IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. ALEX M. AZAR II, *in his official capacity as Secretary of Health and Human Services*, Defendant.[1]	Civil Action No. 17-2645 (EGS)

DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Defendant Alex M. Azar II, in his official capacity as Secretary of the Department of Health and Human Services, hereby moves for summary judgment in his favor on all claims presented in this action. A memorandum of points and authorities and a proposed order accompany this motion.

Dated: March 23, 2018

Respectfully submitted,

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[1] Pursuant to Fed. R. Civ. P. 25(d), Alex M. Azar II is substituted as the defendant in this action in his official capacity as Secretary of Health and Human Services

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DEFENDANT'S MEMORANDUM IN SUPPORT OF HIS CROSS-MOTION FOR SUMMARY JUDGMENT AND IN OPPOSITION TO PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

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INTRODUCTION

In 2014, for the first time in thirty years, Congress overhauled the fee schedule used by Medicare to pay for Clinical Diagnostic Laboratory Tests ("CDLTs"). Congress understood that modernizing this fee schedule could lead to significant reductions in reimbursements for certain tests, and even went so far as to fix the percentage that a given payment could be reduced each year, to mitigate the impact of the new fee schedule. Yet Plaintiff, a laboratory trade association, blames the Department of Health and Human Services ("the agency," "Defendant," or "HHS") for implementing these statutory directives, and thereby lowering certain Medicare payment amounts.

Plaintiff seeks to enjoin the new fee schedule through a circuitous challenge to the agency's rulemaking. Specifically, Plaintiff argues that the agency improperly defined the "applicable laborator[ies]" that would be required to report certain private sector payment data to the agency, data that would then be used to determine the new Medicare payment amounts. 42 U.S.C. § 1395m-1(a)(2). Plaintiff further avers that the definition of "applicable laboratories" caused an insufficient number of hospital laboratories to report their data to the agency. These hospitals purportedly charge more for CDLTs than do other kinds of laboratories, and Plaintiff argues that the absence of hospital laboratory data caused the new fee schedule to be lower than it otherwise would have been.

This challenge fails at the outset, as the Court lacks subject matter jurisdiction over Plaintiff's suit for three independent reasons. First, the statute expressly bars any judicial challenge to the "establishment of payment amounts" in the new fee schedule. *Id*. § 1395m-1(h)(1). Plaintiff's suit is a direct attack on the Medicare payment amounts established here, and is therefore barred. Second, Plaintiff lacks standing because it fails to show that the agency's definition of "applicable laboratory" caused any economic injuries. Rather, the Court is left to

speculate as to both the actual cause of any lowered Medicare payments, and whether the sought relief would redress those purported injuries. Third, Plaintiff has failed to present to the agency a concrete claim for reimbursement and exhaust all administrative remedies, as required for a challenge arising out of the Medicare statute. For each of these reasons, the Court should dismiss Plaintiff's claims.

In addition, Plaintiff's claims fail on the merits. Plaintiff argues initially that the agency's rulemaking disregarded the unambiguous language of the relevant statute. Yet in previous comments and letters to the agency, Plaintiff repeatedly asserted that the statute lacked definitions for the terms at issue, and the agency thereby was required to answer "complicated" interpretive questions. *See, e.g.*, ECF No. 1-4 at 99. Accordingly, Plaintiff's argument is essentially that the agency's interpretation of the statute is unreasonable, and that the Final Rule should have been crafted differently in the agency's discretion. However, the agency logically defined "applicable laboratory," in part, as a laboratory that actually receives Medicare revenues by billing under its own National Provider Identifier ("NPI") number. Administrative Record ("AR") 00013; 81 Fed. Reg. 41,036, 41,047 (June 23, 2016). This definition is in lockstep with the statutory directive, which states that an "applicable laboratory" must be one that receives certain Medicare "revenues." 42 U.S.C. § 1395m-1(a)(2). Plaintiff offers no workable alternative definition, let alone one clearly superior to that in the agency's Final Rule. Plaintiff thus provides no plausible basis for the Court to find the agency's actions unreasonable, or arbitrary and capricious, and as a consequence this Court should enter judgment for Defendant.

BACKGROUND

I. Statutory Background

Medicare is a federal health insurance program for the elderly and disabled. *See* 42 U.S.C. § 1395 *et seq.* (the "Medicare statute"). Part A of Medicare provides insurance coverage for inpatient hospital care, home health care, and hospice services. *Id.* § 1395c. Part B of Medicare provides supplemental coverage for other types of care, such as hospital outpatient services and visits to the doctor. *Id.* §§ 1395k(a)(1), 1395x(s). At issue in this case is payment for the provision of a particular type of medical care, CDLTs, which encompass a wide variety of laboratory tests that range from "routine blood tests to ground-breaking genetic and molecular tests." Pl's Mot. for Summ. J. ("Pl. Mot.") at 4, ECF No. 13.

For Medicare beneficiaries, the cost of these CDLTs is generally covered by Medicare, but the statutory source of the payment, and the nature of the payment to the test provider, is dependent on the context in which the testing is done. For instance, if a beneficiary is an inpatient at a hospital, that hospital will be paid under Medicare Part A, pursuant to the Medicare Hospital Inpatient Prospective Payment System for Acute Care Hospitals ("IPPS"). Under the IPPS, "hospitals are prospectively compensated for inpatient services at a fixed rate that is not based on the actual cost of the services provided." *Shands Jacksonville Med. Ctr. v. Burwell*, 139 F. Supp. 3d 240, 244 (D.D.C. 2015). That is, hospitals are paid by Medicare based on the relevant Medicare Severity Diagnostic-Related Group ("MS-DRG"), depending on a given patient's diagnosis, and Medicare provides a single IPPS payment "in full satisfaction of the bundle of covered items and services provided during a single inpatient hospital stay." *Appalachian Reg'l Healthcare, Inc. v. Shalala*, 131 F.3d 1050, 1053 (D.C. Cir. 1997).

The companion to the IPPS is the Hospital Outpatient Prospective Payment System ("OPPS"), whereby Medicare Part B pays hospitals directly for the outpatient services they provide to beneficiaries. *See* 42 U.S.C. § 1395*l*(t) (establishing OPPS). Under the OPPS, with certain exceptions, the agency makes payments to hospitals for the services they provide based on amounts that are determined prospectively for each upcoming year. *See id.* Just as the IPPS uses MS-DRGs, for OPPS payment purposes, individual items and services that are clinically similar and comparable in cost are bundled into Ambulatory Payment Classification ("APC") groups. *See* 42 U.S.C. § 1395*l*(t)(2). Thus, under both the IPPS and OPPS payment systems, Medicare effectively compensates hospitals for the cost of CDLTs as an unspecified part of payment for an overall package, or packages in the case of the OPPS, of services provided to a patient.

An entirely different mode of reimbursement applies for laboratory tests when a Medicare beneficiary receives those tests while neither a hospital inpatient nor outpatient. In such circumstances, when the beneficiary receives a laboratory test, the health care provider, such as an independent laboratory or doctor's office, is reimbursed pursuant to the Medicare Clinical Laboratory Fee Schedule ("CLFS") or the Physician Fee Schedule ("PFS"). AR 00004; 81 Fed. Reg. at 41,038. Distinct from the IPPS and OPPS, when a health care provider is reimbursed pursuant to the CLFS or PFS, the provider receives a distinct and identifiable payment for each test performed. *See* Pl. Mot. at 27-28 (describing the CLFS as a "fee-for-service" model).[2]

[2] The Physician Fee Schedule operates in a similar fashion to the CLFS, providing payment for each laboratory test conducted. Most tests that routinely require both a professional and technical component to provide the test results are paid under the PFS, as opposed to tests that require no interpretation by a physician or other practitioner – those are governed by the CLFS. *See* 42 C.F.R. § 414.40(b)(2).

Medicare used to make payments under the CLFS at the lesser of the (1) laboratory's charged price, (2) the local fee schedule amount established by the Medicare contractor, or (3) a National Limitation Amount ("NLA"). Under the previous system, the CLFS amounts were updated for inflation based on the percentage change in the Consumer Price Index for All Urban Consumers and reduced by a multi-factor productivity adjustment, but were not otherwise updated or changed. 42 U.S.C. § 1395*l*(a)(1)(D)(i)(I), (b) & (h). In practice, most tests were previously paid at the NLA. AR 00004; 81 Fed. Reg. at 41,038. While the details of this process are not relevant here, it bears noting that the fee schedule varied depending on where, among 56 localities, the test was performed. *See* HHS, Office of Inspector General ("OIG"), Variation in the Clinical Laboratory Fee Schedule at 1, OEI-05-08-00400 (July 2009), https://oig.hhs.gov/oei/reports/oei-05-08-00400.pdf (last visited Mar. 12, 2018). Over thirty years, through this complex and varied process, many of the payment amounts for CDLTs became "outdated" and some tests may not have been "priced appropriately[,]" due to automation or the development of more "expensive and complex tests[.]" AR 00005; 81 Fed. Reg. 41,039.

In addition, the cost imposed on Medicare through the CLFS was significant. In 2014, over 27 million Medicare beneficiaries received a CDLT covered by Medicare Part B, totaling 451 million lab tests performed, under 1,146 different "procedure codes." *See* HHS, OIG, Medicare Payments for Clinical Laboratory Tests in 2014: Year 1 of Baseline Data at 3, OEI-09-15-00210 (September 2015), https://oig.hhs.gov/oei/reports/oei-09-15-00210.pdf (last visited Mar. 12, 2018). In total, Medicare Part B expended $7 billion that year alone for CDLTs paid under the CLFS. *Id*.

In response to concerns about costs under the CLFS, Congress passed the Protecting Access to Medicare Act of 2014 ("PAMA"), which, among other things, mandated significant

changes in the way that Medicare pays for CDLTs under the CLFS. Pub. L. No. 113-93, § 216, 128 Stat. 1040 (2014), *codified at* 42 U.S.C. § 1395m-1. The statute set forth a process by which the Secretary was to establish new payment amounts for the CLFS. First, "applicable laboratories" are required to periodically report to the agency the payment rates (and the test volume paid at such rates) that they received from private payors, such as private insurance companies, for each CDLT. 42 U.S.C. § 1395m-1(a)(2). The statute defined "applicable laboratory" only as a "laboratory" that, "with respect to its revenues under this subchapter, a majority of such revenues are from this section, section 1395*l*(h) of this title, or section 1395w–4 of this title." *Id*. In other words, subsection (a)(2) stated only that a "laboratory" would be required to report data to HHS if it received "revenues" from Medicare, and a majority of those revenues were received from the CLFS or the PFS. The statute thereby excluded from reporting any "applicable laboratory" if a majority of its Medicare revenues were paid pursuant to the IPPS and/or OPPS payment systems. However, the statute left unspecified the precise meaning of a "laboratory" and how to determine its received "revenues."

The statute then instructed the Secretary to determine the "weighted median" of the private payor data reported to the agency. 42 U.S.C. § 1395m-1(b)(1)(A). That is, the Secretary must "array[]" all private payor payment rates for laboratories reporting collected data for each CDLT, weighted by testing volume, and determine the median of all such payment rates. *Id*. §1395m-1(b)(2). The "weighted median" amount would generally constitute the new Medicare payment amount for the CDLT under the new CLFS.[3] *Id.*

[3] Different payment methodologies are specified for Advanced Diagnostic Laboratory Tests ("ADLTs") and "new" CDLTs. 42 U.S.C. §§ 1395m-1(b)(3)(C), (c)(1), (d).

Congress recognized that these new payment amounts, as intended, could be significantly lower than the amounts on the then-current CLFS. It accordingly set a floor for the yearly reduction in Medicare payment rates for a given CDLT on the newly revised CLFS. *Id.* § 1395m-1(b)(3)(B); *see also* Rachel E. Sachs, *Innovation Law and Policy: Preserving the Future of Personalized Medicine*, 49 U.C. Davis L. Rev. 1881, 1903 (2016) (noting that "Congress [felt] the unusual need to cap the percentage by which CLFS rates may be reduced in any given year."). Specifically, the statute specified that from 2017-2019, the payment rate for a given CDLT may not be reduced by more than 10% from the preceding year, and from 2020 to 2022, the payment amounts cannot be reduced by more than 15% from the previous year. 42 U.S.C. § 1395m-1(b)(3).

In order to effect the rapid and smooth transition to the new CLFS, Congress broadly insulated "the establishment of payment amounts under this section," from any "administrative or judicial review" under the Medicare statute "or otherwise[.]" *Id.* § 1395m-1(h)(1).

II. Rulemaking Background

On October 1, 2015, the Centers for Medicare & Medicaid Services ("CMS"), the component agency of HHS authorized to administer the Medicare program, published its proposed rule, 80 Fed. Reg. 59,386-01 (October 1, 2015), interpreting and implementing the statutorily-required revisions to the CLFS. This was a significant effort, as Plaintiff noted in an early letter to the agency, because PAMA modified the "Medicare reimbursement rate methodology under the Clinical Laboratory Fee Schedule . . . for the first time in about three decades." *See* AR 02369; ECF No. 1-4 at 56. The rulemaking process was particularly challenging because, as Plaintiff also pointed out, while CMS was tasked with collecting data from certain laboratories with regard to specified revenues, "[n]either the term 'laboratory' nor

the term 'revenue' is defined in PAMA or elsewhere in the Social Security Act." *See* ECF No. 1-4 at 39; AR 02371 (same). Thus, as Plaintiff put it, the agency "must first decide how to define the 'laboratory' whose revenues it must look at. Then, it must determine what revenues are to be looked at." ECF No. 1-4 at 99; *see also id.* at 58 (Plaintiff argued that "Section 216 of PAMA gives CMS some direction about what it considers an 'applicable laboratory,' but the agency will have to define the parameters of that term further").

CMS discussed its proposed definition for "applicable laboratory" at length in the proposed rule. Agreeing that there was no definition of "laboratory" specified in the statute, as a first step the agency proposed to incorporate the definition stated in the Clinical Laboratory Improvement Amendments of 1988 ("CLIA"), which set forth the safety and health standards for any laboratory to perform "testing on human specimens for a health purpose." AR 00074; 80 Fed. Reg. at 59,391. CLIA defines a laboratory as a "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.*

HHS also had to determine, as Plaintiff put it, "what is meant by revenues" in the statute. ECF No. 1-4 at 39, 71. Namely, the agency had to further define "applicable laboratory," to determine when the "laboratory itself receives 'revenues' for its services." *Id.* at 99. The agency noted that: "Laboratory business models vary throughout the industry. For example, some laboratories are large national networks with multiple laboratories under one parent entity. Some laboratories are single, independent laboratories that operate individually. Some entities, such as

hospitals or large practices, include laboratories as well as other types of providers and suppliers." AR 00075; 80 Fed. Reg. at 59,392.

CMS explained that, despite the wide diversity of laboratories, all "[e]ntities that enroll in Medicare must provide a [Taxpayer Identification Number ("TIN")], which we use to identify the entity of record that is authorized to receive Medicare payments." *Id*. Health care providers such as laboratories that transmit certain health information in electronic form are also required to obtain a National Provider Identifier ("NPI") number. *Id*. In order to bill Medicare for services, a provider must do so pursuant to its individual NPI number. *See* 42 C.F.R. §§ 424.505 & 424.506 (stating that the NPI is used as the Medicare billing number and requiring a provider or supplier enrolled in Medicare to include its NPI when submitting Medicare claims). Further, "[w]hen the TIN-level entity reports tax-related information to the IRS, it does so for itself and on behalf of its component NPI-level entities." AR 00075; 80 Fed. Reg. at 59,392. The agency proposed to "rely on the TIN as the mechanism for defining the entity we consider to be the applicable laboratory[,]" that is, the laboratory that receives Medicare revenues under the statute. *Id*.

The agency also proposed establishing a low expenditure threshold to further define an "applicable laboratory." *See* 42 U.S.C. § 1395m-1(a)(2) (stating that the "Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory . . . ."). The agency suggested that if a laboratory received $50,000 or less in Medicare revenues in a given data collection period, it would not be required to report its private payor data. AR 00077; 80 Fed. Reg. at 59,394. HHS estimated that such a threshold would exclude approximately 94 percent of physician office laboratories, and 52 percent of independent laboratories from reporting. *See* 81 Fed. Reg. at 41,095; HHS, OIG,

Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data at 8, OEI-09-16-00040 (September 2016), https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf (last visited Mar. 13, 2018).

After the proposed rule was published in the Federal Register, the agency received some 1,300 public comments expressing a wide range of views on virtually every aspect of the rulemaking. CMS published its Final Rule on June 23, 2016. 81 Fed. Reg. 41,036 (June 23, 2016). As relevant here, the agency noted comments that disagreed with the proposal to define "applicable laboratory" in part as the TIN-level entity. Certain commenters argued that this requirement would prevent hospital laboratories from reporting their private payor rates because those laboratories do not have their own TIN. AR 00011; 81 Fed. Reg. 41,046. In response, the agency first noted that the statute inherently limits reporting primarily to independent laboratories and physician laboratories through the majority of Medicare revenues criterion. AR 00011; 81 Fed. Reg. at 41,045. That is, "[m]ost hospital laboratories will not meet the majority of revenues threshold because their revenues under the IPPS and OPPS alone will likely far exceed the revenues they receive under the CLFS and PFS[,]" so they would likely never meet the majority of revenues requirement. *Id.*

At the same time, HHS agreed that in certain instances, hospital laboratories could function essentially as stand-alone laboratories that receive Medicare revenues. That is, these "hospital outreach laboratories" are "distinguishable from hospital laboratories in that they are enrolled in Medicare separately from the hospital of which they are a part, that is, they can be enrolled as independent laboratories that do not serve hospital patients." *Id*. In that circumstance, these hospital outreach laboratories may possess their own "NPI (separate from the hospital) and bill[] for [their] hospital outreach services (that is, services furnished to patients

other than inpatients or outpatients of the hospital) using [their] unique NPI . . . ." AR 00012; 81 Fed. Reg. 41,046. By contrast, HHS explained that those hospital laboratories that "are not hospital outreach laboratories . . . would be unlikely to get their own NPI and bill Medicare for laboratory services" because any Medicare revenues are primarily "payments made to the hospital under the IPPS and OPPS." *Id.* Thus, HHS recognized that where a hospital laboratory bills under its own NPI, the laboratory has distinct and identifiable Medicare "revenues." The agency therefore, in the Final Rule, adopted the suggestion of many commenters to change the definition of applicable laboratory from the TIN-level entity to an NPI-level entity, specifically to enable "private payor rates to be reported for hospital outreach laboratories . . . ." *Id.*

The agency also considered, but rejected, other alternative definitions for "applicable laboratory" suggested by commenters. Plaintiff, along with other commenters, first suggested that an applicable laboratory should be defined solely on the basis of its certificate assigned under CLIA, because it would "allow an analysis of a laboratory's Medicare revenues at the most granular level . . . ." AR 03398; ECF No. 1-4 at 159. In response, the agency noted that the CLIA certificate is used to ensure that the physical premises of "a laboratory meet[] applicable health and safety regulations in order to furnish laboratory services. CLIA certificates are not associated with Medicare billing so, unlike for example, the NPI, with which revenues for specific services can easily be identified, the CLIA certificate cannot be used to identify revenues for specific services." AR 00012; 81 Fed. Reg. at 41,046. The agency could "not see how a hospital would determine whether its laboratories would meet the majority of Medicare revenues threshold (and the low expenditure threshold) using the CLIA certificate as the basis for defining an applicable laboratory." *Id.*

Further, the agency explained that all IPPS payments and most OPPS payments are not "paid on a fee-for-service basis," and instead include services that are "bundled" into a single prospective payment to the hospital. *Id*. The agency explained that under Plaintiff's proposal a hospital would be potentially required to determine the Medicare "revenues" that were attributable only to its laboratory, including those parts of bundled IPPS and OPPS payments relevant to laboratory services. But it was entirely "unclear" to the agency as to how specific hospital laboratory "revenues" could be separated from IPPS and OPPS bundled payments. *Id*. The agency accordingly rejected Plaintiff's proposal to define "applicable laboratory" solely on the basis of a CLIA certificate.

The only other alternative proposal set forth by Plaintiff involved the use of an "adjustment factor" whereby a hospital would essentially estimate that six percent of its IPPS and OPPS Medicare revenues were attributable to its laboratory for laboratory services, and use the resulting revenue amounts as a proxy for the total Medicare revenues of the hospital laboratory, to determine if it met the majority of revenues threshold. *See* AR 03399; ECF No. 1-4 at 160; *see* Pl. Mot. at 35. Plaintiff further suggested that, in lieu of the six percent estimate, "a hospital would be permitted to use its actual revenues and payment-to-charges ratio to show that its Medicare revenues from the CLFS and/or the PFS were more or less than 50 percent of the hospital laboratory's total Medicare revenues . . . ." AR 03399-3401; ECF No. 1-4 at 161-62. Plaintiff conceded that even under this proposal "many hospitals would not qualify as applicable laboratories, but the calculation would capture those hospitals with significant laboratory outreach programs." AR 03401; ECF No. 1-4 at 162.

The agency considered and rejected this proposal as well. As noted above, the agency specifically defined "applicable laboratory at the NPI level" in order to "address[] the industry's

concern that hospital outreach laboratories not be excluded from the definition of applicable laboratory." AR 00012; 81 Fed. Reg. at 41,046. The agency believed that only hospital outreach laboratories, that is, those hospital laboratories that primarily serve non-hospital-patients, would be likely to obtain their own NPI and bill Medicare separately from the hospital. *Id.* By contrast, those hospital laboratories that did not have a significant outreach program would be "unlikely to get their own NPI and bill Medicare for laboratory services . . . ." *Id.* Thus, the agency concluded that its use of the NPI criterion would "enable hospital outreach laboratories to be applicable laboratories[,]" such that it was unnecessary to "establish a hospital adjustment factor . . . ." *Id.*

In light of the definition of "applicable laboratory" adopted in the Final Rule, the agency also changed the low expenditure threshold initially proposed. Pursuant to the Final Rule, an "applicable laboratory" does not include entities that receive less than $12,500 in Medicare revenues from the CLFS in a data collection period with respect to their tests that are not ADLTs. Entities that are not "applicable laboratories" are excluded from reporting private payor data. Similar to the threshold set forth in the proposed rule, the revised low expenditure threshold was expected to exclude approximately 95 percent of physician office laboratories and approximately 55 percent of independent laboratories from reporting. AR 00016-17; 81 Fed. Reg. at 41,050-51.

III. Procedural History

Following promulgation of the Final Rule in June 2016, the private payor data of "applicable laboratories" was required to be reported to the agency between January 1, 2017 and March 31, 2017. *See* Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System at 2 (Sept. 22, 2017),

https://www.cms.gov/ Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/ Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf ("CMS Reporting Summary") (last visited Mar. 13, 2018). Based upon the private payor data submitted, the agency published its proposed CLFS rates, to be effective January 1, 2018, on September 22, 2017, and requested comments to be submitted by October 23, 2017. *See* CMS, PAMA Regulations, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/ PAMA-Regulations.html (last visited Mar. 13, 2018). The agency posted the final rates on November 17, 2017. *Id*. Plaintiff filed the instant suit on December 11, 2017.

ARGUMENT

I. This Court Lacks Jurisdiction Over the Complaint

A. PAMA Section 216 Bars Judicial Review

1. The Statute Expressly Bars Any Challenge to the "Establishment of Payment Amounts"

42 U.S.C. § 1395m-1(h)(1) expressly precludes judicial review of Plaintiff's claims. Although the "APA generally establishes a cause of action for those suffering legal wrong because of agency action, or adversely affected or aggrieved by agency action[,]" the "APA does not apply . . . to the extent that . . . statutes preclude judicial review." *Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408 (D.C. Cir. 2012) (citations omitted); *see also* 5 U.S.C. § 701(a)(1). To determine "[w]hether and to what extent a particular statute precludes judicial review[,]" a court must look to the statute's "express language . . . the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 345 (1984).

Plaintiff concedes that, "[t]o afford the Secretary discretion in setting applicable rates, Congress prohibited either 'administrative or judicial review' of 'the establishment of payment

amounts' for the reimbursement of clinical laboratory services." Compl. ¶ 40 (quoting 42 U.S.C. § 1395m-1(h)(1)). Plaintiff seeks to avoid this jurisdictional bar by characterizing its challenge as one that concerns only the reporting of data, not the use of that data to establish new Medicare reimbursement rates for laboratory services. Compl. ¶¶ 3-4. In support of this argument, Plaintiff contends that § 1395m-1 is subdivided into subsection (a), concerning the reporting of data, and all other subsections, concerning payment, and it is only those latter subsections that are shielded from review. Pl. Mot. at 20. This cramped reading of the statute should be rejected.

It is a "cardinal rule that a statute is to be read as a whole," *King v. St. Vincent's Hosp.*, 502 U.S. 215, 221 (1991), and here it is plain that § 1395m-1 sets forth the complete process by which the Secretary must establish payment amounts. Indeed, subsection (a)(2) "Definition of applicable laboratory," at issue here, follows the heading: "Reporting of private sector payment rates *for establishment of Medicare payment rates*[.]" 42 U.S.C. § 1395m-1(a) (emphasis added). The heading for subsection (b)(1) similarly concerns the "[u]se of private payor rate information *to determine Medicare payment rates*[.]" *Id.* § 1395m-1(b)(1) (emphasis added). Thus, while the subsections concern different steps in promulgating the new fee schedule, Congress made clear that they both govern the "establishment of Medicare payment rates." *Id.* § 1395m-1(a)(2).[4]

The D.C. Circuit recently rejected a virtually identical attempt to plead around a jurisdictional bar in the Medicare statute. *See Fla. Health Scis. Ctr., Inc. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 519 (D.C. Cir. 2016). In that case, the plaintiff acknowledged that

[4] Further, subsection (b) and others incorporate language from subsection (a), belying any argument that the statute can be neatly cleaved between those parts that concern payment and those that concern reporting. *See, e.g.*, 42 U.S.C. § 1395m-1(b)(2) (stating that for each test "reported under subsection (a) . . . the Secretary shall calculate a weighted median for the test for the period"); *id*. § 1395m-1(d)(1)-(2).

the statute barred review of the agency's use of particular data, but argued that it could bring a challenge to the agency's selection of data. The court rejected this attempt, holding that "the dispositive issue is whether the challenged [action is] inextricably intertwined with an action that all agree *is* shielded from review, regardless of where that action lies in the agency's decision tree." *Id*. at 521.

Accordingly, where the challenged decision is "indispensable" or "integral" to the agency action shielded from review, jurisdiction is lacking. *See Tex. All.*, 681 F.3d at 409, 411 (holding that where "awarding of contracts" was protected from suit, the financial standards regulation that determined eligibility for contracts was also shielded); *Fla. Health*, 830 F.3d at 519 (holding that where agency "estimate" of hospital's uncompensated care was barred from review, the choice of data used to reach the estimate was also protected from suit); *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1129 (D.C. Cir. 2017) (holding that where "the process" of hospital application to the agency was precluded from suit, the agency's final "determination" on the application was similarly barred). In each of its recent rulings, the D.C. Circuit has urged a broad view of preclusion provisions in the Medicare statute, holding that a "functional analysis" should be used to avoid "frustrating the Congress's desire to place certain administrative actions beyond review." *Knapp*, F.3d at 1131.

The instant case falls squarely under this precedent. There can be little doubt that the reporting of private payor rates for laboratory tests is "integral to" or "inextricably intertwined" with the "establishment of payment amounts" for those tests. *See Fla. Health*, 830 F.3d at 519 (citation omitted); 42 U.S.C. § 1395m-1(h)(1). In fact, the reported private sector payment rates, and the associated volume of tests corresponding to each private payor rate, are generally the only data used by the agency in establishing the new CLFS payment rates. 42 U.S.C. § 1395m-

1(b)(1)(A)-(2) (stating that "[i]n general" the "payment amount" established must be "equal to the weighted median . . . for the test" of all "payment rates reported"); *see also Fla. Health*, 830 F.3d at 519 (finding choice of "underlying data" to be "integral" to the agency's protected estimate because "the data are the entire basis for the estimate"). Plaintiff itself admits that the statute instructs the Secretary to "take the reported information collected from all applicable laboratories and to use it to establish new Medicare reimbursement rates for clinical laboratory services." Compl. ¶ 3.

Plaintiff is thus left to argue that while the output of payment rates may not be challenged, the input, or the collection of data by the Secretary, is susceptible to suit. But the D.C. Circuit has "rejected the categorical distinction between inputs and outputs . . . ." *See Fla. Health*, 830 F.3d at 519. Rather, the language of the statute demonstrates that the data collection by the Secretary is "indispensable," or "integral" or "inextricably intertwined with" the establishment of payment amounts. *Id*. Plaintiff's claims cannot proceed without "eviscerat[ing] the bar on judicial review." *Id*. (quoting *El Paso Nat. Gas Co. v. United States*, 632 F.3d 1272, 1278 (D.C. Cir. 2011)).

Plaintiff's suit, if successful, also would undo years of painstaking effort by the agency, pursuant to congressional mandate, not only in the rulemaking process itself, but in the corresponding data collection process. Enjoining the new fee schedule would inject considerable confusion into the CLFS payment system, and would conceivably require the agency to reanimate the previous fee schedule, with its numerous separate rates for different localities and potentially outmoded payment amounts. Congress did not intend such a "severe[] disrupt[ion of] this complex and delicate administrative scheme," and so it included statutory language expressly precluding judicial review to avoid such disruption. *Block*, 467 U.S. at 348.

At bottom, Plaintiff complains that "Medicare payment amounts . . . 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." Pl. Mot. at 37. Congress insulated the "establishment of payment amounts" from precisely this type of challenge, and as a consequence Plaintiff's claims are barred.

2. Plaintiff Cannot Show an Ultra Vires Agency Action

Likely anticipating that its claims are precluded by statute, Plaintiff argues further that "[t]he Court also has jurisdiction because the Secretary's Final Rule is *ultra vires*." *Id.* at 21. This doctrine provides an extremely narrow avenue of review, permitting examination of agency action where statutory jurisdiction is lacking, but only "when an agency 'patently misconstrues a statute, disregards a specific and unambiguous statutory directive, or violates a specific command of a statute.'" *Organogenesis Inc. v. Sebelius*, 41 F. Supp. 3d 14, 23 (D.D.C. 2014) (citation omitted); *see Fla. Health*, 830 F.3d at 522 ("To challenge agency action on the ground that it is *ultra vires*, [the plaintiff] must show a patent violation of agency authority. . . . A violation is 'patent' if it is 'obvious' or 'apparent.'") (citations omitted); *see also Griffith v. FLRA*, 842 F.2d 487, 492 (D.C. Cir. 1988) (noting that *ultra vires* doctrine is an "implicit but narrow exception"). Thus, any narrow review under this "*ultra vires* doctrine" is not and cannot be a full-blown review on the merits – if it were, the statutory preclusion provision would be rendered meaningless.

Here, for the reasons explained in more detail below, the Secretary's definition of "applicable laboratory" easily survives under *Chevron* review. It follows that this definition also passes muster under the even more deferential standards of *ultra vires* review. It is far from "obvious" that Congress intended an "applicable laboratory" to be defined, in part, as something

other than a laboratory that bills Medicare under a distinct NPI number. Indeed, as Plaintiff explained repeatedly, "[n]either the term 'laboratory' nor the term 'revenues' is defined in PAMA or elsewhere in the Social Security Act." ECF No. 1-4 at 39; AR 02371. The agency was accordingly tasked with crafting a reasonable definition for "applicable laboratory." Given the conceded absence of any definition for "laboratory" or "revenues," Plaintiff cannot show that the agency somehow disregarded a patent or obvious requirement of the statute. Plaintiff's claim of *ultra vires* agency action accordingly fails.[5]

B. Plaintiff Lacks Standing

This Court lacks jurisdiction for the additional reason that Plaintiff lacks standing. To establish Article III standing, Plaintiff bears the burden to show: (1) an "actual or imminent," "concrete and particularized" injury-in-fact, (2) a "causal connection between the injury" and the challenged action, and (3) a likelihood that the "injury will be redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61 (1992). As an organization, Plaintiff asserts standing on its own behalf and on behalf of its members. *See* Compl. ¶ 71 ("ACLA and its membership have been substantially harmed"); *Equal Rights Ctr. v. Post Props., Inc.*, 633 F.3d 1136, 1138 (D.C. Cir. 2011).

To sue on its own behalf, an organization, "like an individual plaintiff," must show "actual or threatened injury in fact that is fairly traceable to the alleged illegal action and likely to be redressed by a favorable court decision." *Food & Water Watch, Inc. v. Vilsack*, 808 F.3d 905, 919 (D.C. Cir. 2015) (citation omitted). Yet Plaintiff fails to set forth any allegation of

[5] Because *ultra vires* review only permits the Court to inquire whether there is a patent violation of a requirement imposed by the statutory text, the jurisdictional bar forecloses Plaintiff's claims that the regulation was unreasonable, or that the regulation was arbitrary and capricious. *See Fla. Health*, 830 F.3d at 522–23.

injury concerning its own organization, and instead all of its claimed harms concern individual member laboratories. *See* Compl. ¶ 72(a)-(g). As a consequence, Plaintiff lacks standing to sue on its own behalf.

To establish associational standing, or standing on behalf of member laboratories, Plaintiff must show that "at least one of its members would have standing to sue in [its] own right[.]" *Sierra Club v. EPA*, 292 F.3d 895, 898 (D.C. Cir. 2002). The sum and substance of the injury alleged in the Complaint is that Defendant improperly defined "applicable laboratory" in the Final Rule, which led to fewer hospital laboratories reporting private payor data to Defendant. *See* Compl. ¶ 72(c)-(g). Plaintiff further claims that hospitals generally receive higher private payor rates for laboratory testing. Pl. Mot. at 2. Accordingly, Plaintiff asserts that the lower reporting from hospital laboratories led in turn to lower Medicare payment amounts than would have been established otherwise, causing an unknown amount of economic injury to Plaintiff-member laboratories. Compl. ¶ 69.

Even assuming *arguendo* that the claim of a speculative and unspecified amount of economic harm suffices for a concrete and particularized injury,[6] each link in Plaintiff's attenuated chain of causation is deficient. First, Plaintiff fails to provide any support for its claim that the definition of "applicable laboratory" caused a lower number of hospital laboratories to report data than would have occurred otherwise. That is, to establish causation, Plaintiff must show that some larger number of hospital laboratories would have qualified as applicable laboratories but for the purportedly unlawful definition used in the Final Rule. *See Nat'l Law*

[6] The basis of Plaintiff's claim of injury is unclear. Plaintiff argues vaguely that the agency will establish Medicare "payment rates that are far below private-sector rates." Pl. Mot. at 3. At no point does Plaintiff specify which CDLT payment amounts were improperly lowered, what private-sector rates will exceed the Medicare payment amounts, or any other basis for its claimed injury.

Ctr. on Homelessness & Poverty v. Kantor, 91 F.3d 178, 183 (D.C. Cir. 1996) (holding that, "[t]o demonstrate . . . injury was caused," Plaintiff must show that data was improperly gathered, "*as compared to a feasible, alternative methodology*"). Plaintiff neglects to set forth any allegation, let alone specific facts, as to the number and identity of the hospital laboratories that it contends should have been required to report data.

Plaintiff claims that "hospital outreach laboratories receive[d] approximately 26 percent of the payments made under Medicare's Clinical Laboratory Fee Schedule in 2015" and that there are some 7,000 hospitals that "provide laboratory services to non-hospital patients under the Clinical Laboratory Fee Schedule." Pl. Mot. at 32. But these numbers tell the Court nothing about how many hospital laboratories actually should have qualified as "applicable laboratories" under the statute, in that they receive a "majority" of Medicare revenues pursuant to the CLFS and PFS payment systems, and would exceed the Final Rule's low expenditure threshold. *See* 42 U.S.C. § 1395m-1(a)(2).[7] Without even an estimate on these questions, this Court is forced to guess at whether the Final Rule's "applicable laboratory" definition actually resulted in fewer hospital laboratories to report than would have occurred otherwise.[8]

Plaintiff also fails to support the next link in its causal chain: that the hospital laboratories that should have reported data actually received higher payments for the specific CDLTs

[7] At one point, Plaintiff vaguely asserts that the agency's data collection left "thousands of hospital laboratories out of the equation," Pl. Mot. at 32, while failing to specify whether there are actually thousands of hospital laboratories that would qualify as "applicable laboratories," and any basis for that claim.

[8] Plaintiff also alleges that it suffered injury from the cost of its member laboratories' compliance with the statute's reporting requirements, while other laboratories were exempted from reporting. Compl. ¶ 72(a). Because Plaintiff provides no estimate as to how many laboratories would report under a different definition of "applicable laboratory," there is no basis to conclude that the agency's definition caused any improper disparity in reporting requirements and associated cost.

reported by Plaintiff's members, or other laboratories, such as independent and physician office laboratories. Instead, Plaintiff vaguely asserts that hospital laboratories "often" or "typically" receive higher payments than those provided to "large independent laboratories." *See* ECF No. 1-2 ¶ 16; ECF No. 1-3 ¶ 14. These nebulous allegations are insufficient at the summary judgment stage, where Plaintiff must set forth "specific facts" supporting its standing. *Lujan*, 504 U.S. at 561.

Finally, Plaintiff must show that because this unknown number of hospital laboratories with unknown private payor rates did not report data, the new fee schedule was lower than it would otherwise have been. Of course, without knowing how many hospital laboratories would otherwise have qualified as "applicable laboratories," what their private payor rates were for specific CDLTs, and the associated volume for each CDLT, the Court must further guess as to whether the allegedly deficient reporting actually caused injurious, lower payment rates. *See Fla. Audubon Soc.'y v. Bentsen*, 94 F.3d 658, 670 (D.C. Cir. 1996) ("Such a protracted chain of causation fails both because of the uncertainty of several individual links and because of the number of speculative links that must hold for the chain to connect the challenged acts to the asserted particularized injury.").

Plaintiff thus fails to show any specific facts establishing that Defendant's definition of "applicable laboratory" caused the harm alleged here. *See Elec. Privacy Info. Ctr. v. Presidential Advisory Comm'n on Election Integrity*, 878 F.3d 371, 379 (D.C. Cir. 2017) ("Speculation is ordinarily fatal to standing . . . and that is the case here."); *Nat'l Fed'n of the Blind v. Spellings*, 562 F. Supp. 2d 74, 80 (D.D.C. 2008) (explaining that there is no causation where plaintiffs had not shown that challenged action, "as opposed to . . . any number of other reasons," caused their injuries).

Plaintiff also cannot establish redressability. That inquiry "examines whether the relief sought, assuming that the court chooses to grant it, will likely alleviate the particularized injury alleged by the plaintiff." *Fla. Audubon Soc'y*, 94 F.3d at 663-64. As the D.C. Circuit has highlighted, "[t]he key word is 'likely.'" *West v. Lynch*, 845 F.3d 1228, 1235 (D.C. Cir. 2017) (citation omitted). "Relief that does not remedy the injury suffered cannot bootstrap a plaintiff into federal court; that is the very essence of the redressability requirement." *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 107 (1998).

To show redressability here, Plaintiff must show that if the Court were to enjoin the Final Rule and order "appropriate revisions," Compl. Prayer for Relief (C), that remedy would likely lead to larger numbers of hospital laboratories reporting data and in turn cause Medicare payment amounts to be higher. But without any facts as to the number of hospital laboratories that will qualify under an "appropriate" definition of "applicable laboratory," and the private payor rates and testing volume for each CDLT that will be reported, the Court is left with only conjecture as to what might result from a different definition. Nor has Plaintiff set forth a specific, alternative definition which would likely provide relief from its alleged injuries. *Accord Banner Health v. Price*, 867 F.3d 1323, 1334 (D.C. Cir. 2017) ("A plaintiff lacks standing . . . if they fail to show that they would benefit under their alternate methodology."); *Nat'l Law Ctr.*, 91 F.3d at 183 (denying standing because court could "hardly assume" that the use of "as-yet unidentified methodologies . . . will redound to appellants benefit"). The absence of any support for causation and redressability defeats Plaintiff's claim of standing.

C. Plaintiff Has Failed to Present Its Claim to the Agency or to Exhaust that Claim

Finally, even if Plaintiff had standing, and the Secretary's definition of "applicable laboratory" for purposes of establishing payment amounts were reviewable, the proper vehicle

for review would not be in this anticipatory suit, but instead in a suit brought only after Plaintiff had first satisfied the Medicare statute's exhaustion requirements. Plaintiff has not met those requirements, and this Court lacks jurisdiction.

The Medicaid statute provides that "[n]o action against the United States, the [Secretary of Health and Human Services], or any officer or employee thereof shall be brought under section 1331 . . . of Title 28 [i.e., the general federal question statute] to recover on any claim arising under" the Medicare statute. 42 U.S.C. § 405(h); *see also id.* § 1395ii (incorporating § 405(h)). Such claims must be "channeled" through the Medicare statute's administrative procedures. *Shalala v. Ill. Council on Long Term Care, Inc.*, 529 U.S. 1, 12 (2000). Only after exhausting those procedures can a claimant seek judicial review under the Medicare statute, which contains its own jurisdictional provision separate from § 1331's grant of general federal question jurisdiction. *See* 42 U.S.C. § 1395ff(a)(1)(C), (b), (d); *id.* § 405(b), (g)-(h).

The Supreme Court has made clear that "the bar of § 405(h) reaches beyond ordinary administrative law principles of 'ripeness' and 'exhaustion of administrative remedies,'" and "demands the 'channeling' of virtually all legal attacks through the agency." *Ill. Council*, 529 U.S. at 12-13 (citation omitted). Even where, as here, a party brings a "facial challenge" to a "Medicare rule[]," it "must exhaust the agency review process regardless of whether the matter involves a direct constitutional, statutory, or regulatory challenge." *Three Lower Ctys. Cmty. Health Servs., Inc. v. HHS*, 317 F. App'x 1, 2 (D.C. Cir. 2009) (per curiam); *see Ill. Council*, 529 U.S. at 5 (explaining that anticipatory challenges to the lawfulness of a provision that might later bar recovery of benefits must proceed "through the special review channel that the Medicare statutes create"); *see also Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell ("NAHC&H")*, 77 F. Supp. 3d 103, 109 (D.D.C. 2015) ("A challenge that arises under the Medicare [statute]

must be brought via Section 405 irrespective of whether it may be equally framed as a challenge under other laws or the Constitution."). Mere "added inconvenience or cost" is no excuse for failing to exhaust administrative remedies. *See Council for Urological Interests v. Sebelius*, 668 F.3d 704, 708 (D.C. Cir. 2011); *Heckler v. Ringer*, 466 U.S. 602, 619 (1984) (holding that claimants "must adhere to the administrative procedure which Congress has established for adjudicating their Medicare claims" even when they "would clearly prefer an immediate appeal to the District Court rather than the often lengthy administrative review process").

The Supreme Court has "defined two elements that a plaintiff must establish in order to satisfy" the administrative prerequisites under Medicare. *Am. Hosp. Ass'n v. Hargan*, No. CV 17-2447 (RC), 2017 WL 6734176, at *5 (D.D.C. Dec. 29, 2017), *appeal filed* (D.C. Cir. Jan. 11, 2018). First, Plaintiff must overcome the "non-waivable, jurisdictional 'requirement that a claim for benefits shall have been presented to the Secretary.'" *Id*. (quoting *Matthews v. Eldridge*, 424 U.S 319, 328 (1976)). The second hurdle is a waivable "requirement that the administrative remedies prescribed by the Secretary be exhausted." *Id*. Here, Plaintiff has neither presented the agency with a claim for benefits, nor exhausted the agency's administrative remedies. Section 405(h) accordingly prohibits Plaintiff's suit.

Plaintiff avers that the channeling provisions in § 405(h) do not bar review for three reasons; none has merit. First, Plaintiff argues that because there is no "viable" administrative process applicable, it should not be required to present and exhaust a claim. Pl. Mot. at 21. But this narrow exception to the channeling requirement applies only where § 405(h) would "result not merely in 'added inconvenience or cost in an isolated, particular case,' but in the '*complete* preclusion of judicial review.'" *Council for Urological Interests*, 668 F.3d at 713 (quoting *Ill. Council*¸ 529 U.S. at 22-23). Thus, the channeling provision applies so long as "Medicare Act

review of a claim is available to some, though perhaps not all, of a class of affected parties." *Id*. at 708. Plaintiff concedes that "at least one of [its] 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." Pl. Mot. at 22. Plaintiff thereby admits that administrative and judicial review is available for the claims at issue here, such that § 405(h) bars the instant suit.

Second, despite this fatal concession, Plaintiff argues that the channeling requirements do not apply because Plaintiff has "presented [its] claims to the Secretary and the Secretary has denied relief for these claims." Compl. ¶ 13. Specifically, Plaintiff contends that, via comments and meetings with the agency, it has "present[ed] [its] claim that the Final Rule is arbitrary, capricious, and in excess of statutory authority." *Id*. ¶ 14. But numerous courts have recognized that such comments are no substitute for an actual "claim for . . . benefits" and thus fail to satisfy the presentment requirement. *See Three Lower Ctys.*, 317 F. App'x at 3 (holding presentment not satisfied by plaintiff's "letter to the [Provider Reimbursement Review Board] requesting a jurisdictional ruling[,]" because "[t]he Medicare Act . . . requires that parties present all such challenges to the agency in the context of a fiscal year reimbursement claim"); *Am. Hosp. Ass'n,* 2017 WL 6734176, at *6 ("[C]omments submitted in a rulemaking are not individualized, 'concrete claim[s] for reimbursement,' as courts routinely require to satisfy presentment."); *NAHC&H*, 77 F. Supp. 3d at 109 n.1 (holding presentment not satisfied by association's submission of "comments to the agency and . . . meeting with agency officials to voice disagreement with the [Medicare] rule"). Indeed, while Plaintiff vaguely asserts that one of its own members has recognized the necessity of presenting a concrete claim for reimbursement, Plaintiff does not allege that its anonymous member has actually presented a claim, as required to bring suit. Pl. Mot. at 22.

Third and finally, Plaintiff argues that "[i]mmediate judicial review is appropriate" because exhausting administrative remedies here would be futile. *Id*. This argument ignores the fact that presentment is an "absolute" jurisdictional "prerequisite" to judicial review under the Medicare statute and cannot be excused due to futility. *Action All. of Senior Citizens v. Leavitt*, 483 F.3d 852, 857 (D.C. Cir. 2007). Plaintiff has not presented a claim for reimbursement to the agency and the Complaint should be dismissed on that basis alone.

The separate requirement that administrative procedures be followed to completion may be excused only in "exceptional cases," because "'the bar of § 405(h) reaches beyond ordinary administrative law principles [such as] exhaustion of administrative remedies' and 'demands the channeling of virtually all legal attacks through the agency.'" *Am. Orthotic & Prosthetic Ass'n, Inc. v. Sebelius*, 62 F. Supp. 3d 114, 123 (D.D.C. 2014) (quoting *Ill. Council*, 529 U.S. at 13).

This is not one of the "exceptional cases" fitting the futility exception. Assuming that administrative and judicial review of Plaintiff's claim were not statutorily precluded, which they are, Plaintiff has administrative avenues through which this action could be "channeled," as Plaintiff itself recognizes. Pl. Mot. at 22. Plaintiff contends that no HHS administrative review body would have authority to "decide the question of law that is relevant to this matter in controversy." *Id*. at 22-23. But the Supreme Court has made clear that this is no excuse for refusing to channel claims through the agency, *see Ill. Council*, 529 U.S. at 23 (channeling required even where agency lacks authority to consider certain questions, because "[t]he fact that the agency . . . may lack the power to" resolve certain questions "is beside the point because it is the 'action' arising under the Medicare Act that must be channeled through the agency."). So long as Plaintiff may channel an "action" through the agency, a court may later consider "any statutory . . . contention that the agency . . . cannot[] decide." *Id.*

Plaintiff recognizes that the administrative process allows parties to seek "expedited access to judicial review" where the relevant board may not have the authority "to decide the question of law or regulation relevant to the matters in controversy . . . ." 42 U.S.C. § 1395ff(b)(2)(A); Pl. Mot. at 23. But expedited review may only be granted to parties who have "filed an [administrative] appeal," *see* 42 U.S.C. § 1395ff(b)(2)(A), and the statute does not otherwise obviate the established requirements to present a claim and follow the relevant administrative processes to completion. In sum, Plaintiff has not satisfied the strict channeling requirements under the Medicare statute and as a result, this Court lacks jurisdiction.

II. The Agency Reasonably Defined the Term "Applicable Laboratory"

A. Standard of Review

If this Court were to reach the merits of Plaintiff's claims, judgment should be entered for Defendant nonetheless. In evaluating the merits, the Court must assess the parties' competing readings of the Medicare statute under the familiar two-step *Chevron* framework. "First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter[.]" *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842-43 (1984). But if the "statute is silent or ambiguous with respect to the specific issue," the Court proceeds to *Chevron* step two, under which the agency's interpretation of the statute will be upheld so long as it is "reasonable." *Id*. at 843-44. Indeed, "if the agency's reading fills a gap or defines a term in a reasonable way in light of the Legislature's design, we give that reading controlling weight, even if it is not the answer 'the court would have reached if the question initially had arisen in a judicial proceeding.'" *Regions Hosp. v. Shalala*, 522 U.S. 448, 457 (1998) (quoting *Chevron*, 467 U.S. at 843 n. 11) (citations omitted).

B. *Chevron* Step One – The Statute Lacks an Unambiguous Definition for "Applicable Laboratory"

Plaintiff first argues that the Secretary's definition of "applicable laboratory" contradicts the express terms of the statute. "To prevail under Chevron step one, [Plaintiff] must do more than offer a reasonable or, even the best, interpretation of the [statute]. Instead, [it] must show that the statute unambiguously forecloses the agency's interpretation." *Petit v. U.S. Dep't of Educ.*, 675 F.3d 769, 781 (D.C. Cir. 2012). In other words, Plaintiff "must demonstrate that the challenged term is susceptible of only one possible interpretation." *Id*. To that end, Plaintiff argues that "[t]here is no relevant ambiguity as to what the statute requires," and that the statute's requirements are "unambiguous." Pl. Mot. at 24-25.

This argument lacks merit. The statute tautologically states that an "'applicable laboratory' means a laboratory" that receives a majority of its Medicare revenues from the CLFS or the PFS. 42 U.S.C. § 1395m-1(a)(2). The statute does not speak to the precise issue of how to define a "laboratory" that receives Medicare "revenues," and Plaintiff's argument on *Chevron* step one accordingly fails.

Plaintiff contends that, under the *expressio unius* canon, Congress's grant of authority to the Secretary to establish a low volume or low expenditure threshold, 42 U.S.C. § 1395m-1(a)(2), must be read to deny the Secretary the authority to exempt other laboratories from the statute. Pl. Mot. at 26. This misreads both the statute and the rulemaking. The Secretary did not purport to use any authority to create new exemptions from the statute; instead, he read the statute's definition of a laboratory that received Medicare revenues to require an analysis of whether a laboratory receives those revenues, or whether a laboratory is part of a larger entity that does so. The *expressio unius* canon does not limit the Secretary's power to answer that question. *See Catawba Cnty., N.C. v. EPA*, 571 F.3d 20, 36 (D.C. Cir. 2009) (when reviewing

agency action, courts "have consistently recognized that a congressional mandate in one section and silence in another suggests not a prohibition but simply a decision not to mandate any solution in the second context, *i.e.*, to leave the question to agency discretion").

Indeed, in comments and letters submitted in the rulemaking process, Plaintiff repeatedly conceded that "neither the term 'laboratory' nor the term 'revenues' is defined in PAMA or elsewhere in the [Social Security] Act." AR 02371; ECF No. 1-4 at 39. Plaintiff explained that "CMS first must determine whether an 'applicable laboratory' includes a hospital laboratory, where a majority of the laboratory's Medicare revenue comes from the CLFS, the PFS, or the new Section 1834A of the Social Security Act." ECF No. 1-4 at 39. Plaintiff further recognized that there was no easy answer to this question, as it noted: "It is fairly easy to determine what the 'laboratory' is with regard to independent laboratories, as there the laboratory entity is easily identifiable. It is somewhat more complicated with regard to a hospital laboratory." *Id.* at 99. Plaintiff went on to note that Defendant had to answer the additional question: "What 'revenues' are to be looked at, when determining whether a majority come from the sections specified in the statute?" *Id*. That is, Defendant had to determine when a "hospital laboratory may be said to be receiving revenues." *Id*. To be sure, Plaintiff stated its opinion as to which definitions "seem[] reasonable," or were "most appropriate." *Id*. at 100. But more to the point, Plaintiff's letters and comments concede that Congress did not speak unambiguously as to these critical terms, and the agency was therefore required to answer certain "complicated" definitional questions in its reasonable discretion. *See id*. at 99-100.[9]

[9] Plaintiff now switches course to argue that the Secretary's definition violates the rule against superfluity by purportedly reading the "majority" of revenues requirement out of the statute. Pl. Mot. at 30. Plaintiff's newly minted argument fails; the Secretary has not ignored that language of the statute, but has given it effect. But, in order to do so, the Secretary first needed to define the entity whose revenues would be analyzed.

Plaintiff appears now to have changed its mind, and argues that Defendant "disregarded a specific and unambiguous statutory directive[.]" Pl. Mot. at 24 (quoting *Griffith*, 842 F.2d at 493). This argument is undone both by Plaintiff's own past comments and Plaintiff's failure to specify in its Motion what regulatory definition of "applicable laboratory" was clearly required by the statute. Plaintiff avers that Defendant is required to examine the "revenues of each laboratory," *id*. at 28, but nowhere does Plaintiff explain how to determine the laboratory entity that receives revenues. This is a telling omission in the context of a purportedly unambiguous statute.

The closest that Plaintiff comes to suggesting an alternative definition is in their apparent request that the supposedly "extra-textual requirement[]" of the NPI criterion be excised from the Final Rule. *See id* at 27. In that instance, the regulation would define an "applicable laboratory" solely pursuant to the definition set forth in the CLIA, and a provider would therefore have to determine the "revenues" of each laboratory, as defined by their individual CLIA certificate. While the practical problems with such a definition are explained in greater detail below, it suffices to note here that the CLIA certificate in no way defines a laboratory that can be said to receive Medicare revenues. Rather, a CLIA certificate merely ensures that defined physical premises meet certain safety and hygiene requirements in order to conduct laboratory testing. AR 00012; 81 Fed. Reg. at 41,046. The CLIA certificate has no intrinsic relationship to the business-level entity that bills Medicare, nor does the agency provide Medicare payments to the building or other area recognized in a CLIA certificate. *See id*.

Again, Plaintiff itself recognized these points in a related context. That is, the statute defines an Advanced Diagnostic Laboratory Test ("ADLT") in part as a CDLT that is "offered and furnished only by a single laboratory . . . ." 42 U.S.C. § 1395m-1(d)(5). In the proposed

rule, the agency suggested that a "single laboratory" be defined as "a facility with a single CLIA certificate," such that an entity with multiple CLIA certificates "would not be a single laboratory." AR 00079; 80 Fed. Reg. at 59,397. In its rulemaking comments, Plaintiff "vehemently disagree[d] with CMS's proposal" because it "does not comport with the reality of how laboratories operate . . . ." AR 03413; ECF No. 1-4 at 174. Plaintiff noted that "a separate CLIA certificate is required for each laboratory location," and that some locations controlled by the same entity may conduct activities related to an ADLT, while other locations perform "wholly unrelated" activities. *Id*. Thus, to account for the fact that CLIA-level facilities are commonly owned and controlled by a larger corporate organization, Plaintiff protested the use of a single CLIA certificate as a "cramped definition for 'single laboratory.'" *Id*. Instead, Plaintiff suggested that a "single laboratory," for purposes of an ADLT, should mean a "laboratory and its parent corporation, wholly owned subsidiaries, and other entities under common ownership." *Id*.

Plaintiff's argument should not be read to suggest that its proposed definition for "single laboratory" was appropriate for use in subsection (a). Rather, Plaintiff highlights the absence of any clearly unambiguous definition of "applicable laboratory," or even the more granular "single laboratory." Even if Plaintiff were to assert that an "applicable laboratory" should be defined by reference to a single CLIA certificate, its own comments make plain that such a descriptor is not clearly required by the statute.

Thus, Plaintiff admits that "neither the term 'laboratory' nor the term 'revenues' is defined in PAMA or elsewhere in the Social Security Act," AR 02371; ECF No. 1-4 at 39, leaving the definitions to the agency's reasonable discretion. This "is the antithesis of a *Chevron* step one statutory directive." *See Anna Jacques Hosp. v. Burwell*, 797 F.3d 1155, 1164 (D.C. Cir. 2015). Plaintiff cannot establish that "Congress has directly spoken to the precise question

at issue," Pl. Mot. at 24 (citation omitted), such that "applicable laboratory" is susceptible to "only one possible interpretation." *See Petit*, 675 F.3d at 781. The Court should therefore proceed to determine under *Chevron* Step Two whether the agency's definition is reasonable.

C. *Chevron* Step Two – The Agency Employed a Reasonable Definition

At *Chevron* Step Two, a court should give an agency interpretation "controlling weight" so long as it "fills a gap or defines a term in a reasonable way . . . ." *Regions Hosp.*, 522 U.S. at 457. Indeed, *Chevron* deference applies anytime an agency exercises its delegated authority to fill gaps in a statute. *See Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 173 (2007) ("[T]he ultimate question is whether Congress would have intended, and expected, courts to treat an agency's rule, regulation, application of a statute, or other agency action as within, or outside, its delegation to the agency of 'gap-filling' authority"). "In addition, the 'tremendous complexity' of the Medicare program enhances the deference due the Secretary's decision." *Cmty. Care Found. v. Thompson*, 318 F.3d 219, 225 (D.C. Cir. 2003) (citation omitted). Under this heightened degree of deference, it was certainly reasonable for the agency to define an "applicable laboratory," in part, as a laboratory that receives Medicare revenues pursuant to its own NPI number.

As Plaintiff states in its brief, "[n]o 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." Pl. Mot. at 25. Absent an unambiguous definition in the statute, it fell to the agency to define the entity that qualifies as a laboratory and receives Medicare revenues. *See* ECF No. 1-4 at 39. As a first step, the agency incorporated the definition in CLIA as the initial basis for its definition of an "applicable laboratory," namely the physical facility that engages in certain types of laboratory testing. But,

the agency recognized, since "CLIA certificates are not associated with Medicare billing . . . the CLIA certificate cannot be used to identify revenues for specific services." AR 00012; 81 Fed. Reg. at 41,046. Accordingly, in Plaintiff's words, the agency needed to further define "applicable laboratory" to make clear when "the laboratory itself receives 'revenues' for its services." ECF No. 1-4 at 99.

In the Proposed Rule, HHS noted that "[e]ntities that enroll in Medicare must provide a [Taxpayer Identification Number ("TIN")], which we use to identify the entity of record that is authorized to receive Medicare payments." *Id.* The agency initially proposed to define "applicable laboratory," in part, as the entity that "[r]eports tax-related information to the Internal Revenue Service (IRS) under a Taxpayer Identification Number (TIN) with which all of the National Provider Identifiers (NPIs) in the entity are associated . . . ." AR 00103; 80 Fed. Reg. at 59,420.

In the Final Rule, the agency specifically took note of comments that disagreed with this definition. Those commenters generally argued that because a hospital laboratory does not maintain its own TIN, it could not meet the majority of Medicare revenues requirement and thereby qualify as an "applicable laboratory." In response, the agency first explained that the statute supports "limiting reporting primarily to independent laboratories and physician offices." AR 00011; 81 Fed. Reg. at 41,045. That is, "[m]ost hospital laboratories will not meet the majority of revenues threshold because their revenues under the IPPS and OPPS alone will likely far exceed the revenues they receive under the CLFS and PFS." *Id.* Plaintiff does not dispute the Secretary's assessment that most hospital laboratories would not meet the majority of revenues threshold, and thereby fails to refute the agency's conclusion that the statute limits reporting primarily to independent and physician office laboratories.

In any event, the agency "agree[d] with commenters . . . that hospital outreach laboratories should be accounted for in the new CLFS payment rates." *Id.* The agency described a "hospital outreach laboratory" as one that is "distinguishable from hospital laboratories in that they are enrolled in Medicare separately from the hospital of which they are a part, that is, they can be enrolled as independent laboratories that do not serve hospital patients." *Id.* In order to enable hospital outreach laboratories to report private payor data, namely those entities that receive their own Medicare revenues, the agency revised its definition of "applicable laboratory" to require entity reporting at the NPI-level rather than at the TIN-level. *Id.* The agency explained that the "primary benefit to this approach is that it would allow a hospital outreach laboratory, either currently enrolled in Medicare as an independent laboratory (in which case it would already have its own NPI) or that obtains a unique NPI (separate from the hospital) and bills for its hospital outreach services (that is, services furnished to patients other than inpatients or outpatients of the hospital) using its unique NPI, to meet the definition of an applicable laboratory." AR 00012; 81 Fed. Reg. at 41,046. By contrast, hospital laboratories that "are not outreach laboratories, on the other hand, would be unlikely to get their own NPI and bill Medicare for laboratory services because the laboratory services they furnish are typically primarily paid for as part of bundled payments made to the hospital under the IPPS and OPPS." *Id*.

Numerous commenters, including multiple hospital associations, supported the use of the NPI to permit hospital outreach laboratories to report private payor data. *See, e.g.*, AR 01474 (Florida Hospital Association "recommend[ed] that CMS define an applicable laboratory at the [NPI] level. Doing so would increase the number of hospital-based laboratories that would report as applicable laboratories, without imposing [an] unreasonable reporting burden on

hospitals"); *see also* AR 01979, 02293, 02318, 02322, 02361, 02603, 03487. At bottom, the agency thoughtfully considered objections to the use of TINs in defining "applicable laboratory," and revised the definition to use NPIs instead, for the express purpose of enabling hospital outreach laboratories to qualify as applicable laboratories.

In response, Plaintiff makes three primary arguments challenging the agency's definition of "applicable laboratory." First, Plaintiff argues that the agency's definition improperly requires a distinct NPI. Second, Plaintiff contends that, in the specific context of hospital laboratories, the agency's definition unreasonably focuses on the Medicare revenues of the hospital as a whole. Third, Plaintiff urges that the Final Rule is unreasonable because it did not cause data to be gathered from one sector of the laboratory market. Plaintiff's arguments fail to show that the Final Rule is unreasonable.

1. The Final Rule Reasonably Defines an "Applicable Laboratory" as a Laboratory That Bills Medicare Under its Own NPI

Plaintiff first argues that the Final Rule unreasonably imposes a "new requirement found nowhere in the statutory text: an 'applicable laboratory' is an entity that 'bills Medicare Part B under its own National Provider Identifier (NPI).'" Pl. Mot. at 27 (citation omitted). Yet the definition in the Final Rule logically follows from the fact that only entities that bill Medicare independently receive distinct revenues from Medicare.

That is, in order to bill Medicare for services, and thereby receive Medicare revenues, a provider must do so pursuant to its individual NPI number. *See, e.g.,* 42 C.F.R. §§ 424.505 & 424.506 (stating that the NPI is used as the Medicare billing number and requiring a provider or supplier enrolled in Medicare to include its NPI when submitting Medicare claims).; *Assn. of Am. Physicians & Surgeons, Inc. v. Sebelius*, 901 F. Supp. 2d 19, 40 (D.D.C. 2012)

("[I]nsurers—including Medicare—are required to use the NPI as the identifier for health care providers on all standard electronic transactions that require a health care provider identifier[.]").

Section 216(a) of PAMA required the agency to define "applicable laboratory" by reference to the specific laboratory entity that receives Medicare revenues. 42 U.S.C. § 1395m-1(a)(2). It was therefore reasonable for the agency to define an "applicable laboratory," in part, as one that bills Medicare pursuant to a distinct NPI. As relevant here, the agency noted that a hospital outreach laboratory receives Medicare revenue, as required by the statute, when it holds its own "NPI (separate from the hospital) and bills for its hospital outreach services (that is, services furnished to patients other than inpatients or outpatients of the hospital) using its unique NPI . . . ." AR 00012; 81 Fed. Reg. at 41,046. The Final Rule thus reasonably defined "applicable laboratory," in part by use of an NPI, the standard identifier required by providers to bill and receive Medicare revenues.

2. Absent a Distinct NPI, Hospital Laboratories Lack Separately-Identifiable Revenues, as Required by Statute

a. The Final Rule Reasonably Focuses on the Medicare Revenues Received at the NPI-Level

Plaintiff next argues that the Final Rule improperly considers the Medicare revenues of a hospital, rather than the hospital laboratory alone, in determining whether an "applicable laboratory" receives a majority of its Medicare revenues from the CLFS and PFS. Under the Final Rule, in determining whether an "applicable laboratory" meets the majority of Medicare revenues criterion, a provider must examine the Medicare revenues billed pursuant to a given NPI number. In the case of a laboratory, which is only a "small component part" of a hospital and bills pursuant to the hospital's NPI, the relevant Medicare revenues are those of the hospital itself. *See* Pl. Mot. at 28. Plaintiff complains that because hospitals often receive large IPPS and

OPPS payments, those revenues "will dwarf the revenues attributable to the laboratory under the Clinical Laboratory Fee Schedule or the Physician Fee Schedule," and hospital laboratories will likely not qualify as "applicable laboratories" in such circumstances. *Id*. at 14.

However, as set forth above, without an NPI a provider cannot bill for or receive any Medicare revenues. In the context of a hospital laboratory lacking a distinct NPI, it is accordingly the hospital that actually bills Medicare and receives Medicare payments. As Plaintiff itself previously explained, "the *hospital* bills for the testing and is paid based on the Clinical Laboratory Fee Schedule, just as any independent laboratory is." ECF No. 1-4 at 100 (emphasis added); *see also* AR 03398; ECF No. 1-4 at 159 ("[I]t is necessary to identify the 'universe' of Medicare revenues paid to the hospital for laboratory services."); Pl. Mot. at 2 (noting that many hospital laboratories "bill Medicare for laboratory services under the NPI used by the hospital as [a] whole"). Again, 42 U.S.C. § 1395m-1(a)(2) requires that an "applicable laboratory" is a laboratory that has distinct and identifiable Medicare "revenues." It was certainly reasonable for the agency to define an "applicable laboratory" as the NPI-level entity that bills for and receives Medicare revenues for laboratory testing. The agency's rule is not rendered unreasonable simply because sometimes the hospital as a whole bills under its NPI and receives Medicare revenues.

b. The Agency's Definition Avoids Significant Pitfalls Threatened by Plaintiff's Alternative Proposals

To adopt a different definition of "applicable laboratory," as Plaintiff demands, the agency would have to identify which Medicare revenues are received by a hospital, as generated only from services provided by the hospital's component laboratory, which does not itself receive revenues. Such an inquiry is inconsistent on its face with the statutory command that an "applicable laboratory" itself receives Medicare revenue. But even if the agency were to attempt

such an inquiry, it would rapidly run into significant obstacles. For instance, to determine if a hospital laboratory lacking an NPI obtained a majority of its Medicare revenues from the CLFS or PFS, the agency would need to decide whether IPPS and OPPS bundled payments constituted Medicare revenues received by the hospital laboratory. ECF No. 1-4 at 99. Plaintiff fails to provide a reasonable answer to this question, and in fact Plaintiff has reversed its position at least twice on this very issue.

Initially, Plaintiff claimed that Medicare IPPS and OPPS revenues should not be counted as hospital laboratory revenues. In its letter of January 13, 2015 to CMS, Plaintiff argued that "when a hospital provides laboratory services to inpatients and outpatients, the laboratory does not receive revenues as such. Rather, the hospital receives a bundled payment that covers all of the services provided by the hospital." *Id*. "Therefore," Plaintiff concluded, "the laboratory does not receive any identifiable revenues for these services." *Id*. at 100. By contrast, Plaintiff averred that "the only time a hospital laboratory is receiving actual revenues is when it is acting as an outreach laboratory," namely when the "hospital bills for the testing and is paid based on the Clinical Laboratory Fee Schedule . . . ." *Id*.

Plaintiff did an about-face in its November 23, 2015 comments regarding the proposed rule. Instead of arguing that a hospital laboratory never received revenues for payments provided to the hospital under IPPS and OPPS, Plaintiff apparently believed that some "portion of the bundled Medicare payments received at the TIN-level are attributable to laboratory services," thereby qualifying as laboratory revenues. AR 03399; ECF No. 1-4 at 160. Plaintiff proposed that "CMS should require hospitals to use a basic calculation" to estimate the "percentage of total hospital Medicare revenues [that] are hospital laboratory-related Medicare revenues." *Id*.

Then, after the promulgation of the Final Rule, Plaintiff changed course yet again, arguing that IPPS and OPPS payments should not count as Medicare revenues of a hospital laboratory. Indeed, Plaintiff met with the agency on April 27, 2017 and was asked to provide "specific recommendations for changes" to the Final Rule. ECF No. 1-4 at 259. Rather than simply refer the agency back to its comments on the proposed rule, Plaintiff proposed to define "Medicare revenues" only as payment for claims submitted on certain billing forms used to submit "claims for hospital laboratory outreach (non-patient) claims . . . ." *Id*. at 260. Plaintiff thereby again argued that Medicare payments received by the hospital pursuant to the IPPS and OPPS systems should not be regarded under the statute as revenues received by the hospital laboratory. *See id.*

Plaintiff's first and third proposals suggest that hospital laboratories simply ignore IPPS and OPPS payments, and count only non-patient revenues under the CLFS and PFS as applicable Medicare "revenues" of the hospital laboratory. Such a definition is improper, as it would "read[] the 'majority of' Medicare revenues requirement out of the statute[.]" *See* Pl. Mot. at 2 (citing 42 U.S.C. § 1395m-1(a)(2)). That is, because only CLFS and PFS payments would constitute applicable Medicare "revenues," those payments would by definition constitute a majority of Medicare revenues for every hospital laboratory, and the majority of Medicare revenues criterion would be rendered a nullity.

On the other hand, Plaintiff's second proposal, set forth in its official comments to the Proposed Rule, argued that hospitals should attempt to determine the portion of IPPS and OPPS payments attributable to the hospital laboratory. Plaintiff may favor this approach once more, arguing in their Motion: "[t]here is no reason hospitals cannot determine which revenues should be attributed to the clinical diagnostic laboratory services provided by their laboratories." *Id.* at

44.[10] Yet the D.C. Circuit disagrees, holding that "because a PPS payment is calculated without regard to a hospital's actual cost, it cannot be easily separated and allocated to particular items or services." *Appalachian Reg'l*, 131 F.3d at 1053. Indeed, Plaintiff previously acknowledged that IPPS and OPPS payments constitute "bundled" reimbursements for "all of the services provided" and "[w]hile some small amount of that payment may be attributable to hospital services, those amounts are not broken out or identified, *nor is there any way to determine what portion constitutes revenues of the laboratory*." ECF No. 1-4 at 99 (emphasis added). The agency similarly concluded in the Final Rule that "as laboratory services provided to hospital inpatients and outpatients are typically not separately paid," where a hospital laboratory lacked its own NPI number, "it is unclear to us how revenues for these services would be determined . . . ." AR 00012; 81 Fed. Reg. at 41,046. In line with the D.C. Circuit and Plaintiff's original position, the agency reasonably rejected a definition of "applicable laboratory" that would require a hospital laboratory to somehow determine the portion of prospective bundled payments made to hospitals that are attributable to laboratory services.

At bottom, Plaintiff has been unable to settle on a theory of when Medicare revenues are "received" by a hospital laboratory that lacks a distinct NPI. Plaintiff's quandary arises from the fact that hospital laboratories without an NPI do not independently bill for or receive any Medicare revenues; rather it is the hospital itself that bills Medicare and is paid all revenues under IPPS, OPPS, CLFS, and other payment systems. As Plaintiff's struggle makes clear, there is no clear and reasonable definition of the Medicare revenues that are "received" by a laboratory

[10] Plaintiff briefly asserts that hospitals could use certain "charge[]" data to determine "which revenues should be attributed to the clinical diagnostic laboratory services provided by their laboratories." Pl. Mot. at 34. However, the amounts charged by a hospital for different services would not indicate how much of the revenue the hospital received in a bundled payment was attributable to lab services.

that does not itself bill Medicare. Thus, the agency logically defined "applicable laboratory" as a laboratory that bills Medicare pursuant to its own NPI, and thereby has distinct Medicare "revenues."

3. The Statute Determined Which Laboratories Would Report Data

Plaintiff finally claims that the Final Rule is unreasonable because the resulting data collection "omits a large segment of the market," namely certain hospital laboratories. Pl. Mot. at 32. But as noted above, Plaintiff fails to set forth even a guess as to how much of this "market" should have qualified as applicable laboratories, in that they satisfy the majority of Medicare revenues criterion and exceed the low revenue threshold.[11] Absent any specific facts concerning the data that should have been collected, Plaintiff cannot show the Final Rule to be unreasonable.

Furthermore, any complaint about limited data collection lies with Congress, not the agency. If Congress truly wished to collect private payor data from "all sectors of the laboratory market," as Plaintiff contends, then it could simply have mandated that any and all laboratories report private payor data. *See* Pl. Mot. at 8 (citation omitted). Instead, Congress added the specific requirement that an applicable laboratory must be one that receives a majority of its Medicare revenue from the CLFS or PFS, rather than from hospital inpatient and outpatient fee

[11] Plaintiff also appears to fault the definition of "applicable laboratory" as the cause of reported data that was not "representative of the different types of laboratories that compete in the market." Pl. Mot. at 15. That is, Plaintiff complains that the "definition excludes approximately 95 percent of physician office laboratories and approximately 55 percent of independent laboratories from reporting data." Compl. ¶ 54. This is incorrect. The agency explained in the Final Rule that its *low expenditure threshold* would effectively exclude 95 percent of physician office laboratories (over 200,000 laboratories), and 55 percent of independent laboratories from reporting. AR 00017; 81 Fed. Reg. 41050-51; HHS, OIG, Medicare Payments for Clinical Diagnostic Laboratory Tests in 2015: Year 2 of Baseline Data at 8. Plaintiff does not challenge the low expenditure threshold.

schedules.[12] Even under Plaintiff's proposed alternative definition, Plaintiff concedes that "many hospitals would not qualify as applicable laboratories . . . ." ECF No. 1-4 at 162. What excludes hospital laboratories from the data reporting requirement is not the agency's definition of an "applicable laboratory," but rather Congress's decision to generally exclude from reporting those laboratories that are not primarily paid under the CLFS or PFS.

D. The Definition is Not Arbitrary or Capricious

In a final reach, Plaintiff claims that the Final Rule is arbitrary and capricious because the "Secretary has not reasonably responded to serious objections to his approach." Pl. Mot. at 35. While agencies must respond to public comments submitted in a rulemaking, this obligation "is not 'particularly demanding.'" *Ass'n of Private Sector Colls. & Universities v. Duncan*, 681 F.3d 427, 441-42 (D.C. Cir. 2012) (quoting *Pub. Citizen, Inc. v. Fed. Aviation Admin.*, 988 F.2d 186, 197 (D.C. Cir. 1993)). Indeed "it is settled that 'the agency is not required to discuss every item of fact or opinion included in the submissions made to it in informal rulemaking.'" *Pub. Citizen*, 988 F.2d at 197 (quoting *Automotive Parts & Accessories Ass'n v. Boyd*, 407 F.2d 330, 338 (D.C. Cir. 1968)). "Instead, the agency's response to public comments need only 'enable [the court] to see what major issues of policy were ventilated . . . and why the agency reacted to them as it did.'" *Id.*

[12] Plaintiff cites repeatedly to a colloquy between Senators purportedly discussing the intent of PAMA Section 216. *See* Pl. Mot. at 8, 26 (citing 160 Cong. Rec. S2860 (daily ed. May 8, 2014)). This exchange occurred over one month *after* PAMA was enacted, making it a curious example of subsequent, or "post-enactment legislative history [that] is not only oxymoronic but inherently entitled to little weight," *Cobell v. Norton*, 428 F.3d 1070, 1075 (D.C. Cir. 2005), because it "provides 'an unreliable guide to legislative intent.'" *Verizon v. FCC*, 740 F.3d 623, 639 (D.C. Cir. 2014); *see also Sullivan v. Finkelstein*, 496 U.S. 617, 632 (1990) (Scalia, J., concurring in part) ("Arguments based on subsequent legislative history . . . should not be taken seriously, not even in a footnote.").

The Final Rule exhaustively responded to all significant comments. Relevant here, Plaintiff proposed two alternative definitions for "applicable laboratory." First, Plaintiff suggested that an "applicable laboratory" be defined solely as a "laboratory" under CLIA. AR 03396. But the agency considered and rejected this idea for several reasons. As noted above, because laboratory services for hospital inpatients and outpatients are generally bundled into a single payment to the hospital, or several bundled payments in the case of the OPPS, it was "unclear" how a laboratory within a hospital as identified by its CLIA certificate could determine what amount of Medicare revenues issued to the hospital were performed for laboratory testing. AR 00012; 81 Fed. Reg. at 41,046. The agency also anticipated that hospitals would accordingly object to such a definition. *Id*. Plaintiff appeared to recognize these critical drawbacks, as it conceded that "this approach may be problematic to the agency," and did not support this proposal in any depth. AR 03398; ECF No. 1-4 at 159.

Second, Plaintiff suggested that hospitals use an "adjustment factor" to determine whether their laboratories qualified as an applicable laboratory. That is, Plaintiff admitted that it is "difficult to identify laboratory revenues when the laboratory services are included in bundled payments" for IPPS and OPPS services. AR 03399; ECF No. 1-4 at 160. Plaintiff proposed that hospitals use an estimate of six percent of their IPPS and OPPS revenues as attributable to laboratory services, to determine whether the hospital's laboratory received more than 50% of its revenues from CLFS and PFS. *Id*. The agency also considered and rejected this proposal.

In the Final Rule HHS explained that it was not necessary to use an "adjustment factor" because, in defining "applicable laboratory" pursuant to use of an NPI, hospital laboratories would be included in the reporting requirements if they held or obtained their own NPIs. AR 00012; 81 Fed. Reg. at 41046. The agency's response shows that it "clearly thought about the

[Plaintiff's] objections and provided reasoned replies – all the APA requires."[13] *City of Portland, Oregon v. EPA*, 507 F.3d 706, 714 (D.C. Cir. 2007).

Notably, Plaintiff does not appear to support the use of an "adjustment factor" any longer. As described above, when Plaintiff was recently asked by the agency to propose specific changes to the Final Rule, Plaintiff did not cite its proposed "adjustment factor," but rather advanced an entirely new suggestion, to define "revenues" as only those received pursuant to certain non-patient billing forms. ECF No. 1-4 at 260. The agency should not be faulted for rejecting a proposal that Plaintiff itself has disowned.

CONCLUSION

Defendant respectfully asks that his cross-motion for summary judgment be granted and that Plaintiff's motion for summary judgment be denied.

Dated: March 23, 2018

Respectfully submitted,

CHAD A. READLER
Acting Assistant Attorney General

JOEL McELVAIN
Assistant Branch Director

[13] Nor was any additional response required concerning a few comments Plaintiff identifies, expressing concern that future payment amounts "in many cases may be artificially low." *See* AR 02081. The Secretary was not required to respond separately to every speculative concern voiced by commenters, especially where the agency had already decided to modify the definition of "applicable laboratory" to address the genesis of those concerns. *See Tex. Mun. Power Agency v. EPA*, 89 F.3d 858, 876 (D.C. Cir. 1996) ("[T]he failure to respond to comments is significant only insofar as it demonstrates that the agency's decision was not based on a consideration of the relevant factors.").

/s/ *Michael L. Drezner*
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CERTIFICATE OF SERVICE

I hereby certify that on March 23, 2018, a copy of the foregoing Cross-Motion for Summary Judgment and in Opposition to Plaintiff's Motion for Summary Judgment was filed electronically via the Court's ECF system, which effects service upon counsel of record.

/s/ Michael L. Drezner
Michael L. Drezner