IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION,
1100 New York Avenue, N.W., Suite 725W
Washington, D.C. 20005

Plaintiff,

v.

ALEX M. AZAR,
In His Official Capacity as Secretary of Health and Human Services,
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Defendant.

Civil Action No. 17-2645 (EGS)

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Plaintiff American Clinical Laboratory Association hereby moves for summary judgment in its favor on the claims asserted in its Complaint for the reasons explained in the accompanying Memorandum of Points and Authorities in Support of Plaintiff's Motion for Summary Judgment. There are no disputed issues of material fact. The administrative record demonstrates that the final rule of Defendant Alex M. Azar, acting in his official capacity as Secretary of Health and Human Services, as set forth in *Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; Final Rule*, 81 Fed. Reg. 41,036 (June 23, 2016); *see also* 42 C.F.R. § 414.502, is impermissible and an unreasonable failure to comply with an unambiguous statutory directive; ultra vires agency action; and an unlawful, arbitrary, and capricious exercise of the Secretary's authority.

WHEREFORE, and as set forth more fully in the accompanying memorandum, summary judgment for Plaintiff is warranted under the Administrative Procedure Act, 5 U.S.C. § 706 and the Social Security Act, 42 U.S.C. § 1395m-1.

Respectfully submitted,

Dated: February 14, 2018

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MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
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INTRODUCTION AND SUMMARY OF ARGUMENT

This action seeks to prevent significant disruptions to the nation's health care system by correcting the Secretary of Health and Human Service's refusal to comply with an unambiguous directive by Congress. If the Secretary's statutory violation is not corrected, it will ultimately lead to the scaling back of services and, in some instances, the shuttering of clinical diagnostic laboratories that, especially in remote and rural areas, are the only source of critical diagnostic services for numerous elderly and disabled Medicare beneficiaries.

In 2014, Congress enacted section 216 of the Protecting Access to Medicare Act ("PAMA") to modernize the Medicare program by ensuring that the Medicare reimbursement provided to clinical diagnostic laboratories more closely reflects the payments that laboratories receive in the commercial market. *See* Pub. L. No. 113-93, § 216, 128 Stat. 1040, 10552 (2014), codified at 42 U.S.C. § 1395m-1. One of PAMA's central features is a congressional mandate that the Secretary collect information from all "applicable laboratories" regarding the private-sector payments they receive. The statute defines "applicable laboratory" broadly to include any laboratory that obtains a majority of its Medicare revenues from fee schedules used to reimburse laboratories for testing services provided to beneficiaries who are not registered hospital patients. *See* 42 U.S.C. § 1395m-1(a)(2). As the Secretary has acknowledged, Congress designed the statute to require the Secretary to collect private-sector information from all significant participants in the laboratory market. A major component of that market is the thousands of hospital laboratories that, in addition to serving hospital patients, compete with other laboratories to provide services on an outreach basis to non-hospital patients.

In implementing his data-collection obligations, the Secretary promulgated a final rule that unlawfully rewrites the definition of "applicable laboratory" and contradicts Congress's

express instructions. The Secretary's final rule requires that to qualify as an "applicable laboratory," the laboratory must bill the Medicare program under its own National Provider Identifier ("NPI"). 42 C.F.R. § 414.502(b). As the Secretary has acknowledged, that requirement excludes virtually all hospital laboratories from the data-reporting obligations that Congress imposed, because most hospital laboratories do not have their own NPI — instead, they bill Medicare for laboratory services under the NPI used by the hospital as whole. The Secretary's final rule also effectively reads the "majority of" Medicare revenues requirement out of the statute, exempting hospital laboratories from their statutory reporting obligations, even when a majority of their Medicare revenues are from the fee schedules that Congress specified.

This rewrite of the definition of "applicable laboratory" — excluding by executive fiat an entire category of market participants from the data-reporting requirements — violates the statute and dramatically undermines the purpose of Congress's mandate that the Secretary collect private-sector information. In 2016, hospital laboratories received approximately 26 percent of the payments made under Medicare for providing laboratory services to non-hospital patients. But out of the approximately 7,000 hospital laboratories that billed Medicare for services provided to non-hospital patients, no more than 21 reported information to the Secretary — less than half of one percent of all hospital laboratories in the country. Because hospital laboratories often receive higher private-sector payments for the testing services they provide — as much as 1.5 to 4 times higher than the rates paid to large independent laboratories — the Secretary's final rule ensures that, contrary to Congress's intent, the information collected by the Secretary does not reflect the private-sector market as a whole.

The Secretary's final rule should be vacated for at least three reasons.

First, the final rule is contrary to and cannot be reconciled with the plain statutory requirements. Indeed, the rule is such a clear violation of Congress's unequivocal commands and so exceeds the express limits that Congress imposed on the Secretary's authority, it should be struck down as *ultra vires*.

Second, the final rule is unreasonable. The Secretary's attempt to rewrite the statute to exempt hospital laboratories from the reporting requirements is inconsistent with the statute's design, structure, and purpose.

Third, the final rule is arbitrary and capricious. The Secretary's only reason for exempting hospital laboratories from their statutory reporting obligations — the purported administrative challenges of determining which hospital laboratories meet the statutory requirements — cannot justify his failure to comply with the statute that Congress enacted. The Secretary has also failed to respond meaningfully to comments, brushing off with no reasoned explanation both serious objections to his approach and proposed alternatives that would have complied with Congress's directives.

If the Secretary's statutory violation is not corrected, the consequences will be severe. Because the data-collection parameters imposed by the final rule are destined to lead to the Secretary establishing payment rates that are far below private-sector rates, some laboratories will be forced out of business, others will be forced to scale back essential services, and patients will be deprived of the services they need. Instead of modernizing the Medicare program to better reflect the private sector market, as Congress intended, the Secretary's statutory rewrite has put his own parochial interests ahead of the program and subverted Congress's reforms. None of this should be allowed to occur. Instead, the Court should enforce the statute as written and strike down the Secretary's final rule.

STATEMENT OF FACTS

A. Statutory Background

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. They range from routine blood tests to ground-breaking genetic and molecular tests. The laboratories that perform these tests play a vital role in the nation's health care system. They include laboratories connected to hospitals, laboratories located in physician offices, and independent laboratories, which (as their name suggests) are not affiliated with any other health care provider.

The Medicare Program. Through the federal Medicare program, the Centers for Medicare & Medicaid Services ("CMS") is the nation's largest purchaser of clinical laboratory services. Part B of the Medicare program reimburses laboratories for services provided to eligible elderly and disabled persons. *See* 42 U.S.C. § 1395k(a)(1); 42 U.S.C. § 1395x(s). To be entitled to reimbursement, a laboratory must comply with a strict set of regulatory requirements. Part B "pays for covered diagnostic laboratory services" only when they are provided by a laboratory that "meets the applicable requirements" of the regulations implementing the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"). *See* 42 C.F.R. § 410.32(d)(1)(v); *see also* Pub. L. No. 100-578, 102 Stat. 2903 (1988), codified at 42 U.S.C. § 263a.

Medicare beneficiaries, like privately insured patients, may receive clinical diagnostic laboratory services in a variety of contexts. A beneficiary will sometimes need tests performed when he or she is a registered patient of a hospital, either as an inpatient who has been formally admitted to the hospital for an overnight stay or as an outpatient who has not been formally admitted but is nonetheless receiving services through the hospital (for example, in an emergency department). Some beneficiaries have tests performed as part of services they receive

as residents of skilled nursing facilities. The more familiar context, however, is when a beneficiary who is not a registered hospital patient visits a doctor and is told to have tests performed as part of a course of treatment. In those situations, unless the doctor's office has an on-site laboratory, the beneficiary will typically go to a local laboratory — either an independent laboratory or a hospital laboratory that is providing outreach services to the community — to have the tests performed.

For payment purposes, the Medicare program has long distinguished between the different contexts in which beneficiaries receive laboratory testing services. When a beneficiary visits a local laboratory for services ordered by her doctor and is not a hospital patient, the Medicare program makes a separate payment for each test the beneficiary receives on a fee-for-service basis under either the Clinical Laboratory Fee Schedule or the Physician Fee Schedule. *See* 42 U.S.C. § 1395*l*(h)(1)(B).[1] Both independent laboratories and hospital laboratories providing outreach services are paid in this way. In contrast, when a hospital laboratory performs tests for a registered hospital patient, payment is ordinarily bundled into a lump-sum payment for all the services provided and billed by the hospital as a whole, 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); 42 U.S.C. § 1395*l*(t). This bundled payment covers the services provided by the laboratory as well as the other services provided by other components of the hospital that are billed to the Medicare

[1] In requesting reimbursement for laboratory services under the Clinical Laboratory Fee Schedule or the Physicians Fee Schedule, providers use standardized paper forms or electronic file formats. These forms or files report various required elements of data, including the Healthcare Common Procedure Coding System ("HCPCS") code, for each service. For most laboratory tests, the appropriate HCPCS code is a five-digit number in the range 80000 through the 89000s.

program, such as radiology services, operating room services, pharmacy services, and room and board.

Services reimbursed on a fee-for-service basis under the Clinical Laboratory Fee Schedule and Physician Fee Schedule are a large segment of the market, with hospital laboratories that provide outreach services competing directly with independent laboratories and other laboratories. *See, e.g.*, Medicare Claims Processing Manual (Pub. No. 100-04), Ch. 16, § 10 ("[w]hen a hospital performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory"). In 2016, hospital laboratories received approximately 26 percent of the payments made under Medicare's 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"). By comparison, independent laboratories and physician office laboratories received approximately 55 percent and 18 percent, respectively, of the payments made under the Clinical Laboratory Fee Schedule. *Id.*

Before PAMA, clinical laboratory services provided on a fee-for-service basis to non-hospital patients were reimbursed at 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*(a)(1)(D)(i)(I); *see also* 42 U.S.C. §§ 1395*l*(h)(1)(B)–(C), (h)(4)(B). This system, which Congress established in 1984, *see* Deficit Reduction Act of 1984, Pub. L. No. 98-369, § 2303(d), 98 Stat. 494, 1064 (1984), was criticized because it imposed arbitrary differences in reimbursement amounts. By 2007, 56 carrier localities existed and, as a result, any given laboratory test could have multiple different payment

amounts on the Clinical Laboratory Fee Schedule depending on where the test was performed. *See* 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. In a 2007 study, the government found that variations in reimbursement amounts were not tied to geographic differences in wage costs or other factors, *id.* at 9, and "may . . . not have reflected real differences in cost," *id.* at 11.

Congress addressed these concerns in 2014 when it enacted Section 216 of PAMA. PAMA imposed new requirements on both the Secretary and laboratories with the objective of reforming the reimbursement system to be more uniform and consistent with the private sector. *See* PAMA § 216, amending 42 U.S.C. § 1395m-1. Section 216's central feature is its data-reporting provisions, which require laboratories to report and the Secretary to collect private-sector pricing information for clinical laboratory tests from all "applicable laboratories." In advance of collecting the information, the statute requires the Secretary to engage in notice-and-comment rulemaking. The statute separately directs the Secretary to take the collected market information and, through a separate process set out in the statute, use the data to establish new market-based rates under the Clinical Laboratory Fee Schedule.

PAMA's Data-Reporting Requirements. Section 216(a) requires "applicable laboratories" to report "applicable information" to the Secretary and for the Secretary to collect that information within a defined "data collection period." 42 U.S.C § 1395m-1(a)(1). In crafting this provision, Congress wanted to ensure that the Secretary collected information from laboratories that provide diagnostic services to beneficiaries who are not registered hospital patients and receive payment for those services under a fee schedule. Congress defined

"applicable laboratory" broadly to include any laboratory that receives a "majority of" its Medicare revenues from the Clinical Laboratory Fee Schedule or the Physician Fee Schedule:

> 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.

42 U.S.C. § 1395m-1(a)(2); *see id*. § 1395*l*(h) (establishing the Clinical Laboratory Fee Schedule); *id*. § 1395w-4 (establishing the Physician Fee Schedule).[2]

In enacting this data-reporting provision, Congress intended 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 Senator Richard Burr, affirmed by Senator Orrin Hatch). If Congress had wanted to impose reporting obligations on only independent laboratories, it would not have needed to include a "majority of" revenues requirement. As a practical matter, not just a majority but virtually all of an independent laboratory's Medicare revenues are paid on a fee-for-service basis under either the Clinical Laboratory Fee Schedule or the Physician Fee Schedule. A key purpose behind the revenues requirement is therefore to distinguish between, on one hand, hospital laboratories that earn a majority of their Medicare revenues from the hospital side of their business, where they furnish services to registered hospital patients and, on the other hand, hospital laboratories that earn a

[2] The reference to "this section" in PAMA's definition of "applicable laboratory" indicates that, for purposes of future data reporting, payments received by laboratories under the PAMA pricing scheme are to be included in calculations of the "majority of . . . revenues" test along with revenues under the Clinical Laboratory Fee Schedule and Physician Fee Schedule. Because PAMA pricing has only just been implemented, PAMA revenues to date have not impacted laboratories' "majority of . . . revenues" calculations. For simplicity's sake, this brief refers to revenues under the Clinical Laboratory Fee Schedule and Physician Fee Schedule without repeated references to PAMA revenues.

majority of their Medicare revenues from the outreach side of their business, where they compete with independent laboratories to provide testing services to beneficiaries that are not hospital patients.

Congress granted the Secretary only narrow authority to exempt certain laboratories from the statutory reporting requirements. Specifically, Congress permitted the Secretary to "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." 42 U.S.C. § 1395m-1(a)(2). Apart from this narrow exception, Congress gave the Secretary no discretion to excuse applicable laboratories from complying with the statute's data-reporting requirements. Instead, PAMA reflects Congress's intent that the Secretary would collect data from all applicable laboratories and ensure "complete reporting." *Id.* § 1395m-1(a)(6). Congress specified that laboratories would be required to "certify the accuracy and completeness of the information reported" under the statute. *Id*. § 1395m-1(a)(7). It also authorized substantial civil penalties (up to $10,000 per day) for "each failure to report." *Id*. § 1395m-1(a)(9).

Because it was imposing new substantive obligations on regulated parties, Congress also included certain protections in the law. It directed that the information provided by laboratories would be held in strict confidence. *See id*. § 1395m-1(a)(10). It protected specified information from public disclosure. *See id.* § 1395m-1(a)(11). And it mandated that the Secretary implement the statutory reporting requirements by "establish[ing] through notice and comment rulemaking" the "parameters for data collection." *Id*. § 1395m-1(a)(12); *see also* 5 U.S.C. §§ 701–704.

PAMA's Separate Rate-Setting Requirements. In addition to the new data-reporting requirements, Congress enacted a separate set of provisions instructing the Secretary on how the private-payor information, once collected, should be used to establish reimbursement rates.

Congress directed the Secretary to calculate a weighted median "[f]or each laboratory test with respect to which information is reported." 42 U.S.C. § 1395m-1(b)(2). Congress also defined when the revised payment amounts would apply, *see id.* § 1395m-1(b)(4), and required the Secretary to consult with an advisory panel on establishing rates for new tests, *see id.* § 1395m-1(f).

Instead of requiring the agency to undertake public notice-and-comment rulemaking (as it mandated with the data-collection requirements), Congress directed the Secretary to provide only an explanation to the public of the applicable payment rates. *See id*. § 1395m-1(c)(4). It also precluded judicial review of the payment amounts established by the Secretary. The statute states: "There 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 provision prohibiting judicial review of the Secretary's final rule establishing the "parameters for data collection." *Id*. § 1395m-1(a)(12).

B. The Secretary's Final Rule

On October 1, 2015, the Secretary issued a proposed rule establishing the parameters for collecting data from laboratories under 42 U.S.C. § 1395m-1(a). *See* 80 Fed. Reg. 59,386 (Oct. 1, 2015). Instead of applying the statutory definition of "applicable laboratory" — any laboratory that receives the "majority of" its Medicare revenues from the Clinical Laboratory Fee Schedule or Physician Fee Schedule — the Secretary proposed a new definition of "applicable laboratory" that would cover any entity with a unique, IRS-issued taxpayer identification number ("TIN") that is either a laboratory or has a laboratory as one of its components. 80 Fed. Reg. at 59,392. The Secretary also solicited comments on defining "applicable laboratory" by reference to a national provider identifier ("NPI") used to bill for claims. *Id.* An NPI is a unique 10-digit

number issued to health care providers by CMS that is used in transactions with commercial and government health plans, including the Medicare program.

In his proposed rule, the Secretary stated that an "entity" with a TIN or NPI could qualify as an applicable laboratory if "it has at least one component that is a laboratory." 80 Fed. Reg. at 59,392. The Secretary then made clear that in applying the "majority of" revenues test, he would consider the Medicare revenues of the *entity as a whole*, and not just the Medicare revenues of the laboratory itself. *See id*. As the Secretary 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.

Id. at 59,393.

The Secretary's proposed approach was heavily criticized. *See generally* Doc. 10 at 5 (rulemaking record index); A.R. 106–4032 (public comments to rulemaking); A.R. 4033–4447 (other correspondence and materials submitted during rulemaking). The statute does not exclude laboratories that lack a separate TIN or NPI from the data-reporting requirements. Nor does it permit the Secretary to determine a laboratory's revenues by tallying the total revenues, including non-laboratory-related revenues, of a larger entity (the hospital) of which the laboratory is only a small component. These departures from the statutory scheme effectively carve out hospital laboratories from the statute's data-reporting requirements. There is no requirement that a hospital laboratory have its own NPI or TIN to bill the Medicare program. 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 hospital itself and not

have its own, separate NPI for billing purposes. *See, e.g.*, Doc. 1-4, Khani Decl. ¶ 32 (stating that "[v]ery few hospital laboratories have laboratory-specific NPIs — even those with robust laboratory outreach programs — and they generally submit claims under the hospital's NPI").

Hospitals use their NPI to bill Medicare for non-laboratory services provided by other components of the hospital, such as oncology services, radiology services, and surgery. Because the Secretary proposed to take into account the revenues of the *entire hospital*, including revenues *unrelated* to laboratory tests, for purposes of evaluating whether the statute's "majority of" revenues requirement is satisfied, hospital laboratories that do not have a separate NPI would never meet the "majority of" revenue test. That is because a hospital's *overall* Medicare revenues — which include revenues attributable to services provided and billed by other components of the hospital and not just the clinical diagnostic tests provided and billed by the laboratory — will inevitably far exceed the Medicare revenues of the hospital laboratory under either the Clinical Laboratory Fee Schedule or the Physician Fee Schedule.

In response to the proposed rule, the Secretary received nearly 1,300 comments. *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; *see also* A.R. 106–4032. The American Clinical Laboratory Association ("ACLA"), among many others, objected to the Secretary's unlawful decision to exclude almost all hospital laboratories from the statutory reporting requirements. ACLA "vehemently disagree[d] with CMS's inaccurate assumption that 'the statute intends to limit reporting primarily to independent laboratories and physician offices . . . and not include other entities (such as hospitals, or other health care providers) . . . .'" Doc. 1-4, Khani. Decl., Ex. 14 at 4 (ACLA comments); *see also* A.R. 3392–3424, 4092–4123. To the contrary,

"Congress intended that all sectors of the laboratory market . . . be represented . . ., including hospital outreach laboratories. If Congress meant to exclude all hospitals . . ., it easily could have done so directly, but it did not." *Id*.

On June 23, 2016, the Secretary issued a final rule. *See Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; Final Rule*, 81 Fed. Reg. 41,036 (June 23, 2016). In his response to comments, the Secretary acknowledged his obligation to include a broad base of data reflective of private-payor rates. As the Secretary explained, 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. 81 Fed. Reg. at 41,042; *see also id.* at 41,045 (noting the "advantage" of having "broader representation of the national laboratory market"). 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] . . . .

42 C.F.R. § 414.502.

Subpart (2) — the new requirement that the entity must bill Medicare Part B under its own NPI to satisfy the definition of "applicable laboratory" — has no basis in the statute. It also ensures, as compared to the statutory requirements, that the Secretary's final rule is vastly under-

inclusive. As a practical matter, the Secretary's final rule exempts almost all hospital laboratories from the statutory reporting requirements, no matter how much each hospital laboratory's revenue is from the Clinical Laboratory Fee Schedule or the Physician Fee Schedule. As noted above, almost no hospital laboratory bills under an NPI that is separate from the NPI the hospital uses to bill for other services provided to hospital patients by other components of the hospital; as a result, the Medicare revenues attributable to the hospital as a whole under multiple types of Medicare payment systems (such as the Inpatient Prospective Payment System and the Outpatient Prospective Payment System) will dwarf the revenues attributable to the laboratory under the Clinical Laboratory Fee Schedule or the Physician Fee Schedule. In short, by defining "applicable laboratory" by reference to the Medicare revenues of the hospital as a whole, the Secretary's final rule fails to do what Congress required — distinguish between those *laboratories* that receive the majority of *their* Medicare revenues from the Clinical Laboratory Fee Schedule or the Physician Fee Schedule and those *laboratories* that receive a majority of *their* Medicare revenues from other sources.

Using 2015 data, the Office of Inspector General had predicted that the final rule would require reporting by only 12,547 laboratories out of a total of 261,524 laboratories (based on the number of unique NPIs that billed the Medicare program for laboratory services in 2015). *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"). In other words, the Office of Inspector General estimated that the Secretary's final rule would require only 5 percent of all laboratories that serve Medicare beneficiaries to report their data. *See id.* 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, which included only 658 independent laboratories, 1,106 physician office laboratories, 21 hospital laboratories, and 157 "other" entities. *See* 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"). In short, instead of obtaining a broad base of private-payor information from all applicable laboratories, as Congress directed, the Secretary collected data from less than 1 percent of laboratories nationwide.

The data collected by the Secretary is not representative of the different types of laboratories that compete in the market. That is contrary to the Secretary's acknowledgement of the value of including a broad base of laboratories. *See* 81 Fed. Reg. at 41,042 ("The [Clinical Laboratory Fee Schedule] applies to a wide variety of laboratories (for example, national chains, physician offices, hospital laboratories, etc.), and . . . it was important that we define laboratory broadly enough to encompass every laboratory type that is subject to the" Clinical Laboratory Fee Schedule); *id.* at 41,045 (noting the "advantage" of having "broader representation of the national laboratory market"). In 2016, independent laboratories received approximately 55 percent of Medicare Clinical Laboratory Fee Schedule payments, and yet 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. *Id.*

Excluding hospital laboratories from the data-reporting requirements means that the data collected by the Secretary is not representative of the private-payor market. Hospital laboratories often receive substantially higher private-payor rates as a result of differences in competitive markets, volumes of services, and other factors. Doc. 1-2, Decl. of John Kolozsvary ¶ 16. In fact, "private payors typically pay hospitals . . . as much as 1.5 to 4 times higher than the rates they pay large independent laboratories for the same laboratory tests." Doc. 1-3, Decl. of Dermot Shorten ¶ 14. Estimates suggest that on average, hospital laboratories receive private-payor rates than are 160 percent higher than the rates paid by Medicare, while other types of laboratories receive rates that are on average "much lower than current Medicare rates." *Id*. There is no doubt that the Secretary understood that these differences are significant. When he published new rates, the Secretary inadvertently failed to delete a "hidden data" tab that was included on the Excel file. *See* "Hidden Data" tab in CY 2018 Final Private Payor Rate-Based CLFS Payment Rates, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html. That tab, which analyzes the impact of including or excluding data from the two largest independent laboratories, shows that the Secretary understood that collecting data principally from large independent laboratories (and excluding hospital laboratories) would result in a data set that would dramatically reduce Medicare payments.

The consequences of the Secretary's data-collection efforts are significant and underscore just how far he missed the mark set by Congress. The Congressional Budget Office estimated that, by moving to a new market-based system, overall Medicare payments made under the Clinical Laboratory Fee Schedule would be reduced by approximately $100 million dollars the first year of section 216's implementation. But that estimate assumed that the Secretary would

comply with the statute and collect information from the market as a whole. By excluding virtually all hospital laboratories from the data-reporting requirements, the Secretary's final rule has resulted in an industry-crippling reduction in Medicare payments by more than $600 million. *See* Congressional Budget Office, Cost Estimate for the Protecting Access to Medicare Act of 2014, *available at* https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/cost estimate/house-introduced-protecting-access-medicare-act-2014-march-26-20140.pdf; *see also* CMS Reporting Summary at 1 (estimating a decrease of approximately $670 million in calendar year 2018)).

The effects of not collecting market data as Congress instructed are particularly acute for small community and rural hospital laboratories. Those laboratories will be forced to significantly scale back if not completely eliminate the outreach laboratory services they provide because they will no longer be able to afford to provide those services to non-hospital patients. *See* Doc. 1-2, Kolozsvary Decl. ¶ 27. Laboratories that provide clinical diagnostic services to non-ambulatory patients in skilled nursing facilities and nursing homes will also be forced to significantly scale back their services, and many of these laboratories will be forced out of business. *See* Doc. 1-1, Decl. of Peter Gudaitis ¶¶ 23–24; *see also* Shorten Decl. ¶ 19 (explaining why larger laboratories will not be able to step in to provide these services). As laboratories close or are required to scale back services, Medicare beneficiaries and other patients will suffer by being deprived of the essential laboratory services they need. *See* Doc. 1-2, Kolozsvary Decl. ¶ 27; Doc. 1-1, Gudaitis Decl. ¶ 28–31; Doc. 1-3, Shorten Decl. ¶ 19.

C. Procedural History

Both before and after the Secretary published the final rule, ACLA repeatedly met with representatives from CMS to present and explain its concerns. *See* Doc. 1-4, Khani Decl. ¶¶ 11–

61. Engagement with CMS included 22 in-person meetings, 14 letters, 1 presentation at a public meeting, 3 telephone conferences, and 2 rounds of comments submitted through the rulemaking process. *See id*. ¶ 12. Despite ACLA's having repeatedly presented these objections, however, the Secretary refused to comply with Congress's mandates. Instead, the Secretary went on to take the next step called for under the statute and established new reimbursement rates, which have now been published. *See* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html.

On December 11, 2017, ACLA brought this action on behalf of its members. Doc. 1, Compl. ACLA represents the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, end-stage renal disease, hospital, and nursing home laboratories. Doc. 1, Compl. ¶ 18. Its members perform tens of millions of tests each year that are reimbursed under the Medicare program, and it was a strong supporter of the market-based reforms Congress implemented under PAMA. Doc. 1, Compl. ¶¶ 2, 18.

In this action, ACLA pleads claims under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706, and the Social Security Act, 42 U.S.C. § 1395m-1, alleging that the Secretary's final rule violates the plain statutory language and is an *ultra vires* action in excess of statutory authority, relies on an unreasonable construction of the statute, and is arbitrary and capricious. *See* Doc. 1, Compl. at 25–31. To remedy these violations, ACLA seeks permanent injunctive relief to (1) direct the Secretary to withdraw or suspend his final rule until such time as it can be brought into compliance with the statute, and (2) direct the Secretary to withhold applying the new Clinical Laboratory Fee Schedule until such time as the Secretary has made appropriate revisions to his final rule. *Id*. at 32.

JURISDICTIONAL STATEMENT

This Court has jurisdiction because ACLA is challenging the Secretary's final rule rewriting the definition of "applicable laboratory." *See* 42 C.F.R. § 414.502; *see also* 80 Fed. Reg. at 41,036. ACLA has standing because its members are directly regulated by, and subject to, the requirements of the Secretary's final rule. There is no question that ACLA and certain of its identified members have suffered concrete, particularized injuries as a result of the Secretary's failure to comply with Congress's mandates and that a judgment in ACLA's favor will redress that injury. *See* Doc. 1-1, Gudaitis Decl. ¶¶ 22–23; Doc. 1-2, Kolozsvary Decl. ¶¶ 27, 30; Doc. 1-3, Shorten Decl. ¶¶ 16, 20–30; *see also* Doc. 1, Compl. ¶ 72. The Secretary's rule is quintessential final agency action for purposes of judicial review under the APA. *See Ctr. for Law & Educ. v. U.S. Dep't of Educ.*, 209 F. Supp. 2d 102, 110 n.9 (D.D.C. 2002) ("final agency action" with regard to an agency rulemaking is "typically the promulgation of the final rule"); *see also* 5 U.S.C. §§ 702, 704.

A. The Court Has Jurisdiction To Review The Agency's Final Rule.

There is a "strong presumption" that Congress intended judicial review of final agency action. *Mach Mining, LLC v. EEOC*, 135 S. Ct. 1645, 1651 (2015) (citing *Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667, 670 (1986)). An agency bears a "heavy burden" in attempting to overcome that presumption, *id.*, which can be "rebutted only by a clear showing that judicial review would be inappropriate." *Nat. Res. Def. Council, Inc. v. SEC*, 606 F.2d 1031, 1043 (D.C. Cir. 1979).

There is no indication that Congress intended to preclude judicial review of the Secretary's final rule implementing the statute's data-reporting requirements. Far from suggesting that "Congress wanted [CMS] to police its own conduct," *Mach Mining*, 135 S. Ct. at

1651, the statute mandates that the agency undertake public notice-and-comment rulemaking. *See* 42 U.S.C. § 1395m-1(a)(12). In doing so, Congress recognized that it was delegating legislative power to the agency to promulgate a rule that would affect private parties' substantive rights. *See Mendoza v. Perez*, 754 F.3d 1002, 1023 (D.C. Cir. 2014) (explaining that notice-and-comment rulemaking is required when a rule "trenches on substantial private rights and interests") (citations omitted); *cf. Dept. of Transp. v. Ass'n of Am. Railroads*, 135 S. Ct. 1225, 1240 (2015) (Thomas, J., concurring in judgment) (discussing separation-of-powers concerns raised when Congress delegates legislative power to an agency). Congress also specified in detail the data-reporting requirements that the Secretary must implement, precluding any suggestion that the Secretary's data-collecting obligations fall within the very narrow exception to judicial review when there "is no law to apply" and the matter is committed to unchecked agency discretion. *See* 5 U.S.C. § 701(a)(2); *see also Heckler v. Chaney*, 470 U.S. 821, 830 (1985).

There is no doubt that Congress knows how to bar judicial review when it wants to. In a separate provision of PAMA, Congress prohibited judicial review of the Secretary's "establishment of payment amounts." 42 U.S.C. § 1395m-1(h)(1); *see also* 42 C.F.R. § 414.507(e) (recognizing that there is "no administrative or judicial review . . . of the payment rates established under this subpart"). Congress's decision to include an express provision precluding challenges to the "establishment of payment amounts," but not to include a provision precluding challenges to the Secretary's final rule establishing the "parameters for data collection," demonstrates that Congress did not intend to strip courts of jurisdiction to review the Secretary's final rule. It is axiomatic that "[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." *Dean v. United States*, 556 U.S. 568, 573 (2009) (quoting *Russello v. United States*, 464 U.S. 16, 23 (1983)); *see also Mississippi ex rel. Hood v. AU Optronics Corp.*, 134 S. Ct. 736, 742 (2014).

The Court also has jurisdiction because the Secretary's final rule is *ultra vires*. *See Griffith v. Fed. Labor Relations Auth.*, 842 F.2d 487, 493 (D.C. Cir. 1988); *see also Trudeau v. FTC*, 456 F.3d 178, 190 (D.C. Cir. 2006) ("[J]udicial review is available when an agency acts *ultra vires*, even if a statutory cause of action is lacking." (internal quotation marks omitted)). For reasons described below, the Secretary has "disregarded a specific and unambiguous statutory directive" and, as a result, this Court may consider the legality of his *ultra vires* rule irrespective of any bar on judicial review. *See United Food and Commercial Workers v. NLRB*, 694 F.2d 276, 278 (D.C. Cir. 1982); *see also Physicians Nat'l House Staff Ass'n v. Fanning*, 642 F.2d 492, 496 (D.C. Cir. 1980) (courts may review *ultra vires* action where the agency has "violated some specific command" of a statute); *see also Cuozzo Speed Techns. v. Lee*, 136 S. Ct. 2131, 2141–42 (2016) (noting that courts always have authority to grant review when an agency acts "outside its statutory limits".

B. There Is No Other Bar To Judicial Review.

Courts have held that section 405(h) of the Social Security Act, incorporated into the Medicare statute through 42 U.S.C. § 1395ii, precludes judicial review under section 405(g) of claims that have not been "channeled" through the agency's administrative-review process. *See* 42 U.S.C. §§ 405(g), (h); *see also Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 17 (2000). But sections 405(h) and 405(g) do not apply here. There is no administrative process that provides a viable avenue for reviewing the data-reporting obligations imposed by the Secretary's final rule. *See Council for Urological Interests v. Sebelius*, 668 F.3d 704, 708

(D.C. Cir. 2011) ("section 405(h) is inapplicable where the Medicare Act offers no avenue for review of a particular category of statutory or constitutional claims"); *see also Bowen v. Michigan Academy of Family Physicians*, 476 U.S. 667 (1986). In its complaint, ACLA is not raising "[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. *Illinois Council*, 529 U.S. at 14.

In any event, even if sections 405(h) and 405(g) did apply, their jurisdictional requirements have been satisfied. ACLA's objections have been repeatedly presented to the agency, both in comments and in other correspondence, and the agency has declined to correct its final rule. *See* Doc. 1-4, Khani Decl. ¶ 12; *see also Action Alliance of Senior Citizens v. Sebelius*, 607 F.3d 860, 862 n.1 (D.C. Cir. 2010) (suggesting that plaintiff had cured "jurisdictional defect" by submitting letter to agency raising objections). Moreover, at least one of ACLA's members is in the process of submitting its objections to CMS in the context of a claim for payment, stating their intention to seek expedited access to judicial review.

Immediate judicial review is appropriate because ACLA's claims raise pure legal issues, there are no factual disputes that could impede their judicial resolution, and there is nothing to indicate that the administrative appeals process could result in the agency overturning its final rule. *See Hall v. Sebelius*, 689 F. Supp. 2d 10, 23–24 (D.D.C. 2009) ("exhaustion may be excused where an agency has adopted a policy or pursued a practice of general applicability that is contrary to the law" (quotation omitted)); *see also Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell*, 77 F. Supp. 3d 103, 112 (D.D.C. 2015); *see also Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992). In fact, the agency's adjudicators are bound to follow the Secretary's data-reporting regulation and, accordingly, they have no authority to decide the question of law

that is relevant to this matter in controversy. *See* 42 C.F.R. § 405.1063(a) (all laws and regulations pertaining to Medicare are binding on administrative law judges). In these circumstances, both the Social Security Act and the Secretary's regulations allow claimants to bypass the administrative hearing process and seek expedited access to judicial review. *See* 42 U.S.C. § 1395ff(b)(2); 42 C.F.R. § 405.990. Any further exhaustion is unnecessary and futile.

STANDARD OF REVIEW

"[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal," and "[t]he 'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). Under the APA, agency action must be set aside if it is "in excess of statutory jurisdiction, authority, or limitations." 5 U.S.C. § 706(2)(C).

Agency action is invalid when it is contrary to the plain meaning of the governing statute. "[W]hen the statute's language is plain, the sole function of the courts — at least where the disposition required by the text is not absurd — is to enforce it according to its terms." *Hartford Underwriters Ins. Co. v. Union Planters Bank, N.A.*, 530 U.S. 1, 6 (2000) (internal citations and quotation marks omitted); *see also Coal Emp't Project v. Dole*, 889 F.2d 1127, 1131 (D.C. Cir. 1989). It is an "essential function of the reviewing court . . . to guard against bureaucratic excesses by ensuring that administrative agencies remain within the bounds of their delegated authority." *Bensman v. Nat'l Park Serv.*, 806 F. Supp. 2d 31, 40 (D.D.C. 2011). When the agency's interpretation is "in conflict with the statute's plain language" and not "consistent with the statutory purpose," the agency's decision receives no deference. *Coal Emp't Project*, 889 F.2d at 1131; *see also Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984).

Agency action is also invalid if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). An agency must "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). In addition, the agency must consider "alternative[s]" that are "neither frivolous nor out of bounds" and explain its rejection of those alternatives. *Chamber of Commerce v. SEC*, 412 F.3d 133, 145 (D.C. Cir. 2005). "An agency's 'failure to respond meaningfully' to objections raised by a party renders its decision arbitrary and capricious." *PSEG Energy Res. & Trade LLC v. FERC*, 665 F.3d 203, 208 (D.C. Cir. 2011) (quoting *PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005)).

ARGUMENT

I. The Secretary's Final Rule Violates The Statute.

When "Congress has directly spoken to the precise question at issue," both the agency and this Court must give effect to Congress's stated intent. *Chevron*, 467 U.S. at 842–43. It is a "core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2446 (2014). The Secretary's final rule is invalid because it violates the statute's unambiguous requirements. The final rule is also *ultra vires* because the Secretary has "disregarded a specific and unambiguous statutory directive" and relied on a patent "misconstruction" of what the statute requires. *Griffith*, 842 F.2d at 493 (internal citations omitted); *see also Leedom v. Kyne*, 358 U.S. 184, 185 (1958).

In section 216 of PAMA, Congress required the Secretary to collect private-sector payment information from all "applicable laboratories," and unambiguously defined which

laboratories are required to report information to the Secretary. *See generally* 42 U.S.C. § 1395m-1(a). In a provision entitled, "Definition of applicable laboratory," Congress directed that "the term 'applicable laboratory' means a laboratory that, with respect to its revenues under this subchapter, a majority of such revenues" are from either the Clinical Laboratory Fee Schedule (as established under 42 U.S.C. § 1395m-1 and 42 U.S.C. § 1395*l*(h)) or the Physician Fee Schedule (as established under 42 U.S.C. § 1395w-4). 42 U.S.C. § 1395m-1(a)(2).

There is no relevant ambiguity as to what the statute requires. No one disputes that the statute directs the Secretary to collect data from all laboratories that receive a majority of their Medicare revenues from either the Clinical Laboratory Fee Schedule or the Physician Fee Schedule. *See* 81 Fed. Reg. at 41,039, 41,014 (agreeing with this interpretation). Nor does anyone dispute that Congress instructed the Secretary to collect private-sector payment information from all laboratories meeting the statutory definition, and intended the statutory requirements to "appl[y] to a wide variety of laboratories," including "for example, national chains, physician offices, hospital laboratories, etc." *Id*. at 41,042; *see also id*. (recognizing the importance of defining "laboratory broadly enough to encompass every laboratory type that is subject to the" Clinical Laboratory Fee Schedule). Nor is there any dispute that when considering the universe of "laboratories" subject to the statutory requirements, the Secretary appropriately looked to the Clinical Laboratory Improvement Amendments of 1998, which define "laboratory" to include any "facility for the biological, microbiological, serological, chemical, immunohematological, 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." *Id*. (citing 42 C.F.R. § 493.2).

The statutory text and structure confirm that Congress did not authorize the Secretary to exempt applicable laboratories from the statutory requirements. In defining "applicable laboratory," Congress granted the Secretary only *limited* authority to "establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory . . . , as the Secretary determines appropriate." 42 U.S.C. § 1395m-1(a)(2). Under the *expressio unius est exclusion alterius* canon, this express exception admits no implied exceptions. *See Chevron U.S.A. Inc. v. Echazabal*, 536 U.S. 73, 80 (2002) (Under the "interpretive canon, *expressio unius est exclusio alterius*, 'expressing one item of [an] associated group or series excludes another left unmentioned.'" (quoting *United States v. Vonn*, 535 U.S. 55, 65 (2002)). By authorizing the Secretary to exclude certain laboratories in limited and narrowly defined circumstances — laboratories meeting a low volume or low expenditure threshold — from the statutory requirements, Congress denied the Secretary authority to exclude laboratories in other circumstances. To the contrary, as Congressional leaders have confirmed, Congress intended "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 Senator Richard Burr, affirmed by Senator Orrin Hatch).

The Secretary's final rule cannot be reconciled with these statutory directives. The Secretary has not identified any absurdity or even any relevant ambiguity in the statute that might authorize him to deviate from the statute's express 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"). Nonetheless, instead of applying the statutory definition — and collecting data from all

laboratories that receive a majority of their Medicare revenues from the Clinical Laboratory Fee Schedule or Physician Fee Schedule — the Secretary conjured his own novel "regulatory definition." 81 Fed. Reg. at 41,042. That regulatory definition imposes a new requirement found nowhere in the statutory text: an "applicable laboratory" is an entity that "[b]ills Medicare Part B under its own National Provider Identifier (NPI)." 42 C.F.R. § 414.502. Moreover, the Secretary has made clear that, when evaluating whether a laboratory meets the "majority of" revenues requirement, instead of considering the Medicare revenues received by the laboratory itself, as the statute directs, the Secretary will consider the overall Medicare revenues received by any entity of which the laboratory is a component.

The result of the Secretary's final rule is to dramatically change the statutory requirements. The statute states:

> [T]he term "applicable laboratory" means a *laboratory* that, with respect to *its revenues* under this subchapter [i.e., the laboratory's Medicare revenues], a majority of such revenues are from [the Clinical Laboratory Fee Schedule and Physician Fee Schedule].

42 U.S.C. § 1395m-1(a)(2) (emphasis added). The regulations effectively rewrite the definition:

> [T]he term "applicable laboratory" means any *entity* with an NPI that has at least one component that is a laboratory that, with respect to *the entity's* revenues under this subchapter [i.e., the entity's Medicare revenues], a majority of such revenues are from [the Clinical Laboratory Fee Schedule and Physician Fee Schedule].

These extra-textual requirements are impermissible because, in purpose and effect, they exempt virtually all hospital laboratories from the data-reporting requirements, including hospital laboratories that receive the majority of their Medicare revenues from the Clinical Laboratory Fee Schedule or the Physician Fee Schdule. *See* 81 Fed. Reg. at 41,045 ("We believe the statute supports the effective exclusion of hospital laboratories . . . ."). In almost all circumstances, hospital laboratories do not have a separate NPI used to bill Medicare for services provided by

the hospital laboratory to non-hospital patients on a fee-for-service basis under the Clinical Laboratory Fee Schedule or the Physician Fee Schedule. Instead, almost all hospital laboratories bill their services using the same NPI that is used by the hospital *as a whole* to bill for *other, non-clinical laboratory services*. As a result, the total Medicare payments connected to the hospital's NPI — that is, the Medicare revenues received by the hospital for the myriad services that the hospital as a whole provides to registered patients — will inevitably far exceed the Medicare revenues that the hospital laboratory receives on a fee-for-service basis for clinical laboratory services provided to non-patients under the Clinical Laboratory Fee Schedule or Physician Fee Schedule. *See* 81 Fed. Reg. at 41,046 (acknowledging that under the final rule, "the majority of Medicare revenues threshold" is "applied" to the "entire hospital" and not just "the hospital's laboratory").

That contravenes Congress's express directions. Congress unequivocally instructed the Secretary to examine the revenues of each *laboratory* to determine whether a majority of that *laboratory*'s revenues are under the Clinical Laboratory Fee Schedule and the Physician Fee Schedule. The equation that Congress required defines the denominator as the total Medicare revenues *of the laboratory* for services reimbursed under any source of Medicare revenue, and the numerator as the Medicare revenues *of the laboratory* for services reimbursed under the Clinical Laboratory Fee Schedule and Physician Fee Schedule. Nothing in the statute authorizes the Secretary to inflate the denominator by including unrelated revenues for services attributable to a much larger entity (the hospital) of which the laboratory is only a small component part. Yet that is precisely what the Secretary has done. *See Barnhart v. Sigmon Coal Co., Inc.*, 534 U.S. 438, 462 (2002) ("We will not alter the text in order to satisfy the policy preferences of" an agency).

The difference between the statute and the Secretary's final rule is stark:

Equation as required by PAMA:

$$\frac{\text{Laboratory's Revenues from Fee Schedules (CLFS|PFS)}}{\textit{Laboratory's}\ \text{Total Medicare Revenues}}$$

Equation as rewritten in the Secretary's final rule:

$$\frac{\text{Laboratory's Revenues from Fee Schedules (CLFS|PFS)}}{\textit{Hospital's}\ \text{Total Medicare Revenues (revenues from the laboratory } \textit{and} \text{ from other hospital components)}}$$

Had Congress intended to exclude hospital laboratories from the statutory data-reporting requirements, it could have easily done so. *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). Congress knew that hospital laboratories receive payments for laboratory tests provided to non-hospital patients under the Clinical Laboratory Fee Schedule and the Physician Fee Schedule; in fact, it identified them by name in the statute. *See* 42 U.S.C. § 1395m-1(b)(1)(B) ("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 a part of a bundled payment under section 1395*l*(t) of this title.").

Far from exempting hospital laboratories from the data-collection requirements, however, Congress imposed the "majority of" Medicare revenues requirement to ensure that the Secretary would collect data from hospital laboratories that compete in providing laboratory services to non-hospital patients. Indeed, because independent laboratories and physician office laboratories bill for their laboratory services almost exclusively under the Clinical Laboratory Fee Schedule and the Physician Fee Schedule, it is a foregone conclusion that virtually all of their revenues

will be derived from those two schedules. The "majority of" revenues requirement is therefore most relevant in distinguishing between different types of hospital laboratories. Those hospital laboratories that still receive a majority of their Medicare revenues from serving registered hospital patients — and thus do not have a large outreach business — are not required to report private-payor data. In contrast, those hospital laboratories that do have a significant outreach business and do compete with other laboratories in the commercial market — in other words, laboratories whose Medicare revenues are mostly the result of providing services to non-hospital patients — are required to report private-payor data.

The final rule effectively reads out of the statute the "majority of" revenues requirement, rendering that essential requirement meaningless. *See Torres v. Lynch*, 136 S. Ct. 1619, 1628 n.8 (2016) (noting "ordinary assumption that Congress, when drafting a statute, gives each provision independent meaning"). In doing so, the Secretary has violated the basic canon that "statute[s] should be construed so that effect is given to all [of their] provisions, so that no part will be inoperative or superfluous, void or insignificant." *Angelex Ltd. v. United States*, No. 15-0015, 2017 WL 4355920, at *7 (D.D.C. Sept. 28, 2017) (quoting *Hibbs v. Winn*, 542 U.S. 88, 101 (2004)).

Because the Secretary's final rule violates the plain statutory text, it should not be allowed to stand. *See, e.g., Bennett v. Donovan*, 4 F. Supp. 3d 5, 12 (D.D.C. 2013) (striking down agency interpretation that statute unambiguously forecloses). Indeed, the Secretary's final rule is such a patent violation of the statute that it amounts to *ultra vires* action. *See Griffith*, 842 F.2d at 493. The Secretary's decision to rewrite the statutory requirements to consider the Medicare revenues of the hospital as a whole for payments received for all types of services, including non-laboratory services, instead of considering only the revenue of the hospital

laboratory itself, is an "obvious" violation of what Congress required. It is also manifestly in excess of the authority delegated to the Secretary by Congress, which only authorized the Secretary to create exemptions for low-volume or low-expenditure laboratories.

II. The Secretary's Final Rule Is Unreasonable.

Even if the Secretary had identified some relevant ambiguity in PAMA's requirements (which he did not), the Secretary's definition of "applicable laboratory" would still be invalid. This Court may defer to an agency's interpretation of an ambiguous statutory provision only if the interpretation falls within "the bounds of reasonableness." *Goldstein v. SEC*, 451 F.3d 873, 881 (D.C. Cir. 2006). A "reasonable statutory interpretation must account for both 'the specific context in which . . . language is used' and 'the broader context of the statute as a whole.'" *Util. Air Regulatory Grp.*, 134 S. Ct. at 2442 (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997)). An agency interpretation that is "'inconsisten[t] with the design and structure of the statute as a whole, . . . does not merit deference.'" *Id.* (quoting *University of Tex. Sw. Medical Ctr. v. Nassar*, 133 S. Ct. 2517, 2529 (2013)).

The Secretary's final rule satisfies neither of these requirements. For all the reasons explained above, the Secretary's exclusion of one of the largest groups of providers of laboratory services from the statutory reporting requirements is unreasonable. *See American Bar Ass'n v. FTC*, 430 F.3d 457, 468 (D.C. Cir. 2005) (holding that agency action in excess of its statutory authority is both impermissible and unreasonable). Excluding hospital laboratories from the data-reporting requirements cannot be reconciled with Congress's stated overarching purpose of requiring the Secretary to collect private-payor information to ensure that reimbursement under Medicare's Clinical Laboratory Fee Schedule is comparable to payments made in the private sector. *See* 81 Fed. Reg. at 41,046 (acknowledging "that the purpose of the revised Medicare

payment system is to base [Clinical Laboratory Fee Schedule] payment amounts on private payor rates"). Nor is it consistent with Congress's goal that the Secretary collect private-sector information from all laboratories that meet the "majority of" revenues requirement.

The Secretary's decision to exclude hospital laboratories from the data-reporting requirements is also unreasonable because it omits a large segment of the market and can only lead to payments that are inconsistent with private-sector payments. In terms of Medicare spending, hospital outreach laboratories receive approximately 26 percent of the payments made under Medicare's Clinical Laboratory Fee Schedule in 2015. *See* OIG 2016 Data Report at 2. As the Office of Inspector General calculated, there are over 7,000 hospitals that compete in the market and provide laboratory services to non-hospital patients under the Clinical Laboratory Fee Schedule, *see* OIG 2015 Data Report at 8. Yet the Secretary collected data from only 21 hospital laboratories — far less than 1 percent of all hospital laboratories nationwide — and even these hospital laboratories can avoid reporting data during the next reporting period by using the hospital's NPI to bill the Clinical Laboratory and Physician Fee Schedules. That absurd result, leaving thousands of hospital laboratories out of the equation, is so far from what Congress intended that it should have prompted the Secretary to select an alternative approach. *See Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) (statutory interpretations that "would product absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available").

The Secretary appears to have recognized that excluding hospital laboratories from the data-reporting requirements will ultimately result in payment rates that, contrary to Congress's intent, are far below the rates reflected in the private sector as a whole. When the Secretary published his established rates, he inadvertently failed to delete a "hidden data" tab within the

Excel file he made available on CMS's website. *See* "Hidden Data" tab in CY 2018 Final Private Payor Rate-Based CLFS Payment Rates, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html (showing columns labeled "payment difference" and "payment percentage change," comparing what appears to be the "count" of HCPCS codes when the data from two large independent laboratories is included and excluded). This "hidden data" shows that the Secretary understood that excluding hospital laboratories, and collecting data principally from independent laboratories, would result in a data set that would dramatically reduce payments far below those that were made before PAMA was implemented. The Secretary's hidden data tab thus further underscores the unreasonableness of the Secretary's position.

Most significantly, the Secretary's final rule provides no explanation why the *statute* reasonably permits the Secretary to exclude all hospital laboratories that do not bill Medicare under their own NPI from the date-reporting requirements. 42 C.F.R. § 414.502. To be sure, the final rule asserts in *ipse dixit* fashion that "the statute supports the effective exclusion of hospital laboratories," 81 Fed. Reg. at 41,045, and that "the statute supports limiting reporting to primarily independent laboratories and physician office laboratories," *id.* at 41,046. But the final rule provides no textual analysis to justify that conclusion. Instead, the Secretary appears to have relied entirely on an assertion of administrative convenience. In response to comments, the Secretary noted that because "laboratory services provided to hospital inpatients and outpatients are typically not separately paid" — but are instead "bundled" with payments made to the hospital as a whole — it is "unclear" how Medicare "revenues from" laboratory services provided to hospital patents "would be determined for the denominator of the ratio" called for under the statute. *Id*. at 41,046; *see also id*. (rejecting approach to focus on revenues attributable

to the hospital laboratory because of "the difficulties many hospitals would have in determining whether their laboratories are applicable laboratories").

That makes no sense. Basic cost accounting principles have long addressed how to allocate revenues between business units that provide services for which a bundled payment is received. There is no reason hospitals cannot determine which revenues should be attributed to the clinical diagnostic laboratory services provided by their laboratories. Indeed, when hospitals bill the Medicare program for bundled payments they are required to include separate charges for all of the services provided, including laboratory services, on their claims as well as revenue codes that are used to track these charges to the different components of the hospital's business (such as the hospital's laboratory). The Secretary has failed to consider and explain adequately why this data cannot be used to determine laboratory revenues received in bundled payments.

In any event, an agency is not free to "throw up its hands" when confronted with accounting challenges. *Cobell v. Salazar*, 573 F.3d 808, 813 (D.C. Cir. 2009); *see also Schurz Commc'ns, Inc. v. FCC*, 982 F.2d 1043, 1050 (7th Cir. 1992) (agency cannot just "throw[] up [its] hands" and "split[] the difference" with "unprincipled compromises"). Nor does an agency have any authority to disregard "clear statutory terms that turn out not to work in practice." *Util. Air Regulatory Grp.*, 134 S. Ct. at 2446. As the Supreme Court has recognized, any agency cannot "resolve the practical problems" caused by a statutory requirement "by eliminating [the requirement] altogether." *Comm'r of Internal Revenue v. Engle*, 464 U.S. 206, 227 (1984). Even if it would make a statute "simpler to administer," an agency has no authority to adopt an interpretation that is unreasonable in light of the statute's language and overall purpose. *Id.*

III. The Secretary's Final Rule Is Arbitrary And Capricious.

The Secretary's final rule is also arbitrary and capricious. The Secretary has not reasonably responded to serious objections to his approach. Nor has he articulated a "rational connection" between the facts and his rewrite of the statutory definition. His only purported reason for rewriting the statute — the administrative challenges of asking hospitals to track Medicare revenues attributable to the laboratory services they provide — is an unexplained abuse of discretion.

Dozens of commenters, including ACLA and its members, repeatedly objected that the Secretary's rule would exclude hospital laboratories and urged the Secretary to adopt an approach that would require hospital laboratories to comply with the statutory data-reporting requirements. *See, e.g.*, A.R. 121–122; 123–124; 127; 129–130; 182–183; 1473–74; 1580–81; 1949–50; 1977–79; 1990–92; 2287; 2292–93; 2359–61; 2372; 2407–08; 2581–82; 2765–66; 2780–81; 3256–57; 3393–94; 3396–98; and 3862, 3864–66. Commenters also urged the Secretary to adopt an approach that would require hospital laboratories to determine what portion of a hospital's overall Medicare revenues are attributable to clinical diagnostic services provided by the laboratory (and not by other components of the hospital). *See* 81 Fed. Reg. at 41,046; *see also* Doc. 1-4, Khani. Decl., Ex. 14 (ACLA comments); A.R. 3392–3424, 4092–4123. Among other suggestions, a commenter suggested that a hospital could "establish an adjustment factor based on its payment-to-charges ratio" to determine what portion of the hospital's overall Medicare revenues are attributable to the hospital laboratory. 81 Fed. Reg. at 41,046; *see also* Doc. 1-4, Khani. Decl., Ex. 14 at 7; A.R. 3399, 4098.

The Secretary did not reasonably respond to these comments and offered no reasoned explanation for rejecting the alternative approaches that commenters urged. *See PPL*

Wallingford Energy, 419 F.3d at 1198 ("An agency's failure to respond meaningfully to objections raised by a party renders its decision arbitrary and capricious.") (internal quotation marks omitted). Instead, while the Secretary purported to understand the importance of collecting market data from hospitals that provide outreach services to non-hospital patients, he asserted, without any reasoned explanation, that "it is [not] necessary to establish a hospital adjustment factor to enable hospital outreach laboratories to be applicable laboratories." 81 Fed. Reg. at 41,046. In the Secretary's view, the NPI requirement would be adequate because it would allow hospital laboratories *in their discretion* to become "applicable laboratories" by obtaining a separate NPI. *Id*.

That response is wholly inadequate. The statute does not permit laboratories to opt in and out of the mandatory reporting requirements. Nor is it rational for those requirements to be optional, where Congress's intent was to obtain data from the market as a whole. The burden was on the Secretary to provide some reasoned basis for not adopting an approach that would do the job that Congress directed him to do — determine which hospital laboratories satisfy the "majority of" revenues requirement that Congress imposed. *See Nat'l Treasury Employees Union v. Horner*, 654 F. Supp. 1159, 1164 (D.D.C. 1987) (noting that agency's "self-serving" claim of "impracticability" was not entitled to deference). The Secretary has not come close to meeting that burden.

The Secretary's failure to comply with Congress's directives imposes an unfair and arbitrary data-reporting burden on only some laboratories, and the Secretary has never justified why hospital laboratories should be exempt from the burdens imposed on their competitors, which do not have the ability to opt in or out of the data-reporting requirements. *See* 81 Fed. Reg. at 41,093 (recognizing "there could be substantial costs associated with" complying with

the data-reporting requirements); *see also Hall v. McLaughlin*, 864 F.2d 868, 872 (D.C. Cir. 1989) ("[r]easoned decisionmaking requires treating like cases alike"). As the Secretary recognized, the statute's data-reporting obligations were significant and costly. *See* 81 Fed. Reg. at 41,093 (In discussing the "Cost of Data Collection and Reporting Activities" for laboratories, the Secretary stated that "there could be substantial costs associated with compliance with [42 U.S.C. § 1395m-1]."). Collecting the data required under the statute is a "difficult, resource-intensive, and burdensome task" that cost some companies millions of dollars to complete. Doc. 1-3, Shorten Decl. ¶ 21; *see also id.* ¶¶ 20–30. There is no reason some laboratories should be burdened with these substantial costs and the risk of civil penalties, while their competitors are arbitrarily exempt. *See id.* ¶ 30.

The Secretary also has no reasoned response to the serious objection that, as a result of his final rule, Medicare payment amounts for clinical diagnostic tests will not be based on private-payor rates, but instead will be based on data collected from a small segment of the market with private-payor rates that are dramatically lower than the market as a whole. *See* A.R. 2081, 2407, 2447 (expressing concerns that Secretary's approach will artificially reduce Medicare payments and result in systematic underpayments); *see also Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (an agency "is required to give reasoned responses to all significant comments in a rulemaking proceeding"). The Secretary's final rule will likely force some laboratories out of business and deprive patients of ready access to essential services, especially in remote rural areas. *See, e.g.*, A.R. 4407–08 (expressing concern that some laboratories could be forced "to either scale back or discontinue their test," with "significant ramifications for patient access to testing, particularly in rural and other underserved areas"); A.R. 4409 (expressing concerns that some community or regional laboratories could be forced

"out of business altogether"); Doc. 1-2, Kolozsvary Decl. ¶ 27; Doc. 1-1, Gudaitis Decl. ¶ 28–31; Doc. 1-3, Shorten Decl. ¶¶ 14–19. At a minimum, the Secretary should have addressed these grave concerns. His failure to do so is a quintessential example of arbitrary and capricious agency action.

The only individual likely to benefit from the Secretary's final rule appears to be the Secretary himself. *Cf. Alabama Power Co. v. FERC*, 993 F.2d 1557, 1570 n.8 (D.C. Cir. 1983) (no deference due to agency when a proposed interpretation serves only the agency's own interests). By failing to comply with Congress's mandate, the Secretary has set the stage to dramatically reduce the payments that Medicare makes for laboratory services. He has also avoided doing the work that Congress intended him to do. Collecting data from a small, cherry-picked sample of laboratories does not come close to completing the task that Congress assigned. The Secretary's refusal to comply with Congress's mandate should not be tolerated. Instead, the Court should strike down the Secretary's final rule.

CONCLUSION

The Court should grant summary judgment to ACLA and set aside the Secretary's final rule rewriting the statutory definition of "applicable laboratory."

Respectfully submitted,

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Dated: February 14, 2018

CERTIFICATE OF SERVICE

I hereby certify that on February 14, 2018, a copy of the foregoing Motion was filed electronically via the Court's ECF system, which effects service upon counsel of record.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION,
1100 New York Avenue, N.W., Suite 725W
Washington, D.C. 20005

Plaintiff,

v.

ALEX M. AZAR,
In His Official Capacity as Secretary of Health and Human Services,
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Defendant.

Civil Action No. 17-2645 (EGS)

[PROPOSED] ORDER GRANTING PLAINTIFF'S
MOTION FOR SUMMARY JUDGMENT

THIS CAUSE comes before the Court upon Plaintiff's Motion for Summary Judgment, filed on February 14, 2018.

UPON CONSIDERATION of the Motion, the pertinent portions of the administrative record, and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that Plaintiff's Motion for Summary Judgment is GRANTED on all counts of the Complaint. Any pending motions are hereby DENIED AS MOOT.

IT IS FURTHER ORDERED that the Secretary of Health and Human Service's definition of "applicable laboratory" in 42 C.F.R. § 414.502 is invalid because it does not comport with the requirements of Section 216 of the Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, § 216, 128 Stat. 1040, 1053 (2014).

IT IS FURTHER ORDERED that (1) the Secretary must withdraw or suspend his final rule, *Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; Final Rule*, 81 Fed. Reg. 41,036 (June 23, 2016); *see also* 42 C.F.R. § 414.502, until such time as it can be brought into compliance with the statute, and (2) the Secretary must withhold applying the new Clinical Laboratory Fee Schedule until such time as the Secretary has made appropriate revisions to the final rule.

DONE AND ORDERED in Chambers in Washington, District of Columbia, this ____ day of _____, 2018.

_____
EMMET G. SULLIVAN
UNITED STATES DISTRICT JUDGE