United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued May 4, 2018 Decided July 17, 2018

No. 18-5004

AMERICAN HOSPITAL ASSOCIATION, ET AL.,
APPELLANTS

v.

ALEX MICHAEL AZAR II, IN HIS OFFICIAL CAPACITY AS THE SECRETARY OF HEALTH AND HUMAN SERVICES AND UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
APPELLEES

Appeal from the United States District Court
for the District of Columbia
(No. 1:17-cv-02447)

Michael R. Smith argued the cause for appellants. With him on the briefs were *Carlos T. Angulo* and *Wen W. Shen*.

Chad I. Golder and *Sarah G. Boyce* were on the brief for *amici curiae* 35 State and Regional Hospital Associations in support of plaintiff-appellants.

Laura Myron, Attorney, U.S. Department of Justice, argued the cause for appellees. With her on the brief were *Chad A. Readler*, Acting Assistant Attorney General, *Jessie K. Liu*, U.S. Attorney, and *Mark B. Stern*, Attorney, *Robert P. Charrow*, General Counsel, U.S. Department of Health and

Human Services, *Kelly M. Cleary*, Deputy General Counsel, *Janice L. Hoffman*, Associate General Counsel, *Susan M. Lyons*, Deputy Associate General Counsel for Litigation, and *Robert W. Balderston*, Attorney.

Before: SRINIVASAN, MILLETT, and KATSAS, *Circuit Judges*.

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

KATSAS, *Circuit Judge*: To obtain judicial review of claims arising under the Medicare Act, a plaintiff must first present the claims to the Secretary of Health and Human Services. In this case, we consider whether a plaintiff may satisfy this presentment requirement by filing comments in an informal rulemaking. We also consider whether a plaintiff may cure any failure to present through administrative filings made while a case is pending on appeal.

I

The Medicare program provides federally-funded health insurance to qualifying elderly and disabled individuals. 42 U.S.C. § 1395 *et seq.* Part A of Medicare covers primarily inpatient hospital services, while Part B includes coverage for outpatient hospital care. *See id.* §§ 1395c, 1395j, 1395k.

The Outpatient Prospective Payment System ("OPPS"), a component of Part B, reimburses hospitals that provide covered outpatient services. *Id.* § 1395*l*(t). Under the OPPS, hospitals receive set payments for particular services rendered, as determined under a formula that is fixed in advance and adjusted annually. *See id.* A hospital seeking reimbursement must file an administrative claim with a Medicare administrative contractor (also known as a "fiscal

intermediary") acting on behalf of the Secretary. 42 C.F.R. § 424.32. If dissatisfied with the contractor's initial determination, the hospital then may pursue within HHS various other avenues for redetermination, reconsideration, hearings, and appeals. *See* 42 U.S.C. § 1395ff; 42 C.F.R. § 405.904. Congress has precluded judicial review of various classifications, calculations, and adjustments of the OPPS reimbursement rates. *See id.* § 1395*l*(t)(12).

This case involves the so-called "340B Program," which allows certain hospitals to purchase outpatient drugs from manufacturers at or below specified prices. *See* Public Health Services Act § 340B, 42 U.S.C. § 256b. When hospitals treat Medicare beneficiaries with these drugs, they are reimbursed through OPPS.

In setting the annual reimbursement rates for drugs obtained through the 340B Program, the Secretary must use either the "average acquisition cost" of the drug, taking into account "hospital acquisition cost survey data," or, if those data are unavailable, the "average price" of the drug, as established under different provisions of Medicare. 42 U.S.C. § 1395*l*(t)(14)(A)(iii). The relevant cross-referenced provision fixes payment rates at 106% of the average sales price. *See id.* § 1395w-3a(b). If the average-price metric is used, this 106% figure may be "adjusted by the Secretary as necessary for purposes of [OPPS]." *Id.* § 1395*l*(t)(14)(A)(iii)(II). The Secretary does not have acquisition cost survey data, so he historically has set the OPPS reimbursement rate for drugs purchased through the 340B Program at 106% of the average sales price, without any adjustments. *See* Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 77 Fed. Reg. 68,210, 68,382–86 (Nov. 15, 2012).

The regulation at issue here sets the OPPS reimbursement rate for these drugs for 2018. It reduces the rate from 106% to 77.5% of the average sales price. Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, 82 Fed. Reg. 52,356, 52,493–511 (Nov. 13, 2017). In reducing the rate, the Secretary invoked his authority to adjust the average-price determination for OPPS purposes. *See id.* at 52,496. To justify the reduction, he cited various studies indicating that hospitals participating in the 340B Program are able to buy covered drugs at amounts significantly below the average sales price. *See id.* at 52,494.

The plaintiffs in this case are three hospitals and three hospital associations. They sued to challenge the regulation on November 13, 2017, the very day it was published in the Federal Register, and before its effective date of January 1, 2018. The plaintiffs claimed that, under 42 U.S.C. § 1395*l*(t)(14)(A)(iii), the Secretary lacked authority to establish an average-price metric keyed to estimates of average acquisition costs, rather than actual survey data of those costs. Further, they claimed that a nearly 30% reduction cannot qualify as a mere payment adjustment. Without submitting any individual claims for reimbursement to HHS, they sought declaratory and injunctive relief against the new regulation.

The district court held that the plaintiffs had failed to present claims for reimbursement to the Secretary, as required to obtain judicial review of claims under Medicare, and it therefore dismissed the complaint for lack of subject-matter jurisdiction. *Am. Hospital Ass'n v. Hargan*, 289 F. Supp. 3d 45 (D.D.C. 2017).

II

We review *de novo* a dismissal for lack of subject-matter jurisdiction. *See, e.g.*, *Fla. Health Scis. Ctr. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 518 (D.C. Cir. 2016).

Three statutes create the scheme for obtaining judicial review of Medicare claims. First, 42 U.S.C. § 405(h) divests the district courts of federal-question jurisdiction "on any claim arising under" Title II of the Social Security Act, and it bars any "decision of the Commissioner of Social Security" from being judicially reviewed, "except as herein provided" in other Title II provisions. Second, 42 U.S.C. § 405(g) provides for judicial review of Social Security Act claims, thus creating the exception "herein provided." In pertinent part, it permits any person to file a civil action, "after any final decision of the Commissioner of Social Security made after a hearing to which he was a party," to "obtain a review of such decision" in federal district court. Third, 42 U.S.C. § 1395ii states that certain provisions in § 405 and elsewhere in Title II "shall also apply with respect to" Title XVIII of the Social Security Act—*i.e.*, the Medicare Act—"to the same extent as they are applicable with respect to" Title II, with any reference to the "Commissioner of Social Security" considered as one to the Secretary of HHS. *See, e.g.*, *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 7–9 (2000); *Heckler v. Ringer*, 466 U.S. 602, 614–15 (1984); *Nat'l Kidney Patients Ass'n v. Sullivan*, 958 F.2d 1127, 1130–31 (D.C. Cir. 1992). Although § 1395ii does not specifically enumerate § 405(g) as one of the incorporated Title II provisions, these decisions treat it as such, presumably on the theory that expressly incorporating the judicial-review bar in § 405(h) also effectively incorporates the exception "herein provided" in § 405(g). *See United States v. Blue Cross & Blue Shield of Ala., Inc.*, 156 F.3d 1098, 1103 (11th Cir. 1998).

Two preliminary points are undisputed. First, despite these channeling provisions for Medicare claims, federal-question jurisdiction remains available where necessary to preserve an opportunity for judicial review. *See, e.g.*, *Ill. Council*, 529 U.S. at 19–20. But the hospitals do not, and could not, contend that this is such a case. The question presented here is not *whether* they may obtain review of their challenges to the new OPPS reimbursement regulation, but *when* and *how* they may do so through the special-review scheme for Medicare claims. Second, there is no dispute that the hospitals' claims arise under the Medicare Act for purposes of § 405(h), which provides the "substantive basis" for the claims. *See Ill. Council*, 529 U.S. at 12 (quoting *Ringer*, 466 U.S. at 615).

The Supreme Court has held that § 405(g) imposes two distinct preconditions for obtaining judicial review of covered Medicare claims. First, the plaintiff must have "presented" the claim to the Secretary; this requirement is not waivable, because without presentment "there can be no 'decision' of any type," which § 405(g) clearly requires. *Mathews v. Eldridge*, 424 U.S. 319, 328 (1976). Second, the plaintiff must fully exhaust all available administrative remedies, though this more demanding requirement is waivable. *See id.* Here, the district court concluded that the plaintiffs had not satisfied the presentment requirement. We agree.

When the plaintiffs filed this lawsuit, neither the hospital plaintiffs, nor any members of the hospital-association plaintiffs, had challenged the new reimbursement regulation in the context of a specific administrative claim for payment. Nor could they have done so, for the new regulation had not yet even become effective. Therefore, they had neither presented their claim nor obtained any administrative decision at all, much less the "final decision" required under § 405(g).

The hospitals contend that they satisfied the presentment requirement by filing comments opposing the regulation during the rulemaking. This argument is hard to square with the text of § 405(g)—a regulation cannot easily be described as a "final decision," and a notice-and-comment rulemaking cannot easily be described as a "hearing" in which all commenters have assumed "party" status. To the contrary, a "final decision" is akin to a "final disposition," which the Administrative Procedure Act labels an "order" and distinguishes from a regulation or "rule." 5 U.S.C. § 551(6). The APA also distinguishes the notice-and-comment procedures at issue here from formal rulemaking procedures requiring a "hearing." *Id.* § 553(c). And it distinguishes between commenters in informal rulemaking, who have only an "opportunity to participate" in the proceeding, *id.*, and those involved in formal rulemaking, who assume "party" status, *id.* § 556(d).

The hospitals' argument is also foreclosed by precedent, which makes clear that the presentment requirement generally prevents anticipatory legal challenges to Medicare rules and regulations. For example, in *Ringer*, the Supreme Court held that § 405(g) barred a patient from seeking prospective relief to establish that a particular kind of surgery was "'reasonable and necessary' within the meaning of the Medicare Act." 466 U.S. at 620. The Court reasoned that the presentment requirement applied to claims "for future benefits," and required the plaintiff to "give[] the Secretary an opportunity to rule on a concrete claim for reimbursement." *Id.* at 621–22. In this context, the requisite "concrete claim for reimbursement" must have meant a claim seeking specific payments through the reticulated Medicare scheme for administrative claims, *see* 42 C.F.R. § 424.32, and appeals, *see id.* § 405.904, rather than merely general comments filed in an informal rulemaking.

Likewise, in *Illinois Council*, the Supreme Court held that an association of providers was barred from "claiming that certain Medicare-related regulations violated various statutes and the Constitution." 529 U.S. at 5. The Court explained that § 405(g) and (h) channel "most, if not all, Medicare claims through this special review system," *id.* at 8, including "virtually all legal attacks" on regulations, *id.* at 13. The Court rejected proposed limitations to these channeling provisions "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," as well as "a distinction that limits the scope of § 405(h) to claims for monetary benefits." *Id.* at 13–14. None of this would make sense if the overarching "special review system" were nothing more than notice-and-comment rulemaking.

Finally, in *National Kidney Patients' Association*, this Court held that § 405(g) blocked Medicare providers from challenging a "rate reduction" in a new regulation by "proceed[ing] directly to district court, seeking a preliminary injunction" against the regulation. 958 F.2d at 1129–30. We identified the problem not as the plaintiffs' failure to participate in the rulemaking, but as their bypassing "*initial* administrative determination" in the "concrete setting" of a specific reimbursement decision. *Id.* at 1133. *See also Three Lower Ctys. Cmty. Health Servs., Inc. v. U.S. Dep't of Health & Human Servs.*, 317 F. App'x 1, 3 (D.C. Cir. 2009) (per curiam) ("The Medicare Act … requires that parties present all such challenges to the agency in the context of a fiscal year reimbursement claim.").

Against all of this, the plaintiffs invoke *Eldridge* and *Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860

(D.C. Cir. 2010). Neither decision suggests that filing comments in an informal rulemaking can constitute presentment. In *Eldridge*, the named plaintiffs had "fully presented" specific claims for disability benefits—to both a district and regional Social Security Office—and had secured an agency decision denying the benefits. 424 U.S. at 329. In *Action Alliance*, our entire discussion of presentment was a statement that the plaintiffs had "cured" their prior failure to present. 607 F.3d at 862 n.1. Because we did not explain what constituted the cure, the decision has no precedential value on that specific point. *See United States v. Sheffield*, 832 F.3d 296, 308 n.3 (D.C. Cir. 2016). In any event, the plaintiffs in *Action Alliance* were embroiled with HHS in a specific payment dispute, which arose from the agency's efforts to recover Medicare payments erroneously made to them. *See* 607 F.3d at 861. The presentment "cure" presumably consisted of letters, sent to HHS on behalf of each plaintiff, invoking an alleged statutory right to a waiver. *See Action Alliance of Senior Citizens v. Johnson*, 607 F. Supp. 2d 33, 37–38 (D.D.C. 2009). And the result was an agency decision denying the waivers. *See id.* at 38. Neither case suggests that submitting comments in response to a proposed rule about reimbursement rates—wholly detached from any specific payment dispute—is the kind of "concrete claim for reimbursement" required for presentment. *See Ringer*, 466 U.S. at 622.

Alternatively, the hospitals contend that they cured their presentment problem through payment demands made to HHS during the pendency of this appeal. Those demands come too late to establish subject-matter jurisdiction in the district court. "It has long been the case that 'the jurisdiction of the court depends upon the state of things at the time of the action brought.'" *Grupo Dataflux v. Atlas Global Grp.*, 541 U.S. 567, 570 (2004) (quoting *Mollan v. Torrance*, 22 U.S. (9 Wheat.) 537, 539 (1824)). And when this action was brought, no

plaintiff had presented any concrete claim for reimbursement implicating the new regulation, which had not even become effective.

The hospitals respond that, under *Mathews v. Diaz*, 426 U.S. 67 (1976), defects in subject-matter jurisdiction can be cured at any time, even on appeal. *Diaz* does not reach that far. There, the plaintiff satisfied the presentment requirement "while the case was pending in the District Court"—at a time when leave to supplement the complaint could still have been granted. *See id.* at 75. No motion to supplement had been filed, but the Court solved that problem under 28 U.S.C. § 1653, which provides that "[d]efective allegations of jurisdiction may be amended, upon terms, in the trial or appellate courts." *See* 426 U.S. at 75 & n.9. Here, where the alleged presentment occurred only when the case was on appeal, the district court could not have granted leave to amend or supplement to reflect any post-filing presentment. As for § 1653, that provision merely allows appellate courts to consider additional allegations that the district court did in fact have jurisdiction. It does not allow for the retroactive creation of district-court jurisdiction based on new facts that occurred only during an appeal. *See, e.g.*, *Novak v. Capital Mgmt. & Dev. Corp.*, 452 F.3d 902, 906–07 (D.C. Cir. 2006) (on appeal, plaintiffs added allegations regarding diversity of citizenship when the complaint was filed); *D.C. ex rel. Am. Combustion, Inc. v. Transamerica Ins. Co.*, 797 F.2d 1041, 1044 (D.C. Cir. 1986) (on appeal, plaintiff added allegations "that diversity was present" below); *Fry v. Layne-Western Co.*, 282 F.2d 97, 99 (8th Cir. 1960) (per curiam) (on appeal, parties were permitted to add allegations "to show, if possible, that federal jurisdiction did, in fact, exist" below).

III

Because the plaintiffs failed to satisfy the presentment requirement of 42 U.S.C. § 405(g), the district court properly dismissed this case for lack of subject-matter jurisdiction. Given our disposition, we need not consider whether the plaintiffs' failure to satisfy the exhaustion requirement of § 405(g) falls within any futility or other exception. We also need not consider the Secretary's alternative threshold contention that 42 U.S.C. § 1395*l*(t)(12) would foreclose judicial review of the claims at issue even if the plaintiffs had satisfied the presentment and exhaustion requirements. Finally, because subject-matter jurisdiction was lacking here, we have no authority to consider the merits.

Affirmed.