United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued April 23, 2019 Decided July 30, 2019

No. 18-5312

AMERICAN CLINICAL LABORATORY ASSOCIATION,
APPELLANT

v.

ALEX MICHAEL AZAR, II, IN HIS OFFICIAL CAPACITY AS SECRETARY 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 him on the briefs were *Mark D. Polston*, *Elizabeth N. Swayne*, and *Amelia G. Yowell*.

R. Scott Caulkins and *Jeffrey J. Sherrin* were on the brief for *amicus curiae* American Association of Bioanalysts in support of plaintiffs-appellant.

David McAloon was on the brief for *amici curiae* The College of American Pathologists, et al. in support of appellant.

Dennis Fan, Attorney, U.S. Department of Justice, argued the cause for appellee. With him on the brief were *Abby C.*

Wright, Attorney, *Robert P. Charrow*, General Counsel, U.S. Department of Health & Human Services, *Janice L. Hoffman*, Associate General Counsel, *Susan Maxson Lyons*, Deputy Associate General Counsel, and *Debra M. Laboschin*, Attorney. *Alisa B. Klein*, Attorney U.S. Department of Justice, entered an appearance.

Before: GRIFFITH, MILLETT and PILLARD, *Circuit Judges*.

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

PILLARD, *Circuit Judge*: The Protecting Access to Medicare Act (PAMA, or the Act) seeks to align Medicare reimbursement rates for laboratory tests with rates paid for such tests in the private market. To enable the Secretary of Health and Human Services (HHS) to ascertain the private market's reimbursement rates, PAMA requires "applicable laboratories" to report private payor data to the Secretary that the Medicare program then uses to set new, presumably lower, Medicare reimbursement rates. The Secretary must implement the statute's definition of "applicable laboratory" before it can be used to collect the requisite data. In 2016, the Secretary issued a final rule doing so, and plaintiff American Clinical Laboratory Association (ACLA) filed suit claiming the rule unlawfully excluded most hospital laboratories from the Act's reporting requirements.

Based on PAMA's prohibition of judicial review of "the establishment of payment amounts," the district court dismissed ACLA's complaint for lack of subject matter jurisdiction. We conclude that the statutory provision stripping jurisdiction to review payment amounts does not cover the statute's data-collection provision. We also reject ACLA's claim that the Secretary's rule was *ultra vires*. We thus reverse

and remand to the district court to consider in the first instance whether the rule comports with the APA.

I. Background

The federal Medicare program, which pays for healthcare for elderly and disabled individuals, *see* 42 U.S.C. § 1395 *et seq*., is the nation's largest purchaser of clinical laboratory services. In 2013, the HHS Office of Inspector General concluded that Medicare was paying 18 to 30 percent more than private insurance companies for a range of common laboratory tests. Congress responded by enacting the Protecting Access to Medicare Act, Pub. L. No. 113-93, 128 Stat. 1040 (2014). A central goal of the Act is to set Medicare reimbursement rates for laboratory tests at approximately the price private insurers pay for the same tests. *See* 42 U.S.C. § 1395m-1(b)(1)(A).

To inform the Secretary's rate setting, the statute requires "applicable laborator[ies]" within the private sector to report "private payor" data—both the price and volume of laboratory tests—to HHS every three years. *Id*. § 1395m-1(a). The statute defines the term "private payor" as a "health insurance issuer and a group health plan," a "Medicare Advantage plan," or a "medicaid managed care organization." *Id.* § 1395m-1(a)(8). It calls on the Secretary to establish parameters for data collection through notice and comment rulemaking. *Id.* § 1395m-1(a)(12). Applicable laboratories that fail to report accurate data face monetary penalties of up to $10,000 per day. *Id.* § 1395m-1(a)(9).

In separate provisions, the statute explains how the Secretary is to use private payor data on each laboratory test already available in the market to calculate a "weighted median" rate, which becomes Medicare's reimbursement rate for that test. *Id.* § 1395m-1(b). For new tests that do not have

private payor data, the Secretary is to use a "gapfilling process" and consult with an expert advisory panel to establish the new test's Medicare payment rate. *Id.* §§ 1395m-1(c)-(d), (f). Because the market-approximating Medicare rates are likely to be lower than existing Medicare rates, the statute allows for a multi-year "[p]hase-in" process to transition to the market-based rates. *Id.* § 1395m-1(b)(3). Finally, the statute declares that "[t]here shall be no administrative or judicial review . . . of the establishment of payment amounts under this section," *id.* § 1395m-1(h)(1), thereby barring otherwise available review by the Departmental Appeals Board and Provider Reimbursement Board as well as the federal courts.

This appeal is about whether the Secretary's implementation of PAMA's definition of "applicable laboratories" is subject to review in response to a claim that it unlawfully excludes hospital laboratories—which tend to charge higher prices than standalone laboratories—from the dataset used to determine new Medicare rates. *See* Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System, 81 Fed. Reg. 41,036 (June 23, 2016). Laboratory tests are available to the public through three main types of laboratories: physician-office laboratories (which in 2015 comprised 17 percent of all labs), independent laboratories (50 percent of all labs), and hospital laboratories (33 percent of all labs). The statute does not expressly discuss those distinct types of institutional settings, instead generally defining an applicable laboratory as "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). In plain terms, that definition refers to a laboratory that receives most of its overall Medicare funding from the Physician Fee Schedule (PFS) or the Clinical Laboratory Fee Schedule (CLFS). Those Medicare fee schedules are typically used to

pay for laboratory services provided by independent laboratories and physician-office laboratories. We refer to this part of the statute's definition of applicable labs as the majority-payments test.[1]

Applying the majority-payments test to hospital laboratories has proved more complicated than for independent laboratories and physician-office laboratories. Medicare reimburses laboratory services provided by hospital laboratories in a range of different ways, and it is not obvious which, if any, are relevant to PAMA. When hospital laboratories serve admitted inpatients and registered outpatients, Medicare does not use the PFS or CLFS, but pays for those services through distinct fee schedules that bundle the laboratory testing with other hospital services. *See* Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System, 80 Fed. Reg. 59,386, 59,393 (Oct. 1, 2015). A hospital laboratory serving only inpatients and outpatients accordingly is not an applicable laboratory under PAMA because it receives no Medicare reimbursements from the applicable fee schedules.

However, some hospitals also provide "outreach services"—that is, laboratory services for people who are neither inpatients nor outpatients. Hospitals' outreach services may compete for such business with independent laboratories, and Medicare reimburses hospitals for those services under the

[1] The statute authorizes the Secretary to establish a "low volume or low expenditure threshold" to exclude especially small laboratories. 42 U.S.C. § 1395m-1(a)(2). The Secretary has set the low expenditure threshold at $12,500, meaning that labs receiving less than $12,500 of Medicare revenue from the CLFS and PFS are exempt from reporting requirements. ACLA does not challenge that provision, which exempts approximately 95 percent of physician-office laboratories.

PFS and CLFS. 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 PFS and CLFS.

In October 2015, the Secretary proposed a rule to implement the data reporting provision of PAMA. *See* 80 Fed. Reg. at 59,386. The Secretary acknowledged that it was "important" to "define laboratory broadly enough to encompass every laboratory type that is subject to" the applicable fee schedules, *id.* at 59,391, so proposed to include any "entity that includes a laboratory" as well as any "entity that itself is a laboratory," *id.* at 59,392. But to make the threshold identification of the relevant entity to be scrutinized under the statutory majority-payments test, the proposed rule defined "entity" as the institutional unit associated with a distinct taxpayer identification number (TIN). *Id.* at 59,387. A TIN is the institutional identifier Medicare service providers use to report to the IRS tax-related information about all types of Medicare payments. *Id.* at 59,421.

The practical effect of applying the majority-payments test to an entity defined by its TIN would be that essentially no hospital laboratory could qualify as an applicable laboratory. *See id.* at 59,393. An independent laboratory that takes Medicare payments has a TIN, but so does an entire hospital that takes Medicare payments. Identifying the relevant entity at the level of the TIN would mean that, for purposes of the majority-payments test, Medicare reimbursements to a hospital lab under the PFS and CLFS would be compared to the entire hospital's Medicare revenue rather than to its laboratory's Medicare revenue. Hospitals, in contrast to stand-alone laboratories, receive Medicare reimbursements for a wide range of services—everything from surgeries to room and board—so even if the hospital laboratory received the majority

of its Medicare revenue from the PFS and CLFS, the majority of the hospital's overall Medicare revenues would not come from those fee schedules.

Insofar as hospitals' Medicare revenue associated with those fee schedules is dwarfed by their other types of Medicare revenue, reliance on the TIN to define the relevant entity would exclude all hospital-based laboratories from the "applicable laboratories" reporting requirement at the threshold, without subjecting the laboratories as such to the majority-payments test. The Secretary anticipated that consequence, explaining: "[W]e believe the statute intends to limit reporting primarily to independent laboratories and physician offices . . . and not to include other entities (such as hospitals, or other health care providers) that do not receive the majority of their revenues from PFS or CLFS services." *Id.* at 59,393.

Many healthcare entities and other stakeholders opposed that part of the proposed rule, arguing that reading the statute's definition of applicable laboratory to generally exclude hospital laboratories violated PAMA. *See, e.g.*, 81 Fed. Reg. at 41,045. Why did that matter? A major laboratory services provider asserted that hospital laboratories receive 1.5 to 4 times higher private payor reimbursement rates than independent laboratories for the same test. (The record does not specify whether that estimate isolated reimbursement pursuant to the PFS or CLFS schedules, or included laboratory tests provided—presumably at greater cost—as part of inpatient and outpatient services). The American Hospital Association advocated in favor of requiring hospital laboratories to report their rate data, believing that would "generally increase the weighted median," and make the new Medicare rates "more representative of overall market rates." Joint Appendix (J.A.) 595 (letter to Acting Administrator of Centers for Medicare & Medicaid Services).

Commenters advocated identifying entities by their National Provider Identifier (NPI) numbers rather than their TIN. Healthcare providers use NPI numbers to bill Medicare. Because more hospital laboratories have NPI numbers distinct from those of their associated hospitals, they reasoned, identifying the relevant entity at the NPI level would mean hospital laboratories with their own NPI numbers would be evaluated for whether they, considered separately, meet the majority-payments test defining "applicable laboratories."

In the final rule issued in June 2016, the Secretary accepted that suggestion and defined applicable laboratories at the NPI level rather than the TIN level.[2] 81 Fed. Reg. at 41,037. The final rule reiterated the Secretary's reading of the statute as excluding the majority of hospital laboratories because those laboratories receive most of their Medicare revenue from bundled payments for inpatients and outpatients rather than from the CLFS or PFS. *Id.* at 41,045. However, the Secretary "agree[d] with commenters" that hospital outreach laboratories—*i.e.*, "laboratories that furnish laboratory tests for patients that are not admitted hospital inpatients or registered outpatients of the hospital" and that "are enrolled in Medicare separately from the hospital of which they are a part"—"should be accounted for" in the new payment rates. *Id.*

As it turns out, however, NPIs suffer from virtually the same flaw as TINs because "[v]ery few hospitals have laboratory-specific NPIs, and they generally submit claims under the hospital's NPI." J.A. 271 (letter from ACLA to Department of Health and Human Services Office of Inspector

[2] The rule rejected commenters' alternative suggestion that entities be identified by their Clinical Laboratory Improvement Amendments (CLIA) certificate, which is used to certify that a laboratory meets health and safety regulations, because that certificate is not associated with Medicare billing. 81 Fed. Reg. at 41,045-46.

General). In 2016, approximately 2,000 out of 260,000 total laboratories nationwide (0.7 percent) reported data to the Secretary. Out of the approximately 7,000 hospital laboratories in the United States, only 21 (0.3 percent) reported data, comprising about one percent of all the reporting labs. Much of the data collected by the Secretary came from the country's two largest independent laboratories—Quest and Labcorp—which have lower cost structures than other laboratories. *See* J.A. 70-71 (Declaration from Senior Vice President of Quest Diagnostics). According to ACLA, that skewed the Medicare reimbursement rates low. The government, for its part, maintains that the data used to calculate the 2018 rates "was sufficient and resulted in accurate weighted medians of private payor rates." *See* Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions, 83 Fed. Reg. 59,452, 59,672 (Nov. 23, 2018).

In 2018, the Secretary finalized another rule—not at issue here—that amended the implementation of "applicable laboratories" in an effort to include more hospital-based outreach laboratory services in the next set of data. *Id.* at 59,452. As HHS explained, "we are confident that our current policy supports our collecting sufficient applicable information . . . and that we received sufficient and reliable applicable information with which we set [2018 rates]," but "we continue to consider refinements to our policies that could lead to including even more applicable information for the next data reporting period." *Id.* at 59,672. The 2018 rule requires laboratories providing outreach services to report data using the CMS–1450 14x TOB—a billing form used only by hospital outreach laboratories. *Id.* at 59,673-75. The new rule, in effect, categorizes as an applicable laboratory that portion of a hospital laboratory that provides outreach services—even if those services comprise only a minority of the laboratory's overall services. *See id.* at 59,673 ("[W]e believe that if we

were to utilize such an approach in defining applicable laboratory, all hospital outreach laboratories would meet the majority of Medicare revenues threshold . . .”). Notably, this approach was not encompassed by the relief that ACLA seeks here. ACLA is emphatic that the statute requires the Secretary to use the hospital laboratory as the denominator in the majority-payments test. *See* Appellant’s Br. 65. The Secretary will use the new data about hospital laboratories’ outreach services in a revised fee schedule as of January 1, 2021. 80 Fed. Reg. at 59,667.

Plaintiff in this case, American Clinical Laboratory Association, is a trade association of laboratories. It submitted comments to the Secretary both before the 2015 proposed rule and before the 2016 final rule. *See* J.A. 82. ACLA brought suit in 2017 to challenge the 2016 rule’s implementation of applicable laboratory as contrary to the statute and arbitrary and capricious in violation of the APA. The district court dismissed for want of jurisdiction. *Am. Clinical Lab. Ass’n v. Azar*, 334 F. Supp. 3d 301, 309 (D.D.C. 2018). This Court reviews *de novo* a district court’s legal determination as to subject matter jurisdiction. *See Piersall v. Winter*, 435 F.3d 319, 321 (D.C. Cir. 2006).

II. Standing

Although the Secretary scarcely challenges standing on appeal, we have an independent obligation to assure ourselves that ACLA has standing to challenge the final rule. *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94-95 (1998). The “constitutional minimum” of standing requires that a plaintiff have suffered a concrete and particularized injury that is fairly traceable to the challenged conduct and is likely to be redressed by a favorable decision. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560-61 (1992). In order to have associational

standing, ACLA must demonstrate that "at least one of [its] members satisfies" this test. *See Am. Library Ass'n v. FCC*, 401 F.3d 489, 492 (D.C. Cir. 2005). At the motion to dismiss stage, "general factual allegations of injury resulting from the defendant's conduct may suffice" to establish standing. *Lujan*, 504 U.S. at 561. We hold that ACLA meets those familiar requirements.

First, ACLA has established injury in fact. By adopting an impermissible definition of "applicable laboratories" that excludes virtually all hospital laboratories, ACLA asserts that the rule harms its members in various ways. First, it disproportionately burdens independent laboratories with the cost of data-production obligations not borne by its hospital-based competitor laboratories. ACLA submitted a declaration from the Senior Vice President of Quest Diagnostics, an ACLA member, asserting that "laboratories that reported private payor information were significantly disadvantaged as compared to other laboratories that, while required to report under PAMA, were excused from that obligation by the Secretary." J.A. 73. Second, it artificially depresses the reimbursement rates by excluding data from a portion of the market that receives higher-than-average Medicare reimbursements for its laboratory services. An affidavit from the Chief Executive Officer of Joint Venture Hospital Laboratories, LLC, an ACLA member, attests that the "elimination of . . . hospital[] laboratories from the reporting requirements skews the data" that is used to calculate the weighted median of commercial payor rates and ultimately set the Medicare reimbursement rate. J.A. 61. And, because "hospital laboratories typically receive higher commercial rates than other types of laboratories," the Medicare reimbursement rates are lower than they would be if the Secretary collected more data from hospital laboratories. *Id.*; *see also* U.S. Gov't Accountability Office, GAO 19-67, *Medicare Laboratory Tests;*

Implementation of New Rates May Lead to Billions in Excess Payment 12 (2018), https://www.gao.gov/assets/700/695756.pdf (hospital laboratories "typically receive relatively higher private-payer rates . . . by leveraging the market power of their affiliated hospital when negotiating rates with private payers."). ACLA has adequately shown that at least one of its members is reimbursed by Medicare at a rate lower than it would be if we were to rule in ACLA's favor and invalidate the challenged limitation in the definition of "applicable laboratory." That establishes injury in fact.

As for causation and redressability, ACLA has met its burden at this stage. *See Lujan*, 504 U.S. at 561. According to the Joint Venture Hospital Laboratories affidavit, excluding data from hospital laboratories "significantly depress[es]" the weighted median payment rates that are used to generate the new Medicare fee schedule. J.A. 62. Another declaration, by the President of Aculabs, Inc. (also a member of ACLA), attests: "If the Secretary's failure to implement Congress's directives is not corrected, the impact on Aculabs' business will be severe" because Aculabs "will not receive Medicare-derived reimbursement sufficient to cover its costs." J.A. 49. Requiring the Secretary to collect more fully representative market data and use it to calculate a new weighted median appears sufficiently likely to increase Medicare reimbursement rates to establish redressability at this stage.

The Secretary briefly protests that ACLA cannot claim lower repayment rates as an injury for standing purposes because the statute expressly prohibits challenging the rates. *See* Appellee's Br. 25-26. That argument conflates two issues. It is true that ACLA cannot challenge the rates themselves under the statute's jurisdiction-stripping provision. *See* 42 U.S.C. § 1395m-1(h)(1). But that does mean the rates cannot be the source of ACLA's members' injury in a challenge to the

data-collection rule. What matters is that ACLA's challenge (here, to the definition of applicable laboratory for purposes of data collection) is sufficiently linked to its asserted injury (lower reimbursement rates). *See Sierra Club v. EPA*, 292 F.3d 895, 899 (D.C. Cir. 2002). We assess in the next section the distinct issue whether ACLA's challenge is an impermissible back-door effort to challenge reimbursement rates in circumvention of the statutory bar.

III. Jurisdiction Stripping

The primary question on appeal is whether PAMA's provision eliminating administrative and judicial review of the "establishment of payment amounts," 42 U.S.C. § 1395m-1(h)(1), bars our review of the rule the Secretary promulgated to implement the statute's data-collection provision, 81 Fed. Reg. 41,036. When deciding whether a statute bars judicial review, we begin with "the strong presumption that Congress intends judicial review of administrative action." *Smith v. Berryhill*, 139 S. Ct. 1765, 1776 (2019) (quoting *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986)). Even where, as here, a statutory provision expressly prohibits judicial review, the presumption applies to dictate that such a provision be read narrowly. *See Dart v. United States*, 848 F.2d 217, 221 (D.C. Cir. 1988). "When a statute is 'reasonably susceptible to divergent interpretation, we adopt the reading that accords with traditional understandings and basic principles: that executive determinations generally are subject to judicial review.'" *Kucana v. Holder*, 558 U.S. 233, 251 (2010) (quoting *Gutierrez de Martinez v. Lamagno*, 515 U.S. 417, 434 (1995)). "Whether and to what extent a particular statute precludes judicial review is determined not only from its express language, but also from the structure of the statutory scheme, its objectives, its legislative history, and the nature of

the administrative action involved." *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984).

We start with the text: "There shall be no administrative or judicial review under section 1395ff of this title, section 1395*oo* of this title, or otherwise, of the establishment of payment amounts under this section." 42 U.S.C. § 1395m-1(h)(1). The header of subsection (a) of the statute—the part that defines the parameters for data collection—cross-references payment rates in announcing that it deals with "[r]eporting of private sector payment rates for establishment of medicare payment rates." *See id.* § 1395m-1(a). The district court concluded that the language of the jurisdiction-stripping provision combined with the header of subsection (a) meant that data collection was "part and parcel of 'the establishment of payment amounts under this section,' which Congress shielded from judicial review." *Am. Clinical Lab. Ass'n*, 334 F. Supp. 3d at 307.

That conclusion is plausible, but the text does not compel it. Several features of the statute suggest that Congress meant to bar challenges to the "establishment of payment amounts" but not to prevent review of the rule delineating the data collection practices that precede and inform the setting of those amounts. The jurisdiction-stripping provision itself bars review "under section 1395ff of this title, section 1395*oo* of this title, or otherwise." 42 U.S.C. § 1395m-1(h)(1). The two cross-referenced sections cover administrative appeals by patients or providers who wish to contest a coverage determination or reimbursement amount. *See* 42 U.S.C. §§ 1395*oo*, 1395ff. That suggests Congress intended to preclude review of the amounts of money paid in the ultimate reimbursement decisions. Additionally, subsection (a)'s reference to reporting private sector data *for* the establishment of payment amounts suggests that the two are not one and the

same, but rather that collecting data from the private sector is a separate statutory duty preceding the establishment of Medicare payment rates. *See* 42 U.S.C. § 1395m-1(a). Indeed, the final rule on data collection is not an "establishment of payment amounts," but a blueprint for which laboratories must report private payor data to the Secretary, how they must do so, and what consequences they face for noncompliance. 81 Fed. Reg. at 41,037.

The structure of PAMA bespeaks the separation between data collection and pricing. In subsections (b), (c), and (d) on existing, new, and new advanced diagnostic laboratory services, Congress explained that it was directing the Secretary henceforth to calculate "weighted median" market-based prices for existing services and to "gapfill" and consult an expert panel to determine prices for new and new advanced services. In a separate provision, Congress detailed the framework for data collection. *Compare* 42 U.S.C. § 1395m-1(b)-(d) (establishing processes for determining Medicare rates), *with id.* § 1395m-1(a) (establishing processes for collecting private-payor data). Whereas the rate-setting provisions affect reimbursements for Medicare services, the data-collection part of the statute imposes new obligations on private parties (applicable laboratories). The latter requires reporting of confidential data about private market rates—data not otherwise used in any government program—so that the Secretary may analyze it to formulate Medicare rates. *Id.* § 1395m-1(a). The Secretary is required to "establish through notice and comment rulemaking parameters for data collection under this subsection." *Id.* § 1395m-1(a)(12). An applicable lab's failure to provide the specified information exposes it to significant monetary penalties. *Id.* § 1395m-1(a)(9).

Textual and structural analysis of jurisdiction-stripping provisions in other statutes supports the Secretary's position

that Congress did not bar review of PAMA's entire process for collecting data on private-payor rates. *See Bowen*, 476 U.S. at 675-76 (holding that the provision limiting review of amounts of benefit payments under the Medicare program did not bar review of the method by which such amounts were computed). In *Texas Alliance for Home Care Services v. Sebelius*, for example, we concluded that a provision's "broad and unequivocally preclusive language" barring review of "the awarding of contracts" under Medicare also barred review of the "applicable financial standards" that medical equipment suppliers must meet in order to be eligible for those contracts. 681 F.3d 402, 409-11 & n.9 (D.C. Cir. 2012). In that case, the challenged "applicable financial standards" were listed in the statute itself as a "[c]ondition[] for awarding contract[s]." 42 U.S.C. § 1395w-3(b). In other words, the statutory text made clear that the challenged action (defining applicable financial standards) was encompassed within the terms of unreviewable action (awarding contracts). The same was true in *Mercy Hospital, Inc. v. Azar*, where we held that a statute barring judicial review of "prospective payment rates" covered a challenge to the formula the Secretary used to calculate those rates. 891 F.3d 1062, 1067 (D.C. Cir. 2018). Through internal cross-references, the "language of the statute tie[d] together the prospective payment rate and the statutory adjustments" used to calculate that rate. *Id.*

Unlike the provisions at issue in *Texas Alliance* and *Mercy Hospital*, the statutory text here does not subsume the data collection process within the establishment of payment amounts. On the contrary, Congress set out the process for data collection in a separate and distinct subsection and with its own set of rules. Congress also required that the parameters for that data collection be established through notice and comment rulemaking. *See* 42 U.S.C. § 1395m-1(a)(12). Neither of the statutes at issue in *Texas Alliance* or *Mercy Hospital* had

explicit notice and comment requirements. And, as our precedent makes clear, part of the purpose of notice and comment rulemaking is to ensure the parties develop a record for judicial review. *See Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005) ("[Rulemaking n]otice requirements are designed . . . to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review.").

Because the gathering of data under PAMA is not "inextricably intertwined" with the establishment of payment rates, we lack a basis on which to infer that Congress, in eliminating jurisdiction over the latter, clearly meant also to bar review of the former. *Cf. Florida Health Scis. Ctr., Inc. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 521 (D.C. Cir. 2016). We held that we lacked jurisdiction in *Florida Health* for reasons that appear at first blush to apply here. The statute at issue in *Florida Health* required the Secretary to identify as Disproportionate Share Hospitals (DSH) entitled to additional federal compensation those hospitals serving high proportions of poor patients. When the Affordable Care Act directed that DSH status be based largely on the percentage of the nation's overall uncompensated care each hospital provides, the Secretary chose to estimate that percentage by reference to the number of days Medicaid and low-income Medicare patients spent in a given hospital as a proportion of the national total of such patients' hospital days. *Id.* at 517; *see* 42 U.S.C. § 1395ww(r)(2)(C). In other words, the Secretary used a hospital's national share of Medicaid and low-income Medicare patient care as a proxy for its share of uncompensated care. *See Florida Health*, 830 F.3d at 517. The Secretary did so because research supported the correlation between a hospital's national shares of uninsured patients and its poor-insured, and the proxy data was already readily available and

subject to audit. *Id.* The statute expressly precluded review of the Secretary's uncompensated care estimates, *see id.* § 1395ww(r)(3)(A), but plaintiffs sought review of those estimates anyway by challenging the accuracy of the Medicaid data on which they were based, *Florida Health*, 830 F.3d at 518. We held that the statutory bar on the Secretary's "estimate" of how much uncompensated care a hospital provided also barred review of the proxy data on which the Secretary relied. *Id.* at 518-19. We "could not review a decision that was 'indispensable' or 'integral' to, or 'inextricably intertwined,' with the unreviewable agency action." *Id.* at 519 (quoting *Texas Alliance*, 681 F.3d at 409-11).

Important distinctions between the issues in this case and *Florida Health* show that the data collection process at issue here is not "inextricably intertwined" with the unreviewable establishment of payment amounts. Most importantly, unlike PAMA, the statute in *Florida Health* did not have a separate data-collection provision imposing new obligations on private parties nor did it have a notice and comment requirement. It simply directed the Secretary to estimate the amount of uncompensated services using "appropriate data," including data that the Secretary may "determine[]" serves as an adequate proxy for uncompensated care rates. 42 U.S.C. § 1395ww(r)(2)(C). The statute's text and structure made clear that choosing which data to use was part of the Secretary's unreviewable obligation to estimate uncompensated care rates. *Florida Health*, 830 F.3d at 517, 519.

PAMA's data collection provision, on the other hand, is distinct from its rate-estimation provisions. For data collection, the statute obligates clinical laboratories that participate in the Medicare program to report distinct reimbursement rates they receive from private insurers and requires the Secretary to

establish the rules governing that reporting through notice and comment rulemaking. To be sure, the results of that data collection process are used to establish Medicare payment amounts. But the statute's bifurcated structure supports ACLA's view that the two provisions and the processes they require are distinct. This case differs from *DCH Regional Medical Center v. Azar*, 925 F.3d 503 (D.C. Cir. 2019), for similar reasons. We held there that a "methodology" used to generate uncompensated care estimates under the same statute at issue in *Florida Health* was itself unreviewable because there was "no textual basis for separating estimates from their underlying methodology," *id.* at 507; the data-collection provision of PAMA, in contrast, is separate from the provisions establishing payment amounts. That the statutory scheme requires private laboratories to report *non-Medicare* and generally confidential business information (private market rates) to the government on pain of monetary penalties further stands this statutory scheme in sharp contrast to others where the challenged action was found to be intertwined with other agency actions regarding which Congress had barred judicial review.

The government argues that it would make scant sense for Congress to have barred review only of "basic math" while "permitting review of every discretionary step that preceded that math." Appellee Br. 33. But establishing payment amounts sometimes involves more than rote math. For established laboratory services, the Secretary must array private payor data from thousands of laboratories and calculate a weighted median for each separate laboratory service. 42 U.S.C. § 1395m-1(b)(2). For new tests, regarding which private payor data does not yet exist, the Secretary must consider more complicated criteria and consult an expert panel. *See id.* § 1395m-1(c)-(d), (f). That process is a good deal more complex and discretionary than rote math.

In view of PAMA's text, its structure, and the distinct nature of the processes of data collection and establishment of payment rates, we cannot conclude that the bar against reviewing the "establishment of payment amounts" also prevents our review of the rule setting up a new and detailed process for collecting data on market rates that private insurers pay to laboratories. Because the statute is "reasonably susceptible" to this interpretation, we hold that it does not bar judicial review of the Secretary's rule establishing the parameters of data collection under 42 U.S.C. § 1395m-1(a). *Gutierrez de Martinez*, 515 U.S. at 434.

IV. *Ultra Vires*

ACLA also argues that, even if the jurisdictional limitation of Section 1395m-1(h) applies, we should nonetheless review the Secretary's final rule because it "exceeds his statutory authority and is *ultra vires.*" Appellant's Br. 61. Although we hold that the statute itself does not bar review, we nonetheless consider ACLA's *ultra vires* argument because, if valid, it would not just open the courthouse door, but invalidate the rule and obviate any need to remand to the district court for consideration of the arbitrary-and-capricious challenge.

If an agency exceeds "its statutory bounds, judicial review remains available" to curb the rogue action. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359 (2018). To challenge agency action on the ground that it is *ultra vires*, ACLA must show a "patent violation of agency authority." *Indep. Cosmetic Mfrs. & Distribs., Inc. v. U.S. Dep't of Health, Educ. & Welfare*, 574 F.2d 553, 555 (D.C. Cir. 1978). *Ultra vires* review "is intended to be of extremely limited scope," and it "represents a more difficult course . . . than would review under the APA." *Trudeau v. Fed. Trade Comm'n*, 456 F.3d 178, 190 (D.C. Cir. 2006) (internal quotations omitted).

Here, the statute says that applicable laboratory "means *a laboratory that*, with respect to its revenues under this subchapter, a majority of such revenues are from" the PFS and CLFS. 42 U.S.C. § 1395m-1(a)(2) (emphasis added). ACLA argues that choosing to compare a laboratory's total revenues from the PFS and CLFS against the "total Medicare revenues of *any entity* with an NPI (of which the laboratory is often only one component)," Appellant's Br. 64, violates the statute's command that the reporting unit be the laboratory rather than a broader entity. Again, the reporting unit matters because comparing a hospital laboratory's reimbursements from PFS and CLFS to the entire hospital's Medicare revenue (as opposed to just the hospital *laboratory's* Medicare revenue) means that a hospital laboratory without its own, laboratory-specific NPI will not qualify as an applicable laboratory under the statute.

HHS did not clearly step so far outside the scope of the task that Congress gave it as to have acted *ultra vires*. PAMA does not define the term "laboratory," and the Secretary's charge was to operationalize that important term despite its ambiguity. After incorporating industry comments into the final rule, the Secretary chose to identify laboratories by their NPI numbers. *See* J.A. 563-64 (Florida Hospital Association recommending HHS define applicable laboratory at the NPI level rather than the TIN level); *compare* 80 Fed. Reg. at 59,387 (proposing use of TIN numbers), *with* 81 Fed. Reg. at 41,037 (deciding to use NPI numbers). Appellant's objection to the Secretary's efforts, even if meritorious, does not establish that the Secretary acted *ultra vires*. We leave to the district court on remand to address in the first instance the merits of petitioner's arbitrary-and-capricious challenge.

* * *

For the reasons discussed above, we reverse the district court's holding on subject matter jurisdiction and remand for further proceedings consistent with this opinion.

So ordered.