking reimbursement can then challenge the denial of coverage through four levels of administrative review. *See Haro v. Sebelius*, 747 F.3d 1099, 1114 (9th Cir. 2014). First, a party can seek redetermination by the Medicare contractor. 42 U.S.C. § 1395ff(a)(3). Second, a party can seek reconsideration by a "qualified independent contractor," which is not bound by the Medicare contractor's LCD but must give it "substantial deference." *Id.* § 1395ff(c), (c)(3)(B)(ii)(II); 42 C.F.R. § 405.968(b)(2). Third, a party can seek a hearing before an administrative law judge. 42 U.S.C. § 1395ff(d)(1). Fourth, a party can seek review of the administrative law judge's decision before the Medicare Appeals Council. *Id.* § 1395ff(d)(2); 42 C.F.R. § 405.1100; *see* 42 C.F.R. § 405.902. Like independent contractors, administrative law judges and the Medicare Appeals Council are not bound by an LCD but must give it "substantial deference," and if they depart from an LCD, they must explain why. 42 C.F.R. § 405.1062(a)–(b). After exhausting administrative remedies, a claimant can seek judicial review. 42 U.S.C. § 1395ff(b)(1)(A).

B

Since approximately 2008, Odell has provided treatment for a condition called neurological ischemia, which he describes as "a root cause of pain, numbness and loss of functionality in the lower extremities." Odell's treatment involves "nerve blocks for pain together with electrical stimulation."

The Medicare contractor for Odell's area has promulgated a local coverage determination, LCD L28271, for "Injections – Tendon, Ligament, Ganglion Cyst, Tunnel Syndromes and Morton's Neuroma." Odell argues that the contractor has erroneously applied that LCD to deny coverage for his treatment and that the contractor should instead apply LCD L28240, which covers "Blocks and Destruction of Somatic and Sympathetic Nerves."

Based on the limited record before us, it appears that Odell has had some success in challenging the application of LCD L28271 to his treatment at varying levels of administrative review. While the independent contractor has issued unfavorable decisions for certain claims (without relying on any LCD), it has also issued favorable decisions with respect to others. Similarly, Odell has obtained favorable rulings from administrative law judges with respect to certain claims. Those judges concluded that LCD L28240 applied and that Odell's treatment was covered by Medicare. In some instances, however, the Medicare Appeals Council has remanded for a more thorough explanation of the administrative law judges' decisions.

In response to the application of LCD L28271 to his claims, Odell brought this action against the Secretary of Health and Human Services. The complaint also named two other plaintiffs: a corporation that Odell owns and Kenneth

Baker, one of Odell's patients. But because nothing in our analysis turns on the identity of the plaintiffs, we will discuss only Odell.

According to the complaint, the Medicare contractor follows an "unwritten rule" of erroneously applying LCD L28271 to Odell's claims to deny coverage for his treatment. Odell does not argue that LCD L28271 is invalid; instead, he argues that it does not apply to the treatment he provides. In Odell's view, the contractor's "unwritten rule" of applying LCD L28271 to his claims is invalid because that "unwritten rule" was not adopted through notice-and-comment rulemaking, is arbitrary and capricious, and is contrary to the Medicare statute. Odell sought an injunction barring the agency "from imposing an LCD that categorically denies Medicare coverage of . . . Odell's services or applying an unwritten rule to do the same." The Secretary moved to dismiss for lack of subject-matter jurisdiction, and the district court ordered limited jurisdictional discovery. Upon the completion of discovery, Odell moved for a preliminary injunction.

The district court denied the Secretary's motion to dismiss and granted a preliminary injunction. *Odell v. Azar*, 344 F. Supp. 3d 1192, 1207 (D. Nev. 2018). The court recognized that the Medicare statute requires exhaustion of administrative remedies as a prerequisite to bringing an action in court, but it excused Odell's failure to exhaust on the ground that it would be "impractical for Dr. Odell to appeal hundreds of claims on a piecemeal basis," and therefore it would be futile for him to attempt "to challenge the unwritten rule through the administrative process." *Id.* at 1199–1200, 1202. The court then determined that Odell had shown "a likelihood of success on the merits for his claims that the continuous default application of LCD L28271 to his

treatment is arbitrary and capricious in violation of the APA and/or constitutes a new substantive rule that did not go through the required rulemaking process." *Id.* at 1206. It entered an injunction barring the Medicare contractor from applying LCD L28271 to any claim filed by Odell without first conducting "an individual medical review of the claim."

II

We begin—and end—by considering the district court's subject-matter jurisdiction. The judicial-review provision in the Medicare statute incorporates that of the Social Security Act. 42 U.S.C. § 1395ii. That statute, in turn, provides an exclusive mechanism for review of the agency's decisions, expressly displacing the general federal-question jurisdiction of 28 U.S.C. § 1331. *See* 42 U.S.C. § 405(h). It states that "[a]ny individual, after any final decision of the [Secretary of the Department of Health and Human Services] made after a hearing to which he was a party, . . . may obtain a review of such decision by a civil action." *Id.* § 405(g); *see id.* § 1395ff(b)(1)(A). For our purposes, the critical feature of section 405(g) is that it permits review only "after any final decision" of the agency.

The Supreme Court has explained that "the statute empowers district courts to review a particular type of decision by the Secretary, that type being those which are 'final' and 'made after a hearing,'" with that limitation being "central to the requisite grant of subject-matter jurisdiction." *Weinberger v. Salfi*, 422 U.S. 749, 764 (1975). More specifically, the Court has held that "the requirement that a claim for benefits shall have been presented to the Secretary" is "nonwaivable." *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976). In other words, presentment of the claim to the Secretary "is an essential and distinct precondition for § 405(g) jurisdiction." *Id.* at 329.

The Court has confirmed that even when an individual raises a constitutional challenge to agency procedures—a challenge that could be considered "collateral" to any specific "claim for benefits"—the statute nevertheless "contains the nonwaivable and nonexcusable requirement that an individual present a claim to the agency before raising it in court." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 15 (2000); *see also Heckler v. Ringer*, 466 U.S. 602, 622–23 (1984). And we have similarly concluded that a wide range of challenges to the operation of the Medicare program "arise under" the Medicare statute and therefore "require[] an agency decision in advance of judicial review." *Kaiser v. Blue Cross of Calif.*, 347 F.3d 1107, 1111–12 (9th Cir. 2003); *accord Sensory NeuroStimulation, Inc. v. Azar*, 977 F.3d 969, 975 (9th Cir. 2020).

The district court recognized that Odell had not exhausted his administrative remedies, but it reasoned that exhaustion could be excused because, in the court's view, exhaustion would have been futile. 344 F. Supp. 3d at 1202. That conclusion is debatable, but we need not consider it further because the district court lacked jurisdiction even if Odell's failure to exhaust could be excused. Section 405(g) "contains two separate elements: first, a 'jurisdictional' requirement that claims be presented to the agency, and second, a 'waivable . . . requirement that the administrative remedies prescribed by the Secretary be exhausted.'" *Smith v. Berryhill*, 139 S. Ct. 1765, 1773 (2019) (omission in original) (quoting *Eldridge*, 424 U.S. at 328). Although the requirement of exhaustion may be excused, the requirement of presentment may not. *Illinois Council*, 529 U.S. at 15.

Odell has not satisfied the presentment requirement for any of his claims. To the extent that Odell disputes the

application of LCD L28271 to his past claims, jurisdiction is lacking because he does not challenge any specific "final decision" of the agency. 42 U.S.C. § 405(g). The complaint identifies various instances in which the contractor denied reimbursement and Odell then received a favorable decision from an administrative law judge. Odell does not seek review of any of those favorable decisions—nor could he—and he does not identify any particular adverse decision for which he is seeking review.

Instead, the principal objective of the complaint appears to be to obtain prospective relief from the application of LCD L28271 to Odell's future claims. But there is no subject-matter jurisdiction over those claims because Odell has not yet presented them to the Secretary for a final decision. *See Illinois Council*, 529 U.S. at 15; *Haro*, 747 F.3d at 1112–14. As the District of Columbia Circuit has explained, a plaintiff "cannot satisfy § 405(g)'s presentment requirement with respect to future claims because those claims have not yet arisen." *Porzecanski v. Azar*, 943 F.3d 472, 482 (D.C. Cir. 2019); *see Ringer*, 466 U.S. at 621. Here, no final decision from the Secretary confirms the denial of reimbursement for those future claims, whether based on LCD L28271 or some other basis. Because Odell has not presented the claims, section 405(g) does not permit the exercise of jurisdiction. *See Porzecanski*, 943 F.3d at 482.

Pointing to the various cases in which he has pursued administrative appeals of the contractor's denial of benefits, Odell argues that he has in fact "presented [his] claims to the Secretary on numerous occasions." But "[p]roperly channeling one claim"—or even several claims—"does not permit a plaintiff to resolve other claims or causes of action that have not been channeled." *Porzecanski*, 943 F.3d at 484. In his administrative challenges to denials of prior claims for

reimbursement, Odell may have raised his arguments about the application of LCD L28271. That does not confer jurisdiction on the district court to adjudicate those arguments as they relate to other claims for reimbursement. In other words, "even in the case of claims which appear to rest upon identical questions of law and fact" to other claims that the agency has previously considered, a court still can hear only claims that have been properly presented. *Pacific Coast Med. Enters. v. Harris*, 633 F.2d 123, 138 (9th Cir. 1980).

Odell relies on our decision in *Los Angeles Haven Hospice, Inc. v. Sebelius*, 638 F.3d 644 (9th Cir. 2011), but that case does not support exercising jurisdiction here. *Haven Hospice* involved a facial challenge to a Medicare regulation, and we held that a provider could bring that challenge under 42 U.S.C. § 1395oo(f)(1). That statute "specifically authorizes the district courts to decide pure questions of law," *Haven Hospice,* 638 F.3d at 664, and it applies "notwithstanding any other provisions in section 405," 42 U.S.C. § 1395oo(f)(1). *See Porzecanski*, 943 F.3d at 484 (explaining that the court in *Haven Hospice* "exercised jurisdiction under 42 U.S.C. § 1395oo(f)(1), which sets out a judicial review scheme that deviates from § 1395ii and § 405(g) in important ways").

Odell emphasizes that the Medicare statute does not incorporate section 405(h)—and thus does not preclude other forms of review—in cases "where application of § 405(h) would not simply channel review through the agency, but would mean no review at all." *Illinois Council*, 529 U.S. at 19. That class of cases is narrowly defined, and it does not include those in which some "administrative channel for review exists." *Sensory NeuroStimulation*, 977 F.3d at 983. Here, an administrative channel for review

is available to Odell. When the contractor denies a claim for payment based on the application of LCD L28271, Odell can challenge the denial. Either he will prevail in the administrative process, or he will obtain an adverse final decision of the agency that he can challenge in court.

We recognize that pursuing "the often lengthy administrative review process" on a claim-by-claim basis is more costly than proceeding directly to court to obtain an injunction directing a programmatic change in the agency's approach. *Ringer*, 466 U.S. at 619. The Supreme Court has acknowledged that although the statute "assures the agency greater opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts," that "assurance comes at a price, namely, occasional individual, delay-related hardship." *Illinois Council*, 529 U.S. at 13. Whether that price is worth paying is a judgment for Congress to make. Section 405 reflects that judgment, and it forecloses the exercise of jurisdiction in this case.

VACATED and REMANDED.