United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued December 13, 2021

Decided January 18, 2022

No. 21-5186

RICU LLC, Appellant

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL., APPELLEES

Appeal from the United States District Court for the District of Columbia (No. 1:21-cv-00452)

Jesse Panuccio argued the cause for appellant. With him on the briefs were *David Boies* and *Scott E. Gant*.

Jennifer L. Utrecht, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were Brian M. Boynton, Acting Assistant Attorney General, Abby C. Wright, Attorney, Janice L. Hoffman, Associate General Counsel, U.S. Department of Health and Human Services, Susan Maxson Lyons, Deputy Associate General Counsel for Litigation, and Bridgette Lynn Kaiser, Attorney. Before: SRINIVASAN, *Chief Judge*, ROGERS and JACKSON, *Circuit Judges*.

Opinion for the Court by Circuit Judge ROGERS.

ROGERS, Circuit Judge: On appeal from the dismissal of its complaint, RICU LLC seeks to avoid well-settled authority requiring administrative exhaustion under the Medicare Act by presenting a concrete claim for payment of rendered services to the U.S. Department of Health and Human Services for decision. Instead, RICU LLC relies on its efforts to engage Department officials in a generalized consideration of the reimbursement potential for telehealth services provided by contract physicians located outside of the United States. Alternatively, RICU LLC invokes an exception to the "channeling" requirement where no other path for judicial review exists. For the following reasons, we affirm the dismissal of the complaint for lack of subject matter jurisdiction and do not address RICU LLC's request for a preliminary injunction to reverse the Department's generalized eligibility determination.

I.

According to the complaint, RICU LLC "is one of the largest inpatient telehealth companies in the United States," specializing in remote critical care services. Compl. ¶ 26. RICU LLC currently contracts with approximately 60 intensive care physicians who live and work abroad but were trained in the United States and hold U.S. board certifications and licenses. *See id.* ¶¶ 27–30. These physicians provide critical care telehealth services to "more than 250 hospitals located in 34 states, accessible to more than 35 million Americans," *id.* ¶ 33, through service contracts between RICU LLC and

hospitals or third-party intermediaries, *id.* \P 34. RICU LLC's client hospitals pay hourly for critical care telehealth services provided by RICU LLC's intensive care physicians. *Id.*

Since its enactment in 1965, the Medicare Act, 42 U.S.C. § 1395 et seq., Part A of Title XVIII of the Social Security Act, established a federal health insurance program for the elderly and disabled and barred Medicare reimbursement for "any expenses incurred for items or services . . . which are not provided within the United States," subject to limited exceptions.¹ Indeed, prior to 1999, Medicare did not reimburse for telehealth services.² That changed in 2000 when Congress expanded Medicare to cover certain telehealth services, specifically, those that physicians provided through a telecommunications system to an eligible telehealth individual, "notwithstanding that the individual physician or practitioner providing the telehealth service is not at the same location as the beneficiary."³ An "eligible telehealth individual" is a Medicare Part B enrollee who "receives a telehealth service furnished at an originating site," which is a hospital, clinic, physician's office, or other medical facility where the patient "is located at the time the service is furnished." Reimbursement was authorized for "professional consultations, office visits, and office psychiatry services," and the Secretary of the Department could designate "any additional service."4

By final rule, the Department provided for reimbursements according to its annually-updated Physician Fee Schedule in each of 112 geographic localities in the United

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⁴² U.S.C. § 1395y(a)(4); see also id. § 1395f(f).

² Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4206(a), 111 Stat. 251, 377–78.

³ 42 U.S.C. § 1395m(m)(1).

⁴ *Id.* § 1395m(m)(4)(B), (C)(i), (F)(i).

States. The site of service is the location of the physician or practitioner, not the patient's location.⁵ To qualify for reimbursement, a telehealth service must be on the telehealth list, and before 2020, critical care telehealth services typically provided in a hospital's intensive care unit were not on the telehealth list and therefore were ineligible.⁶ In response to the COVID-19 pandemic, however, Congress authorized the Department "to temporarily waive or modify the application of" Medicare requirements governing telehealth services furnished during the public health emergency.⁷ In early April 2020, the Department adopted an interim final rule adding critical care telehealth services to the telehealth list. The final rule, effective in December 2020, made critical care telehealth services reimbursable through the end of the calendar year in which the COVID public health emergency ends.⁸

On April 22, 2020, RICU LLC sought "urgent clarification" by the Department of whether the emergency eligibility of critical care telehealth services meant that Medicare would reimburse for those services provided by physicians located outside the United States. Email Seth Rabinowitz, Pres., RICU LLC, to Brian R. Pabst, Tech. Adv'r, Centers for Medicare and Medicaid Services ("CMS") (Apr. 22, 2020). By letter of June 20, 2020, the Acting Director of CMS' Chronic Care Policy Group responded that, after "an exhaustive review of the statute and regulations," CMS had determined that Medicare could not reimburse any telehealth services furnished by medical providers outside the United

⁵ 66 Fed. Reg. 55,246, 55,282, 55,284 (Nov. 1, 2001) (codified as amended at 42 C.F.R. § 410.78); *see* 42 U.S.C. § 1395w-4(b)-(e).

⁶ See 42 C.F.R. § 410.78(b), (f).

⁷ 42 U.S.C. § 1320b-5(b)(8), (g)(1)(B).

⁸ 85 Fed. Reg. 19,230, 19,232, 19,236 (Apr. 6, 2020);

⁸⁵ Fed. Reg. 84,472, 84,507, 84,515, 84,527–28 (Dec. 28, 2020).

States because the Medicare Act's ban on foreign payments "remains in effect during a public health emergency and is not affected by telehealth flexibilities for the COVID-19 pandemic." Ltr. Jason Bennett, Act. Dir., Chron. Care Pol'y Grp., CMS (June 1, 2020) at 1. Seeking to overturn this ineligibility determination, RICU LLC contacted increasingly senior CMS officials. *See* Compl. ¶¶ 78–79. In July 2020, CMS advised RICU LLC that its "senior Medicare team and General Counsel's Office" agreed with the determination in the June 2020 letter. Email Kimberly Brandt, Princ. Dep. Adm'r, CMS (July 9, 2020). CMS again confirmed its position on October 28, 2020, following RICU LLC's meeting with highlevel CMS officials. Ltr. Demetrios L. Kouzoukas, Princ. Dep. Adm'r & Dir., Ctr. for Medicare (Oct. 28, 2020) at 1.

In February 2021, RICU LLC filed a complaint in the district court, alleging that the Department's determination that critical care telehealth services provided by physicians who are outside of the United States are ineligible for Medicare reimbursement was contrary to law and arbitrary and capricious, in violation of the Administrative Procedure Act. Compl. ¶¶ 86–108. RICU LLC also moved for a preliminary injunction preventing the Department from denying Medicare reimbursement for telehealth services provided by physicians located outside of the United States. The Department moved to dismiss the complaint, pursuant to Federal Rule of Civil Procedure 12(b)(1), because RICU LLC had not presented a concrete claim for payment to the Department as required by the Medicare Act's channeling procedure in order to obtain judicial review. The district court granted the Department's motion after a hearing and dismissed the complaint for lack of subject matter jurisdiction and denied RICU LLC's motion for a preliminary injunction. RICULLC v. U.S. Dep't of Health & Hum. Servs., No. 21-cv-452, 2021 WL 3709736, at *9 (D.D.C. Aug. 20, 2021).

RICU LLC appeals and filed an unopposed motion for expedition pursuant to 28 U.S.C. § 1657 in view of the shortage of internal critical care physicians during the ongoing COVID-19 pandemic that RICU LLC's telehealth services may alleviate. The court granted expedition. The court reviews the dismissal of the complaint for lack of subject matter jurisdiction *de novo*, *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 825 (D.C. Cir. 2018), assuming the truth of all well-pled material factual allegations in the complaint and granting the plaintiff the benefit of all reasonable inferences from the alleged facts, *Am. Nat. Ins. Co. v. FDIC*, 642 F.3d 1137, 1139 (D.C. Cir. 2011) (citing *Thomas v. Principi*, 394 F.3d 970, 972 (D.C. Cir. 2005)).

II.

On appeal, RICU LLC contends that it satisfied the Medicare Act's presentment requirement when it sought an eligibility determination from the Department under its interim final rule for payment of critical care telehealth services by physicians located abroad. Alternatively, RICU LLC relies on an exception to presentment recognized by the Supreme Court to show that the district court had subject matter jurisdiction over RICU LLC's complaint. Neither contention is persuasive in view of judicial precedent.

A.

Beginning in April 2020, RICU LLC had requested Department guidance on how the interim final rule applied to RICU LLC's services abroad, not resolution of a specific claim for reimbursement. The contention that it nonetheless satisfied the Medicare Act's presentment requirement is foreclosed by Supreme Court and circuit precedent. The Supreme Court has rejected the argument that district court review is available prior to submission of a specific reimbursement claim to the Department, in view of the presentment and exhaustion requirements under the Medicare Act, *Heckler v. Ringer*, 466 U.S. 602, 620–22 (1984), and circuit precedent eliminates any doubt RICU LLC's complaint was properly dismissed by the district court.

By its plain terms, the Medicare Act, 42 U.S.C. § 405(h), strips the court of jurisdiction under 28 U.S.C. § 1331 and § 1346 over "any claim arising under" Title II of the Social Security Act, and prevents review of any decision of the Commissioner of Social Security, "except as herein provided." Section 405(g) provides an exception for a civil action filed by an individual challenging "any final decision of the Commissioner of Social Security made after a hearing to which [the plaintiff] was a party," who is thereby able to "obtain a review of such decision" in the district court. In turn, Section 1395ii provides that certain provisions of Title II of the Social Security Act, including parts of Section 405, specifically subsection (h), "shall also apply" to the Medicare Act "to the same extent as they are applicable with respect to" Title II, with the Secretary of the Department or the agency substituted for "any reference . . . to the Commissioner of Social Security or the Social Security Administration." Although Section 1395ii does not designate subsection (g) as an incorporated provision, the Supreme Court, focusing on the "final decision" required by the third sentence of Section 405(h), has treated Section 405(g) as effectively incorporated as the exception "herein provided." Ringer, 466 U.S. at 614-15 (citing Weinberger v. Salfi, 422 U.S. 749, 760–61 (1975)).

In *Weinberger v. Salfi*, 422 U.S. 749 (1975), a class action seeking benefits under the Social Security Act, the Supreme Court held that the third sentence of Section 405(h) was unambiguous and to be broadly construed, *see id.* at 756–57,

while appropriate deference was due to the Department's interpretation of the undefined statutory term "final decision," id. at 766-67. In light of that precedent, the Supreme Court stated in Heckler v. Ringer, 466 U.S. 602 (1984), that a "claim for future benefits" is a Section 405(h) "claim," and that "all aspects" of any such present or future claim must be "channeled" through the administrative process, id. at 620-21. The Court rejected the argument that district court review was available prior to submission of a specific reimbursement claim for payment to the Department. Id. at 620. Presentment instead demanded that the Department have "an opportunity to rule on a concrete claim for reimbursement," id. at 622, and so, to establish jurisdiction, the plaintiff had to file a claim for payment "after the medical service for which payment is sought has been furnished," id. at 621. The Court has adhered to its interpretation. See, e.g., Smith v. Berryhill, 139 S. Ct. 1765, 1777–78 (2019).

The Supreme Court had previously determined that Section 405(g) creates two prerequisites for judicial review of Medicare claims. First, a plaintiff's *claim* must "have been presented to the Secretary." *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976). The "presentment" requirement is a "nonwaivable element" of jurisdiction for "[a]bsent such a claim there can be no 'decision' of any type," which Section 405(g)'s reference to a "final decision" of the Secretary demands. *Id.* Second, a plaintiff must fully exhaust "the administrative remedies prescribed by the Secretary." *Id.*; *see Berryhill*, 139 S. Ct. at 1773–74 (same, holding Appeal Council's dismissal of untimely request for review of administrative judge's merits decision after a hearing is a "final decision" subject to judicial review).

Subsequently, in Shalala v. Illinois Council on Long Term Care, Inc., 529 U.S. 1 (2000), the Court reaffirmed that taken together, the presentment and exhaustion requirements under the Medicare Act impose a channeling requirement for Medicare Act claims that "reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion,'... doctrines that ... normally require channeling of a legal challenge through the agency," id. at 12 (quoting Salfi, 422 U.S. at 757), and "demands the 'channeling' of virtually all legal attacks through the agency," id. at 13. Relying on Ringer, the Court stated in Illinois Council that "a 'claim for future benefits' is a § 405(h) 'claim,' and that 'all aspects' of any such present or future claim must be 'channeled' through the administrative process." Id. at 12 (quoting Ringer, 466 U.S. at 614, 621–22). As a result, the special review scheme "prevents application of the 'ripeness' and 'exhaustion' exceptions" typical in other administrative contexts. Id. at 13. To be clear, the Court spoke broadly, rejecting possible exceptions to the channeling requirement "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." Id. at 13-14. This sweeping statement makes clear that Sections 405(g) and (h) effectively preclude the exercise of district court jurisdiction in the absence of presentment of a concrete dispute, regardless of the nature of the claim at issue.

As the Supreme Court defined and refined the Medicare Act's channeling requirement, this court followed its instruction. For instance, in 1992, the court held in *National Kidney Patients' Ass'n v. Sullivan*, 958 F.2d 1127 (D.C. Cir. 1992), that Section 405(g) prevented a Medicare provider from challenging a new regulation by "proceed[ing] directly to district court" and "seeking a preliminary injunction" against the regulation, *id.* at 1129. Although "the exact meaning of

'presentment' may be unclear," the court was satisfied that "the requirement seems well suited to preventing a provider from securing an advance decision" on its claims. *Id.* at 1131. The provider had "sued before providing the services covered" by the requested injunction, *id.* at 1132, and so the agency had not had an opportunity to make an "*initial* administrative determination in a concrete setting," *id.* at 1133.

More recently, and dispositive here, in *American Hospital* Ass'n v. Azar, 895 F.3d 822 (D.C. Cir. 2018), where the plaintiffs challenged regulatory annual reimbursement rates for certain drugs set by an informal rulemaking, "[w]ithout submitting any individual claims for reimbursement to HHS," id. at 824, the court rejected the contention that submission of comments in that process satisfied presentment, id. at 823, 826–28. The plaintiffs "had neither presented their claim nor obtained any administrative decision at all" because no plaintiff "had challenged the new reimbursement regulation in the context of a *specific* administrative claim for payment." Id. at 826 (emphasis added). So too here. RICU LLC failed to present its challenge in the context of a specific administrative claim for reimbursement of service, and instead raised only a prospective request for guidance as to whether its services provided by physicians located outside of the United States would be eligible for reimbursement under the interim final rule. That is not enough to meet the presentment requirement under Section 405(g).

Against the weight of precedent, RICU LLC relies on *Mathews v. Eldridge*, 424 U.S. 319, *Salfi*, 422 U.S. 749, and *Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860 (D.C. Cir. 2010). None support RICU LLC's position that it can satisfy presentment without submitting a concrete claim for payment to the Department. *Eldridge* addressed the presentment requirement only in passing, noting that the

plaintiff "has fulfilled th[e] crucial prerequisite" of presentment "through his answers to the state agency questionnaire, and his letter in response to the [state agency's] tentative determination that his disability had ceased," which amount to a "specific claim that his benefits should not be terminated because he was still disabled." The Court further noted that the plaintiff had obtained a state agency decision denying the claim, which was accepted by the Social Security Administration. 424 U.S. at 329. Likewise, the named plaintiffs in Salfi for whom the Supreme Court recognized district court jurisdiction had "fully presented their claims" for Social Security benefits under a contested statutory provision and had received both an initial agency denial and a denial on reconsideration from lower-level officials. 422 U.S. at 764-65. In contrast, the court lacked jurisdiction over putative class members who did not allege "that they ha[d] even filed an application" for benefits. Id. at 764. Eldridge and Salfi do not call into question that presentment requires submission of a concrete claim for payment to the Department.

Nor does *Action Alliance*, where the court's discussion of presentment was limited to noting that the plaintiffs had "cured" their earlier failure to present. 607 F.3d at 862 n.1. Because the court never explained how the plaintiffs had satisfied presentment, this case "has no precedential value on that specific point." *Am. Hosp.*, 895 F.3d at 827. In any event, the *Action Alliance* plaintiffs, unlike RICU LLC, were engaged in a concrete payment dispute challenging the Department's recovery efforts of overpayment of Medicare reimbursement benefits to each plaintiff. *Action All.*, 607 F.3d at 861.

Because RICU LLC did not present a concrete claim for payment to the Department in the context of a specific payment dispute, it failed to satisfy the presentment requirement and consequently the district court lacked subject matter jurisdiction to consider its arguments under the Medicare Act.

B.

Alternatively, RICU LLC invokes the *Illinois Council* exception to show that the district court had subject matter jurisdiction over its complaint. There, the Supreme Court recognized a limited exception to the requirements of Sections 405(g) and (h) where their application "would not simply channel review through the agency, but would mean no review at all." *Ill. Council*, 529 U.S. at 19. Because mere postponement of judicial review would not trigger the exception, a party may not invoke *Illinois Council* to avoid channeling when "postponement would mean added inconvenience or cost in an isolated, particular case," unless adherence to the channeling requirement effectively would cut off judicial review under the Medicare Act. *Id.* at 22.

This court has twice applied the *Illinois Council* exception. In *American Chiropractic Ass'n v. Leavitt*, 431 F.3d 812 (D.C. Cir. 2005), the court's analysis arose in the context of a challenge to a Medicare reimbursement regulation, *id.* at 814–15, and centered on "whether the Association could get its claims heard administratively and whether it could receive judicial review after administrative channeling," *id.* at 816. Some members could obtain administrative review by providing services to Medicare enrollees, who could submit specific claims for reimbursement to the Department and make the members their assignees. *Id.* at 816–17. The court concluded that the option to meet the channeling requirement through proxies meant that a path to judicial review under Section 405 existed and the *Illinois Council* exception did not apply. *Id.* at 817–18.

In Council for Urological Interests v. Sebelius, 668 F.3d 704 (D.C. Cir. 2011), the court adhered to the same interpretation of the Illinois Council exception, namely that the exception is "primarily concerned with whether a particular claim can be heard through Medicare Act channels," id. at 712, but held the exception applied in the circumstances. Focusing on whether the purported proxies had adequate incentives to raise the otherwise foreclosed claims, it evaluated "factors that speak to a potential proxy's willingness and ability to pursue the plaintiff's claim," id., and accepted as true allegations in the complaint that the hospitals contracting for members' services "had no incentive" to raise a challenge to the disputed regulations because they had a tense relationship with members, and the disputed regulations would eliminate their financial need to purchase members' services, id. at 713. Unlike the association members in American Chiropractic, here members could not "becom[e] assignees" of their clients' claims and had no other "shared interests" with the hospitals. Id. "[U]nder the specific facts of this case," the court held that the Illinois Council exception applied because "invoking section 405(h) . . . would have the practical effect of 'turn[ing] what appears to be simply a channeling requirement into complete preclusion of judicial review." Id. at 714 (alteration in original) (quoting Ill. Council, 529 U.S. at 22-23). The district court thus had jurisdiction under Section 1331 to consider the merits of the association's challenges. Id.

The parties do not dispute that RICU LLC cannot bring an administrative challenge directly because it is not a Medicare enrolled provider. *RICU LLC*, 2021 WL 3709736, at *6. RICU LLC acknowledges, however, that its client hospitals "continue[] to inquire about whether there is any hope that [the Department] will change course" to allow reimbursement and have "always been extremely satisfied with RICU [LLC]'s services and the quality of the RICU [LLC] physicians." Decl.

of Seth Rabinowitz, Pres., RICU LLC, Supp. Pl.'s Mot. Prelim. Inj. ¶ 37. Indeed, RICU LLC represents that the purpose of its communications with the Department was to determine whether its "client hospitals could bill Medicare for RICU [LLC]'s services provided to Medicare beneficiaries," *id.* ¶ 26, and that "some existing clients have decreased the amount of services they are procuring from RICU [LLC], citing the lack of ability to seek Medicare reimbursement for RICU [LLC]'s services," *id.* ¶ 36. Further, these customers want the Department to allow reimbursement so they can more readily maintain or even expand their contracts with RICU LLC. *See id.* ¶¶ 34–40.

Taking these factual allegations as true, the client hospitals are adequate proxies to channel RICU LLC's general claim that its services are eligible for Medicare reimbursement through a concrete claim for payment. Therefore, the *Illinois Council* exception does not apply to provide federal question jurisdiction in the absence of such presentment.

Accordingly, because RICU LLC has neither satisfied the channeling requirement of Section 405(g) nor demonstrated that the *Illinois Council* exception applies, we affirm the dismissal of the complaint for lack of jurisdiction and so have no jurisdiction to consider the merits of RICU LLC's motion for a preliminary injunction, *see Am. Hosp.*, 895 F.3d at 828.