ORAL ARGUMENT NOT YET SCHEDULED
No. 18-5312

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

AMERICAN CLINICAL LABORATORY ASSOCIATION,

Appellant,

v.

ALEX M. AZAR, II, SECRETARY, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES,

Appellee.

On Appeal from the District Court for the District of Columbia

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BRIEF OF *AMICI CURIAE* THE COLLEGE OF AMERICAN PATHOLOGISTS, THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION, AND THE NATIONAL ASSOCIATION FOR THE SUPPORT OF LONG TERM CARE IN SUPPORT OF APPELLANT AND REVERSAL

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

A. Parties and *Amici*

Except for *amici curiae* the College of American Pathologists ("CAP"), the Advanced Medical Technology Association ("AdvaMed"), and the National Association for the Support of Long Term Care, as well as *amicus curiae* the American Association of Bioanalysts, all parties, intervenors, and *amici* appearing in this Court are listed in the brief for Appellant.

B. Ruling Under Review

References to the ruling at issue appear in the Appellant's brief.

C. Related Cases

Counsel are not aware of any related cases pending in this Court or any other court.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1 and 29(a)(4)(A) and Circuit Rule 26.1, CAP certifies that it is a not-for-profit corporation representing more than 17,000 board-certified pathologists and committed to advocating for sound health policy, particularly as it affects pathologists, the laboratories where they work, and the patients

they serve. CAP is incorporated under the laws of Illinois. It has no parent corporation or publicly traded company with 10% or greater ownership interest.

AdvaMed certifies that it is a trade association, with approximately 300 member companies that develop medical devices, diagnostic tools, and health information systems. AdvaMed has no parent company or publicly traded company with 10% or greater ownership interest.

The National Association for the Support of Long Term Care certifies that it is a trade association that represents providers and suppliers of services to patients in long-term and post acute-care settings. Members include providers of rehabilitation therapy, clinical laboratory services, and portable x-ray services; health information technology developers; and vendors that serve skilled nursing and assisted living providers and other long-term care settings. It has no parent company or publicly traded company with 10% or greater ownership interest.

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GLOSSARY

AdvaMed	The Advanced Medical Technology Association
CAP	The College of American Pathologists
CLFS	The Clinical Laboratory Fee Schedule
CMS	The Centers for Medicare & Medicaid Services
HHS	United States Department of Health and Human Services
HIPAA	Health Insurance Portability and Accountability Act
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

AMICI CURIAE'S STATEMENT OF IDENTITY, INTEREST, AND AUTHORITY TO FILE

CAP is the world's largest medical specialty society of board-certified pathologists—physicians who diagnose and treat patients through laboratory medicine. CAP advocates for sound health policy, particularly as it affects pathologists, the laboratories where they work, and the patients they serve. Through its Laboratory Accreditation Program, CAP plays a prominent role in monitoring the quality of the nation's laboratories. Using pathologist-led teams of laboratory professionals, CAP inspects and accredits more than 8,000 laboratories in the United States.

Most pertinent here, CAP is one of only a few bodies whose accreditation decisions are deemed sufficient by the U.S. Department of Health and Human Services ("HHS") to allow a laboratory to be certified under the Clinical Laboratory Improvement Amendments Act of 1988 ("CLIA"), the federal regulatory regime designed to ensure laboratory quality. 42 U.S.C. § 263a; 42 C.F.R. § 493.1. CLIA certification is a requirement for all U.S. laboratories that test human specimens for health assessment or to diagnose, prevent, or treat disease. A laboratory must be CLIA-certified to receive Medicare or Medicaid reimburse-

ment. For CAP to become an approved accreditation organization, HHS had to find its accreditation standards to be "equal to or more stringent than" those in CLIA. 42 U.S.C. § 263a(e)(2)(A)(ii).

Section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA") calls for a significant change in the manner in which laboratories are reimbursed for the services they provide to Medicare patients. CAP's pathologist members work in many of these laboratories, and CAP inspects and accredits thousands of them. Many of CAP's members serve as medical directors in hospital-based outreach laboratories whose data the Secretary's Final Rule ("Rule") concerning section 216 excluded in calculating a supposedly market-based rate for laboratory tests.

Given CAP's standard-setting responsibilities, the medical expertise of its members, and its first-hand experience monitoring and seeking to improve the nation's laboratories, CAP is concerned that the Secretary's Rule transforms the market-based reimbursement scheme section 216 puts in place. In doing so, the Rule will adversely affect laboratories across the country in a manner Congress neither intended nor authorized.

AdvaMed is the world's largest medical technology association. Its approximately 300 member companies span every field of medical science and range from cutting-edge startups to multinational manufacturers. AdvaMed's member companies are dedicated to advancing clinician and patient access to safe, effective medical technologies in accordance with the highest ethical standards.

AdvaMedDx is an association within AdvaMed, whose member companies produce advanced, innovative in vitro diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early detection of disease, improve population health, and often reduce overall health care costs.

AdvaMed and AdvaMedDx are concerned about regulatory action that gives one segment of the market an unintended advantage over others and about the effect the Secretary's Rule will have on the availability of services and accessibility of innovation in this important healthcare service sector.

The National Association for the Support of Long Term Care represents providers and suppliers of services to patients in long-term care and post-acute care settings. It is concerned that the Rule's data collec-

tion requirements will result in substantial cuts in Medicare payment rates for clinical laboratory services provided to patients in nursing homes, for which the harm is particularly pronounced.[1]

INTRODUCTION

Congress enacted section 216 of PAMA in 2014 to "improv[e] policies for clinical diagnostic laboratory tests." 42 U.S.C. § 1395m-1. The new law replaced an old system in which Medicare reimbursement for clinical laboratories was based on local 1980s rates (the Clinical Laboratory Fee Schedule, or "CLFS") with a new national system designed to reflect continually updated market rates. *See id.* § 1395m-1(a)(3)(A). Key to the new system is the requirement that the Secretary of HHS (the "Secretary") collect comprehensive private payment-rate data from all laboratories that receive the majority of their Medicare revenues from the CLFS or the Physician Fee Schedule (PFS).[2] The statute di-

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[1] Pursuant to Circuit Rule 29(b), undersigned counsel represents that all parties have consented to filing of this brief. No counsel for a party authored this brief in whole or in part, and no person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission. *See* Fed. R. App. P. 29(a)(4)(E).

[2] Services provided to hospital inpatients and outpatients are reimbursed separately based on bundled reimbursement rates that cover other hospital services as well. *See* 42 U.S.C. §§ 1395ww(d), 1395*l*(t), 1395m-1(b)(1)(B). By contrast, hospital laboratories receive payments

rects that laboratories shall submit these reports to the Secretary on a regular basis.

In 2016, the Secretary promulgated a Rule claiming to implement this provision of law. *See* 81 Fed. Reg. 41,036 (June 23, 2016). Yet the Rule does something else entirely. Rather than requiring laboratories to report *their* revenues, as the statute directs, the Rule requires reporting on the revenues of other, *non-laboratory* entities. The end result is a scheme entirely different from—and at odds with—the one Congress designed. And the real-world implications are potentially dramatic. While Congress mandated a system that would be reflective of national market rates for laboratory tests by collecting data from laboratories across the country, the Secretary put in place a rule that excludes reporting from approximately 97% of those laboratories.

The Secretary contends not only that the Rule is consistent with the statute, but also that it is unreviewable by any court. This Court should not accept that dramatic proposition. The statute does not bar

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under the CLFS for "outreach" laboratory services performed on patient specimens typically referred by physicians in the surrounding community. The PFS establishes maximum reimbursement rates under Medicare for physicians and other providers in the fee-for service context—in this instance, pathologists reviewing and interpreting specimens in laboratories.

this Court's review of the Secretary's action; it bars only review of the establishment of payment amounts. Even if the statute's preclusion provision could be read to apply to certain other determinations delegated to the Secretary, the Secretary's action here, which has no basis in the statute, would be subject to judicial review as an *ultra vires* exercise of agency authority.

ARGUMENT

I. The Rule Exceeds the Scope of the Secretary's Authority.

A. The Rule redefines the universe of regulated entities in ways Congress did not permit.

The question at the heart of this litigation is straightforward: whether the Secretary may interpret the phrase "laboratory . . . revenues" to mean "revenues of a laboratory *and other non-laboratory entities*." The Secretary contends that HHS reasonably defined the term "applicable laboratory" in its Rule. Yet the Secretary's so-called "definition" in no way interprets the statutory language. Rather, it casts it aside.

PAMA mandates that "applicable laboratories" report specified payment information to the Secretary every three years. 42 U.S.C. § 1395m-1(a)(1). The Secretary agrees that a "laboratory" is a "facility

for the biological, microbiological, serological, chemical, immuno-hematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings." 42 U.S.C. § 263a(a). Given this well-established definition, which comes from the very same title of the U.S. Code, and is used throughout CLIA,[3] HHS did not even "consider alternative definitions" for purposes of the Rule, as it could find none "that would be appropriate." 81 Fed. Reg. at 41,042.

Section 216 directs a specified class of laboratories to report private payor information to the Secretary. The laboratories covered by the statutory reporting requirement are a subset of all laboratories (*i.e.*, "*applicable* laboratories"). Section 216 states that "'applicable laboratory' means a laboratory that, with respect to *its* revenues under this subchapter, a majority of *such* revenues are from this section, [the CLFS],

[3] As recently as October 17, 2018, the Department of Veterans' Affairs relied, in consultation with HHS, on this same definition of "laboratory" in a proposed rule regarding clinical laboratories. *See* 83 Fed. Reg. 52,345 (Oct. 17, 2018).

or [the PFS]." 42 U.S.C. § 1395m-1(a)(2) (emphasis added).[4] The statute is clear that the revenues to which it refers are the revenues of the *laboratory*. Thus, to the extent that the Secretary purports to interpret this language, he must interpret the phrase "revenues of *the laboratory*."

Since the Secretary has, without controversy, determined what a "laboratory" is, it follows inexorably that the revenues in question must be the revenues of *that* entity—*i.e.*, the laboratory's revenues. But that is not what the Rule does. The revenues the Rule requires laboratories to report are, instead, the revenues of "all component [National Provider Identifier] NPI entities, *and not just those NPI entities that are laboratories*." 81 Fed. Reg. at 41,043 (emphasis added). The Rule provides virtually no explanation of the relevance of an "NPI" in this context. And, indeed, there is none. An NPI is a ten-digit reporting number that identifies a facility for Health Insurance Portability and Ac-

[4] The statute gives the Secretary limited discretion to exempt an additional class of small applicable laboratories from the reporting requirement—namely, those that satisfy "a low volume or low expenditure threshold," which the Secretary is permitted to establish "as [he] determines appropriate." *Id.* The Secretary does not rely upon this exemption authority here.

countability Act (HIPAA) standard transactions.[5] It is irrelevant to whether a medical facility is a laboratory.

In other words, having found that the only "appropriate" definition of a "laboratory" is what one would recognize as a laboratory—namely, a "facility for the . . . other examination of materials derived from the human body"—the Secretary rewrites the statute to change the *subset* of "applicable laboratories" covered by section 216 as both laboratories *and* non-laboratory entities that do not perform laboratory functions.

To be sure, under a different Rule, the Secretary might have argued that certain revenues of parent or affiliated healthcare entities could be viewed as representing the revenues of the laboratory itself. Certainly, *some* of a hospital's revenues, for instance, could be reasonably attributed to laboratory operations. But that is not what the Rule

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[5] Health care providers that "transmit[] any health information in electronic form in connection with a [HIPAA standard] transaction," 45 C.F.R. § 160.102 must obtain NPIs. 45 C.F.R. § 162.410(a). A health care provider can have a single NPI or apply for its subparts (*i.e.*, departments, laboratories, pharmacies, or different branches that operate as part of the organization) to have their own NPIs. *See* CMS, *NPI: What You Need To Know* 4 (Dec. 2016), https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/Downloads/NPI-What-You-Need-To-Know.pdf.

does. The test the Rule establishes does not identify *which* of the hospital's revenues are the revenues of the laboratory. Nor does the Secretary claim it does. Instead, the Secretary claims that doing so would be challenging. Azar Br. Summ. J. 38–39, *Am. Clinical Lab. Ass'n v. Azar*, No. 17-2645, 2018 WL 1870679 (D.D.C. Mar. 23, 2018). But challenge is no excuse for non-compliance with a statutory directive. *Cf. Comcast Corp. v. FCC*, 579 F.3d 1, 7 (D.C. Cir. 2009).

Furthermore, the Secretary makes almost no effort in the Rule—or in the briefing below—to provide any substantive reason to believe that the revenues of non-laboratory entities that share the same NPI *should* be viewed as representing the revenue of the laboratory itself.[6] The Secretary notes that "[h]ealth care providers, which include laboratories that transmit any health information in electronic form in connection with a HIPAA transaction for which the Secretary has adopted a standard, are required to obtain NPIs and use them according to the NPI regulations." 81 Fed. Reg. at 41,042. But the Secretary provides no reason to believe that the revenues of all of the entities associated

[6] Nor could he, considering that the plain meaning of laboratory revenues means funds resulting from laboratory services, irrespective of the NPI.

with one NPI should be viewed as, in any meaningful way, a proxy for, or estimation of, the revenues of *the laboratory* that may be one of the entities covered by the NPI.

The end result is that the Rule, far from interpreting statutory language, adds new criteria to limit the scope of the entities who are subject to PAMA's reporting requirement—criteria that are found nowhere in the statute and that do not even derive from it. *See Cent. United Life Ins. v. Burwell*, 827 F.3d 70, 73 (D.C. Cir. 2016) ("Nothing in the [statute] suggests Congress left any leeway for HHS to tack on additional criteria."). The Rule does so in a manner that is both unrelated to any discretion the statute affords the Secretary and *facially inconsistent* with the Secretary's own definition of what it means to be a "laboratory." Having defined a "laboratory" as being a laboratory in the ordinary sense of the word, the term "applicable laboratory" must be a subset or type of laboratory, not another animal entirely—as the Secretary would have this Court find.

B. The Secretary's Rule is contrary not only to the plain language of PAMA, but also the legislation's clear intent.

The Rule's definition of "applicable laboratory" is inconsistent not only with the text of section 216(a) but also with the broader statutory scheme.

Prior to PAMA, the Medicare reimbursement methodology for clinical laboratory tests under the CLFS had been largely unchanged since it was established in 1984. Those rates were based on a per-jurisdiction assessment of historical charges for laboratory tests, adjusted for inflation.[7] PAMA set about to replace this system with one based on market-based information, computed nationally and continually updated. This change recognized the diversity and dynamism of the clinical laboratory market, in which a variety of types of laboratories offer an array of testing capabilities to different populations. More than 250,000 HHS-regulated laboratories operate across the United States in a variety of clinical settings—including in hospitals, independent settings,

[7] *See* HHS OIG, *Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data* 2 (Sept. 2016), https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf.

physicians' offices, ambulances, nursing homes, etc.[8] New types of tests, and demand for testing, are evolving rapidly. U.S. laboratories perform billions of tests each year in response to increased demand driven by improvements in diagnostic technology (which can reduce the need for surgical and other invasive procedures), an aging population, patient-driven demands, and increased focus on preventive services, monitoring, and diagnosis.[9]

PAMA's section 216 reporting requirement was designed to capture real-world, private-market data from laboratories across the United States to ensure that Medicare rates appropriately reflect that diverse market. Congress established a detailed data reporting scheme to capture this information. Within that scheme, it gave the Secretary

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[8] *See* CMS, *CLIA Update – July 2018, Laboratories by Type of Facility* ("CMS, Laboratories by Type"), https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/factype.pdf (last visited Dec. 5, 2018).

[9] *See* Jack Curran, *IBISWorld Industry Report 62151: Diagnostic & Medical Laboratories in the US* 16 (June 2017); Washington G-2 Reports, *Lab Industry Strategic Outlook: Market Trends & Analysis 2009* 12 (Jan. 2009); Kalorama Info., *Clinical Laboratory Services Market* 149, 162-63 (Mar. 2017) ("New technologies in testing will likely continue to fuel growth in combination with an aging population, increasing disease incidence and prevalence, a focus on prevention and early detection, and new trends in personalized medicine.").

discretion to set "parameters for data collection" through notice and comment rulemaking. 42 U.S.C. § 1395m-1(a)(12).

Further, the statute specifies the tasks the Secretary shall accomplish through this rulemaking. For instance, and as noted above, the Secretary has discretion to "establish a low volume or low expenditure threshold for excluding" certain "applicable laboratories." *Id.* § 1395m-1(a)(2). The Secretary shall "specif[y]" the time at which applicable laboratories shall report required information. *Id.* § 1395m-1(a)(1); *id.* § 1395m-1(a)(4). The Secretary may aggregate reporting in certain cases. *Id.* § 1395m-1(a)(6). The statute, in other words, is clear about which "parameters for data collection" are committed to the Secretary's discretion. Redefining the term "applicable laboratory"— which the statute itself defines—is not one of them.

The reporting scheme the Act creates is important to the operation of the system for Medicare reimbursement that PAMA implements. It is so important, in fact, that reporting by applicable laboratories is not only mandatory, it is backed up with significant penalties. Should the laboratories fail to report as required, the Secretary can apply civil monetary penalties of up to $10,000 per day. *Id.* § 1395m-1(a)(9).

Against this backdrop, and particularly given the specificity with which Congress determined which data-collection-related tasks are delegated to the Secretary and how, the Secretary's claim that he can exclude reporting from approximately 97% of laboratories strains credulity. Fewer than 2,000 laboratories reported under the Secretary's Rule, as compared to 58,593 laboratories Medicare Part B reimbursed in 2016.[10] Under the new Rule, *only 21 hospital laboratories* determined themselves to be "applicable laboratories" under the Secretary's definition.[11] Independent laboratories accounted for 90% of the test volume during the first reporting period. To put these numbers in context, according to 2017 data, hospital laboratories accounted for 48.2% of labor-

[10] *See* CMS, *Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System* 3 (Sept. 22, 2017) ("CMS, Summary of Data Reporting"), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf; HHS OIG, *Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data* (Sept. 2017), https://oig.hhs.gov/oei/reports/oei-09-17-00140.pdf.

[11] CMS, *Summary of Data Reporting* at 3.

atory market share by test volume, while independent laboratories accounted for 29.5%.[12]

The downstream effect of this skewed reporting on the laboratories that should have been included is profound. The diversity of clinical laboratories means that they receive different rates for laboratory tests from private payors. Private payors typically pay hospital labs, for instance, at higher rates than large national independent laboratory chains. Those independent laboratories, which account for the greater part of reporting under the Secretary's Rule, are able to accept lower third-party payor reimbursement rates than other laboratories because their costs are generally lower due to their economies of scale and purchasing power.[13] Hospitals, on the other hand, serve inpatients and

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[12] *Hospital Labs Still Dominate In Volume Testing*, Laboratory Economics 5 (June 2017).

[13] *See* Julie Wolcott et al., The Lewin Grp., *Laboratory Medicine: A National Status Report* 77 (May 2008) ("[s]everal factors have contributed to the competitive advantages of the large [laboratory] corporations: national managed care contracts; efficient, centralized billing management; lower supply costs; extensive high complexity testing capabilities; and the ability to invest in Web-based systems. . . . Given their test volume, large laboratories are able to negotiate more favorable contracts with reagent and supply vendors, sometimes at costs 30 to 50% less than those paid by hospitals and smaller independent laboratories.").

outpatients who have immediate needs during hospital visits, may offer around-the-clock services, and frequently provide the most complex clinical laboratory tests.[14] They offer more facilities for patients across the United States than independent laboratories.[15] The majority of hospital laboratories conduct so-called "outreach testing," whereby they "serv[e] as the reference laboratory for others in the community with limited testing capabilities" by performing laboratory testing for individuals who are not hospital patients.[16] By effectively filtering out data from hospital laboratories that report under an NPI associated with the rest of the hospital, and including predominately independent laboratories like Quest Diagnostics and LabCorp, the Secretary has all but ensured that all laboratories will receive lower Medicare reimbursement rates than they otherwise would have. And that, in turn, will threaten the

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[14] *See* Mario Plebani, *Clinical Laboratories: Production Industry or Medical Services?*, Clinical Chem. Lab. Med. 995, 1000 (2015); Curran, *supra* 18.

[15] *See* CMS, Laboratories by Type, *supra*.

[16] *See* Wolcott, *supra* 70–71; Valerie Neff Newitt, *Market Based? A View of PAMA Process, Pricing* 6, CAP Today (Sept. 2017) ("More than 9,000 hospitals in the U.S., about 80 percent of which provide outreach services, produce more than half of the laboratory tests performed in the U.S. Half of this is inpatient; half is outreach and outpatient." (internal quotation marks omitted)).

existence of certain laboratories, particularly in settings where costs are higher, including in rural markets, nursing facilities, and hospitals.[17]

Though the statute speaks for itself, Members of Congress have also spoken clearly about section 216's purpose. Senators Burr and Hatch are on the record stating that "the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services, and as such, that all sectors of the laboratory market should be represented in the reporting system."[18] A bipartisan group of forty-four Members of Congress affirmed the same understanding of section 216 in a letter to the Acting Administrator of the Centers for Medicare and Medicaid Services.[19] These Members explained that "[t]he goal of this new reporting system is to develop a market-based reimbursement sys-

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[17] As Appellant notes, HHS now belatedly seeks to blunt the effects of its extra-statutory rule. *See* Ap. Br. at 27. In a Rule released on November 1, 2018, the Department acknowledges the objective "to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment amounts" so that the weighted median the statute requires "appropriately reflects the private market rate for a CDLT." 83 Fed. Reg. 59,452, 59,668 (Nov. 23, 2018). In its new rule, the Secretary seeks to achieve this objective by redefining what costs are properly included as "Medicare" revenues under section 216 of the Act. *See id.*

[18] 160 Cong. Rec. S2860 (daily ed. May 8, 2014).

[19] Letter of Bill Pascrell, Jr., Member of Congress, et al. to Andy Slavitt, Acting Administrator of CMS (Dec. 16, 2015).

tem to replace the current fee schedule. Clinical laboratories ranging from community independent laboratories, physician office laboratories, hospital-based laboratories, national laboratories, and other laboratories would report private market data, and [the Secretary] would calculate median rates so that Medicare rates could be reset based on a true picture of the laboratory market."[20] Yet it is precisely this "true picture" that the Secretary's Rule distorts by excluding the majority of the nation's laboratories on the basis of criteria at odds with the statute's text and purpose.

II. The Secretary's Action Is Not Shielded From Judicial Review.

Having reworked the statute, the Secretary now claims that his action is unreviewable in light of a provision in another subsection of the statute that says that "[t]here shall be no administrative or judicial review . . . of the establishment of payment amounts under this section." 42 U.S.C. § 1395m-1(h). This argument fails. First, the language of this provision is limited to the Secretary's "establishment of payment amounts," not his notice-and-comment rulemaking authority to set "parameters for data collection." *Id.* § 1395m-1(a)(12). Second, regardless

[20] *Id.* at 1.

whether Section 216(h) can be read to apply to certain other determinations the statute delegates to the Secretary, this Court's review would not be foreclosed here given that the Secretary's action was not authorized by the statute.

A. PAMA does not restrict this Court's review of the Secretary's action.

Courts carefully scrutinize assertions that Congress has restricted judicial review of governmental action. Given the principles at hand, which go to the core of our system of governmental checks and balances, courts apply a "strong presumption" against preclusion. *Dart v. United States*, 848 F.2d 217, 221 (D.C. Cir. 1988). Thus, the burden lies with the Secretary to point to "specific language, specific legislative history, and inferences of intent drawn from the statutory scheme as a whole" that Congress intended to bar review. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) (internal quotations and citation omitted). Indeed, even when a "statute is reasonably susceptible to divergent interpretation, [courts] adopt the reading that accords with traditional understandings and basic principles: that executive determinations generally are subject to judicial review." *Gutierrez de Martinez v. Lamagno,* 515 U.S. 417, 434 (1995).

This strong presumption is heightened in cases like this one, where the issue concerns a pure matter of statutory interpretation—the type of matter in which this Court is expert—rather than a fact-specific determination in an individual case that is delegated by statute to the agency's expert discretion. *See Ralpho v. Bell*, 569 F.2d 607, 622–23 (D.C. Cir. 1977) ("courts have assumed it less likely that Congress intended to prohibit review of a claim that the activities of an agency are facially invalid"); *cf. Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. v. Brock*, 783 F.2d 237, 245 (D.C. Cir. 1986) ("[W]hen a legal challenge focuses on an announcement of a substantive statutory interpretation, courts are emphatically qualified to decide whether an agency has acted outside of the bounds of reason").

In this case, unlike others in which courts have found preclusion of judicial review, the language Congress crafted to exempt certain of the Secretary's actions from review is specific. It applies not to "any question of law or fact," for example, *Kirkhuff v. Nimmo*, 683 F.2d 544, 546 (D.C. Cir. 1977), or to any matter under section 216, but instead only to "the establishment of payment amounts" under section 216. 42 U.S.C. § 1395m-1(h)(1). Congress did not regard the Secretary's rule-

making under section 216(a)(12) to be rulemaking to "establish[] . . . payment amounts." The statute says as much. Section 216(a)(12) explains that rulemaking is required to "establish . . . *parameters for data collection* under . . . subsection" (a). *Id.* § 1395m-1(a)(12) (emphasis added).

In addition, section 216(a)(12) directs the Secretary to promulgate rules that are specifically directed to the data reporting in subsection 216(a) and to do so no later than one year in advance of the first reporting deadline, and therefore long before payment amounts are established. The fact that Congress directs the Secretary to undertake this action through notice-and-comment rulemaking is further evidence of Congress's intent that these rules be handled pursuant to Administrative Procedure Act procedures, under which "judicial scrutiny of the broadest gauge" applies, *Ralpho*, 569 F.2d at 617. Indeed, it would have been particularly odd for Congress to direct that the Secretary proceed through notice-and-comment rulemaking, thereby making clear that the rules regarding data reporting *in particular* should be subject to stakeholder scrutiny and comment, only then to preclude *any* judicial review

of these rules (rules setting "parameters for data collection") under the rubric of "payment amounts."

The distinction between the setting of specific payment amounts and the formulation of general rules for the data reporting requirements is elucidated by Supreme Court precedent. In *Bowen v. Michigan Academy of Family Physicians*, the Court held that the challenge to Medicare Part B regulations was not foreclosed by a provision limiting review of "any determination . . . of . . . the amount of benefits under part A." 476 U.S. 667, 674 (1986). Specifically, the Court stated that this language "simply does not speak to challenges mounted against the *method* by which such amounts are to be determined rather than the *determinations* themselves." *Id.* "As a result, an attack on the validity of a regulation is not . . . an 'amount determination' which decides 'the amount of the Medicare payment to be made on a particular claim.'" *Id.* at 676-77. The same is true here.

In reaching the opposite conclusion, the court below relied on *Florida Health Sciences Center v. Secretary of Health and Human Services*, 830 F.3d 515 (D.C. Cir. 2016), finding that case to be "comparable." *See Am. Clinical Lab. Ass'n v. Azar*, --- F. Supp. 3d ---, No. 17-2645, 2018

WL 4539681, at *6 (D.D.C. Sept. 21, 2018). Yet this Court in *Florida Health* was careful to note that the plaintiff "ha[d] not brought a challenge to any general rules leading to the Secretary's estimate." 830 F.3d at 522. Moreover, the statute in *Florida Health*, unlike here, directed the reader to the very paragraph that directed the Secretary to select the data in question, and gave her absolute discretion in so doing. *See* 42 U.S.C. § 1395ww(r)(2)(C). Here, by contrast, the statute: separates parameters for data collection from the establishment of payment amounts; directs the Secretary what data to collect; mandates notice-and-comment rulemaking for the data collection parameters; and establishes a bar on judicial review that refers to payment *amounts*. *See generally* 42 U.S.C. § 1395m-1. Reading *Florida Health* to stand for the proposition that any steps precedent or inputs to a determination must be shielded from review if Congress has limited review of the ultimate determination would read far too much into the case and turn the presumption favoring judicial review on its head.

B. The Secretary's action is *ultra vires*.

This Court's review is not foreclosed for the further reason that the Secretary acted outside the scope of his authority. A provision pre-

cluding judicial review does "not apply to shield the Secretary's unauthorized action." *Amgen Inc. v. Smith*, 357 F.3d 103, 114 (D.C. Cir. 2004). Indeed, "[i]f the Secretary is not so authorized, even a procedurally proper and reasonably explained decision would be contrary to law because it would be *ultra vires*." *Id.* Article III courts have a particular role to play in determining whether an agency has acted in excess of its delegated authorities. *See Dart*, 848 F.2d at 223. "When an executive acts *ultra vires*, courts are normally available to reestablish the limits on his authority." *Id.* at 224.

This principle is particularly important in cases like this one, where it appears the Department would have this Court preclude *any* judicial or administrative review of its implementation of the statute. Finding that the judiciary is barred from any and all judicial oversight of the Secretary's implementation of PAMA would not only dramatically over-read Congress's preclusion of review of "payment amounts," it would amount to a "standing invitation [to the Department] to disregard statutory requirements and to exceed powers conferred," *Ralpho*, 569 F.2d at 617. *See Bd. of Governors v. MCorp Fin., Inc.*, 502 U.S. 32, 43 (1991) ("[C]entral to our decision in [*Leedom v. Kyne*, 358 U.S. 184

(1958)] was the fact that the Board's interpretation of the Act would wholly deprive the union of a meaningful and adequate means of vindicating its statutory rights.").

This prospect is particularly troubling given the direct impact this regulation has on laboratories. The district court below stated that the rule "does not constitute regulation of the laboratories' 'primary conduct,'" relying on *National Park Hospital Ass'n v. Department of Interior*, 538 U.S. 803 (2003). *Am. Clinical Lab. Ass'n*, 2018 WL 4539681, at *7. But *National Park* points, if anything, to the opposite conclusion. The Court in that case observed that the regulation there "do[es] not command anyone to do anything or to refrain from doing anything; . . . [it] do[es] not subject anyone to any civil or criminal liability; [and it] create[s] no legal rights or obligations." *Id.* at 809 (some alterations in original; internal quotation marks omitted). Not so here. Thus, as the Supreme Court has recognized, this is "a situation in which primary conduct is affected"—a situation in which "special records [must be] compiled" and submitted to the Department on pain of financial penalties. *Toilet Goods Ass'n v. Gardener*, 387 U.S. 158, 164 (1967). Finding that the Secretary's plainly erroneous and unauthorized implementa-

tion of the statute is unreviewable would leave laboratories bound by an ongoing reporting requirement without recourse to challenge its legality.[21]

This Court's decision in *Southwest Airlines v. TSA*, 554 F.3d 1065 (D.C. Cir. 2009) is instructive. The statute at issue in that case, which included a jurisdiction-stripping provision, stated that TSA could charge airlines fees that were capped based on an amount airlines paid "for screening passengers and property." *Id.* at 1068. The TSA included in its calculations costs for *non*-passengers as well as passengers. This Court invalidated the fee determinations, notwithstanding the jurisdiction-stripping provision, stating that the jurisdiction-stripping provision "mean[s] simply that 'the courts may not review the [government's] actions *where the [government] has acted within the scope of its authority*' under the controlling statute." *Id.* at 1071 (quoting *COMSAT Corp. v. FCC*, 114 F.3d 223 (D.C. Cir. 1997) (emphasis added)). Where the government had not acted within the scope of such authority, "the jurisdic-

[21] Additionally, exhaustion requirements are inapplicable to purely legal questions such as those here where the question is one of the agency's statutory authority, and is "strictly a legal issue" in which "[n]o factual development or application of agency expertise will aid the court's decision." *See Athlone Indus. v. Consumer Prod. Safety Comm'n*, 707 F.2d 1485, 1489 (D.C. Cir. 1983).

tion-stripping provision does not apply." *Id.* The same analysis this Court applied in *Southwest Airlines* applies here. Here, as in *Southwest Airlines*, the relevant test is "whether [the government] has made the kind of determination required by the statute." *Id.* at 1071. And here, as in *Southwest Airlines*, the government cannot read the term "majority of [the laboratory's] revenues" to mean "majority of [the laboratory's and non-laboratory entities'] revenues." "Passenger" cannot mean "and non-passengers"; "laboratory" cannot mean "and non-laboratories."

The Secretary's *ultra vires* action cannot stand.

CONCLUSION

For the foregoing reasons, this Court should reverse the judgment below.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), I hereby certify that:

1. This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 29(a)(5) and 32(a)(7)(B) because it contains 6,376 words, excluding material exempted by Rule 32(f).

2. This brief complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6), because it has been prepared in proportionally spaced typeface using Microsoft Word 2016 in 14-point Century Schoolbook type.

December 11, 2018 /s/ *David W. McAloon*

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CERTIFICATE OF SERVICE

I hereby certify that on this 11th day of December, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF System, which will send notice of such filing to all registered CM/ECF users.

/s/ *David W. McAloon*

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