United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued February 25, 2022 Decided July 15, 2022

No. 21-5122

AMERICAN CLINICAL LABORATORY ASSOCIATION,
APPELLANT

v.

XAVIER BECERRA, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,
APPELLEE

Appeal from the United States District Court
for the District of Columbia
(No. 1:17-cv-02645)

Ashley C. Parrish argued the cause for appellant. With her on the briefs were *Mark D. Polston* and *Gabriel Krimm*.

McKaye L. Neumeister, Attorney, U.S. Department of Justice, argued the cause for appellee. With her on the brief were *Brian M. Boynton*, Acting Assistant Attorney General at the time the brief was filed, *Abby C. Wright*, Attorney, *Janice L. Hoffman*, Associate General Counsel, U.S. Department of Health & Human Services, and *Susan Maxson Lyons*, Deputy Associate General Counsel for Litigation.

Before: MILLETT, WILKINS, and JACKSON[*], *Circuit Judges*.

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

WILKINS, *Circuit Judge*: The Protecting Access to Medicare Act of 2014 ("PAMA" or "Act"), Pub. L. No. 113-93, 128 Stat. 1040, requires "applicable laborator[ies]" to report private payor—e.g., an insurance company—rates for laboratory tests to the Secretary of Health and Human Services ("HHS"). The Medicare program then uses private market payment rate data to set new Medicare reimbursement rates for laboratory tests. Specifically, PAMA directs the Secretary to calculate the "weighted median" of private payor data, which informs Medicare payment rates. 42 U.S.C. § 1395m-1(b)(1)(A). The Act provides that once Medicare rates are calculated, "the payment amounts . . . shall continue to apply until the year following the next data collection period." *Id.* § 1395m-1(b)(4)(A). The Act further states that "[t]he payment amounts . . . shall not be subject to any adjustment." *Id.* § 1395m-1(b)(4)(B).

In 2016, the Secretary issued a final rule that implemented PAMA's definition of "applicable laboratory." Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System, 81 Fed. Reg. 41,036 (June 23, 2016) ("2016 Rule"). The American Clinical Laboratory Association ("ACLA") filed a lawsuit challenging the 2016 Rule as arbitrary and capricious under the Administrative Procedure Act ("APA") on the basis that it depresses Medicare reimbursement rates by excluding most hospital laboratories

[*] Circuit Judge, now Justice, Jackson was a member of the panel at the time the case was argued but did not participate in this opinion.

from PAMA's reporting requirements. Specifically, ACLA contends that because hospital laboratories tend to charge higher prices than standalone laboratories, their exclusion from reporting obligations results in an artificially low weighted median.

This Court assumes familiarity with the procedural, regulatory, and factual background of this case, which another panel of this Court laid out in a prior opinion. *See Am. Clinical Lab'y Ass'n v. Azar*, 931 F.3d 1195 (D.C. Cir. 2019) ("*ACLA I*"). In *ACLA I*, we reversed the District Court's dismissal of ACLA's complaint challenging the 2016 Rule for lack of subject matter jurisdiction, *see Am. Clinical Lab'y Ass'n v. Azar*, 334 F. Supp. 3d 301 (D.D.C. 2018) (holding that PAMA bars judicial review of the Secretary's data collection practices), and remanded to the District Court to consider in the first instance whether the 2016 Rule is consistent with the APA. *See ACLA I*, 931 F.3d at 1198.

On remand, the parties cross-moved for summary judgment. The District Court again declined to reach the merits of ACLA's APA challenge to the 2016 Rule, based on its determination that the Secretary had issued a new rule ("2018 Rule") that superseded the 2016 Rule and mooted ACLA's lawsuit. *Am. Clinical Lab'y Ass'n v. Becerra*, No. 17-2645, 2021 WL 1197729, at *3–6 (D.D.C. Mar. 30, 2021). In relevant part, the 2018 Rule provides a more expansive definition of "applicable laboratory" and subjects more hospital laboratories to PAMA's reporting requirements. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions, 83 Fed. Reg. 59,452 (Nov. 23, 2018) ("2018 Rule"). ACLA appeals the District Court's dismissal for mootness on the grounds that ACLA members continue to suffer from "downstream effects"

of the 2016 Rule, notwithstanding the Secretary's promulgation of the 2018 Rule. Appellant Opening Br. at 35.

We conclude that the case is not moot. Accordingly, we reverse the District Court's dismissal for lack of subject matter jurisdiction and reach the merits of ACLA's APA claim.

I.

Under the Act, an applicable laboratory is "a laboratory that, with respect to its revenues under this subchapter, a majority of such revenues are from this section, section 1395*l*(h) of this title, or section 1395w-4 of this title." 42 U.S.C. § 1395m-1(a)(2). This definition refers to a laboratory that receives most of its overall Medicare funding from the Physician Fee Schedule or the Clinical Laboratory Fee Schedule. *ACLA I*, 931 F.3d at 1199–1200. These fee schedules, in turn, typically "pay for laboratory services provided by independent laboratories and physician-office laboratories." *Id.* at 1200. As a general matter, hospital laboratories that provide "outreach services"—services for people who are neither hospital inpatients or outpatients—fall within the ambit of PAMA's definition of an applicable laboratory, so long as they receive most of their Medicare revenue from the Physician Fee Schedule or Clinical Laboratory Fee Schedule. *Id.*

The 2016 Rule implemented PAMA's definition of "applicable laboratory" by identifying laboratories that would be subject to reporting requirements by their National Provider Identifier ("NPI") number. (Healthcare providers generally use an NPI number to bill Medicare.) But as this Court previously observed in *ACLA I*, "very few hospitals have laboratory-specific NPIs, and they generally submit claims under the hospital's NPI." 931 F.3d at 1202 (alteration accepted)

(internal quotation marks and citation omitted). Therefore, because hospital laboratories that provide outreach services do not typically have their own NPIs, the 2016 Rule exempts these entities from data reporting requirements, even if they meet PAMA's statutory definition of an "applicable laboratory." *See* 42 U.S.C. § 1395m-1(a)(2). As such, ACLA contends that the 2016 Rule excludes "a large swath of the clinical laboratory marketplace from the statutory reporting requirements," which "reduces the weighted median of all reported tests, [thereby] depressing the Medicare reimbursement rates." Appellant Opening Br. at 2, 14.

Before this Court issued *ACLA I*, the Secretary promulgated the 2018 Rule, which "requires laboratories providing outreach services to report data using the CMS-1450 14x TOB—a billing form used only by hospital outreach laboratories." *ACLA I*, 931 F.3d at 1202 (citing 2018 Rule, 83 Fed. Reg. at 59,673–75). In so doing, the Secretary amended the definition of "applicable laboratory" to include hospital laboratories that provide outreach services. This presumably resolved ACLA's key grievance with the 2016 Rule. Nevertheless, because the 2018 Rule was "not at issue" in *ACLA I*, a panel of this Court ultimately determined that ACLA had associational standing to challenge the 2016 Rule and that PAMA's jurisdiction-stripping provisions—with respect to judicial review of payment amounts—did not bar judicial review of a final rule. *ACLA I*, 931 F.3d at 1202, 1203–08. Accordingly, the Court reversed the District Court's holding on subject matter jurisdiction and remanded to the District Court to adjudicate the merits of ACLA's arbitrary-and-capricious challenge to the 2016 Rule. *Id.* at 1209.

On remand, the District Court reasoned that because ACLA's lawsuit did not challenge the 2018 Rule, "the only remedy that would be available to plaintiff here would be

retrospective relief for any past payments that were calculated using the only [sic] 2016 Rule – that is, payments calculated for 2018-20 based on data collected data [sic] in early 2017 using the challenged definition." *Am. Clinical Lab'y Ass'n*, 2021 WL 1197729, at *5 (citation omitted). But PAMA "bars judicial review of 'the establishment of [Medicare] payment amounts.'" *Id.* (quoting 42 U.S.C. § 1395m-1(h)). Accordingly, the District Court held that "even if the Court were to rule in plaintiff's favor on the merits, it could not order the agency to revise any payment amounts in the fee schedules used to determine 2018-20 payments or any particular payments to plaintiff's members." *Id.* at *5 (citation omitted). "Further, the Court could not vacate [the 2016 Rule] and order the Secretary to bring his regulations into compliance with the Medicare statute since the [2016 Rule's] definition is no longer in effect." *Id.* at *6. Accordingly, the District Court determined that ACLA's lawsuit was moot and dismissed the case for lack of subject matter jurisdiction for a second time. *Id.*

II.

This Court reviews the district court's dismissal for lack of subject matter jurisdiction *de novo*. *Fla. Health Scis. Ctr., Inc. v. Sec'y of Health & Hum. Servs.*, 830 F.3d 515, 518 (D.C. Cir. 2016); *ACLA I*, 931 F.3d at 1202–03.

The "constitutional minimum of standing contains three elements": (1) a concrete and particularized "injury-in-fact"; (2) that is fairly traceable to the challenged conduct; and (3) is likely to be redressed by a favorable decision. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992). To demonstrate associational standing, ACLA must show that "at least one of [its] members satisfies the three elements" outlined in *Lujan*.

See Am. Libr. Ass'n v. FCC, 401 F.3d 489, 492 (D.C. Cir. 2005) (citing *Lujan*, 504 U.S. at 560).

We begin by assuring ourselves, as we must, that ACLA had standing at the time it filed its complaint, *Friends of the Earth, Inc. v. Laidlaw Env't Servs. (TOC), Inc.*, 528 U.S. 167, 180 (2000), and that ACLA presented sufficient evidence of its standing in support of the motion for summary judgment under review, *Lujan*, 504 U.S. at 561.

In *ACLA I*, we held that ACLA had established associational standing at the outset of the litigation. *See ACLA I*, 931 F.3d at 1203–04. ACLA also presented sufficient evidence of standing in support of its motion for summary judgment. ACLA has maintained associational standing through its members, including Aculabs, Inc. ("Aculabs"). J.A. 44; *see Narragansett Indian Tribal Hist. Pres. Off. v. FERC*, 949 F.3d 8, 12 (D.C. Cir. 2020). As evidenced by a declaration from its president, Aculabs suffered two injuries.

First, Aculabs has suffered a competitive injury, compared to hospital-based laboratories. Pursuant to PAMA, Aculabs reports private payor data to the Secretary, J.A. 50–52, but the Secretary exempts other market participants—like hospital-based laboratories—from PAMA's reporting requirements, which puts Aculabs at a competitive disadvantage. Appellant Opening Br. at 34–35; *see ACLA I*, 931 F.3d at 1203. Second, the 2016 Rule's data collection regime has injured Aculabs by skewing the reimbursement rates on the Clinical Laboratory Fee Schedule lower. J.A. 50–51; *see ACLA I*, 931 F.3d at 1203. Consequently, Aculabs projects significant financial harm: it will not receive enough Medicare reimbursement to cover its costs. J.A. 51. In sum, Aculabs' injuries-in-fact—its competitive injury and lower reimbursement rates—are fairly traceable to the 2016 Rule, and they were redressable at the

time ACLA filed its complaint. *ACLA I*, 931 F.3d at 1204; *see* U.S. Gov't Accountability Off., GAO-19-67, *Medicare Laboratory Tests: Implementation of New Rates May Lead to Billions in Excess Payment* 12 (2018); Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* 297, 306, 324 (2021). The injuries are still redressable today because declaratory relief that the 2016 Rule is invalid will prevent its reinstatement in the future. *See Friends of the Earth*, 528 U.S. at 185 ("[A] plaintiff must demonstrate standing separately for each form of relief sought.").

Furthermore, contrary to the District Court's determination, the fact that the Secretary replaced the 2016 Rule with the 2018 Rule did not moot this case. We conclude that HHS—as "the party asserting mootness"—has not met "[t]he 'heavy burden of persua[ding]' the court that the challenged conduct cannot reasonably be expected to start up again[.]" *Id.* at 189 (alteration in original) (citation omitted).

For example, in the 2018 Rule, the agency reiterated that it "continue[d] to believe that the NPI is the most effective mechanism for identifying Medicare revenues[.]" 83 Fed. Reg. at 59,672. The agency acknowledged that it would "only know the impact of the [new] data [collection scheme] on [Clinical Laboratory Fee Schedule] rates by collecting data from hospital outreach laboratories." *Id.* at 59,674. Further, HHS expressly left open the possibility of "revisit[ing] the use of the CMS-1450 14x TOB through future rulemaking" if "it becomes apparent that the data from hospital outreach laboratories do not result in a significant change in the weighted median of private payor rates," *id.*, which is what the agency expects to happen. *See, e.g.*, Appellee Br. at 41 ("ACLA . . . failed to establish that any increase in the number of laboratories reporting would have ultimately influenced the fee schedule."),

60 ("There is . . . no reason to think that the data set used [under the 2016 Rule] was inaccurate. . . ."), 62 ("'[A]dditional reporting may not be likely to change payment rates, irrespective of how many additional smaller laboratories are required to report.'") (quoting 2016 Rule, 81 Fed. Reg. at 41,049). Furthermore, during oral argument, HHS continued to defend its policy of relying on NPIs. *See* Oral Arg. Tr. 13:2–14:3. Accordingly, pursuant to the voluntary cessation doctrine, the government failed to meet its burden to establish that "there is no reasonable expectation that" the agency will restore the 2016 Rule. *Zukerman v. U.S. Postal Serv.*, 961 F.3d 431, 442 (D.C. Cir. 2020) (internal quotation marks and citations omitted).

In other words, the record evidence in this case reflects that the agency has only "temporarily alter[ed] [its] questionable behavior." *City News & Novelty, Inc. v. City of Waukesha*, 531 U.S. 278, 284 n.1 (2001); *see also City of Mesquite v. Aladdin's Castle, Inc.*, 455 U.S. 283, 289 (1982) (declining to find mootness because "[t]here is no certainty that a similar course would not be pursued if [the city's] most recent amendment were effective to defeat federal jurisdiction"); *Deja Vu of Nashville, Inc. v. Metro. Gov't of Nashville & Davidson Cnty., Tenn.*, 274 F.3d 377, 387 (6th Cir. 2001) (declining to find mootness despite change in city ordinance because the city "repeatedly expressed its intention to reenact those portions of the Ordinance judged unconstitutional by the district court at the earliest opportunity").

To be sure, "[c]ourts have noted that structural obstacles to reimposing a challenged law—such as a full repeal and the need to undertake new lawmaking—generally moot a case." *Alaska v. U.S. Dep't of Agric.*, 17 F.4th 1224, 1229 n.5 (D.C. Cir. 2021). And certainly, the government will more easily meet its burden to demonstrate mootness where structural

obstacles are combined with a record "where nothing suggests" voluntary cessation. *Id.* In contrast, in *American Bankers Association v. National Credit Union Administration*, 934 F.3d 649 (D.C. Cir. 2019), this Court determined that a challenge to an agency rule was not moot because the government "evince[d]" the "inten[tion] to reinstitute" the challenged portion of the rule. *Id.* at 661. Such is the case here.

Furthermore, on remand, the District Court ruled that it lacked subject matter jurisdiction over ACLA's lawsuit because the Medicare statute requires claim presentment and exhaustion, pursuant to 42 U.S.C. § 405(h), but ACLA satisfied neither requirement. *Am. Clinical Lab'y Ass'n*, 2021 WL 1197729, at *4. Again, we disagree.

"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." *Am. Hosp. Ass'n v. Azar*, 895 F.3d 822, 823 (D.C. Cir. 2018). Section 405(h) "divests the district courts of federal-question jurisdiction 'on any claim arising under' Title II of the Social Security Act." *Id.* at 825 (quoting 42 U.S.C. § 405(h)). Another statute, 42 U.S.C. § 1395ii, provides that section 405(h) applies to the Medicare Act. *Am. Hosp. Ass'n*, 895 F.3d at 825. We conclude that ACLA fulfilled the requirements of presentment and exhaustion through its member, BioReference Laboratories ("BioReference"), which presented claims to the agency and exhausted its administrative remedies. *See* Appellant Reply Br. at 12–13. The government does not dispute the fact that BioReference is a member of ACLA.

III.

Because we have jurisdiction over ACLA's lawsuit, we will turn to the merits of ACLA's APA challenge to the 2016

Rule. In short, ACLA contends that the 2016 Rule's implementation of the term "applicable laboratory" contravenes the APA because its reliance on NPIs ultimately excludes hospital laboratories that provide outreach services from data reporting requirements. Accordingly, the 2016 Rule results in inaccurate marketplace data and depresses Medicare reimbursement rates.

Under the familiar standards of the APA, we must "set aside agency action" that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). "We will uphold the agency's action if the agency 'examine[d] the relevant data and articulate[d] a satisfactory explanation for its action including a rational connection between the facts found and the choice made.'" *Baystate Franklin Med. Ctr. v. Azar*, 950 F.3d 84, 89 (D.C. Cir. 2020) (quoting *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)). Agency action is arbitrary and capricious "if the agency has relied on factors which Congress has not intended it to consider"; "entirely failed to consider an important aspect of the problem"; "offered an explanation for its decision that runs counter to the evidence before [it]"; or "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *State Farm*, 463 U.S. at 43. "The scope of review under the 'arbitrary and capricious' standard is narrow and a court is not to substitute its judgment for that of the agency." *Id.*

We hold that the 2016 Rule is arbitrary and capricious because the agency "failed to consider an important aspect of the problem." *Id.* PAMA provides that an applicable laboratory "means a laboratory that" receives "a majority" of its Medicare revenues from the Physician Fee Schedule or Clinical Laboratory Fee Schedule. *See* 42 U.S.C. § 1395m-

1(a)(2). "Considered as a freestanding entity, a hospital laboratory that offered outreach services could fit the statutory definition of an applicable laboratory if it received most of its Medicare revenue from the [Physician Fee Schedule] and [Clinical Laboratory Fee Schedule]." *ACLA I*, 931 F.3d at 1200. Thus, hospital laboratories that provide outreach services may, in some instances, constitute "applicable laboratories" under PAMA. *Cf.* 2016 Rule, 81 Fed. Reg. at 41,045 (noting that "[m]ost hospital laboratories will *not* meet the majority of revenues threshold") (emphasis added).

The 2016 Rule is arbitrary and capricious because it failed to reasonably explain the agency's use of NPIs to identify laboratory revenue. Pursuant to the 2016 Rule's data-reporting requirements, the Secretary decided to identify laboratories by their NPIs. *ACLA I*, 931 F.3d at 1208. The statute does not, however, answer the precise question of how to identify "[a laboratory's] revenues under this subchapter." 42 U.S.C. § 1395m-1(a)(2). Depending on how revenue is identified, "a hospital laboratory without its own, laboratory-specific NPI [does] not qualify as an applicable laboratory" under the Secretary's definition, and thus hospital outreach laboratories without NPIs would not be subject to reporting requirements. *ACLA I*, 931 F.3d at 1208. This is problematic, given that the agency specifically determined that its rule should capture data from hospital outreach laboratories. *See* 2016 Rule, 81 Fed. Reg. at 41,045–46; 2018 Rule, 83 Fed. Reg. at 59,668, 59,671, 59,674. ACLA even submitted comments during the rulemaking process that should have alerted HHS to the fact that few hospital laboratories have NPIs, but HHS nevertheless failed to address the Rule's under-inclusive nature. *See* 2016 Rule, 81 Fed. Reg. at 41,046–47.

Thus, the agency, without adequate explanation, exempted a sizable portion of the laboratories covered by the statute from

data reporting requirements. Furthermore, the agency admitted at oral argument that it did not even know how many outreach laboratories had NPIs, and it has never disputed ACLA's argument that the number is low. *See* Oral Arg. Tr. 11:22–12:11. Indeed, only 21 hospital laboratories—out of a total of 1,942 reporting laboratories—reported their data, even though hospital laboratories accounted for nearly a quarter of Medicare payments made under the Clinical Laboratory Fee Schedule in 2015. J.A. 63, 432. And those 21 hospitals represented only "one percent of all reporting entities and less than one half of one percent of all hospital labs paid under Medicare Part B for lab services in 2015." J.A. 433. For these reasons, we conclude that the agency did not justify its decision to identify applicable laboratory revenues by NPIs.

IV.

For the foregoing reasons, the judgment of the District Court is reversed and the case is hereby remanded for further proceedings consistent with this opinion. The District Court is instructed to enter a declaratory judgment in favor of ACLA. This relief is prospective and will neither require the Secretary to accelerate the data reporting period for laboratories nor recalculate past Medicare reimbursement rates, in light of PAMA's provision stripping jurisdiction to review Medicare payment amounts, *see* 42 U.S.C. § 1395m-1(h)(1). Furthermore, because HHS has already replaced the 2016 Rule with the 2018 Rule—which provides an updated methodology for collecting information from laboratories—we deny ACLA's request to vacate the 2016 Rule.

So ordered.