IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. ALEX M. AZAR, in his official capacity as Acting Secretary of Health and Human Services, Defendant.	Case No. 1:17-cv-02645

AMICUS CURIAE BRIEF OF THE COLLEGE OF AMERICAN PATHOLOGISTS IN SUPPORT OF PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTEREST OF *AMICUS CURIAE*

The College of American Pathologists (CAP) is the world's largest medical specialty society of board-certified pathologists—physicians who diagnose and treat patients through laboratory medicine. On behalf of more than 17,000 members, CAP advocates for sound health policy, particularly as it affects pathologists, the laboratories where they work, and the patients they serve. In addition, 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 laboratories in the United States and more than 50 other countries for compliance with rigorous test validation, proficiency testing, recordkeeping, and quality assurance standards developed and administered by CAP and its members. Today, CAP accredits more than 8,000 laboratories in the United States and across the world.

Most pertinent here, CAP is one of only a few accrediting 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).[1] To achieve this "deemed status," CAP had to submit its accreditation standards to HHS for review, and HHS found CAP's standards to be "equal to or more stringent than" those of CLIA.[2] CLIA certification is a requirement for all U.S. laboratories that test human specimens for health assessment or to diagnose, prevent, or treat disease. Moreover, a laboratory may not receive Medicare or Medicaid reimbursement unless it is certified under CLIA. Thus, by attaining CAP

[1] 42 U.S.C. § 263a; 42 C.F.R. § 493.1.

[2] 42 U.S.C. § 263a(e)(2)(A)(ii).

accreditation, a laboratory establishes that it meets the highest scientific and clinical standards while also satisfying regulatory and reimbursement requirements.

The Protecting Access to Medicare Act of 2014 (PAMA), and the Secretary's final rule implementing it, call for a far-reaching change in how the nation's medical laboratories are reimbursed for their services to Medicare patients. CAP's pathologist members work in many of these laboratories, and CAP inspects and accredits thousands of them. Indeed, many of CAP's members serve as medical directors in hospital-based outreach laboratories whose pricing data the final rule *excluded* in calculating a supposedly market-based rate. Given CAP's standard-setting responsibilities, the medical expertise of its members, and its first-hand experience monitoring and continually improving the nation's laboratories, CAP is concerned that the Secretary's final rule will harm laboratories across the country by undermining Congress' market-based reimbursement scheme. CAP submits this amicus brief to urge the Court to require the Secretary to consider the full range of laboratory pricing data, including from hospital laboratories, so that Medicare patients may maintain access to laboratory services that are vitally important to their diagnosis, treatment, and care.[3]

INTRODUCTION

Congress enacted section 216 of PAMA to establish a market-based system for Medicare reimbursement of clinical laboratory tests. Section 216 reformed an outmoded system, enacted in 1984, known as the Clinical Laboratory Fee Schedule (CLFS).[4] During the intervening 30 years, the market for laboratory tests has grown dramatically in its scope, complexity, and importance.

[3] No counsel for any party authored this brief in whole or in part and no entity or person, aside from *amicus curiae*, their members, and counsel, made any monetary contribution towards the preparation and submission of this brief. All parties have consented to the filing of this brief.

[4] Pub. L. No. 113-93, § 216, 128 Stat. 1040, 1053 (2014) (codified at 42 U.S.C. § 1395m-1).

But the CLFS continued to reimburse laboratories based on local test costs measured in the 1980s, with only limited inflation adjustments. PAMA aimed to modernize laboratory reimbursement by basing Medicare payments on the national weighted median market rate paid by private payors (*i.e.*, commercial insurers such as United Healthcare, Aetna, CIGNA, and Anthem) for each reported laboratory test.[5]

To implement PAMA's scheme of national market-based reimbursement, Congress first required the Secretary to collect comprehensive and accurate reimbursement data. PAMA required data from *all* independent and hospital-based laboratories that receive most of their Medicare revenues from serving beneficiaries who are not hospital in-patients or out-patients. Congress therefore broadly defined "applicable laboratory" to include any laboratory that receives a "majority of" its Medicare revenues from the Clinical Laboratory Fee Schedule or the Physician Fee Schedule (PFS).[6]

Yet the Secretary's regulation implementing this data-collection requirement undermines the very purpose of the statute—not to mention its plain language—by excluding large numbers of laboratories from the national reporting scheme Congress established. The regulation does not simply ask which laboratories receive a majority of Medicare revenues from the CLFS and PFS fee schedules identified in the statute. Rather, the Secretary added an arbitrary and atextual criterion by excluding any laboratory that does not bill under its own "National Provider Identifier" number (NPI). Whether a laboratory bills under its own NPI, however, has no relationship to the source of the laboratory's Medicare revenues. Under this rule, the private payment rates received

[5] 42 U.S.C. § 1395m-1(b)(2).

[6] *Id.* § 1395m-1(a)(2) ("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.").

by a large segment of the nation's laboratories are excluded from the statutory data-collection requirements and, as a result, are ultimately not considered in calculating nationwide "market rates."

In particular, the rule excludes data collection from hospital laboratories, skewing the resulting reimbursement calculation. Hospital laboratories typically receive higher rates from private payors than do independent laboratories.[7] Although hospital laboratories account for the more than a quarter of all Medicare payments under the CLFS, fewer than two dozen hospital laboratories—out of more than 9,000—reported pricing data under the final rule. For Congress' system to work as designed, the Secretary must collect and consider the rates at which private payors reimburse laboratory tests across all segments of the laboratory market. Gerrymandering results by arbitrarily excluding those laboratories contradicts the statute Congress enacted, leads to skewed reimbursement rates, and threatens the quality and viability of the laboratories most in need of market-based reimbursement. This Court should invalidate the rule.

ARGUMENT

I. SECTION 216 OF PAMA REQUIRES THE SECRETARY TO CALCULATE MARKET RATES BASED ON PRIVATE PAYOR DATA FROM ALL SEGMENTS OF THE LABORATORY MARKET

Timely, accurate, and reliable laboratory diagnostic results are essential to quality patient care. Laboratories play a vital role in diagnosing disease, enabling preventive care, and monitoring chronic conditions. Since Congress enacted the CLFS in 1984, the nation's laboratory services have changed dramatically. Today, for example, pathologists use biological samples to diagnose

[7] Hospital laboratories receive payments under the CLFS for "outreach" laboratory services performed on patient specimens typically referred by physicians in the surrounding community. By contrast, for hospital inpatients and outpatients, hospitals received bundled payments that cover a broad variety of patient services, including laboratory. *See* 42 U.S.C. §§ 1395ww(d), 1395*l*(t), 1395m-1(b)(1)(B); *cf.* Medicare Clinical Diagnostic Laboratory Tests Payment System, 81 Fed. Reg. 41,036, 41,046 (June 23, 2016) [hereinafter, "Final Rule"].

rare diseases, identify prenatal chromosomal abnormalities, and determine predispositions to certain forms of cancer. Doctors order laboratory tests for any number of reasons during all manner of patient visits. In 2014, Medicare beneficiaries received an average of 17 laboratory tests per year.[8] U.S. laboratories perform billions of tests annually and demand for clinical laboratory testing is on the rise. The rising demand is 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]

Congress' broad definition of "applicable laboratory" under PAMA reflects the wide variety of clinical laboratories that perform these life-saving tests for diverse patient needs. Today more than 250,000 HHS-regulated laboratories operate across the United States in a variety of clinical settings.[10] Laboratories can be in hospitals, independent settings, physicians' offices, ambulances, federally qualified health centers, ambulatory surgery centers, end stage renal disease

[8] Office of the Inspector Gen., HHS, *Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data* 3 (Sept. 2015), https://oig.hhs.gov/oei/reports/oei-09-15-00210.pdf.

[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* at 12 (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.").

[10] *See* CMS, *CLIA Update-January 2018, Laboratories by Type of Facility*, https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/Downloads/factype.pdf (last visited Feb. 5, 2018) [hereinafter "CMS, Laboratories by Type"]; *see also* Julie Wolcott et al., *Laboratory Medicine: A National Status Report* 3 (May 2008).

facilities, hospice care, prisons, and other institutions.[11] Over just the last decade, the number of laboratories in the United States has increased by more than 60% according to HHS data.[12]

Despite rising demand for and diversity of laboratory services, Medicare payment rates for laboratory tests remained largely frozen, aside from inflation adjustments, from 1984 until PAMA's enactment in 2014. By the early 2000s, the Institute of Medicine had observed that the CLFS Congress put in place in the 1980s did not reflect "market changes" since that time.[13] As HHS's Office of Inspector General explained, "Medicare's payment rates for lab tests were established in 1984 on the basis of prevailing charges for lab tests in each Medicare carrier jurisdiction."[14]

Section 216 of PAMA sought to "improv[e] [these] policies for clinical diagnostic laboratory tests." It did so by first requiring the Secretary to collect comprehensive data from U.S. clinical laboratories about the rates private payors paid. Then it separately directed the Secretary to use the collected data in connection with a formula to establish market-based Medicare reimbursement rates.

The reporting requirements apply to "applicable laboratories," which must report private-payor information "for each clinical diagnostic laboratory test that the laboratory furnishes."[15] The statute defines "applicable laboratory" as a laboratory that derives the majority of its Medicare revenues from "this section, section 1395*l*(h) [the CLFS], or section 1395w-4 [the Physician Fee

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[11] CMS, Laboratories by Type, *supra*.

[12] *See* Kalorama Info., *supra* at 38.

[13] Office of the Inspector Gen., HHS, *Comparing Lab Test Payment Rates: Medicare Could Achieve Substantial Savings* 4 (June 2013), https://oig.hhs.gov/oei/reports/oei-07-11-00010.pdf (citing Inst. of Med., *Medicare Laboratory Payment Policy: Now and in the Future* (Jan. 2000)).

[14] *Id.* at 10-11.

[15] 42 U.S.C. § 1395m-1(a)(1).

Schedule (PFS)]."[16] The statute provides specific (but limited) authority to the Secretary to carve out certain laboratories by establishing "a low volume or low expenditure threshold for excluding a laboratory from the definition . . . , as the Secretary determines appropriate."[17] The statute does not mention any other exclusions: laboratories that satisfy the majority-of-revenues provision "shall report to the Secretary." [18] The reporting scheme is thus broad and comprehensive, covering "[t]he payment rate … that was paid *by each* private payor" for "*each* clinical diagnostic laboratory test that the laboratory furnishes" to ensure that complete commercial market information is collected from laboratories nationwide.[19]

II. THE SECRETARY'S DEFINITION OF "APPLICABLE LABORATORY" IS CONTRARY TO THE STATUTE

Notwithstanding the statute's text, purpose, and sound policy, the Secretary's regulation establishing the "parameters for data collection" under section 216 defines "applicable laboratory" to *exclude* important segments of the U.S. laboratory market. The rule effectively excludes an entire segment of the market—hospital outreach laboratories that compete directly with other laboratories the Secretary's rule includes. Because the statute directs the Secretary to collect data from all laboratories that satisfy a majority-of-revenues test, and then to base reimbursement rates on the weighted median of that data, excluding large numbers of laboratories will generate skewed reimbursement rates. Thus the resulting rates will not reflect private payor data from this critical segment of the market—hospital outreach laboratories. This directly undermines Congress' scheme by importing new, unintended limitations on which laboratories may report data in ways

[16] *Id.* § 1395m-1(a)(2).

[17] *Id.*

[18] *Id.* § 1395m-1(a)(1).

[19] *Id.* § 1395m-1(a)(1), (3) (emphases added).

that skew the resulting reimbursement calculation. *See Caterpillar Logistics Servs., Inc. v. Solis*, 674 F.3d 705, 710 (7th Cir. 2012) ("The Secretary can get no more information out than the [industry] puts in: GIGO (garbage in, garbage out).").

A. The Secretary's Definition of "Applicable Laboratory" Contradicts the Text of Section 216

PAMA provides a "definition of applicable laboratory" at odds with the Secretary's rule. Section 216 states: "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, [the CLFS], or [the PFS]. The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary determines appropriate."[20]

In its final rule, however, the Secretary redefines "applicable laboratory" as an entity that: (1) is a laboratory as defined under CLIA; (2) "*[b]ills Medicare Part B under its own National Provider Identifier (NPI)*"; (3) receives more than 50 percent of its Medicare revenues from the CLFS or PFS; and (4) receives at least $12,500 of its Medicare revenues from the CLFS, with certain exceptions.[21]

This adds new and inapposite NPI criteria to the definition that materially change the way the statute operates by excluding segments of the laboratory market. First, the statute leaves to the Secretary's discretion only one aspect of the definition: the option to set either a low volume or a low expenditure threshold to exclude certain smaller laboratories.[22] The statute does not delegate (and, indeed, implicitly withholds) authority to create carve-outs for *other* sub-categories of

[20] *Id.* § 1395m-1(a)(2).

[21] 42 C.F.R. 414.502 (emphasis added).

[22] *Id.*

laboratories. *See, e.g.*, *Cent. United Life Ins. Co. 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."). Yet that is precisely what the Secretary did. Allowing the Secretary to freely exclude *other* categories of laboratories at its own discretion would supplant Congress' explicit definition and specific exceptions with the Secretary's policy judgment.

In addition to adding criteria the statute does not permit, the rule effectively rewrites language Congress wrote into the statute. The Secretary agrees that CLIA's definition of "laboratory"—contained in the same title of the U.S. Code—is the only relevant definition of that term.[23] The rulemaking therefore did not even "consider alternative definitions" of the term "laboratory."[24] After stating that "applicable laboratory" means "*a laboratory*," the statute prescribes a so-called "majority of revenues" test. That test instructs that of an applicable laboratory's "revenues under this subchapter," a "majority of such revenues" must come "from this section, [the CLFS], or [the PFS]."[25] Therefore "laboratories" that meet the majority-of-revenues test (and any low volume/expenditure threshold) are applicable laboratories under the statute.

Yet the rule, instead of recognizing the *laboratory's* revenues as the relevant measure for assessing the majority-of-revenues test, includes revenues from non-laboratory operations as well. The rule defines "revenues" as all revenues associated with the same NPI as the laboratory—

[23] Final Rule, 81 Fed. Reg. at 41,042. CLIA defines laboratories as "facilit[ies] 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).

[24] Final Rule, 81 Fed. Reg. at 41,042.

[25] 42 U.S.C. § 1395m-1(a)(2) (emphasis added).

including revenues from non-laboratory operations. As agency guidance explains, where a laboratory bills Medicare under an NPI associated with the laboratory and other operating units (such as a physician's office or other parts of a hospital), then the majority-of-revenues calculation includes revenues of all units reporting under that NPI, regardless whether they provide laboratory services.[26] These extra, non-laboratory revenues diminish the significance of CLFS and PFS laboratory revenues relative to the entity's entire Medicare revenues. The effect is to exclude laboratories that otherwise would satisfy the majority-of-revenues test, and would be included in the data collection, if the Secretary adhered to the statutory definition. In cases where a laboratory shares an NPI with other units, therefore, the rule does not collect the "*laboratory*['s] . . . revenues,"[27] as the statute directs.

The Secretary, moreover, fails to provide any adequate explanation of why the statute provides him the discretion to add NPI as an additional requirement for defining an applicable laboratory. Nothing suggests Congress understood or intended "laboratory" to sweep in other units with little to do with the laboratory services section 216 addressed, and thereby to distort which laboratories were and were not included in the agency's data collection. *See, e.g.*, *Aid Ass'n for Lutherans v. U.S. Postal Serv.*, 321 F.3d 1166, 1177–78 (D.C. Cir. 2003) (agency lacked statutory authority "effectively to regulate [certain rates] out of the market" through "delegation to fill alleged gaps in the statute").

[26] *See* CMS, *Frequently Asked Questions, Medicare Program—Medicare Clinical Diagnostic Laboratory Tests Payment System Final Rule* 5–10 (Mar. 9, 2017), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CMS-1621-F-FAQ.pdf.

[27] 42 U.S.C. § 1395m-1(a)(2) (emphasis added).

B. The Secretary's Definition Also Contradicts Section 216's Clear Purpose

By redefining "applicable laboratory" as a laboratory plus any other operating units under the same NPI, the rule virtually guarantees that laboratories functioning within larger healthcare institutions will be excluded from data reporting. The effect is to leave independent laboratories as the predominant reporting entities.

This rule captures only a small fraction of laboratories' information.[28] Indeed, in the first round of reporting, fewer than 2,000 laboratories reported as "applicable laboratories."[29] This is approximately *3%* of the more than 61,000 laboratories that Medicare Part B reimbursed in 2015.[30] Distorting the majority-of-revenues test, moreover, does not merely reduce the total number of reporting laboratories; it selectively excludes a segment of the market that receives higher reimbursement rates, thereby harming *all* laboratories that serve a Medicare population by generating lower rates for all covered laboratories.

This effect of this exclusion is far-reaching. According to 2017 data, hospital laboratories account for 48.2% of laboratory market share by test volume, while independent laboratories account for 29.5%. (Quest Diagnostics independently accounts for 9.8% and LabCorp 6.7%).[31]

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[28] An HHS Office of the Inspector General report from September 2016 estimated that only five percent of laboratories would be required to report data under the new rule. *See* Office of the Inspector Gen., HHS, *Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data* 7–8 (Sept. 2016), https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf (HHS "estimates that about half of independent labs will be required to report their private payer data, whereas only a small portion of physician office labs and few hospital labs will be required to . . . report data. Thus, new payment rates will be based primarily on private payer data from independent labs.") (footnotes omitted).

[29] CMS, *Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System* 3 (Sept. 22, 2017), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf [hereinafter, "CMS, Summary of Data Reporting"].

[30] CMS, Year 2 of Baseline Data, *supra* at 3.

[31] *Hospital Labs Still Dominate In Volume Testing*, Lab. Econ., June 2017, at 5.

Yet during the first reporting period under the new rule, a mere *1%* of the reported test volume came from hospital laboratories. Only 21 hospital laboratories determined themselves to be "applicable laboratories" under the Secretary's definition.[32] Independent laboratories reported *90%* of the test volume during the first reporting period. Physicians' office laboratories were a distant runner-up at 7.5% of test volume (and 57% of the NPIs submitted).[33] The data the rule generates will therefore predominantly reflect the market for physician-office and independent laboratory tests.

The impact of this skewed data reporting on the resulting reimbursement rates is profound. Laboratories have different cost structures based on the types of services they offer and the institutional settings in which they operate. In particular, hospital laboratories have different cost structures than large national independent laboratory chains that are able to benefit from economies of scale and accept lower third-party payor reimbursement rates.[34] Crucially for PAMA's market-based scheme, private payors recognize these differences in costs and rates by reimbursing hospital laboratories at higher rates than they pay competing independent laboratories. As one report explains, "[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."[35]

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

[33] *Id.*

[34] *See* Wolcott, *supra* at 76–77.

[35] *Id.* at 77.

Hospitals, on the other hand, must meet a particularly wide array of patient needs, serving inpatients and outpatients who have immediate needs during hospital visits, offering around-the-clock services, and frequently providing the most complex clinical laboratory tests.[36] In total, they offer more facilities for patients across the United States than independent laboratories.[37] In addition to serving inpatients, the majority of hospital laboratories also conduct outreach testing, by which they can "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.[38]

By effectively excluding hospital laboratories from its final rule, the Secretary has filtered out data from these higher-cost laboratories that receive more from private payors for their testing services, thereby ensuring the results will predominantly reflect data from lower-cost players. If laboratory reimbursement rates are set based on this skewed data, *all* laboratories can expect to receive lower Medicare reimbursement rates, which will in turn threaten laboratories that depend on Medicare reimbursement to offer services in settings and locations where costs are higher.[39] The rule is therefore likely to reduce quality of and access to laboratory services overall, hitting hardest those laboratories that reach patient groups that are not (or cannot) be served by independent laboratories—patients served in rural markets, nursing facilities, and hospitals, for

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

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

[38] *See* Wolcott, *supra* at 70–71; Valerie Neff Newitt, *Market Based? A View of PAMA Process, Pricing*, CAP Today, Sept. 2017, at 6 ("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)).

[39] *See* Richard J. Cross III, *The Health Care Crisis You Don't Know About*, Balt. Sun (Sept. 20, 2017), http://www.baltimoresun.com/news/opinion/oped/bs-ed-op-0921-laboratory-services-20170920-story.html

example.[40] Access to laboratory services remains a challenge, for instance, in rural areas, including some that are not served by independent laboratories.[41] While "[g]eographic access to physicians has improved during the past five years, . . . laboratories have not diffused to rural areas as quickly."[42]

Congress did not intend this result. Section 216's purpose was to generate rates that reflect the entire national commercial market for laboratory tests across laboratory segments. That market certainly includes the crucial, higher-cost hospital laboratories the rule ignores. The statute therefore directed the Secretary to collect comprehensive data from the commercial market, and set a reimbursement formula premised on comprehensive market data.[43] Setting reimbursement rates based on independent laboratories' rates alone, or on the *lowest* private payor rates, would have presented Congress with a different policy choice than the one it made. Instead, Congress created an entire data collection and calculation regime premised on *representative* private payor

[40] *See id*.; The Dark Report, *Why Small Labs, Hospitals Are at Risk from PAMA Cuts* 4, 5 (Nov. 28, 2016), https://www.xifin.com/sites/default/files/documents/Why%20Small%20Labs%2C%20Hospitals%20Are%20at%20Risk%20from%20PAMA%20Cuts-Dark%20Report.pdf (noting that "small labs (often the only independent labs serving nursing homes in their regions), community hospitals, and rural hospitals will take a financial hit that may put them out of business" and that "if these smaller lab test providers are the only source for lab testing and they go out of business, private health insurers recognize that it is highly unlikely that the nation's largest independent labs would step in to serve these communities").

[41] *See* Amy M. Gass Kandilov et al, *The National Market for Medicare Clinical Laboratory Testing: Implications for Payment* Reform, Medicare & Medicaid Research Rev. E1, E12 (2012), https://www.cms.gov/mmrr/Downloads/MMRR2012_002_02_A04.pdf ("Independent laboratories as a whole have a much smaller market share in rural counties, with their lower market share offset by a much higher market share for laboratories in [Critical Access Hospitals (CAHs)].").

[42] Curran, *supra* at 21.

[43] 42 U.S.C. § 1395m-1(b)(2).

rates.[44] Excluding hospital laboratories that compete directly with independent laboratories[45] directly undermines Congress's intent that the Secretary calculate rates based on reporting that reflects the actual commercial market for laboratory tests.

Members of Congress have been clear that the effect of this rule directly contradicts section 216's purpose. It was passed to "establis[h] a system requiring laboratories to report market rates to establish Medicare reimbursement. . . . [T]he 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, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-services basis under the fee schedule." [46] 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 (CMS).[47] They explained, that "[t]he goal of this new reporting system is to develop a market-based reimbursement system 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 to that Medicare rates could be reset based on a true picture of the

[44] Section 216 mentions hospital laboratories specifically—and in no way suggests Congress excluded them. The statute makes clear that the new CLFS rates apply to all laboratory tests furnished by hospital laboratories that are not paid for as part of a bundled payment. *Id.* § 1395m-1(b)(1)(B).

[45] *See, e.g.*, Washington G2 Reports, *supra* at 22; Kandilov, *supra* at E10-11 ("individual hospitals and systems are actually, or potentially, strong local competitors to independent laboratories").

[46] 160 Cong. Rec. S2860 (daily ed. May 8, 2014) (statement of Senator Burr, confirmed by Senator Hatch, who further stated "the intent of the provisions of the bill . . . is to ensure that Medicare rates reflect true market rates, and that commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories").

[47] Letter of Bill Pascrell, Jr., Member of Congress, et al. to Andy Slavitt, Acting Administrator of CMS (Dec. 9, 2015).

laboratory market."[48] By excluding at least one important segment of the laboratory market, data collected under the final rule will not represent a "true picture" of that market.

III. THE SECRETARY'S SKEWED DEFINITION OF "APPLICABLE LABORATORIES" IS ARBITRARY AND CAPRICIOUS

In addition to exceeding the authority Congress delegated to the Secretary, the decision to define a laboratory according to the NPI under which it bills is arbitrary and capricious. It generates skewed results and, for reasons the Secretary fails to explain, does not accord with the Secretary's own stated policy in adopting the rule.

The final rule conceded that it "*should* define applicable laboratory so that hospital outreach laboratories would not, in effect, be excluded."[49] The Secretary agreed that "it is important not to prevent private payor rates from being reported for hospital outreach laboratories so that we may have a broader representation of the national laboratory market to use in setting CLFS payment amounts."[50] In fact, at points the rule goes even further to say—correctly—that "[t]he CLFS applies to a wide variety of laboratories (for example, national chains, physician offices, hospital laboratories, etc.), and [the Secretary] believed it was important that we define laboratory broadly enough to encompass *every laboratory type that is subject to the CLFS*."[51]

These statements are impossible to square with the final rule. The rule's requirement that an applicable laboratory be one that "[b]ills Medicare Part B under its own [NPI]" excludes nearly all hospital laboratories, *including* the hospital outreach labs the rule said it intended to include. The data collected during the first collection period (January 1, 2016 to June 30, 2016) under the

[48] *Id.*

[49] Final Rule, 81 Fed. Reg. at 41,045 (emphasis added).

[50] *Id.*

[51] *Id.* at 41,042 (emphasis added).

new rule confirms this fact. A grand total of 21 hospital laboratories reported as "applicable laboratories" under this definition—and 4 of those laboratories did not report with their own "non-hospital NPI as required."[52] This number represents less than 1% of the 9,062 hospital laboratories CMS reports existed as of January 2018.[53] The agency states that one of the reasons it adopted NPI as a component of the definition of an applicable laboratory is to ensure that hospital outreach laboratories could qualify under the definition.[54] But it acknowledged shortly after issuing the final rule that it had no "information currently on the number of hospital outreach labs that have their own NPI."[55]

Using NPI as a measure of a laboratory is itself arbitrary. NPI is a ten-digit reporting tool for HIPAA standard transactions. It is found nowhere in the statute or governing regulatory scheme—and is irrelevant to whether a medical facility is a laboratory.[56] The final rule nowhere explains why a particular institution's practice of billing under multiple different or a single NPI should have *any* relevance to whether its private payor data should be considered relevant to assessing the commercial market for laboratory tests. While it may be *easier* for laboratories with

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[52] CMS, Summary of Data Reporting, *supra* at 4.

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

[54] *See, e.g.*, CMS, Summary of Data Reporting, *supra* at 2 ("CMS defined an applicable laboratory at the NPI level *in order to allow* hospital outreach laboratories that independently enroll in Medicare to be an applicable laboratory . . . .") (emphasis added).

[55] Transcript of MLN Connects National Provider Call, *Clinical Diagnostic Laboratory Test Payment System Final Rule Call*, July 6, 2016, at 2:30pm, at 14, https://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2016-07-06-mln-connects-call-clinical-lab-transcript.pdf.

[56] 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. "If a subpart conducts any HIPAA standard transactions on its own (that is, separately from its parent), it must obtain its own NPI." 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.

a unique and exclusive NPI to identify their revenues, this does not explain why others should not be considered "laboratories" under PAMA in the first place. Certainly, neither PAMA nor CLIA distinguishes between laboratories based on their billing structures or institutional type.[57] And for good reason: the entire purpose of section 216 was to collect data from across laboratories nationwide to assess the private-payor market for the tests they offer.

Yet under the rule, whether any given laboratory is an "applicable laboratory" under PAMA depends almost entirely how Medicare billing is structured within any larger institution of which a laboratory is a part. This of course has nothing to do with why Congress might have wanted laboratories to be included or excluded. For instance, if a hospital uses a single NPI for all of its Medicare billing (including outreach laboratory services), the rule mandates that the majority of Medicare revenues criteria be evaluated by adding CLFS and PFS revenue together and dividing by all Medicare revenues for the entire entity. In those circumstances, it is hard to see how a hospital outreach laboratory could satisfy the majority of revenues provision. The result bears no relationship to the test the statute sets out. It is quintessentially arbitrary. *See Samaritan Health Serv. v. Bowen*, 811 F.2d 1524, 1526 (D.C. Cir. 1987) (holding Secretary's definition of "nursery" invalid where it led to "arbitrary results" that made reimbursement "depen[d] entirely upon the happenstance of whether [a] newborn received treatment in the Pediatrics unit or the Border or ICU units"—each of which rendered comparable care).

[57] Section 216 itself refers to hospital laboratories specifically but only in discussing when they are entitled to *payment* under its provisions. *See* 42 U.S.C. § 1395m-1(b)(1)(B). This subsection illustrates that Congress knew how to exclude hospital laboratories when it wanted to—and was well aware of bundled payments in enacting the PAMA. Had Congress wanted to carve hospital laboratories out of the *reporting* required by section 216, it would have done so.

* * *

This rule contradicts the statute by importing limitations into the definition of applicable laboratory that Congress did not authorize. It also contradicts Congress' clear purpose—to set a market rate for laboratories based on a complete and representative survey of laboratories' private-payor rates. Left in place the rule would significantly harm all laboratories, and particularly those that serve populations and health needs not addressed by independent laboratories.

CONCLUSION

For the foregoing reasons, this Court should grant plaintiff's motion for summary judgment.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on February 21, 2018, I filed this brief with the United States District Court for the District of Columbia using the CM/ECF system, which will cause it to be served on all counsel of record.

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