ORAL ARGUMENT NOT YET SCHEDULED

No. 18-5312

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN CLINICAL LABORATORY ASSOCIATION,

Plaintiff-Appellant,

v.

ALEX M. AZAR, II,
Secretary, United States Department
of Health and Human Services,

Defendant-Appellee.

Appeal from the United States District Court for the District of Columbia, No. 1:17-cv-02645, Hon. Amy Berman Jackson

---

OPENING BRIEF OF APPELLANT AMERICAN CLINICAL LABORATORY ASSOCIATION

Ashley C. Parrish
Mark D. Polston
Elizabeth N. Swayne
Amelia G. Yowell
KING & SPALDING LLP
1700 Pennsylvania Ave. NW
Washington, D.C. 20006
(202) 737-0500
aparrish@kslaw.com

Counsel for Appellant American Clinical Laboratory Association

December 4, 2018

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

In accordance with Circuit Rule 28(a)(1) of the Rules of this Court, the undersigned, counsel of record for American Clinical Laboratory Association, certifies as follows:

A. Parties, Intervenors, *Amici*

1. Parties Before the District Court

The following is a list of all parties, intervenors, and participants who appeared before the United States District Court for the District of Columbia in the underlying proceedings:

Plaintiff, American Clinical Laboratory Association

Defendant, Alex M. Azar, II, Secretary of the United States Department of Health and Human Services.

The following is a list of *amici* who appeared before the district court:

National Association for the Support of Long Term Care

Advanced Medical Technology Association

American Association of Bioanalysts

College of American Pathologists

2. Parties Before the Court

The following is a list of all parties, intervenors, and *amici* who have appeared in this Court:

Appellant, plaintiff below, is the American Clinical Laboratory Association.

Appellee, defendant below, is Alex M. Azar, II, Secretary of the United States Department of Health and Human Services.

B. Rulings Under Review

The rulings under review are:

American Clinical Laboratory Association v. Azar, Memorandum Opinion, ECF Docket No. 47, No. 1:17-cv-02645-ABJ, --- F. Supp. 3d --- (D.D.C. Sept. 21, 2018) (The Honorable Amy Berman Jackson); and

American Clinical Laboratory Association v. Azar, Order, ECF Docket No. 46, No. 1:17-cv-02645-ABJ (D.D.C. Sept. 21, 2018) (The Honorable Amy Berman Jackson). No official reporter citation exists.

C. Related Cases

This case has not previously been before this Court or any other court. Counsel are not aware of any related cases pending in this Court or any other court.

CORPORATE DISCLOSURE STATEMENT

In accordance with Federal Rules of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, plaintiff-appellant American Clinical Laboratory Association certifies that it has no parent company and no outstanding shares in the hands of the public. No publicly-held corporation has a ten percent or greater ownership interest in American Clinical Laboratory Association.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

REGULATIONS

LEGISLATIVE MATERIAL

RULES

OTHER AUTHORITIES

GLOSSARY

ACLA	American Clinical Laboratory Association
CMS	The Centers for Medicare & Medicaid Services
HHS	United States Department of Health and Human Services
NPI	National Provider Identifier
OIG	Office of Inspector General
PAMA	The Protecting Access to Medicare Act
Secretary	Secretary, United States Department of Health and Human Services

INTRODUCTION

This appeal asks the Court to determine the proper scope of a statute's jurisdictional bar and to reaffirm the principle that Congress must speak clearly if it intends to overcome the strong presumption in favor of judicial review of final agency action. Applying that presumption is particularly important in this case because the challenged agency action is not the exercise of an administrative function falling within the agency's discretion (such as a rule of agency procedure or a calculation of payment rates), but a legislative rule that on threat of substantial civil penalties imposes new substantive obligations on regulated parties.

The statute at the center of this appeal is section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"). *See* Pub. L. No. 113-93, § 216, 128 Sta. 1040, 10552 (2014), codified at 42 U.S.C. § 1395m-1 (Add-1). Congress enacted PAMA to ensure that Medicare payments that laboratories receive for providing clinical diagnostic services more closely reflect the full range of payments they receive in the commercial market. Congress accomplished that goal by requiring

the Secretary of Health and Human Services to complete two separate, functionally distinct regulatory actions.

First, PAMA mandates that all "applicable" laboratories report, and the Secretary collect, confidential information regarding the payments that laboratories receive when providing services to the private sector. 42 U.S.C. §§ 1395m-1(a)(1)–(2). Considering the different types of laboratories that exist — including the thousands of laboratories located in hospitals, physician offices, independent facilities, and other settings — Congress specified which of these laboratories would be required to report their confidential data: *any* laboratory that receives a majority of *its* Medicare revenues from certain specified fee schedules. Congress designed the statute to ensure that the collected data would be representative of the market as a whole, but it provided few other details about how the Secretary should collect data from laboratories. Instead, it directed the Secretary to undertake through notice-and-comment rulemaking to establish the "parameters" of the data-collection process, and authorized the Secretary to impose substantial civil penalties for non-compliance. *Id.* §§ 1395m-1(a)(1)–(2), (9), (12).

Second, PAMA requires the Secretary to take the market data he is required to collect and, under a separate administrative process, establish the payment amounts that the Medicare program will pay for existing diagnostic tests, new diagnostic tests, and other laboratory services. *Id.* §§ 1395m-1(b)(1)–(5), (c), (d). The statute directs the Secretary to apply a formula to establish the "payment amounts" for existing diagnostic tests, *id.* § 1395m-1(b)(1)–(5), and to consult with experts on "the establishment of payment rates" for new diagnostic tests, *id.* § 1395m-1(f)(1).

The statute bars judicial review of "the establishment of payment amounts." *Id.* § 1395m-1(h)(1). But it includes no provision prohibiting review of the Secretary's final rule establishing the "parameters" of laboratories' data-reporting obligations. *Id.* § 1395m-1(a)(12). Nevertheless, the district court below held that PAMA's jurisdictional bar should be interpreted broadly to preclude review of the Secretary's final rule. In the district court's view, Congress foreclosed review because the relevant provisions appear in the same section of the statute and Congress directed the Secretary to use the confidential data that laboratories report to later establish payment amounts.

The district court's decision is wrong and should be reversed. It gives too little weight to the strong presumption favoring judicial review of administrative action. Nor can it be squared with PAMA's text or fundamental principles of administrative law. The presumption that Congress does not intend to shield agency action from judicial review applies with particular force where, as here, an agency promulgates a legislative rule that imposes substantive obligations on regulated parties. Indeed, if the district court were correct, the statutory bar would prevent a laboratory from challenging the Secretary's final rule as in excess of his delegated powers in response to an enforcement action imposing civil penalties for alleged noncompliance. *See id.* § 1395m-1(a)(9). There is no clear indication that Congress intended such an extraordinary departure from the basic principle that when an agency seeks to impose legally binding obligations, judicial review is necessary to safeguard lawful and accountable government.

The district court also failed to address whether the Secretary's final rule falls within an exception to any jurisdictional bar. Had the court undertaken the required inquiry, it would have recognized that the Secretary's final rule is *ultra vires* because it exceeds his lawful

authority and, as the Secretary has since acknowledged, violates Congress's unambiguous statutory directive to collect data from any "laboratory" that receives a majority of its Medicare revenues from the relevant fee schedules. Instead, the Secretary's rule rewrites the statute's majority-of-revenues test to take into account non-laboratory revenue and, through this rewrite, exempts virtually all hospital laboratories from the data-reporting requirements.

Because hospital laboratories are significant participants in Medicare and compete with independent laboratories and physician office laboratories in the private market, the Secretary's rule guarantees that the data collected does not reliably represent the private market as Congress intended. The result of this *ultra vires* act is to impose significant competitive disadvantages on the laboratories required to shoulder the financial and operational burdens of reporting confidential data, while impermissibly exempting their competitors from the statutory requirements. It also undermines PAMA's overarching objectives by ensuring that Medicare payment amounts will not reflect the range of payments made in the private market, no matter how the Secretary may exercise his discretion when establishing

payment amounts. If the Secretary's violation of Congress's clear mandate is not corrected, laboratories and the patients they serve will continue to be harmed, with many laboratories forced out of business.

This Court should reverse the district court and remand for further proceedings.

JURISDICTION

The district court had jurisdiction under 28 U.S.C. § 1331. The district court also had jurisdiction under 42 U.S.C. §§ 405(g), (h). ACLA's claims present purely legal questions and the Medicare statute offers no avenue for administrative review for this category of claims. *See Council for Urological Interests v. Sebelius*, 668 F.3d 704, 708 (D.C. Cir. 2011). The claims that ACLA seeks to litigate are not "[c]laims for money, claims for other benefits, claims of program eligibility, [or] claims that contest a sanction or remedy" that rest on fact-related circumstances that can be channeled through the administrative process. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 14 (2000). Moreover, to the extent required under sections 405(h) and 405(g), ACLA repeatedly presented its objections to the agency, both in comments and in other correspondence, *see* JA082 ¶ 12, and at least one

of ACLA's members submitted its objections to the Centers for Medicare & Medicaid Services ("CMS") in the context of an appeal of a claim for payment. JA429–30. Those objections were rejected at the first level of administrative appeal, and recently rejected at the second level of administrative appeal on the ground that "the challenge to the validity of the" final rule is not appealable through the administrative process. The agency has concluded that it lacks authority to decide the question of law and that the procedures under 42 C.F.R. § 405.990 for expedited access to judicial review apply.

On September 21, 2018, the district court entered final judgment dismissing the case for lack of subject-matter jurisdiction. ACLA timely filed its notice of appeal on October 19, 2018. *See* Fed. R. App. P. 4(a)(1)(B). This Court has jurisdiction under 28 U.S.C. § 1291.

ISSUES PRESENTED

1. Did Congress clearly express an intent to prohibit judicial review of the Secretary's final rule imposing new substantive data-reporting obligations on certain laboratories when it (a) directed the Secretary to engage in notice-and-comment rulemaking to "establish" the "parameters" for data collection, (b) in different statutory provisions directed the Secretary to take separate action to establish Medicare payment amounts, and (c) expressly barred review "of the establishment of payment amounts" but did not purport to bar review of the final rule establishing the parameters for collecting data?

2. Does the Secretary's final rule, which rewrites the statutory definition of "applicable laboratory" in a way that exempts virtually all hospital laboratories from the statutory data-reporting requirements, fall within an exception to any jurisdictional bar because it is *ultra vires,* exceeds the Secretary's lawful authority, and violates Congress's unambiguous statutory directive that the Secretary collect data from any laboratory that receives a majority of its Medicare revenues from certain specified fee schedules?

STATUTES AND REGULATIONS

The relevant statutory and regulatory provisions appear in the addendum.

STATEMENT OF FACTS

A. Medicare Payments For Laboratory Services

Clinical diagnostic laboratory services are tests performed on specimens from the body, such as blood or urine, that are used to monitor, diagnose, and treat patients. The laboratories that provide these services play a vital role in the nation's health care system. They include laboratories connected with hospitals (hospital laboratories), laboratories located in physician offices, and independent laboratories not affiliated with any other health care provider.

Through the federal Medicare program, CMS is the nation's largest purchaser of clinical diagnostic laboratory services. Medicare beneficiaries receive laboratory services in different contexts. In some circumstances, a beneficiary will need tests performed as a registered patient of a hospital, either as an inpatient who has been admitted to the hospital or as an outpatient who has not been admitted but is nonetheless receiving services through the hospital. In other circumstances, a beneficiary may have tests performed as a resident of

a skilled nursing facility. The most familiar circumstance, however, is when a beneficiary visits a doctor's office and is told to be tested. Unless the doctor's office has an on-site laboratory, the beneficiary will typically have the tests performed at a local laboratory — either an independent laboratory or a hospital laboratory that serves individuals in the community who are not hospital patients (providing what are known as "outreach" services).

For payment purposes, Medicare distinguishes between the different contexts in which beneficiaries receive laboratory services. When a hospital laboratory performs tests for a registered hospital patient, payment in most instances is bundled with other services provided and billed by the hospital, either under the Inpatient Prospective Payment System (when the patient is an inpatient) or under the Outpatient Prospective Payment System (when the patient is an outpatient). *See* 42 U.S.C. § 1395ww(d); *id.* § 1395*l*(t). The bundled payment covers both the services provided by the laboratory and the services provided by other components of the hospital, such as radiology services, operating room services, pharmacy services, and room and board.

In contrast, when a beneficiary is not a hospital patient and visits a hospital laboratory or other laboratory for services ordered by a doctor, Medicare makes payment on a fee-for-service basis under one of two fee schedules, either the Clinical Laboratory Fee Schedule or the Physician Fee Schedule. *See id.* §§ 1395*l*(h)(1)(B), 1395w-4(a)(1). Independent laboratories and hospital laboratories providing outreach services are both paid in this way, with both receiving a significant portion of the payments made by Medicare under the Clinical Laboratory Fee Schedule. *See* Office of Inspector General ("OIG"), Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data, OEI-09-16-00140 (Sept. 2017) at 2, *available at* https://oig.hhs.gov/oei/reports/oei-09-17-00140.pdf ("OIG 2016 Data Report") (in 2016, independent laboratories received 55 percent of Clinical Laboratory Fee Schedule payments; hospital outreach laboratories received 26 percent). Services reimbursed on a fee-for-service basis make up a large segment of the market, with hospital laboratories that provide outreach services competing directly with independent laboratories and other laboratories. *See, e.g.*, CMS, Medicare Claims Processing Manual (Pub. No. 100-04), Ch. 16, § 10,

available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c16.pdf ("When a hospital laboratory performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory").

Before PAMA, clinical laboratory services provided on a fee-for-service basis were reimbursed for the lesser of either (1) the laboratory's charge or (2) the local amount under the Clinical Laboratory Fee Schedule, which varied based on a "regional, statewide, or carrier service area basis." 42 U.S.C. § 1395*l*(h)(1)(B)–(C), (h)(4)(B); *see also* 42 U.S.C. § 1395*l*(a)(1)(D)(i)(I). The system resulted in significant differences in reimbursement amounts in different parts of the country. OIG, Variation in the Clinical Laboratory Fee Schedule, OEI-05-08-00400 (July 2009) at 1, *available at* https://oig.hhs.gov/oei/reports/oei-05-08-00400.pdf. Any given laboratory test could have multiple payment amounts on the Clinical Laboratory Fee Schedule depending on where the test occurred. *See id.* Variations were not tied to geographic differences in wages or other factors, *id.* at 9, and "may . . . not have reflected real differences in cost," *id.* at 11.

B. The Protecting Access to Medicare Act

In 2014, Congress enacted PAMA, the most extensive reform of the Medicare Clinical Laboratory Fee Schedule since it was established. Through PAMA, Congress sought to modernize Medicare reimbursements by "ensur[ing] that Medicare rates reflect true market rates for laboratory services." 160 Cong. Rec. S2860 (May 8, 2014) (statement of Sen. Richard Burr, affirmed by Sen. Orrin Hatch).

Congress accomplished this goal through two sets of statutory provisions:

Legislative Rulemaking Establishing Parameters for Data Collection. Congress first directed the Secretary to promulgate regulations setting the parameters for collecting confidential private payor data from all "laboratories" that receive a majority of their Medicare revenues from the Clinical Laboratory Fee Schedule and the Physician Fee Schedule. 42 U.S.C. §§ 1395m-1(a)(1)–(2). Under PAMA, "applicable laborator[ies]" must report "applicable information" to the Secretary, and the Secretary must collect that information within a defined "data collection period." *Id.* § 1395m-1(a)(1).

Intending for "all sectors of the laboratory market [to] be represented in the reporting system," 106 Cong. Rec. S2860, Congress defined "applicable laboratory" to include any "laboratory" that receives a "majority of" its Medicare revenues from the Clinical Laboratory Fee Schedule or the Physician Fee Schedule. 42 U.S.C. § 1395m-1(a)(2); *see also id.* § 1395*l*(h) (establishing the Clinical Laboratory Fee Schedule); *id.* § 1395w-4 (establishing the Physician Fee Schedule). Congress selected this definition to obtain accurate information about prices in the private commercial market, recognizing that some types of laboratories tend to receive higher payments in the private sector, while others tend to receive lower payments. *See* JA058–62 ¶¶ 14–26.

Having cast a wide net, Congress gave the Secretary only limited authority to exempt laboratories from the statutory requirements, permitting the Secretary to "establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory." 42 U.S.C. § 1395m-1(a)(2). Apart from that narrow exception, Congress gave the Secretary no discretion to exempt applicable laboratories from the statute's data-reporting requirements. Instead, consistent with its goal of obtaining accurate market data,

PAMA reflects Congress's intent that the Secretary would collect data from *all* "applicable laboratories." *Id.* § 1395m-1(a)(1).

Congress delegated the specifics of the data-collection process to the Secretary, leaving him to fill in the statutory gaps by promulgating substantive regulations. *Id.* § 1395m-1(a)(12). The Secretary's regulations determine the specific "data collection period," as well as the type and form of the reported information, including any aggregate reporting. *Id.* §§ 1395m-1(a)(4), (6). To ensure "complete reporting," *id.* § 1395m-1(a)(6), Congress authorized the Secretary to impose civil penalties (up to $10,000 per day) for "each failure to report" and any omission or misrepresentation made when data is reported. *Id.* § 1395m-1(a)(9)(A). Those penalties are substantial, potentially exposing laboratories to "hundreds of thousands if not millions in fines" each day. JA074–75 ¶ 24.

Congress mandated that, before the Secretary could impose any legally binding requirements, the Secretary would have to provide notice and allow interested parties to comment. 42 U.S.C. § 1395m-1(a)(12). Congress also included protections for the confidential private payor information that laboratories would be required to report. It

directed the Secretary to hold the information in strict confidence, *id.* § 1395m-1(a)(10), and it protected the information from public disclosure, *id.* § 1395m-1(a)(11).

Administrative Calculation Setting Payment Amounts. In a separate set of provisions, Congress instructed the Secretary to use the collected data to establish new market-based payment amounts. *Id.* § 1395m-1(b)(1)(A). Specifically, the Secretary must calculate a weighted median for each laboratory test with respect to which information is reported, "by arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory." *Id.* § 1395m-1(b)(2). Those new payment amounts "shall continue to apply until the year following the next data collection period," *id.* § 1395m-1(b)(4)(A), and "shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment)," *id.* § 1395m-1(b)(4)(B).

Congress did not require the Secretary to undertake public notice-and-comment rulemaking to establish payment amounts. Nor do the payment amounts established by the Secretary impose substantive

obligations on regulated parties. Instead, because establishing payment amounts in this context is an administrative function, Congress required fewer procedures. It directed the Secretary to consult with an advisory panel and to provide an explanation when establishing payment amounts for new tests. *Id.* §§ 1395m-1(c)(4), (f). It also precluded judicial review of any payment amounts established by the Secretary. According to the statute, "[t]here shall be no administrative or judicial review under section 1395ff of this title, section 1395oo of this title, or otherwise, of the establishment of payment amounts under this section." *Id.* § 1395m-1(h)(1). Congress included no similar provision prohibiting judicial review of the Secretary's regulations establishing the "parameters for data collection." *Id.* § 1395m-1(a)(12).

C. The Secretary's Final Rule

On October 1, 2015, the Secretary issued a proposed rule. *See* JA517–554, 80 Fed. Reg. 59,386 (Oct. 1, 2015). Instead of applying the statutory definition of "applicable laboratory," the Secretary solicited comments on a new definition of "applicable laboratory" that would include any entity with one or more national provider identifiers

("NPIs") that is either a laboratory *or has a laboratory as one of its components*. JA524, 80 Fed. Reg. at 59,392 (emphasis added). An NPI is a unique 10-digit billing number, issued by CMS to health care providers, that is used in transactions with commercial and government health plans.

The Secretary indicated that in applying the "majority of" revenues test, he would consider the total Medicare revenues of any entity with one or more NPIs (even if the laboratory is just one component of that larger entity), and not limit his consideration to only the Medicare revenues received by the laboratory itself, as the statute directs. *Id.* He explained:

> [F]or the entity evaluating whether it is an applicable laboratory, the "majority of Medicare revenues" determination would be based on the collective amount of its Medicare revenues received during the data collection period, whether the entity is a laboratory under [42 C.F.R.] § 493.2 or is not, but has at least one component that is. We propose that the determination of whether an entity is an applicable laboratory would be made across the entire entity, including all component NPI entities, and not just those NPI entities that are laboratories.

JA525, 80 Fed. Reg. at 59,393.

In response to the proposed rule, the Secretary received nearly 1,300 comments — most heavily critical of the Secretary's proposal. *See* CMS, Public Comments on Medicare Clinical Diagnostic Lab. Test Payment Sys. CMS-1621-P, *available at* https://www.regulations.gov/docketBrowser?rpp=25&po=0&dct=PS&D=CMS-2015-0109&refD=CMS-2015-0109v-0002. ACLA and other commenters explained that these statutory departures carve out hospital outreach laboratories from Congress's data-reporting requirements. JA618–20. Although the Secretary proposed evaluating an entity's revenues based on its NPI, there is no requirement that a hospital laboratory have its own NPI to bill the Medicare program. JA619. In fact, it is almost always the case that a hospital laboratory will bill for services under the Clinical Laboratory Fee Schedule or Physician Fee Schedule using the NPI of the larger hospital, of which the laboratory is only one small component. *See, e.g.*, *id.*; JA089 ¶ 32.

That is significant because, using the same NPI as the hospital laboratory, a hospital will receive a tremendous amount of Medicare revenues for non-laboratory services, such as oncology services, radiology services, and surgeries, that are not paid under the Clinical

Laboratory Fee Schedule or Physician Fee Schedule. Because the Secretary proposed to sweep in the revenues of the entire hospital, including revenues unrelated to laboratory tests, hospital laboratories providing outreach services to non-hospital patients that do not have a separate NPI will never meet the "majority of" revenues test. JA618–20 For those hospitals, their overall Medicare revenues — which include revenues attributable to services provided and billed by other parts of the hospital — will inevitably far exceed the Medicare revenues of the hospital outreach laboratory under either the Clinical Laboratory Fee Schedule or the Physician Fee Schedule.

The Secretary issued his final rule in June 2016. *See* JA450–516, *Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; Final Rule*, 81 Fed. Reg. 41,036 (June 23, 2016). In response to comments, the Secretary acknowledged that to comply with Congress's directives, "it was important . . . [to] define laboratory broadly enough to encompass every laboratory type that is subject to the [Clinical Laboratory Fee Schedule]." JA457, 81 Fed. Reg. at 41,042. The Secretary also "agree[d] with commentators" that "hospital outreach laboratories should be accounted for" and that it was

"important" that hospital outreach laboratories report data "so that [the Secretary] may have a broader representation of the national laboratory market." JA460, 81 Fed. Reg. at 41,045.

In the final rule, however, the Secretary did the opposite and rewrote the statutory definition of "applicable laboratory" to read:

> (1) Is a laboratory, as defined in § 493.2 of this chapter;
>
> (2) Bills Medicare Part B under its own [NPI];
>
> (3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period [from the Physician Fee Schedule or Clinical Laboratory Fee Schedule];
>
> (4) Receives at least $12,500 of its Medicare revenues [under the Clinical Laboratory Fee Schedule] . . . .

JA513, 81 Fed. Reg. at 41,098, as codified at 42 C.F.R. § 414.502 (Add-6); *see also* JA514, 81 Fed. Reg. at 41,099 ("Applicable information may not be reported for an entity that does not meet the [regulatory] definition of an applicable laboratory"). The new requirement that the entity bill Medicare Part B under its own NPI sweeps into the "majority of Medicare revenues" test an enormous amount of hospital revenues

that have nothing to do with laboratory services and, as a result, exempts almost all hospital outreach laboratories from the statutory reporting requirements (no matter how much each hospital outreach laboratory's revenue is from the relevant schedules).

The final rule does not come close to accomplishing Congress's objective that the Secretary collect data from all sectors of the laboratory market. Using 2015 data, the OIG estimated that the final rule would require only 5 percent of all laboratories that serve Medicare beneficiaries to report their data. *See* OIG, Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data, OEI-09-16-00040 (Sept. 2016) at 3, 7, *available at* https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf ("OIG 2015 Data Report"). The actual data reported fell far below even those low expectations. The Secretary received private payor data from less than 0.7 percent of the laboratories that currently serve Medicare beneficiaries — only 1,942 NPI-level entities, including only 658 independent laboratories, 1,106 physician office laboratories, 157 "other" entities, and just 21 hospital laboratories (out of approximately 7,000 hospital laboratories). *Compare* OIG 2015 Data Report at 8, *with* CMS, Summary of Data

Reporting for Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System at 3, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf ("CMS Reporting Summary").

That data is not representative of the different types of laboratories that compete in the private market, contrary to the Secretary's acknowledgment of the need to include "a wide variety of laboratories." *Cf.* JA457, 81 Fed. Reg. at 41,042. In 2016, independent laboratories received 55 percent of Medicare Clinical Laboratory Fee Schedule payments, but made up more than 90 percent of the reported laboratory test volume collected by the Secretary. *Compare* OIG 2016 Data Report at 2, *with* CMS Reporting Summary at 3. In contrast, hospital laboratories received 26 percent of the Clinical Laboratory Fee Schedule payments in 2016, but the mere 21 hospital laboratories that reported data make up just 1 percent of the reported laboratory test volume. *Compare* OIG 2016 Data Report at 2, *with* CMS Reporting Summary at 3; *see also* JA081 ¶ 9–10.

D. Procedural History

ACLA submitted extensive comments to the agency and, both before and after the Secretary published his final rule, met with CMS to explain its concerns. *See* JA081–99 ¶¶ 11–61. But the Secretary refused to comply with Congress's mandate. Instead, using the non-representative data he had collected, the Secretary followed the process outlined in 42 U.S.C. § 1395m-1(b) and established new payment amounts. *See* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

In December 2017, ACLA filed suit challenging the Secretary's final rule. JA008–40. ACLA alleged that the Secretary's final rule (1) violates PAMA's plain language and is *ultra vires*; (2) relies on an unreasonable construction of the statute; and (3) is arbitrary and capricious. JA032–37 ¶¶ 73–97. To remedy these violations, ACLA sought permanent injunctive relief. JA037–39 ¶¶ 98–102.

Stressing the urgency of the matter, ACLA asked the district court to expedite litigation. *See* ECF No. 6, Joint Mot. To Establish Briefing Sch. ¶ 2 (Dec. 21, 2017). As ACLA explained, because the Secretary did not require all applicable laboratories to report their data, the new

payment amounts he later established were not market-based. Unless the court entered relief requiring the Secretary to comply with the statute's data collection requirements, many "laboratories will be forced to stop providing essential services, especially in remote rural areas," and will ultimately "be forced out of business." JA012 ¶ 10; *see also* JA030 ¶¶ 71–72; JA062–63 ¶ 27; JA049–52 ¶¶ 22–32.

In early 2018, ACLA and the Secretary filed cross-motions for summary judgment. In his papers, the Secretary had little to say in defense of his rule on the merits. Instead, the Secretary claimed that the district court did not have jurisdiction to review the final rule. ECF No. 27, Gov't Cross-Motion at 14–18 (Mar. 23, 2018). In response, ACLA explained that the Secretary's broad interpretation of the jurisdictional bar was contrary to precedent and the strong presumption in favor of judicial review. ECF No. 29, ACLA Combined Opp. & Reply at 3–10 (Apr. 6, 2018). Moreover, even assuming the jurisdictional bar applied, the court had authority to review the Secretary's final rule because it was *ultra vires* and exceeded his statutory authority. *Id.* at 19–23. The parties completed briefing in April 2018.

Five months later, and without holding a hearing as ACLA had requested, the district court dismissed for lack of jurisdiction. The court acknowledged that ACLA's "arguments on the merits raise important questions." JA435. But the court refused to address those questions, concluding that the statutory bar on judicial review "of the establishment of payment amounts" also bars review of the Secretary's substantive rule exempting hospital laboratories from PAMA's data-reporting requirements. JA439–46.

The district court's decision rests on two conclusions. First, the court decided that the jurisdictional bar should apply — even though Congress distinguished the Secretary's substantive regulations establishing the parameters of data collection from the Secretary's later and separate administrative actions establishing payment amounts — because both provisions appear in the same section of the statute. The court also brushed aside concerns that there is a meaningful difference between when an agency promulgates legislative rules that regulate primary conduct and when it takes administrative action to establish the amounts the government will pay for services.

The district court asserted that the final rule did not regulate primary conduct because it did not "regulate the work of laboratories." JA446.

Second, the court concluded that the two separate agency actions were "inextricably intertwined" and, therefore, the judicial review bar applied broadly to both actions. Noting that collecting data is a precursor to establishing payment amounts, the court concluded that ACLA's challenge in this case is "comparable to the challenge in" *Florida Health Sciences Center, Inc. v. Secretary of Health & Human Services*, 830 F.3d 515 (D.C. Cir. 2016). JA440–45.

The district court failed to address ACLA's argument that the Secretary's final rule is *ultra vires* and in excess of his statutory authority. *See* ECF No. 13, ACLA Mot. for Summ. J. at 18, 21 (Feb. 14, 2018).

E. Post-Decision Rulemaking

In November 2018, the Secretary published a new rulemaking that changed the regulatory definition of "applicable laboratory." 83 Fed. Reg. 59,452 (Nov. 23, 2018). The Secretary made this change to require "more hospital outreach laboratories to report data for calculating [Clinical Laboratory Fee Schedule] rates" so that the

collected "dataset . . . is a more robust representation of the laboratory testing market." *Id.* at 59,674.

The Secretary acknowledged that under his final rule's definition of "applicable laboratory," most hospital outreach laboratories are excused from their statutory data-reporting obligations because they do not have separate NPIs to bill for clinical laboratory tests. *Id.* at 59,675. The Secretary also conceded that hospital outreach laboratories that receive a majority of their Medicare revenues from the relevant fee schedules "should not be exempt from reporting the applicable data merely due to their shared use of a billing entity with a hospital." *Id.*

The Secretary's new definition does not remedy the statutory violations infecting the Secretary's final rule. The Secretary will not issue a revised fee schedule taking into account the more "robust" dataset until January 1, 2021. *Id.* at 59,667. In the meantime, ACLA's members and other laboratories will continue to face civil penalties for noncompliance and, because the Secretary's final rule violates the statute, Medicare payment amounts will continue to be inconsistent with those paid in the private market. JA061–62 ¶ 26; JA071–72 ¶¶14–15. If the Secretary's failure to comply with Congress's directives is not

corrected, laboratories will be forced out of business and beneficiaries may be unable to obtain essential laboratory testing services. JA062 ¶ 27 (stating "[a]s a direct result of the Secretary's decision to exclude hospital laboratories from the reporting requirement," some laboratories "will be forced to discontinue offering their outreach laboratory services" in rural communities); JA049–52 ¶¶ 22–24, 28–31 ("If the Secretary's failure to require data reporting from all applicable laboratories is not corrected, it will only be a matter of one or two years before the company started by my father and built by my family for the last 45 years will be forced out of business").

SUMMARY OF ARGUMENT

1. The district court incorrectly held that PAMA's limited jurisdiction-stripping provision, which precludes review "of the establishment of payment amounts," should be interpreted broadly to bar review of the Secretary's final rule exempting hospital outreach laboratories from PAMA's data-reporting requirements. The court failed to apply the strong presumption in favor of judicial review and failed to read the statutory provisions barring review narrowly, as precedent requires.

In PAMA's text and structure, Congress distinguished between the agency action required to impose data-reporting obligations, which must be promulgated through notice-and-comment rulemaking, and the separate administrative act of calculating payment amounts. Congress made that distinction for good reason. Because the Secretary's final rule directly regulates primary conduct, imposing new substantive obligations on private parties, notice-and-comment rulemaking and its attendant judicial review is essential to protecting laboratories' rights, including their right not to be burdened by regulations that exceed the agency's proper authority. In contrast, once the Secretary has promulgated regulations that comply with the statute and survive judicial scrutiny, there are sound policy reasons to prevent parties from filing litigation every time the Secretary uses data he has collected to calculate and establish Medicare payment amounts.

The district court's conclusion that the final rule does not regulate primary conduct and, therefore, Congress did not intend to provide for judicial review misunderstands basic principles of administrative law. A rule regulates primary conduct where, as here, it imposes a substantive obligation on parties to take or refrain from taking action.

Contrary to the district court's conclusion, it is not necessary for the rule to regulate "the work of laboratories." The fact that the final rule imposes new reporting obligations on certain laboratories on threat of civil penalty means that judicial oversight is needed to ensure that the Secretary has acted within the bounds of his authority. Absent especially clear evidence that Congress intended to shield the Secretary's regulation from any review — a step that would raise serious separation-of-powers concerns — the strong presumption in favor of judicial review should apply.

The court also incorrectly held that the Secretary's final rule establishing the parameters for data collection was "inextricably intertwined" with his later, separate action of arraying data and taking the other administrative acts necessary to establish payment amounts. *Cf. Fla. Health*, 830 F.3d at 519. In *Florida Health*, the Secretary's decision as to what data to use was a discretionary decision that could not be separated from the Secretary's estimates. The cost report data — which was not confidential — was already in the Secretary's possession, and the decision as to what data to use was both formally and functionally the same administrative act as making the estimate.

Neither the estimate nor the choice of data imposed new and legally binding obligations on regulated parties.

Here, in contrast, Congress has called for two separate and logically distinct acts: (1) the promulgation of substantive regulations imposing new data-reporting requirements on laboratories, and (2) the separate administrative function of arraying the data to establish the amount of payments provided under Medicare. Although connected, the two acts are not inseparable. Permitting judicial review of the Secretary's substantive regulations, with its own administrative record, but not any of his later administrative acts establishing payment amounts, furthers PAMA's overarching objectives by ensuring that the Secretary stays within the scope of his delegated authority without burdening the courts and agency with litigation every time the Secretary performs a new calculation to establish payment amounts. There is no justification for the district court's broad reading of the statutory bar.

2. Even if the statutory bar did apply, the district court had jurisdiction because the Secretary's final rule is *ultra vires* and exceeds his lawful authority. The Secretary's rule rewrites the statute to

exempt hospital laboratories from the data-reporting requirements that Congress imposed. Instead of looking at the Medicare revenues of the laboratory itself, as Congress directed, the Secretary's final rule considers the Medicare revenues of the larger hospital (of which the laboratory is only a small component), exempting almost all hospital laboratories from Congress's reporting requirements. That violates the statute, as the Secretary has effectively acknowledged in his subsequent rulemaking. Because the Secretary cannot disregard Congress's specific and unambiguous directives, the final rule is *ultra vires*.

STANDING

ACLA's standing is self-evident. It has associational standing because its members are directly regulated by, and subject to, the substantive requirements of the Secretary's final rule. *See Am. Library Ass'n v. FCC*, 401 F.3d 489, 492 (D.C. Cir. 2005).

Where an association's member is "'an object of the action (or forgone action) at issue'" there is "'little question that the action or inaction has caused [the plaintiff] injury, and that a judgment preventing or requiring the action will redress it.'" *Sierra Club v. EPA*, 292 F.3d 895, 899–900 (D.C. Cir. 2002) (quoting *Lujan v. Defs. of*

Wildlife, 504 U.S. 555, 560–61 (1992)). Here, ACLA's members — the laboratories that are required to report information under the Secretary's final rule, JA030 ¶¶ 71–72; JA073–76 ¶¶ 20–30 — are the direct objects of the regulation and were active participants in the Secretary's rulemaking proceeding, *see, e.g.*, JA555–57, JA558–61, JA565–68, JA569–72, JA650–83.

ACLA and its members have the right to have the statute properly implemented and have standing to complain that the Secretary exceeded his statutory authority. *See State Nat'l Bank of Big Spring v. Lew*, 795 F.3d 48, 53 (D.C. Cir. 2015) (recognizing "that a regulated individual or entity has standing to challenge an allegedly illegal statute or rule under which it is regulated"); *Zivotofsky v. Sec'y of State*, 444 F.3d 614, 619 (D.C. Cir. 2006) (finding that party has standing to challenge agency failure to comply with statutory obligations imposed by Congress for party's benefit).

ACLA's members have been "significantly disadvantaged as compared to other laboratories that, while required to report under PAMA, were excused from that obligation by the Secretary." JA073 ¶ 20. For those laboratories not excluded under the Secretary's

new definition, the regulatory burden is "difficult, resource-intensive, and burdensome." JA074 ¶ 21. Laboratories have been forced to design and build systems that record the specific type of data required by the regulations. JA074–75 ¶¶ 22–23, 25–27. For some laboratories, the amount of data that needs to be reported is staggering — spanning tens of millions of transactions. *See* JA075 ¶ 27 (one laboratory "reported information for approximately 93 million [Healthcare Common Procedure Coding System] code-level transactions"). The data collection process for the first collection period cost at least one company almost $2 million, JA074 ¶ 21, and included at just one stage of the production "approximately 240 people work[ing] 6 days a week for approximately 8 weeks," JA076 ¶ 29.

ACLA's members have also suffered, and will continue to suffer, harm from the invalid payment amounts resulting from the Secretary's *ultra vires* rule. Because those amounts are based on data that does not reflect the private market as a whole, they are much lower than Congress intended and cause substantial harm to laboratories and patients. *See* JA049 ¶ 23; JA061–62 ¶ 26–27; JA071–72 ¶¶ 14–15; *see also* ECF No. 21, Amicus Br. of the Nat'l Ass'n for the Support of Long

Term Care p. 6 (Mar. 07, 2018); ECF No. 22, Amicus Br. of the Advanced Med. Tech. Ass'n p. 7 (Mar. 07, 2018); ECF No. 23, Amicus Br. of the Am. Ass'n of Bioanalysts pp. 15–17 (Mar. 07, 2018); ECF No. 25, Amicus Br. of the Coll. of Am. Pathologists p. 13–15 (Mar. 07, 2018).

These injuries are directly traceable to the Secretary's final rule, and can be redressed by an order striking down the Secretary's statutory rewrite and requiring the Secretary to implement the statute that Congress enacted.

STANDARD OF REVIEW

This Court reviews *de novo* a district court's dismissal for lack of subject-matter jurisdiction. *Piersall v. Winter*, 435 F.3d 319, 321 (D.C. Cir. 2006). When considering whether a statute bars judicial review, the Court applies a presumption in favor of judicial review of agency action and reads statutory bars narrowly. *El Paso Nat. Gas Co. v United States*, 632 F.3d 1272, 1276 (D.C. Cir. 2011).

ARGUMENT

I. The District Court Misinterpreted The Statute And Failed To Apply The Strong Presumption in Favor Of Judicial Review.

There is a "strong presumption" that Congress intends judicial review of administrative action. *Mach Mining, LLC v. EEOC*, 135 S. Ct. 1645, 1651 (2015). That presumption can be overcome only with a showing of "clear and convincing" indications that Congress wanted the agency to police its own conduct. *Id.*; *see SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). In attempting to insulate its actions from review, an agency "bears a heavy burden" to show "that Congress prohibited all judicial review of the agency's compliance with a legislative mandate." *Mach Mining*, 135 S. Ct. at 1651 (alterations omitted); *see also Nat. Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 1043 (D.C. Cir. 1979).

There is no clear and convincing indication that Congress intended to prohibit judicial review of the Secretary's final rule. *See Mach Mining*, 135 S. Ct. at 1651. PAMA's text and structure indicate that Congress distinguished between the Secretary's substantive data-reporting regulations and his later administrative act of arraying data to establish payment amounts. That conclusion is reinforced by the

constitutional principle that judicial review is necessary when an agency promulgates a legislative rule that regulates primary conduct.

A. The Statute's Text and Structure Show That Congress Did Not Intend To Bar Judicial Review.

PAMA's text and structure show that Congress directed the Secretary to undertake two separate administrative acts, addressed the Secretary's different obligations in separate statutory provisions, and barred judicial review of only one of those actions. In subsection (a), Congress mandated that the Secretary collect, and maintain in confidence, private payor data from all "applicable laborator[ies]," 42 U.S.C. § 1395m-1(a)(1), (10), and directed the Secretary to "establish through notice and comment rulemaking" the "parameters for data collection," *id.* § 1395m-1(a)(12). In contrast, subsection (b) instructs the Secretary to "determine" payment amounts by "arraying the distribution of all [reported] payment rates," applying a formula, and "calculat[ing] a weighted median." *Id.* § 1395m-1(b)(1)–(5).

According to PAMA's plain language, Congress precluded judicial review of only "the establishment of payment amounts," not the regulations promulgated to establish the parameters for data collection. *Compare id.* § 1395m-1(h)(1) *with id.* § 1395m-1(a)(12). That distinction

is significant. Congress's decision to bar review of the "establishment of payment amounts" but to say nothing about the Secretary's substantive regulations establishing the parameters for data collection demonstrates that Congress did not intend to strip courts of jurisdiction over the Secretary's final rule. *See Miss. ex rel. Hood v. AU Optronics Corp.*, 571 U.S. 161, 169 (2014) ("[W]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (alteration in original) (quoting *Dean v. United States*, 556 U.S. 568, 573 (2009))). If Congress had wanted the jurisdictional bar to apply, it could have written the statute to sweep more broadly. *See SAS Inst.*, 138 S. Ct. at 1355–56 ("[I]f Congress wanted to adopt the Director's approach it knew exactly how to do so.").

It is also significant that Congress mandated that the Secretary's data-collection regulations, unlike his administrative act of establishing payment amounts, would be promulgated through notice-and-comment rulemaking. 42 U.S.C. § 1395m-1(a)(12). That requirement "does not simply erect arbitrary hoops through which federal agencies must jump

without reason." *Sprint Corp. v. FCC*, 315 F.3d 369, 373 (D.C. Cir. 2003). Instead, a central purpose of notice-and-comment rulemaking is to facilitate judicial review by ensuring that agencies develop a record, respond to comments, and explain the reasons for their decisions. *See Sierra Club v. EPA*, 699 F.3d 530, 534 (D.C. Cir. 2012) (notice-and-comment rulemaking forces the agency to develop a record that will "facilitate substantive review"); *see also Judulang v. Holder*, 565 U.S. 42, 53 (2011) ("[c]ourts retain a role, and an important one, in ensuring that agencies have engaged in reasoned decisionmaking").

Notice-and-comment procedures and the opportunity for meaningful judicial review are particularly important where, as here, "the agency action trenches on substantial private rights and interests." *Mendoza v. Perez*, 754 F.3d 1002, 1023 (D.C. Cir. 2014) (quoting *Batterton v. Marshall*, 648 F.2d 694, 708 (D.C. Cir. 1980)). Notice-and-comment requirements "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." *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C. Cir. 2005); *Small Refiner Lead Phase-Down Task Force v.*

EPA, 705 F.2d 506, 547 (D.C. Cir. 1983). These procedures are essential here because setting the parameters for collecting confidential data from laboratories about the payments they receive in the private market is a significant intrusion on private interests.

In light of PAMA's text and structure, it is not possible to say that Congress expressed a clear, unmistakable intent to preclude judicial review of the Secretary's final rule. *See Mach Mining*, 135 S. Ct. at 1651; *Dart v. United States*, 848 F.2d 217, 224–26 (D.C. Cir. 1988). In fact, for the reasons explained above, the only inference fairly discernable from the statute's text and structure is that Congress did not intend to bar judicial review. Instead of applying the presumption in favor of review, however, the district court concluded that certain features of PAMA justify reading the jurisdictional bar very broadly. None of those justifications withstand scrutiny.

The district court recognized that under *Dean v. United States*, Congress is presumed to act "intentionally and purposely" when it includes "particular language in one section of a statute but omits it in another section of the same Act." 556 U.S. at 573. But the court refused to apply that principle. Even though the requirement that the

Secretary establish payment amounts appears in a different provision than the requirement that the Secretary "establish" the "parameters for data collection," and even though the jurisdictional bar refers only to the "establishment of payment amounts," the district court deemed the *Dean* principle "inapplicable" because although the relevant provisions are in different subsections, they "both appear in a single section of PAMA." JA441.

That artificial distinction between statutory sections and subsections misses the point. In *Dean* itself, the Supreme Court looked at different subsections of a single section of a statute to determine whether the extra punishment Congress imposed when a gun is discharged also applies when a gun goes off. Concluding that Congress did not require proof of intent, the Court noted that Congress defined "brandish" in subsection (ii) to include an intent requirement but did not define "discharge" in subsection (iii) to include one. *Dean,* 556 U.S. at 572–73. As a result, the Court refused to "contort[] and stretch[] the statutory language to imply an intent requirement" in subsection (iii). *Id.* at 574; *see also Miss. ex rel. Hood*, 571 U.S. at 169 (applying *Dean* to distinguish between language in different statutory subsections);

United States v. Ali, 718 F.3d 929, 937 (D.C. Cir. 2013) (same). The Court did not care that the two definitions appeared "in a single section" of the statute; instead, it relied on the principle that when Congress uses different words in different provisions, it does so intentionally. By disregarding that principle, and applying the jurisdictional bar to the Secretary's final rule, the district court impermissibly read words into the statute — changing "establishment of payment amounts" to mean "establishment of the parameters for data collection." *See Dean*, 556 U.S. at 572 (courts "ordinarily resist reading words or elements into a statute that do not appear on its face" (quoting *Bates v. United States*, 522 U.S. 23, 29 (1997))).

The district court also observed that private payor data collected by the Secretary is later used for the purpose of establishing payment amounts and that the statutory header links the two acts by referring to the "[r]eporting of private sector payment rates for establishment of Medicare payment rates." JA442–43. But statutory titles and headings are not appropriate indicia of legislative intent. *See Lawson v. FMR LLC*, 571 U.S. 429, 446 (2014) (statutory headings are merely "a short-hand reference to the general subject matter" and "not meant to take

the place of the detailed provisions of the text"). Nor can they "limit the plain meaning of the text." *Bhd. of R.R. Trainmen v. Balt. & O.R. Co.*, 331 U.S. 519, 528–29 (1947). At most, titles and headings can be used as tools for interpreting "ambiguous word or phrases." *Id.* at 529. But the district court did not identify any ambiguity in the text. In any event, the header — "Reporting of private sector payment rates for establishment of medicare payment rates" — is merely a shorthand description of Congress's requirement that the Secretary use the reported data for the establishment of payment rates and, because the confidential data must be held in strict confidence, not for any other purpose. *See* 42 U.S.C. § 1395m-1(a)(10) (limiting the Secretary's use of confidential data); *Lawson*, 571 U.S. at 446.

More fundamentally, the fact that the two statutory obligations are linked is not dispositive. The required inquiry is whether the statute is "reasonably susceptible" to an interpretation that does not preclude judicial review. In addressing that question, the district court failed to apply this Court's teachings. *El Paso*, 632 F.3d at 1276; *Dart*, 848 F.2d at 221; *see also Mach Mining*, 135 S. Ct. at 1651. As this Court has held, there is a strong presumption that Congress intends

judicial review of administrative action "even where . . . the statute expressly prohibits judicial review — in other words, the presumption dictates that such provisions must be read narrowly." *El Paso*, 632 F.3d at 1276. The district court did just the opposite. Rather than interpreting the judicial bar narrowly, the district court read it broadly.

There is no basis for that expansive reading. This Court has recognized that, even when a statute bars judicial review of a particular agency decision, parties may challenge "the general rules" leading to that decision. *Parkview Med. Assocs. v. Shalala*, 158 F.3d 146, 148 (D.C. Cir. 1998). If the district court were correct that "the express provision" precluding judicial review of the establishment of payment amounts "were alone enough to overcome the APA's presumption of reviewability" for any separate agency act that might precede or inform the establishment of payment amounts, "it would not be much of a presumption at all." *Cf. Sackett v. EPA,* 566 U.S. 120, 129 (2012); *see also U.S. Army Corps of Eng'rs v. Hawkes Co.*, 136 S. Ct. 1807, 1816 (2016) ("distinct final agency action" presumptively reviewable). Accordingly, because PAMA is at least susceptible to divergent interpretations, the court was obliged to "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).

B. The Nature of the Administrative Action Confirms That Congress Did Not Intend To Bar Judicial Review.

There is another reason the presumption in favor of judicial review should prevail here — "the nature of the administrative action involved." *Dart*, 848 F.2d at 224 (quoting *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984)). Because the Secretary's final rule regulates primary conduct by imposing new substantive obligations on laboratories on threat of civil penalties, the presumption in favor of judicial review is especially strong. The district court's decision — and its misguided conclusion that the final rule does not regulate primary conduct merely because laboratories' central business activity does not involve reporting data — violates basic principles of administrative law and constitutional government.

The District Court Disregarded The Distinction Between Legislative Rules And Mere Administrative Acts. There is a long-standing logical distinction in administrative law between, on one hand,

coercive actions an agency takes to regulate primary conduct, imposing constraints or obligations on private parties, and on the other, administrative acts that an agency takes that affect only secondary conduct. *See Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986) ("Once the agency publicly articulates an unequivocal position . . . and expects regulated entities to alter their primary conduct to conform to that position, the agency has voluntarily relinquished the benefit of postponed judicial review."). That distinction is grounded in separation-of-powers principles and the imperative of judicial review to ensure that agencies act lawfully, reasonably, and within the proper scope of their delegated powers when they regulate private conduct. *See generally* 5 U.S.C. § 558(b) ("A sanction may not be imposed or a substantive rule or order issued except within jurisdiction delegated to the agency and as authorized by law"); *cf. Mistretta v. United States*, 488 U.S. 361, 369 (1989) (upholding delegation where Congress did not transfer authority to make rules that "bind or regulate the primary conduct of the public").

These distinctions appear and reappear in different contexts in decades of administrative law doctrine and constitutional cases. *See, e.g.*, *Landgraf v. USI Film Prods.*, 511 U.S. 244, 275 (1994) (noting

"rules of procedure regulate secondary rather than primary conduct" and therefore may be applied retroactively). The Administrative Procedure Act, for example, distinguishes between legislative rulemaking, which ordinarily must proceed through notice-and-comment procedures and is subject to judicial review, *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015), and other types of agency action, which are exempt from notice-and-comment procedures and are often shielded from judicial review. *See Mendoza*, 754 F.3d at 1022 (observing that notice-and-comment procedures are "mandatory" for legislative rules, but not for interpretive rules); *Am. Hosp. Ass'n v. Bowen*, 834 F.2d 1037, 1050 (D.C. Cir. 1987) (distinguishing between substantive and procedural rules). The exceptions involve administrative acts setting government benefits, 5 U.S.C. § 553(a)(2), "rules of agency organization, procedure, or practice," *id.* § 553(b)(3)(A); and "interpretive rules [and] general statements of policy, *id.* § 553(b)(3)(A); *see generally Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 252 (D.C. Cir. 2014) (noting that legislative rules, unlike interpretive rules or statements of policy, are subject to pre-enforcement judicial review).

It is not unusual for Congress to limit judicial review when an agency is performing an administrative function — for example, establishing payment amounts or rules of procedure — and its actions affect only private parties' secondary conduct. In those circumstances, the agency is not directly regulating private interests or exercising legislative rulemaking authority and, as a result, there is often no imperative for notice-and-comment rulemaking and less need for judicial oversight. *See, e.g.*, *Mercy Hosp., Inc. v. Azar*, 891 F.3d 1062, 1066 (D.C. Cir. 2018) (addressing jurisdictional bar on appealing prospective payment rates); *Fla. Health*, 830 F.3d at 519 (addressing jurisdictional bar on Secretary's "estimate" of payment amounts); *Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 409 (D.C. Cir. 2012) (addressing jurisdictional bar on establishment of payment amounts, awarding of contracts, and other related administrative acts). Nor is it unusual for Congress to limit judicial review to particular classes of parties harmed by agency action or to bar judicial review in one forum when judicial review is available in another. *See, e.g.*, *Koretoff v. Vilsack*, 614 F.3d 532 (D.C. Cir. 2010).

When an agency is engaged in substantive rulemaking that regulates primary conduct, however, there is a very strong presumption in favor of judicial review. *Cf. Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 891 (1990) ("a substantive rule which as a practical matter requires the plaintiff to adjust his conduct immediately . . . is 'ripe' for review at once"). Judicial oversight is essential to constitutional government because the agency is wielding the coercive power of government to require regulated parties to "engage in, or to refrain from, [certain] conduct." *Texas v. United States*, 523 U.S. 296, 301 (1998); *Toilet Goods Ass'n, Inc. v. Gardner*, 387 U.S. 158, 164–65 (1967). As commentators have recognized, "'the peculiar province of the judicial department' — its unique and indispensable function in our system of government — is 'to adjudicate upon, and protect, the rights and interests of individual citizens.'" Caleb Nelson, *Adjudication in the Political Branches*, 107 Colum. L. Rev. 559, 569 (2007) (citing Thomas M. Cooley, *A Treatise on the Constitutional Limitations Which Rest Upon the Legislative Power of the States of the American Union* 91 (Boston, Little, Brown & Co. 1868))). Courts have rejected agency positions that would "enable the strong-arming of regulated parties into

'voluntary compliance' without the opportunity for judicial review." *Sackett*, 566 U.S. at 130–31.

Congress Took Steps To Protect Laboratories' Private Rights. There is no doubt that Congress was aware of these well-established distinctions when it enacted PAMA. *See Hall v. United States*, 566 U.S. 506, 516 (2012) (courts "assume that Congress is aware of existing law when it passes legislation"). Recognizing that requiring parties to report confidential data would interfere with their private rights, and expose laboratories to potentially "hundreds of thousands if not millions" in civil penalties for non-compliance, Congress directed the Secretary to undertake notice-and-comment rulemaking. 42 U.S.C. § 1395m-1(a)(9)(A); *see also* 42 C.F.R. § 414.504(e); JA074–75 ¶ 24. Congress also put in place protections for the confidential information reported by laboratories. *See, e.g.*, 42 U.S.C. § 1395m-1(a)(10) (information provided by laboratories "is confidential and shall not be disclosed"); *id.* § 1395m-1(a)(11) (protecting information from public disclosure). As record evidence shows, the regulatory burden is substantial. The initial data collection process cost at least one of ACLA's members almost $2 million, *see* JA074 ¶ 21, and included at

just one stage of the production "approximately 240 people work[ing] 6 days a week for approximately 8 weeks," JA076 ¶ 29.

There is no indication — and certainly no clear indication — that Congress intended to strip the judiciary of all authority to review whether the Secretary's final rule "proceeds in accordance with the law's demands." *SAS Inst.*, 138 S. Ct. at 1359. That legal question falls squarely within courts' traditional authority, and nothing in PAMA "withdraws [the courts'] power" to decide it. *Id.* "[A]n attack on the validity of" the Secretary's final rule setting the parameters of data collection is simply "not the kind of administrative action" that establishes payment amounts, which is the only agency action that Congress indicated would be shielded from judicial review. *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 676 (1986).

Permitting challenges to the Secretary's final rule, while barring challenges to the Secretary's establishment of payment amounts, is also consistent with PAMA's objectives. Judicial review of the Secretary's final rule ensures that the Secretary acts within the proper scope of his delegated authority, protects the rights of laboratories directly regulated by the rule, and ensures that the data used to establish

payment amounts is an accurate reflection of the private payor market. As long as courts are available to ensure that the Secretary complies with statutory requirements and acts reasonably and within the scope of his delegated authority when promulgating his legislative rule establishing the parameters for data collection, Congress can be confident that the payment amounts, whenever and however they may later be established, will be consistent with the statute's overarching objectives of having Medicare payment rates approximate the commercial market. If the Secretary's rule is able to survive judicial review, prohibiting review of the Secretary's later administrative act establishing payment amounts avoids enmeshing the courts in technical calculations and discretionary decisions about how to array data every time the Secretary calculates a payment amount for existing or new diagnostic tests. *Cf. Koretoff*, 614 F.3d at 537 (noting that Congress barred consumer suits because otherwise "virtually every American could challenge every agricultural marketing order").

In contrast, reading the jurisdictional bar broadly, as the district court did, renders the statutorily required notice-and-comment procedures largely meaningless and leaves the Secretary with

unchecked discretion to evade Congress's directives. Without judicial review of the final rule, the Secretary can impose his will on laboratories in a way that violates Congress's intent and results in Medicare not reasonably reflecting the payments made in the private market. In short, without allowing laboratories to seek judicial review of the final rule, Congress's "statutory objectives might not be realized." *Alto Dairy v. Veneman*, 336 F.3d 560, 566 (7th Cir. 2003) (quoting *Barlow v. Collins*, 397 U.S. 159, 167 (1970)).

The District Court's Interpretation Raises Grave Constitutional Concerns. The district court's interpretation of PAMA's jurisdictional bar also raises serious constitutional concerns. *See Rust v. Sullivan,* 500 U.S. 173, 190 (1991) (discussing obligation to interpret statutory provisions to avoid constitutional doubt); *see also Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2141–42 (2016). If, as the district court concluded, Congress intended to bar review of the Secretary's final rule, the jurisdictional bar would prohibit parties from challenging the rule even in the context of an enforcement action. *See Sackett*, 566 U.S. at 130–31. The Secretary could impose massive daily monetary penalties for failure to comply with his regulations — even

though those regulations require parties to turn over confidential information — and regulated parties would have no ability to challenge those penalties in court on grounds that the Secretary's rule is contrary to the statute or in excess of the Secretary's lawful authority. That would be a uniquely sweeping and unreviewable delegation of agency authority that would raise serious separation-of-powers concerns. *See id.* at 129; *see also Free Enter. Fund v. Pub. Accounting Oversight Bd.*, 561 U.S. 477, 489–90 (2010); *Dep't of Transp. v. Ass'n of Am. R.R.*, 135 S. Ct. 1225, 1240 (2015) (Thomas, J., concurring in judgment) (discussing serious separation-of-powers concerns raised when Congress delegates legislative power to agencies).

Although the district court acknowledged the importance of these issues, it did not meaningfully address them. JA446. Instead, the district court concluded that the final rule does not regulate laboratories' "primary conduct" merely because their main "work" is providing laboratory services, not supplying confidential data to the government. *Id.* ("the purpose and effect of the Final Rule is not to regulate the work of laboratories"). That assertion misunderstands the administrative and constitutional law principles at stake. Even

National Park Hospitality Association v. Department of Interior, 538 U.S. 803, 810 (2003), the case the court cited, recognizes that a regulation of primary conduct does not turn on the nature of the regulated parties' "work," but rather on whether the regulation forces them to take or refrain from taking action. *Id.* (citing *Toilet Goods Ass'n*, 387 U.S. at 164–65). The need for a judicial check when an agency wields coercive regulatory power does not ebb and flow based on a district court's views as to what a regulated party's primary business activity might be. Instead, it is grounded in fundamental concerns about accountable government and the role that courts play to ensure that agencies act within the scope of their delegated powers — a role that is at its zenith when an agency promulgates legislative rules that regulate private conduct.

C. The District Court Misapplied *Florida Health*.

Relying on *Florida Health*, the district court concluded that because the collection of data is a necessary prerequisite to the establishment of payment amounts, the two acts are "inextricably intertwined." JA444–45. That conclusion misunderstands *Florida Health*.

Unlike this case, *Florida Health* did not involve a legislative rule that regulated parties' primary conduct. 830 F.3d at 517 (noting that final rule did not impose obligation to report data; HHS already had the data); *see also* JA444. Nor did it involve a regulation where failure to comply would subject parties to civil penalties. Nor did it involve a statutory provision reasonably susceptible to an interpretation that Congress distinguished between two different agency acts and indicated that only one would be exempt from judicial review. *Florida Health* thus says nothing about the situation here, where an agency is regulating primary conduct through substantive regulations promulgated through notice-and-comment rulemaking that Congress expressly required.

Florida Health instead addressed a much narrower question: When Congress bars judicial review of an estimate made by an agency, what discretionary acts taken by the agency qualify as part of the estimate and, therefore, fall within the scope of the jurisdictional bar? 830 F.3d at 518 (querying whether the Secretary's decision choosing data "is of the sort shielded from review"). Rejecting any "categorical" distinction between "inputs and outputs," *Florida Health* concluded that

when an agency takes administrative action within the scope of a jurisdiction-stripping provision, enterprising parties should not be allowed to circumvent the jurisdictional bar by artificially dividing the agency action into its inextricably intertwined component parts. *Id.* at 522 ("[Plaintiff] is simply trying to undo the Secretary's estimate of the hospital's uncompensated care by recasting its challenge to the Secretary's choice of data as an attack on the general rules leading to [the] estimate.").

Significantly, in *Florida Health*, the agency's discretionary decision regarding which set of data to use — hospital cost data already in the agency's possession, before or after a certain date — could not in any practical sense be separated from the administrative act of making an estimate. Noting that "[n]o other data factored into the Secretary's estimate," the Court explained that the Secretary's decision as to which set of existing data to use was a discretionary decision that necessarily dictated the Secretary's final estimate. *Id.* at 519 ("the data are the entire basis for the estimate"). In other words, when the Secretary estimated rates, he necessarily had to choose what vintage data to use to reach his estimate. Both the Secretary's estimate and his underlying

choice of data were therefore the same agency action that Congress intended to shield from review. *See* 78 Fed. Reg. 50,496 (Aug. 19, 2013); *Fla. Health*, 830 F.3d at 519.

Here, in contrast, Congress has made clear that there are two separate and logically distinct administrative acts, each subject to different levels of judicial review: (1) promulgating new, legally binding rules to collect confidential information from regulated parties, and (2) then using the collected information to establish payment amounts. Although the acts are related, they are not inseparable. They are not part of the same agency action as was the case in *Florida Health*. The final rule establishing substantive parameters for data reporting and collection has its own administrative record and was published in the Federal Register almost a year before the Secretary took the separate, later administrative act of establishing payment amounts. Permitting a challenge to the first substantive action would not "eviscerate the bar on judicial review" of the second administrative action. *Fla. Health*, 830 F.3d at 518. The Secretary's final rule is simply not "the sort" of agency decision that Congress intended to shield from review. *Id*. at 518-19.

The district court disregarded these fundamental distinctions and misunderstood *Florida Health*'s underlying logic. Instead of focusing on the specific nature of the "agency action shielded from review," as *Florida Health* requires, *id.* at 519, the district court concluded that the agency actions were "inextricably intertwined" merely because they "concern[] which data the Secretary will use in establishing payment amounts." JA444. But that is exactly the type of artificial, "categorical distinction" that *Florida Health* rejected. 830 F.3d at 518. *Florida Health* does not mean that every agency act resulting in an input that is later used by the agency to establish payment amounts is non-reviewable.

Other cases applying *Florida Health* are distinguishable from this case for the same reasons. In *Mercy Hospital, Inc. v. Azar*, for instance, this Court held that a bar on reviewing prospective payment rates "must also include the adjustments used to calculate that rate." 891 F.3d at 1066. As in *Florida Health*, barring judicial review of a discretionary rate necessarily barred judicial review of the adjustment formula used to arrive at the final rate because otherwise plaintiffs would be able to "circumvent[] a statutory bar to review." *Id.* at 1067.

But, unlike the plaintiff in *Mercy Hospital*, ACLA is not challenging either a rate or a rate adjustment. Nor is ACLA challenging a particular formula the Secretary applied to the data once it was collected. Instead, it seeks to require the Secretary to comply with the statute that Congress enacted. ACLA's challenge does not "enmesh the courts in 'the technical and complex determinations'" of rate calculations and "'burden the courts . . . with expensive and time-consuming litigation.'" *Traynor v. Turnage*, 485 U.S. 535, 544 (1988) (quoting *Johnson v. Robison*, 415 U.S. 361, 373 (1974)).

II. The Secretary's Final Rule Is *Ultra Vires* And In Excess of His Statutory Authority.

Even if judicial review were precluded under the statutory bar, there is still jurisdiction because the Secretary's final rule exceeds his statutory authority and is *ultra vires*. The district court erred by failing to address this argument.

Judicial review is always available when an agency engages in "'shenanigans' by exceeding its statutory bounds." *SAS Inst.*, 138 S. Ct. at 1359 (quoting *Cuozzo*, 136 S. Ct. at 2141–42); *see Lepre v. Dep't of Labor*, 275 F.3d 59, 73 (D.C. Cir. 2001) (judicial review is available for clear violations of statutory mandates). Judicial review is also

"available when an agency acts *ultra vires*, even if a statutory cause of action is lacking." *Trudeau v. FTC*, 456 F.3d 178, 190 (D.C. Cir. 2006) (internal citations and quotation marks omitted); *see also Leedom v. Kyne*, 358 U.S. 184, 188–89 (1958). That is true "[e]ven where Congress is understood generally to have precluded review." *Griffith v. Fed. Labor Relations Auth.*, 842 F.2d 487, 492 (D.C. Cir. 1988); *see Lepre*, 275 F.3d at 73; *Dart*, 848 F.2d at 224.

As the Supreme Court has recently clarified, agencies' power to act is "authoritatively prescribed by Congress" and, therefore, when they act improperly or "beyond their jurisdiction, what they do is *ultra vires*." *City of Arlington, Tex. v. FCC*, 569 U.S. 290, 297 (2013). An agency action is *ultra vires* when the agency has exceeded its statutory authority, "disregarded a specific and unambiguous statutory directive," violated a statute's "specific command," or patently misconstrued the statute. *Griffith*, 842 F.2d at 493 (internal citation and quotation marks omitted). Because "agencies could characterize reviewable or unauthorized action as falling within the scope of no-review provisions whose application to such action Congress did not intend," determining whether a court has jurisdiction is often "intertwined with the question

of whether the agency has authority for the challenged action." *Amgen, Inc. v. Smith*, 357 F.3d 103, 113 (D.C. Cir. 2004). Judicial review of these questions is "consistent with the Administrative Procedure Act, which directs courts to set aside agency action 'not in accordance with the law' or 'in excess of statutory jurisdiction, authority, or limitations.'" *SAS Inst.*, 138 S. Ct. at 1359 (internal citation omitted).

The Secretary's final rule is *ultra vires* and exceeds the Secretary's statutory authority because it rewrites a specific, unambiguous PAMA provision in a way that exempts hospital laboratories from the mandatory data-reporting obligations that Congress imposed. *See id.* at 1355 ("Where a statute's language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer."); *Util. Air Reg. Gp. v. EPA*, 134 S. Ct. 2427, 2446 (2014) (noting "core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate"). In PAMA, Congress directed the Secretary to collect data from *any* laboratory that receives a majority of "its" Medicare revenues from the Clinical Laboratory Fee Schedule and the Physician Fee Schedule. 42 U.S.C.

§§ 1395m-1(a)(1)–(2). Congress also expressly limited the Secretary's authority to create exemptions from that requirement. *See id.* § 1395m-1(a)(2). The statute requires the Secretary to determine whether a laboratory is "applicable" by comparing its revenues from the Clinical Laboratory Fee Schedule and the Physician Fee Schedule (the numerator) against its overall total Medicare revenues (the denominator). *Id.* §§ 1395m-1(a)(1)–(2). If a laboratory's revenues from the relevant fee schedules are more than fifty percent of its total Medicare revenues, it is an "applicable laboratory" that must report data. *Id.*

Instead of undertaking the inquiry that Congress required, the Secretary's final rule requires a comparison of a laboratory's total revenues from the relevant fee schedules against the total Medicare revenues of *any entity* with an NPI (of which the laboratory is often only one component). In the case of hospital laboratories, the final rule takes into account massive amounts of Medicare revenues received by the hospital as a whole that are completely unrelated to the outreach services that the hospital laboratory provides. Nothing in the statute authorizes the Secretary to inflate the denominator by including

unrelated Medicare revenues for services attributable to a much larger entity (the hospital) of which the laboratory is only a small component part. To the contrary, as the Secretary has now conceded, "[t]he statute specifically directs [the Secretary] to identify applicable 'laboratories' and not 'providers' or 'suppliers.'" 83 Fed. Reg. at 59,675.

The difference between the statutory directive and the Secretary's final rule is glaring:

> **Equation as required by PAMA**:
>
> $$\frac{\text{Laboratory's Revenues from Fee Schedules (CLFS | PFS)}}{\text{Laboratory's Total Medicare Revenues}}$$
>
> **Equation as rewritten by the Secretary**:
>
> $$\frac{\text{Laboratory's Revenues from Fee Schedules (CLFS | PFS)}}{\text{Hospital's Total Medicare Revenues}}$$
> *(revenues from the laboratory* plus *revenues from other hospital components)*

The Secretary's rewrite drains all meaning from the "majority of Medicare revenues" requirement as applied to hospital laboratories. *See Nat'l Ass'n of Mfrs. v. Dept' of Def.*, 138 S. Ct. 617, 632 (2018) ("[T]he Court rejects an interpretation of the statute that would render an entire subparagraph meaningless."). It is undisputed that almost every hospital laboratory uses the hospital's overall NPI to bill Medicare, thus ensuring that the hospital's overall revenues — not the laboratory's —

are considered for purposes of determining whether the laboratory must report data under the Secretary's final rule. JA619; JA089 ¶ 32. Because a hospital's total Medicare revenues will always dwarf the revenues of the laboratory itself, the final rule exempts hospital laboratories from the data-reporting requirements, even if a majority of the hospital laboratory's Medicare revenues are from the relevant fee schedules. But "such laboratories . . . should not be exempt from reporting the applicable data merely due to their shared use of a billing entity with a hospital." 83 Fed. Reg. at 59,675.

The consequences of the Secretary's statutory violation are substantial. As noted above, a mere 1 percent of the reported laboratory test volume came from hospital laboratories, even though hospital laboratories received 26 percent of the Clinical Laboratory Fee Schedule payments in 2016. *Compare* OIG 2016 Data Report at 2, *with* CMS Reporting Summary at 3; *see also* JA081 ¶ 9–10.

The Secretary's final rule thus directly contradicts Congress's intent for "all sectors of the laboratory market [to] be represented in the reporting system, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis

under the fee schedule." 160 Cong. Rec. S2860 (Daily ed. May 8, 2014) (statement of Sen. Richard Burr, affirmed by Sen. Orrin Hatch). Far from exempting hospital laboratories, Congress imposed the "majority of" Medicare revenues requirement to ensure that the Secretary would collect accurate data from the laboratory market as a whole. Congress could have easily worded the statute differently if it had intended to grant hospital laboratories a blanket exclusion from the data-reporting requirements. *See Knight v. Comm'r of Internal Revenue*, 552 U.S. 181, 188 (2008) (noting principle that "fact that [Congress] did not adopt" a "readily available and apparent alternative" "strongly" suggests that the alternative should be rejected); *see also SAS Inst.*, 138 S. Ct. at 1355–56. Instead, it expressed its clear intent that all laboratories — including hospital laboratories — would be subject to the same statutory test for determining their reporting obligations.

Consider the following: Had the Secretary announced that instead of collecting data from all types of laboratories to obtain an accurate representation of the private market, he intended to hand select data from only a small subsection of the market to ensure that the payment amounts would not be market-based, no one could dispute

that his approach would be *ultra vires* and in excess of his statutory authority. Both his rule and any rates based on it would be a legal nullity. But that is precisely what he has done here, only in a less transparent, more indirect way. *See Cont'l Air Lines, Inc. v. Civil Aeronautics Bd.*, 522 F.2d 107, 115–16 (D.C. Cir. 1974) (agency cannot frustrate Congressional purpose by doing indirectly what it is prohibited from doing directly).

In his most recent regulations, the Secretary has effectively conceded that his final rule does not comply with the statutory requirements. *See* 83 Fed. Reg. at 59,674. He has acknowledged that Congress did not grant him authority to exempt applicable laboratories from the statutory requirements. ECF No. 27, Gov't Cross Mot. at 29–30 (Mar. 23, 2018). And he has conceded that Congress intended for him to collect data from "a wide variety of laboratories," JA457, 81 Fed. Reg. at 41,042, and "it is important not to prevent private payor rates from being reported for hospital outreach laboratories so that we may have a broader representation of the national laboratory market to use in setting [Clinical Laboratory Fee Schedule] payment amounts," JA460, 81 Fed. Reg. at 41,045. His new approach confirms that,

contrary to his final rule, PAMA does not permit him to "exclude[] laboratories that meet the majority of Medicare revenues threshold from potentially qualifying as an applicable laboratory." 83 Fed. Reg. at 59,675.

Despite these admissions, the Secretary has refused to remedy his statutory violation. Nor has he identified any ambiguity in PAMA that might authorize him to change his statutory interpretation or deviate from the statute's express mandatory terms. *Cf. Nat'l Ass'n of Home Builders v. Defenders of Wildlife*, 551 U.S. 644, 666 (2007) (accepting interpretation that harmonizes statutory provisions but does not "override express statutory mandates"). Contrary to the Secretary's strained explanation, there is no way to interpret "applicable laboratory" to include "hospital as a whole." The Secretary has effectively replaced the word "laboratory" with the words "any entity with an NPI that has at least one component that is a laboratory." On its face, that rewrite is impermissible and a clear overreach of the Secretary's statutory authority, rendering both his final rule and any action taken predicated on that rule in excess of his statutory authority

and therefore *ultra vires* as a matter of law. *SAS Inst.*, 138 S. Ct. at 1359; *Griffith*, 842 F.2d at 493.

* * *

The Secretary's egregious violation of the statutory requirements should not be shielded from judicial review. By rewriting the statute, the Secretary's final rule exempts virtually all hospital laboratories from the data-reporting requirements, ensuring that the data collected does not accurately represent the private market as Congress intended. With every day that passes, more laboratories are at risk of closure and Medicare beneficiaries may be deprived of the essential laboratory services they need because the Secretary has not complied with Congress's directives. ACLA respectfully seeks prompt resolution of this appeal so its case can move forward as expeditiously as possible.

CONCLUSION

The Court should reverse the district court's order dismissing ACLA's claims for lack of subject-matter jurisdiction.

Respectfully submitted,

/s/ *Ashley C. Parrish*
Ashley C. Parrish
Mark D. Polston
Elizabeth N. Swayne
Amelia G. Yowell
KING & SPALDING LLP
1700 Pennsylvania Ave. NW
Washington, D.C. 20006
Telephone: (202) 737-0500
Facsimile: (202) 626-3737
aparrish@kslaw.com

Counsel for Appellant American Clinical Laboratory Association

December 4, 2018

CERTIFICATE OF COMPLIANCE

This brief complies with the length limitations set forth in Federal Rule of Appellate Procedure 32(a)(7) because it contains 12,983 words, as counted by Microsoft Word, excluding the items that may be excluded.

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because this brief was prepared in 14-point Century Schoolbook font, a proportionately spaced typeface, using Microsoft Word 2010.

/s/ *Ashley C. Parrish*
Ashley C. Parrish

ADDENDUM

42 U.S.C. §1394m-1

§ 1395m–1. Improving policies for clinical diagnostic laboratory tests

(a) Reporting of private sector payment rates for establishment of medicare payment rates

(1) In general

Beginning January 1, 2016, and every 3 years thereafter (or, annually, in the case of reporting with respect to an advanced diagnostic laboratory test, as defined in subsection (d)(5)), an applicable laboratory (as defined in paragraph (2)) shall report to the Secretary, at a time specified by the Secretary, applicable information (as defined in paragraph (3)) for a data collection period (as defined in paragraph (4)) for each clinical diagnostic laboratory test that the laboratory furnishes during such period for which payment is made under this part.

(2) Definition of applicable laboratory

In this section, the term ''applicable laboratory'' means 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. The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary determines appropriate.

(3) Applicable information defined

(A) In general

In this section, subject to subparagraph (B), the term ''applicable information'' means, with respect to a laboratory test for a data collection period, the following:

(i) The payment rate (as determined in accordance with paragraph (5)) that was paid by each private payor for the test during the period.

(ii) The volume of such tests for each such payor for the period.

(B) Exception for certain contractual arrangements

Such term shall not include information with respect to a laboratory test for which payment is made on a capitated basis or other similar payment basis during the data collection period.

(4) Data collection period defined

In this section, the term ''data collection period'' means a period of time, such as a previous 12 month period, specified by the Secretary.

(5) Treatment of discounts

The payment rate reported by a laboratory under this subsection shall reflect all discounts, rebates, coupons, and other price concessions, including those described in section 1395w–3a(c)(3) of this title.

(6) Ensuring complete reporting

In the case where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the applicable laboratory shall report each such payment rate and the volume for the test at each such rate under this subsection. Beginning with January 1, 2019, the Secretary may establish rules to aggregate reporting with respect to the situations described in the preceding sentence.

(7) Certification

An officer of the laboratory shall certify the accuracy and completeness of the information reported under this subsection.

(8) Private payor defined

In this section, the term ''private payor'' means the following:

(A) A health insurance issuer and a group health plan (as such terms are defined in section 300gg–91 of this title).

(B) A Medicare Advantage plan under part C.

(C) A medicaid managed care organization (as defined in section 1396b(m) of this title).

(9) Civil money penalty

(A) In general

If the Secretary determines that an applicable laboratory has failed to report or made a misrepresentation or omission in reporting information under this subsection with respect to a clinical diagnostic laboratory test, the Secretary may apply a civil money penalty in an amount of up to $10,000 per day for each failure to report or each such misrepresentation or omission.

(B) Application

The provisions of section 1320a–7a of this title (other than subsections (a) and (b)) shall apply to a civil money penalty under this paragraph in the same manner as they apply to a civil money penalty or proceeding under section 1320a–7a(a) of this title.

(10) Confidentiality of information

Notwithstanding any other provision of law, information disclosed by a laboratory under this subsection is confidential and shall not be disclosed by the Secretary or a Medicare contractor in a form that discloses the identity of a specific payor or laboratory, or prices charged or payments made to any such laboratory, except—

(A) as the Secretary determines to be necessary to carry out this section;

(B) to permit the Comptroller General to review the information provided;

(C) to permit the Director of the Congressional Budget Office to review the information provided; and

(D) to permit the Medicare Payment Advisory Commission to review the information provided.

(11) Protection from public disclosure

A payor shall not be identified on information reported under this subsection. The name of an applicable laboratory under this subsection shall be exempt from disclosure under section 552(b)(3) of title 5.

(12) Regulations

Not later than June 30, 2015, the Secretary shall establish through notice and comment rulemaking parameters for data collection under this subsection.

(b) Payment for clinical diagnostic laboratory tests

(1) Use of private payor rate information to determine medicare payment rates

(A) In general

Subject to paragraph (3) and subsections (c) and (d), in the case of a clinical diagnostic laboratory test furnished on or after January 1, 2017, the payment amount under this section shall be equal to the weighted median determined for the test under paragraph (2) for the most recent data collection period.

(B) Application of payment amounts to hospital laboratories

The payment amounts established under this section shall apply to a clinical diagnostic laboratory test furnished by a hospital laboratory if such test is paid for separately, and not as part of a bundled payment under section 1395*l*(t) of this title.

(2) Calculation of weighted median

For each laboratory test with respect to which information is reported under subsection (a) for a data collection period, the Secretary shall calculate a weighted median for the test for the period, by arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory.

(3) Phase-in of reductions from private payor rate implementation

(A) In general

Payment amounts determined under this subsection for a clinical diagnostic labora-

tory test for each of 2017 through 2022 shall not result in a reduction in payments for a clinical diagnostic laboratory test for the year of greater than the applicable percent (as defined in subparagraph (B)) of the amount of payment for the test for the preceding year.

(B) Applicable percent defined

In this paragraph, the term ''applicable percent'' means—

(i) for each of 2017 through 2019, 10 percent; and

(ii) for each of 2020 through 2022, 15 percent.

(C) No application to new tests

This paragraph shall not apply to payment amounts determined under this section for either of the following.

(i) A new test under subsection (c).

(ii) A new advanced diagnostic test[1] (as defined in subsection (d)(5)) under subsection (d).

(4) Application of market rates

(A) In general

Subject to paragraph (3), once established for a year following a data collection period, the payment amounts under this subsection shall continue to apply until the year following the next data collection period.

(B) Other adjustments not applicable

The payment amounts under this section shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment).

(5) Sample collection fee

In the case of a sample collected from an individual in a skilled nursing facility or by a laboratory on behalf of a home health agency, the nominal fee that would otherwise apply under section 1395*l*(h)(3)(A) of this title shall be increased by $2.

(c) Payment for new tests that are not advanced diagnostic laboratory tests

(1) Payment during initial period

In the case of a clinical diagnostic laboratory test that is assigned a new or substantially revised HCPCS code on or after April 1, 2014, and which is not an advanced diagnostic laboratory test (as defined in subsection (d)(5)), during an initial period until payment rates under subsection (b) are established for the test, payment for the test shall be determined—

(A) using cross-walking (as described in section 414.508(a) of title 42, Code of Federal Regulations, or any successor regulation) to the most appropriate existing test under the fee schedule under this section during that period; or

(B) if no existing test is comparable to the new test, according to the gapfilling process described in paragraph (2).

(2) Gapfilling process described

The gapfilling process described in this paragraph shall take into account the following sources of information to determine gapfill amounts, if available:

(A) Charges for the test and routine discounts to charges.

(B) Resources required to perform the test.

(C) Payment amounts determined by other payors.

(D) Charges, payment amounts, and resources required for other tests that may be comparable or otherwise relevant.

(E) Other criteria the Secretary determines appropriate.

(3) Additional consideration

In determining the payment amount under crosswalking or gapfilling processes under this subsection, the Secretary shall consider recommendations from the panel established under subsection (f)(1).

(4) Explanation of payment rates

In the case of a clinical diagnostic laboratory test for which payment is made under this subsection, the Secretary shall make available to the public an explanation of the payment rate for the test, including an explanation of how the criteria described in paragraph (2) and paragraph (3) are applied.

(d) Payment for new advanced diagnostic laboratory tests

(1) Payment during initial period

(A) In general

In the case of an advanced diagnostic laboratory test for which payment has not been made under the fee schedule under section 1395*l*(h) of this title prior to April 1, 2014, during an initial period of three quarters, the payment amount for the test for such period shall be based on the actual list charge for the laboratory test.

(B) Actual list charge

For purposes of subparagraph (A), the term ''actual list charge'', with respect to a laboratory test furnished during such period, means the publicly available rate on the first day at which the test is available for purchase by a private payor.

(2) Special rule for timing of initial reporting

With respect to an advanced diagnostic laboratory test described in paragraph (1)(A), an applicable laboratory shall initially be required to report under subsection (a) not later than the last day of the second quarter of the initial period under such paragraph.

(3) Application of market rates after initial period

Subject to paragraph (4), data reported under paragraph (2) shall be used to establish the payment amount for an advanced diagnostic laboratory test after the initial period under paragraph (1)(A) using the methodology described in subsection (b). Such payment amount shall continue to apply until the year following the next data collection period.

(4) Recoupment if actual list charge exceeds market rate

With respect to the initial period described in paragraph (1)(A), if, after such period, the

[1] So in original. Probably should be preceded by ''laboratory''.

Secretary determines that the payment amount for an advanced diagnostic laboratory test under paragraph (1)(A) that was applicable during the period was greater than 130 percent of the payment amount for the test established using the methodology described in subsection (b) that is applicable after such period, the Secretary shall recoup the difference between such payment amounts for tests furnished during such period.

(5) Advanced diagnostic laboratory test defined

In this subsection, the term ''advanced diagnostic laboratory test'' means a clinical diagnostic laboratory test covered under this part that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and meets one of the following criteria:

(A) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result.

(B) The test is cleared or approved by the Food and Drug Administration.

(C) The test meets other similar criteria established by the Secretary.

(e) Coding

(1) Temporary codes for certain new tests

(A) In general

The Secretary shall adopt temporary HCPCS codes to identify new advanced diagnostic laboratory tests (as defined in subsection (d)(5)) and new laboratory tests that are cleared or approved by the Food and Drug Administration.

(B) Duration

(i) In general

Subject to clause (ii), the temporary code shall be effective until a permanent HCPCS code is established (but not to exceed 2 years).

(ii) Exception

The Secretary may extend the temporary code or establish a permanent HCPCS code, as the Secretary determines appropriate.

(2) Existing tests

Not later than January 1, 2016, for each existing advanced diagnostic laboratory test (as so defined) and each existing clinical diagnostic laboratory test that is cleared or approved by the Food and Drug Administration for which payment is made under this part as of April 1, 2014, if such test has not already been assigned a unique HCPCS code, the Secretary shall—

(A) assign a unique HCPCS code for the test; and

(B) publicly report the payment rate for the test.

(3) Establishment of unique identifier for certain tests

For purposes of tracking and monitoring, if a laboratory or a manufacturer requests a unique identifier for an advanced diagnostic laboratory test (as so defined) or a laboratory test that is cleared or approved by the Food and Drug Administration, the Secretary shall utilize a means to uniquely track such test through a mechanism such as a HCPCS code or modifier.

(f) Input from clinicians and technical experts

(1) In general

The Secretary shall consult with an expert outside advisory panel, established by the Secretary not later than July 1, 2015, composed of an appropriate selection of individuals with expertise, which may include molecular pathologists, researchers, and individuals with expertise in laboratory science or health economics, in issues related to clinical diagnostic laboratory tests, which may include the development, validation, performance, and application of such tests, to provide—

(A) input on—

(i) the establishment of payment rates under this section for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test; and

(ii) the factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests; and

(B) recommendations to the Secretary under this section.

(2) Compliance with FACA

The panel shall be subject to the Federal Advisory Committee Act (5 U.S.C. App.).

(3) Continuation of annual meeting

The Secretary shall continue to convene the annual meeting described in section 1395*l*(h)(8)(B)(iii) of this title after the implementation of this section for purposes of receiving comments and recommendations (and data on which the recommendations are based) as described in such section on the establishment of payment amounts under this section.

(g) Coverage

(1) Issuance of coverage policies

(A) In general

A medicare administrative contractor shall only issue a coverage policy with respect to a clinical diagnostic laboratory test in accordance with the process for making a local coverage determination (as defined in section 1395ff(f)(2)(B) of this title), including the appeals and review process for local coverage determinations under part 426 of title 42, Code of Federal Regulations (or successor regulations).

(B) No effect on national coverage determination process

This paragraph shall not apply to the national coverage determination process (as defined in section 1395ff(f)(1)(B) of this title).

(C) Effective date

This paragraph shall apply to coverage policies issued on or after January 1, 2015.

(2) Designation of one or more medicare administrative contractors for clinical diagnostic laboratory tests

The Secretary may designate one or more (not to exceed 4) medicare administrative contractors to either establish coverage policies or establish coverage policies and process claims for payment for clinical diagnostic laboratory tests, as determined appropriate by the Secretary.

(h) Implementation

(1) Implementation

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.

(2) Administration

Chapter 35 of title 44 shall not apply to information collected under this section.

(3) Funding

For purposes of implementing this section, the Secretary shall provide for the transfer, from the Federal Supplementary Medical Insurance Trust Fund under section 1395t of this title, to the Centers for Medicare & Medicaid Services Program Management Account, for each of fiscal years 2014 through 2018, $4,000,000, and for each of fiscal years 2019 through 2023, $3,000,000. Amounts transferred under the preceding sentence shall remain available until expended.

(i) Transitional rule

During the period beginning on April 1, 2014, and ending on December 31, 2016, with respect to advanced diagnostic laboratory tests under this part, the Secretary shall use the methodologies for pricing, coding, and coverage in effect on the day before April 1, 2014, which may include cross-walking or gapfilling methods.

(Aug. 14, 1935, ch. 531, title XVIII, § 1834A, as added Pub. L. 113–93, title II, § 216(a), Apr. 1, 2014, 128 Stat. 1053.)

REFERENCES IN TEXT

The Federal Advisory Committee Act, referred to in subsec. (f)(2), is Pub. L. 92–463, Oct. 6, 1972, 86 Stat. 770, which is set out in the Appendix to Title 5, Government Organization and Employees.

MONITORING OF MEDICARE EXPENDITURES AND IMPLEMENTATION OF NEW PAYMENT SYSTEM FOR LABORATORY TESTS

Pub. L. 113–93, title II, § 216(c)(2), Apr. 1, 2014, 128 Stat. 1061, provided that: ''The Inspector General of the Department of Health and Human Services shall—

''(A) publicly release an annual analysis of the top 25 laboratory tests by expenditures under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.]; and

''(B) conduct analyses the Inspector General determines appropriate with respect to the implementation and effect of the new payment system for laboratory tests under section 1834A of the Social Security Act [42 U.S.C. 1395m–1], as added by subsection (a).''

§ 1395n. Procedure for payment of claims of providers of services

(a) Conditions for payment for services described in section 1395k(a)(2) of this title

Except as provided in subsections (b), (c), and (e), payment for services described in section 1395k(a)(2) of this title furnished an individual may be made only to providers of services which are eligible therefor under section 1395cc(a) of this title, and only if—

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the period ending 1 calendar year after the date of service; and

(2) a physician, or, in the case of services described in subparagraph (A), a physician enrolled under section 1395cc(j) of this title, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations) that—

(A) in the case of home health services (i) such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1395x(m)(7) of this title) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy, (ii) a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician, (iii) such services are or were furnished while the individual is or was under the care of a physician, and (iv) in the case of a certification after January 1, 2010, prior to making such certification the physician must document that the physician, or a nurse practitioner or clinical nurse specialist (as those terms are defined in section 1395x(aa)(5) of this title) who is working in collaboration with the physician in accordance with State law, or a certified nurse-midwife (as defined in section 1395x(gg) of this title) as authorized by State law, or a physician assistant (as defined in section 1395x(aa)(5) of this title) under the supervision of the physician, has had a face-to-face encounter (including through use of telehealth and other than with respect to encounters that are incident to services involved) with the individual during the 6-month period preceding such certification, or other reasonable timeframe as determined by the Secretary;

(B) in the case of medical and other health services, except services described in subparagraphs (B), (C), and (D) of section 1395x(s)(2) of this title, such services are or were medically required;

(C) in the case of outpatient physical therapy services or outpatient occupational therapy services, (i) such services are or were required because the individual needed physical therapy services or occupational

42 C.F.R. § 414.502

Subpart G—Payment for Clinical Diagnostic Laboratory Tests

SOURCE: 71 FR 69786, Dec. 1, 2006, unless otherwise noted.

§ 414.500 Basis and scope.

This subpart implements provisions of 1833(h)(8) of the Act and 1834A of the Act—procedures for determining the basis for, and amount of, payment for a clinical diagnostic laboratory test (CDLT).

[81 FR 41098, June 23, 2016]

§ 414.502 Definitions.

For purposes of this subpart—

Actual list charge means the publicly available rate on the first day the new advanced diagnostic laboratory test (ADLT) is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date.

Advanced diagnostic laboratory test (ADLT) means a clinical diagnostic laboratory test (CDLT) covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the single laboratory that designed the test or a successor owner of that laboratory, and meets one of the following criteria:

(1) The test—

(i) Is an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;

(ii) When combined with an empirically derived algorithm, yields a result that predicts the probability a specific

individual patient will develop a certain condition(s) or respond to a particular therapy(ies);

(iii) Provides new clinical diagnostic information that cannot be obtained from any other test or combination of tests; and

(iv) May include other assays.

(2) The test is cleared or approved by the Food and Drug Administration.

Applicable information, with respect to each CDLT for a data collection period:

(1) Means—

(i) Each private payor rate for which final payment has been made during the data collection period;

(ii) The associated volume of tests performed corresponding to each private payor rate; and

(iii) The specific Healthcare Common Procedure Coding System (HCPCS) code associated with the test.

(2) Does not include information about a test for which payment is made on a capitated basis.

Applicable laboratory means an entity that:

(1) Is a laboratory, as defined in §493.2 of this chapter;

(2) Bills Medicare Part B under its own National Provider Identifier (NPI);

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:

(i) This subpart G.

(ii) Subpart B of this part.

(4) Receives at least $12,500 of its Medicare revenues from this subpart G. Except, for a single laboratory that offers and furnishes an ADLT, this $12,500 threshold—

(i) Does not apply with respect to the ADLTs it offers and furnishes; and

(ii) Applies with respect to all the other CDLTs it furnishes.

Data collection period is the 6 months from January 1 through June 30 during which applicable information is collected and that precedes the data reporting period.

Data reporting period is the 3-month period, January 1 through March 31, during which a reporting entity reports applicable information to CMS and that follows the preceding data collection period.

National Provider Identifier (NPI) means the standard unique health identifier used by health care providers for billing payors, assigned by the National Plan and Provider Enumeration System (NPPES) in 45 CFR part 162.

New advanced diagnostic laboratory test (ADLT) means an ADLT for which payment has not been made under the clinical laboratory fee schedule prior to January 1, 2018.

New ADLT initial period means a period of 3 calendar quarters that begins on the first day of the first full calendar quarter following the later of the date a Medicare Part B coverage determination is made or ADLT status is granted by CMS.

New clinical diagnostic laboratory test (CDLT) means a CDLT that is assigned a new or substantially revised Healthcare Common Procedure Coding System (HCPCS) code, and that does not meet the definition of an ADLT.

New test means any clinical diagnostic laboratory test for which a new or substantially revised Healthcare Common Procedure Coding System Code is assigned on or after January 1, 2005.

Private payor means:

(1) A health insurance issuer, as defined in section 2791(b)(2) of the Public Health Service Act.

(2) A group health plan, as defined in section 2791(a)(1) of the Public Health Service Act.

(3) A Medicare Advantage plan under Medicare Part C, as defined in section 1859(b)(1) of the Act.

(4) A Medicaid managed care organization, as defined in section 1903(m)(1)(A) of the Act.

Private payor rate, with respect to applicable information:

(1) Is the final amount that is paid by a private payor for a CDLT after all private payor price concessions are applied and does not include price concessions applied by a laboratory.

(2) Includes any patient cost sharing amounts, if applicable.

(3) Does not include information about denied payments.

Publicly available rate means the lowest amount charged for an ADLT that is readily accessible in such forums as a company Web site, test registry, or price listing, to anyone seeking to know how much a patient who does not have the benefit of a negotiated rate would pay for the test.

Reporting entity is the entity that reports tax-related information to the Internal Revenue Service (IRS) using its Taxpayer Identification Number (TIN) for its components that are applicable laboratories.

Single laboratory, for purposes of an ADLT, means:

(1) The laboratory, as defined in 42 CFR 493.2, which furnishes the test, and that may also design, offer, or sell the test; and

(2) The following entities, which may design, offer, or sell the test:

(i) The entity that owns the laboratory.

(ii) The entity that is owned by the laboratory.

Specific HCPCS code means a HCPCS code that does not include an unlisted CPT code, as established by the American Medical Association, or a Not Otherwise Classified (NOC) code, as established by the CMS HCPCS Workgroup.

Substantially Revised Healthcare Common Procedure Coding System Code means a code for which there has been a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte specific test).

Successor owner, for purposes of an ADLT, means a single laboratory, that has assumed ownership of the single laboratory that designed the test or of the single laboratory that is a successor owner to the single laboratory that designed the test, through any of the following circumstances:

(1) *Partnership.* The removal, addition, or substitution of a partner, unless the partners expressly agree otherwise, as permitted by applicable State law.

(2) *Unincorporated sole proprietorship.* Transfer of title and property to another party.

(3) *Corporation.* The merger of the single laboratory corporation into another corporation, or the consolidation of two or more corporations, including the single laboratory, resulting in the creation of a new corporation. Transfer of corporate stock or the merger of another corporation into the single laboratory corporation does not constitute change of ownership.

Taxpayer Identification Number (TIN) means a Federal taxpayer identification number or employer identification number as defined by the IRS in 26 CFR 301.6109–1.

[71 FR 69786, Dec. 1, 2006, as amended at 72 FR 66401, Nov. 27, 2007; 81 FR 41098, June 23, 2016]

CERTIFICATE OF SERVICE

On December 4, 2018, I caused a copy of the foregoing document to be served electronically on all registered counsel through the Court's CM/ECF system.

/s/ *Ashley C. Parrish*
Ashley C. Parrish