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.

Civil Action No. 17-2645 (ABJ)

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 was likely to lead to significant reductions in payments for certain tests, on the order of billions of dollars, 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]" required to report certain private sector payment data to the agency, data used to determine the new Medicare payment amounts. 42 U.S.C. § 1395m-1(a)(2). Plaintiff further avers that the definition of "applicable laboratory" caused an insufficient number of hospital laboratories to report their data to the agency. These hospitals purportedly are paid more by private payors for CDLTs than are other kinds of laboratories, and Plaintiff argues that the absence of hospital laboratory data caused the new fee schedule rates to be lower than they 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, Plaintiff lacks standing because it fails to show that the agency's definition of "applicable laboratory" caused any economic injuries, and even if so, that the remedy sought would redress the alleged harms. 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. Second, Plaintiff failed to present to the agency a

concrete claim for payment and exhaust all administrative remedies prior to bringing suit, as required for a challenge arising out of the Medicare statute. Third, this suit is moot because the Court cannot provide any effective relief on the basis of Plaintiff's claims. That is, Plaintiff fails to challenge the new definition of "applicable laboratory" which will be applied to the next data-collection cycle, and any adjustments to current payment rates are barred by statute.

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 the D.C. Circuit held to the contrary in the recent appeal in this case, finding that the statute lacked any definition for the relevant term "laboratory," and that the agency was required to locate an appropriate definition despite the term's ambiguity. *See Am. Clinical Lab. Ass'n v. Azar*, 931 F.3d 1195, 1208 (D.C. Cir. 2019). Thus, while clinging to its claim that the statute is unambiguous, Plaintiff is left to argue that that the Secretary was arbitrary in defining "laboratory," 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 preferred 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, either in substance or procedure, and as a consequence this Court should enter judgment for Defendant.

BACKGROUND

I. Statutory Background

This case concerns payment rates for a particular type of medical test, CDLTs, which encompass a wide variety of laboratory tests such as metabolic blood tests and genetic analyses. Medicare payment for CDLTs depends on the context in which the testing is performed. For instance, if a beneficiary is an inpatient at a hospital, that hospital will be paid under Medicare Part A, usually pursuant to the Medicare Hospital Inpatient Prospective Payment System for Acute Care Hospitals ("IPPS"). Under IPPS, Medicare provides a single payment "in full satisfaction of the bundle of covered items and services provided during a single inpatient hospital stay" based on the diagnosis related group ("DRG") of the patient's stay, rather than on the individual services the hospital provided to that patient. *Appalachian Reg'l Healthcare, Inc. v. Shalala*, 131 F.3d 1050, 1053 (D.C. Cir. 1997).

For outpatients, Medicare payments are generally bundled as well. Under the Hospital Outpatient Prospective Payment System ("OPPS"), Medicare pays hospitals for the covered outpatient department services they provide to beneficiaries. *See* 42 U.S.C. § 1395*l*(t) (establishing OPPS). With a few exceptions, the agency makes payments under the OPPS to hospitals for the services they provide based on amounts that are generally determined prospectively for each upcoming year. *See id.* OPPS groups or "packages" items and services that are comparable clinically and in terms of resource into an Ambulatory Payment Classification ("APC") and makes a single payment for all items and services in a particular APC. Certain CDLTs that are listed on the Medicare Clinical Laboratory Fee Schedule ("CLFS") are packaged under OPPS with the primary services provided to the outpatient, and are

billed on the same claims. Thus, when provided as a covered outpatient department service, Medicare pays for CDLTs as part of payment for the APC to which the CDLT is assigned.

In contrast, an entirely different payment system applies to laboratory tests when a Medicare beneficiary receives those tests while neither a hospital inpatient nor outpatient. In such circumstances, the health care provider is reimbursed pursuant to the CLFS or the Physician Fee Schedule ("PFS"). AR 00004; 81 Fed. Reg. at 41,038. Distinct from the general payment methodologies of the IPPS and OPPS that bundle prospective payment based on DRGs or APCs, 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.[1]

The prior formula for determining a given CDLT payment amount was both complex and widely varied, as it was based 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. 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. at 41,039. By 2014, Medicare Part B was expending over $7 billion 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. Protecting Access to

[1] The PFS 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, which are governed by the CLFS. *See* 42 C.F.R. § 414.40(b)(2).

Medicare Act of 2014, Pub. L. No. 113-93, § 216, 128 Stat. 1040 (2014) (codified at 42 U.S.C. § 1395m-1). Section 216 of PAMA 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 Secretary 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)(1)-(2). The statute defines "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.* § 1395m-1(a)(2). 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 that a majority of those revenues were received from the CLFS or the PFS. The statute thereby excluded from the definition of "applicable laboratory" – and therefore a reporting duty – a laboratory that received a majority of its Medicare revenues from the IPPS and/or OPPS payment systems. However, the statute left unspecified the precise meaning of a "laboratory" and how to determine its "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.[2] *Id.*

[2] 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, were likely to be significantly lower than the amounts on the then-current CLFS. Indeed, the Congressional Budget Office estimated that this section of the statute would result in a cost savings to Medicare of $2.5 billion over ten years. *See* Congressional Budget Office, Cost Estimate for the Protecting Access to Medicare Act of 2014 (March 26, 2014), https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/costestimate/house-introduced-protecting-access-medicare-act-2014-march-26-20140.pdf. As a result, Congress set a ceiling for the yearly reduction in Medicare payment rates for a given CDLT. *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"). The statute specifies 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).

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 (Oct. 1, 2015), interpreting and implementing the statutorily-required revisions to the CLFS. The rulemaking process was particularly challenging because, as Plaintiff pointed out, while CMS was tasked with collecting data from certain laboratories with regard to specified revenues, "neither the term 'laboratory' nor the term 'revenues' is defined in PAMA or elsewhere in the Social Security Act." *See* Decl. of Julie Khani 39, ECF No. 1-4 ("Khani Decl."); AR 02371. 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." Khani Decl. 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").

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 sets 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. CMS also had to determine, as Plaintiff put it, "what is meant by 'revenues'" in the statute. Khani Decl. at 39; *id.* at 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: "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*. Moreover, in order to bill Medicare for services, a provider must do so pursuant to its individual National Provider Identifier ("NPI") number, which health care providers that transmit certain health information in electronic form are also required to obtain. *Id*.; *see also* 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*.

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 generally 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, CMS agreed that in certain instances, hospital laboratories could function essentially as stand-alone laboratories that receive Medicare revenues directly. 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, CMS explained, 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, CMS recognized that where a hospital laboratory bills Medicare 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; Khani Decl. 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*. It was "unclear" to the agency 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 alternatives set forth by Plaintiff involved the use of an "adjustment factor." In one iteration, 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; Khani Decl. at 160. In another iteration, 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; Khani Decl. 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; Khani Decl. at 162.

The agency considered and rejected these proposals 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*.

Also 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. *See supra* n.3 (distinguishing ADLTs from CDLTs). This so-called 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, https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf ("CMS Reporting Summary") (last visited Nov. 22, 2019). 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 Nov. 22, 2019). The agency posted the final rates on November 17, 2017. *Id.* Plaintiff filed this suit on December 11, 2017.

LEGAL STANDARDS

In a case brought under the Administrative Procedure Act ("APA"), an agency's decision must be upheld unless arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law. 5 U.S.C. § 706(2)(A). Under this deferential standard, the agency's decision is presumed valid, and the Court considers only whether it "was based on a consideration of the relevant factors and whether there has been a clear error of judgment." *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 416 (1971). An agency's decision may be deemed arbitrary only where the agency "has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency," or its decision "is so implausible that it could not be ascribed to a difference in view or the product of agency expertise." *Motor Vehicle Mfrs. Ass'n v. State Farm*, 463 U.S. 29, 43 (1983). The Court may not "substitute its judgment for that of the agency." *Id.* "This broad deference is all the more warranted when, as here, the regulation concerns 'a complex and highly technical regulatory program'" like Medicare, "in which the identification and classification of relevant 'criteria necessarily require significant expertise and entail the exercise of judgment grounded in policy concerns.'" *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994) (citation omitted).

ARGUMENT

I. The Court Lacks Subject Matter Jurisdiction

A. Plaintiff Fails to Show Specific Facts Necessary to Establish Standing

On appeal, the D.C. Circuit held only that Plaintiff had demonstrated standing sufficient to survive the pleadings stage. Perhaps because the appeal concerned solely the jurisdiction of the Court to hear Plaintiff's challenge, the D.C. Circuit noted that "[a]t the motion to dismiss stage, 'general factual allegations of injury resulting from the defendant's conduct may suffice' to establish standing." *Am. Clinical Lab. Ass'n v*, 931 F.3d at 1203. The court of appeals held that "ACLA meets those familiar requirements." *Id.* Indeed, the D.C. Circuit was careful to hold only that "[a]s for causation and redressability, ACLA has met its burden *at this stage*." *Id*. (emphasis added); *see id*. at 1203-04 (holding only that Plaintiff had demonstrated redressability "at this stage").

At the summary judgment stage, however, the "plaintiff can no longer rest on such 'mere allegations,' but must 'set forth' by affidavit or other evidence 'specific facts'" to establish standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992); *see also Coleman v. Drug Enf't Admin.*, 134 F. Supp. 3d 294, 305 (D.D.C. 2015) ("At the summary judgment stage, the plaintiff faces a higher burden in meeting the elements of standing than when faced with a motion to dismiss.") (internal quotation omitted). While Plaintiff's general factual allegations may have cleared the bar at the pleading stage, they fall far short of providing the "specific facts" required to demonstrate standing at summary judgment. Plaintiff's failure to establish standing is especially glaring with respect to the requirements of causation and redressability.

To establish causation, it is not enough for Plaintiff to simply claim that CLFS reimbursement rates went down, since that was the intended effect of the *statute itself*, which is

unchallenged here. *See Texas v. E.P.A.*, 726 F.3d 180, 198 (D.C. Cir. 2013) (rejecting standing where "industry petitioners' purported injury was caused by automatic operation of the [statute], not the challenged rules"). Rather, Plaintiff must show that it was the *regulatory definition* of "applicable laboratory," in HHS's Final Rule, that caused the reimbursement rates to be lower than they would have been under a purportedly lawful definition. *See also Baz v. U.S. Dep't of Homeland Sec.*, No. 1:18-CV-01013 (CJN), 2019 WL 5102827, at *4 (D.D.C. Oct. 11, 2019) ("[A] plaintiff's injury cannot be redressed by a court order when two independent government actions produce the same harm and only one is challenged."). To do so, Plaintiff must show that the regulatory definition of "applicable laboratory" (1) caused lower reporting from hospital laboratories, which (2) led in turn to lower Medicare payment amounts than would have been established otherwise. Plaintiff fails to support such a theory of causation here.

On the first link in its chain, Plaintiff neglects to set forth any allegation, let alone specific facts, as to the number of hospital laboratories that it contends should have been required to report data, how much data should have been reported, and on which specific CDLTs. That is, Plaintiff claims that "[h]ospital outreach laboratories received approximately 26 percent of payments made under Medicare's Clinical Laboratory Fee Schedule in 2015" and that there are some 7,000 hospitals "providing outreach services under the [CLFS]." Mem. of P. & A. in Supp. of Pl.'s Mot. for Summ. J. 22, ECF No. 53-1 ("Pl.'s Mot."). 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 received a "majority" of Medicare revenues pursuant to the CLFS and PFS payment systems and would have exceeded the Final Rule's low expenditure threshold. *See* 42 U.S.C. § 1395m-1(a)(2). 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.

The second link in Plaintiff's chain is even more problematic, as Plaintiff must show that the absence of data from certain unknown hospitals decreased the payment rates. Importantly, in determining a given payment rate, PAMA requires HHS to select the median private payor payment rate of all tests reported for a given CDLT, weighted by volume. Thus, to establish that any under-reporting by hospitals caused lower payment rates, Plaintiff must demonstrate that the hospitals that supposedly should have reported data would not only have reported higher payment rates, but would have reported such a high volume of those tests that the weighted median payment rate would have increased. However, the most Plaintiff provides is a declaration from an employee of Quest Diagnostics, who asserts his general understanding that "the rates private payors typically pay hospitals are as much as 1.5 to 4 times higher than the rates they pay large independent laboratories for the same laboratory tests." *See* Decl. of Dermot Shorten ¶ 14, ECF No. 1-3. But these vague claims, that hospitals are "typically" paid "as much as" some factor more than "large independent laboratories," again fail to establish that the specific hospital laboratories that supposedly should have reported data, namely those who Plaintiff believes satisfy the majority of revenues criterion, would have done so at rates and in sufficient volume that the median payment rate for relevant CDLTs would actually have increased.

Thus, Plaintiff's argument on causation is best represented by a series of unknown variables, as follows: because of the agency's definition of "applicable laboratory," (1) HHS refrained from collecting data from an unknown number of hospital laboratories, and (2) those laboratories would have reported data on unknown CDLTs, (3) each with a private payor rate of

unknown price, (4) and a test volume of unknown quantity, (5) which would have increased the Medicare payment rate on a given CDLT test by an unknown amount. Absent specific facts to fill each of these gaps, let alone any one of them, Plaintiff fails to demonstrate that the definition of applicable laboratory caused their claimed injury of lower payment rates.

Plaintiff similarly fails to establish redressability here. While the D.C. Circuit found that a mere allegation sufficed at the pleading stage, Plaintiff must now show by specific facts that redefining "applicable laboratory" in the regulation is "likely to increase Medicare reimbursement rates." *Am. Clinical Lab. Ass'n*, 931 F.3d at 1204. But Plaintiff has not even attempted such a showing here. Plaintiff does not suggest what revised definition of applicable laboratory would be acceptable, and why that definition would result in a greater collection of data from hospitals. Nor does Plaintiff establish that the private payor rates and the volume of tests reported by these hospitals would sufficiently increase Medicare payment rates so as to redress the claimed injury.[3]

With so many unknown variables at play, Plaintiff cannot show that such relief is *likely* to redress their claimed harms. "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).[4] Plaintiff thus fails to establish standing and their suit should therefore be dismissed on that ground.

[3] To the extent Plaintiff continues to assert injury arising out of the fact that its purported competitor hospital laboratories were not required to report data, *Am. Clinical Lab. Ass'n,* 931 F.3d at 1203, Plaintiff similarly fails to show that these specific, unnamed, competitor laboratories did not report data because of the definition of "applicable laboratory," and that a new, unspecified definition would in fact cause them to report data.

[4] The D.C. Circuit has previously held that "[w]here an agency rule causes the injury . . . the redressability requirement may be satisfied . . . by vacating the challenged rule and giving the

B. Plaintiff Failed to Exhaust Administrative Remedies

In addition to Plaintiff's lack of standing, the failure to present a claim for payment to the Secretary and exhaust administrative remedies prior to filing suit is also fatal to Plaintiff's case. As the Supreme Court has made clear, the Medicare statute "demands the 'channeling' of virtually all legal attacks through the agency." *Shalala v. Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000) (citing 42 U.S.C. §§ 405(g)–(h), 1395ii); *see also Heckler v. Ringer*, 466 U.S. 602, 627 (1984) ("In the best of all worlds, immediate judicial access for all of these parties might be desirable. But Congress, in § 405(g) and § 405(h), struck a different balance, refusing declaratory relief and requiring that administrative remedies be exhausted before judicial review of the Secretary's decisions takes place."). Plaintiff's attempt to short-circuit that process deprives the Court of jurisdiction over its claims.

Perhaps anticipating this argument, Plaintiff erroneously contends that the Secretary waived this challenge because he did not raise the argument on appeal. Pl.'s Mot. at 15. This claim is baseless. The sole case cited in support of Plaintiff's waiver contention, *Williamsburg Wax Museum, Inc. v. Historic Figures, Inc.*, 810 F.2d 243 (D.C. Cir. 1987), stands for the

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aggrieved party the opportunity to participate in a new rulemaking the results of which might be more favorable to it." *America's Cmty. Bankers v. FDIC*, 200 F.3d 822, 828–29 (D.C. Cir. 2000). Yet such holdings predate the D.C. Circuit's more recent clarification that to show redressability, "the key word" is that the relief sought must be "likely" to redress the claimed injuries. *See West v. Lynch*, 845 F.3d 1228, 1235 (D.C. Cir. 2017). Plaintiff has offered nothing to meet that burden here. And even in the specific context of future agency action, the D.C. Circuit held this year that redressability is absent where the "hurdles" in the way of sought redress are "too significant and numerous" for the Court to find it "likely, as opposed to merely speculative" that the sought relief will indeed redress the claimed injuries. *Exhaustless Inc. v. Fed. Aviation Admin.*, 931 F.3d 1209, 1213 (D.C. Cir. 2019). Certainly here – where Plaintiff fails to set forth any definition of "applicable laboratory" that the agency should have utilized, or any evidence that some hypothetical definition would result in higher payment rates – Plaintiff cannot show that it is likely, as opposed to merely speculative, that the relief sought will redress its claimed injuries.

unremarkable proposition that "a legal decision made at one stage of litigation, *unchallenged in a subsequent appeal* when the opportunity to do so existed, becomes the law of the case for future stages of the same litigation, and the parties are deemed to have waived the right to challenge that decision at a later time." *Id*. at 250 (emphasis added). This case has no bearing here. This Court did not previously address or rule on Defendant's presentment and exhaustion argument, and instead held in Defendant's favor on an entirely separate point. Thus, there was nothing for Defendant to "challenge" on appeal with regard to presentment and exhaustion.

Moreover, the prior appeal in the D.C. Circuit, which resolved one jurisdictional issue, did not resolve whether other, separate jurisdictional issues are present. Indeed, the D.C. Circuit has repeatedly declined to find waiver with regard to a litigant's decision to not raise all possible alternative grounds for *affirming* a District Court decision. *See Crocker v. Piedmont Aviation, Inc.*, 49 F.3d 735, 740 (D.C. Cir. 1995) (rejecting claim of waiver by appellee in part because "forcing appellees to put forth every conceivable alternative ground for affirmance might increase the complexity and scope of appeals more than it would streamline the progress of the litigation"); *see also Yesudian ex rel. U.S. v. Howard Univ.*, 270 F.3d 969, 971 (D.C. Cir. 2001) (rejecting claim of waiver in part because "the party failing to present the issue was the appellee, defending on a field of battle defined by the appellant"). There is accordingly no merit to Plaintiff's contention that this issue has been waived.

Just as before Plaintiff's appeal, there remain "two elements that a plaintiff must establish in order to satisfy" the administrative prerequisites under Medicare. *Am. Hosp. Ass'n v. Hargan*, 289 F. Supp. 3d 45, 51 (D.D.C. Dec. 29, 2017), *aff'd sub nom. Am. Hosp. Ass'n v. Azar*, 895 F.3d 822 (D.C. Cir. 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*. Plaintiff reiterates its past contentions that presentment and exhaustion were not required here, and in any event have now been satisfied. These arguments have no greater force now than when they were first presented.

Plaintiff suggests that these requirements do not apply here because there is "no viable avenue" for reviewing the rule at issue. Pl.'s Mot. at 15. But that claim is belied by the ongoing efforts of their own members: as Plaintiff itself acknowledges, "[a]t least one of ACLA's members submitted its objections to CMS in the context of a claim for payment," which remains pending before an administrative law judge. *Id.* at 15. That step was appropriate, for even where 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 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"). For this reason, litigants are excused from presenting administrative claims 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 v. Sebelius*, 668 F.3d 704, 713 (D.C. Cir. 2011) (quoting *Ill. Council*, 529 U.S. at 22-23) (emphasis added). Plaintiff cannot point to such a preclusion of review here.

Plaintiff's only argument in the alternative is that the presentment and exhaustion requirements have otherwise been satisfied. First, as to presentment, Plaintiff appears to argue that it satisfied this requirement through "comments and other correspondence" during the

rulemaking process. Pl.'s Mot. at 15. But this argument has been squarely rejected by the D.C. Circuit. *See Am. Hosp. Ass'n*, 895 F.3d at 826 (holding that an administrative claim for payment must mean "a claim seeking specific payments through the reticulated Medicare scheme for administrative claims . . . rather than merely general comments filed in an informal rulemaking"). Plaintiff is thus left to argue that it satisfied the presentment requirement because one of its members administratively presented claims for payment, albeit belatedly. Those claims were paid under the CLFS, and the member administratively appealed those claims, which remain pending before an Administrative Law Judge. Pl.'s Mot. at 15.

But "[i]t has long been the case that 'the jurisdiction of the court depends upon the state of things at the time of the action brought.'" *Grupo Dataflux v. Atlas Glob. Grp., L.P.*, 541 U.S. 567, 570 (2004) (quoting *Mollan v. Torrance*, 9 Wheat. 537, 539 (1824)). Plaintiff does not dispute that its members failed to present an administrative claim for adjudication prior to filing suit here, thus precluding this Court from adjudicating this case. *See Am. Hosp. Ass'n.*, 895 F.3d at 827 (affirming dismissal of case "[b]ecause the plaintiffs failed to satisfy the presentment requirement" prior to filing suit in Medicare action); *see also Ill. Council*, 529 U.S. at 24 ("At a *minimum* . . . the matter must be presented to the agency *prior* to review in a federal court.") (emphasis added). To hold otherwise would permit a plaintiff to rush to federal court upon finding any grievance with Medicare, as Plaintiff has done here, and only "present" its claims to the agency once its lawsuit was well underway. Such a rule would eviscerate the Congressional design which "demands the 'channeling' of virtually all legal attacks through the agency." *Ill. Council*, 529 U.S. at 13.

Second, as to exhaustion, the 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). As best as can be discerned, Plaintiff claims that one of its members has sought administrative appeal to an Administrative Law Judge of an unfavorable lower-level administrative determination, but that this proceeding has not concluded. *See* Pl.'s Mot. Ex. C, ECF No. 53-4. Thus, Plaintiff is required to fully exhaust the remedies that its member is currently pursuing. *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.* And Plaintiff's passing assertion that it would be "futile" for their members to continue to pursue the administrative remedies that at least one of them has begun, Pl.'s Mot. at 15, falls fall short of demonstrating the sort of "exceptional circumstances," *Am. Orthotic*, 62 F. Supp. 3d at 114, under which exhaustion has been excused as "clearly worthless," *UDC Chairs Chapter v. Bd. of Trustees of Univ. of D.C.*, 56 F.3d 1469, 1475 (D.C. Cir. 1995) (explaining that a judicial finding of futility "require[s] the 'certainty of an adverse decision' or indications that pursuit of administrative remedies would be 'clearly useless,' and that the "mere 'probability of administrative denial of the relief requested does not excuse failure to pursue' administrative remedies").

C. Plaintiff's Claims are Moot

In addition to the deficiencies identified above, Plaintiff's case should be dismissed as moot because the Court cannot order any relief that would redress Plaintiff's claimed injuries. "To qualify as a case fit for federal-court adjudication, 'an actual controversy must be extant at all stages of review, not merely at the time the complaint is filed.'" *Arizonans for Official English v. Arizona*, 520 U.S. 43, 67 (1997) (quoting *Preiser v. Newkirk*, 422 U.S. 395, 401 (1975)). A case becomes moot where, as here, events after the filing of the Complaint "make[ ] it impossible for the court to grant 'any effectual relief whatever.'" *Church of Scientology of Cal. v. United States*, 506 U.S. 9, 12 (1992); *see also Kennecott Utah Copper Corp. v. U.S. Dep't of Interior*, 88 F.3d 1191, 1207 (D.C. Cir. 1996) (a party "no longer suffer[s] a legally cognizable injury traceable to the alleged violations" where "the court can no longer provide ... any meaningful relief").

Because the statute precludes review of Medicare payment rates directly, *see Am. Clinical Lab. Ass'n.*, 931 F.3d at 1204, Plaintiff attacks the definition of "applicable laboratory" in the rate-setting methodology established in the Final Rule. But the gravamen of Plaintiff's Complaint is that because the Medicare payment rates are too low, they are injuring Plaintiff's members. *See* Compl. ¶ 72, ECF No. 1. Yet Plaintiff does not challenge the agency's future rate setting methodologies, and the court cannot provide a remedy that would change the current CLFS payment rates for 2018 through 2020.

As Plaintiff notes, the Secretary published a "new rulemaking that changed the regulatory definition of 'applicable laboratory'" for data reporting in 2020 to be used to establish payment rates for 2021 through 2023. Pl.'s Mot. at 13. Plaintiff has not challenged this new definition of applicable laboratory, and presumably concedes that it is appropriate. In any event, the rule

governing *future* reporting of data and future calculation of payment rates is not at issue in this case, and cannot be the subject of any relief here.

That leaves only retrospective relief as a potential remedy for Plaintiff. The question for the purpose of mootness is not whether a type of complex and difficult remedy is conceivable in one's imagination, but whether there are legal avenues to provide redress. It is well-settled that a court may not "create a remedy in violation of law," *INS v. Pangilinan*, 486 U.S. 875, 883 (1988) (quotation omitted), and there are at least two legal obstacles in Plaintiff's way to permissible redress here.

The first is the plain language of PAMA Section 216, which establishes that private payor data is to be reported only "every 3 years." 42 U.S.C. § 1395m-1(a)(1). And § 1395m-1(b)(4)(A) and (B) require payment amounts to remain in place until the year *after* the next data collection period, and forbid "any adjustment" to those rates. As explained in the Final Rule, the initial data reporting period was in early 2017, such that the next data reporting period will occur three years later, as required by statute, in early 2020. 81 Fed. Reg. at 41068. Thus, the payment rates established with data reported in 2017 apply for payments made in 2018, 2019, and 2020. Thus, any relief sought by Plaintiff to vacate, alter, or otherwise adjust the current payment rates is prohibited by statute and may not be ordered by the Court. *See Keli v. Rice*, 571 F. Supp. 2d 127, 132 (D.D.C. 2008) (agreeing that case was moot where "the language of the statute unequivocally bars the Court from granting the relief sought").

In addition, any actual court-ordered change to the payment rates at issue remains barred by the statutory preclusion of judicial review. 42 U.S.C. § 1395m-1(h). To be sure, on appeal, the D.C. Circuit held that the statute did not preclude review of HHS's definition of "applicable laboratory" for purposes of data reporting. *Am. Clinical Lab. Ass'n*, 931 F.3d at 1204. But at the

same time, the court held that "[i]t is true that ACLA cannot challenge the rates themselves under the statute's jurisdiction-stripping provision," and their challenge could not constitute "an impermissible back-door effort to challenge reimbursement rates in circumvention of the statutory bar." *Id*. Whatever this Court's authority might be to declare the prior definition of "applicable laboratory" unlawful, to the extent that Plaintiff requests that this Court vacate, alter, or otherwise change the current payment amounts, the statutory bar on review of the "establishment of payment amounts" precludes such relief.

In sum, Plaintiff does not challenge the rule governing the agency's future collection of CDLT data, and so the Court cannot provide relief concerning the definition of "applicable laboratory" governing the next data collection cycle. And the statute precludes "any adjustment" to the payment amounts currently in place. Absent any conceivably lawful relief which could be afforded to Plaintiff, its action is accordingly moot.[5]

II. The Court Should Defer to the Agency's Reasonable Final Rule

Even if Plaintiff established standing, had exhausted its administrative remedies prior to filing suit, and had brought a legal claim for which relief could be afforded here, judgment should still be entered for Defendant, because the definition of "applicable laboratory" in the Final Rule here was reasonable.

[5] If this Court disagrees and concludes that the case is not moot, for the same reasons set forth above, any relief should be limited to declaratory relief, rather than a specific remedy involving the vacatur or alteration of specific payment rates. As noted above, in addition to being barred by statute, such specific redress could require the agency to (1) conduct a new notice-and-comment rulemaking to arrive at a new definition of "applicable laboratory," (2) re-collect 2016 private payor data from applicable laboratories on the basis of that new definition, (3) use that data to re-calculate CLFS payment rates applicable between 2018 and 2020, and (4) implement any difference in specific CDLT rates.

Should the Court proceed to evaluate the merits, it must assess the parties' competing readings of PAMA 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.

A. *Chevron* Step One: The D.C. Circuit Held that the Statute is Ambiguous

Helpfully, the D.C. Circuit has already resolved the inquiry at *Chevron* step one, and did so in Defendant's favor. That is, in rejecting Plaintiff's ultra vires claim, the D.C. Circuit also inherently rejected Plaintiff's argument that Congress has directly spoken to the precise question at issue. Here, the precise question is the definition of "applicable laboratory." If the statute contains a straightforward definition for this term, the agency is obligated to follow that direction. If, on the other hand, the statute does not define or otherwise leaves ambiguous the term "applicable laboratory," then the agency may define the term for purposes of its regulations. The D.C. Circuit held explicitly that the latter situation is present here.

Specifically, the D.C. Circuit recognized that "PAMA does not define the term 'laboratory,' and the Secretary's charge was to operationalize that important term *despite its ambiguity*." *Am. Clinical Lab. Ass'n*, 931 F.3d at 1208 (emphasis added). This binding language, that the statutory term "laboratory" both lacked a definition and was ambiguous, resolves the inquiry at *Chevron* step one in the agency's favor. *See Am. Forest & Paper Ass'n v. F.E.R.C.*, 550 F.3d 1179, 1180 (D.C. Cir. 2008) ("Under step one, we ask whether the statutory language is ambiguous."); *see also Am. Equity Inv. Life Ins. Co. v. SEC*, 613 F.3d 166, 173 (D.C.

Cir. 2010) ("*Chevron* Step One is satisfied because the Act is ambiguous, or at the very least silent[.]"). Thus, because the D.C. Circuit held that the term "laboratory" was ambiguous, Plaintiff's argument at *Chevron* step one — that Congress set forth a clear definition of the term in the statute — necessarily fails.

Plaintiff fails to mention this dispositive holding in its brief. Instead, Plaintiff repeats many of the same arguments here that it previously made to contend that the final rule was *ultra vires*, in that it "rewrites" the language of the statute. *Compare* Combined Opp'n to Def.'s Mot. for Summ. J. and Reply in Supp. of Pl.'s Mot. for Summ. J., ECF No. 29 (arguing that the rule was unlawful and "*ultra vires*" because it "rewrites" the statute) *with* Pl.'s Mot. at 18 (arguing that the rule is "invalid because it rewrites PAMA's definition of 'applicable laboratory'"). But this argument, that there was some definition to "rewrite" at all, cannot be squared with the D.C. Circuit's holding that the statute failed to define "laboratory," and that the Secretary was "charge[d]" with formulating a definition because of this term's "ambiguity." *Am. Clinical Lab. Ass'n*, 931 F.3d at 1208.

If more were needed, Plaintiff itself previously agreed with the D.C. Circuit that the term "laboratory" was not defined in the statute and was ambiguous. 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; Khani Decl. 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." Khani Decl. 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 (emphasis added). 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*. at 100. To be sure, Plaintiff stated its opinion as to which definitions "seem[] reasonable," or were "most appropriate." *Id*. at 99. 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. Thus, as Plaintiff previously recognized, and as the D.C. Circuit held, Congress did not speak to this precise question and Plaintiff's *Chevron* step one argument accordingly fails.

B. *Chevron* Step Two: The Final Rule Was Not Arbitrary Or Capricious

The only question remaining is whether the agency's definition of the ambiguous term "applicable laboratory" was arbitrary or capricious. At *Chevron* step two, a court must give an agency interpretation "controlling weight" so long as it "fills a gap or defines a term in a reasonable way." *Regions Hosp. v. Shalala*, 522 U.S. 448, 457 (1998). Indeed, an agency interpretation of an ambiguous term need only be reasonable to pass muster, and courts must accept such a "construction . . . even if the agency's reading differs from what the court believes is the best statutory interpretation." *Nat'l Cable & Telecomms. Ass'n v. Brand X Internet Servs.*, 545 U.S. 967, 980 (2005). "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 bills Medicare Part B under its own NPI number.

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* Khani Decl. at 39. As a first step, the agency incorporated the definition in CLIA as the basis for its definition of a "laboratory" within the term "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." Khani Decl. 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." 80 Fed. Reg. at 59,392. 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 generally 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.* Tellingly, in both its original briefing and here, 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 these hospital outreach laboratories to report private payor data, the agency adopted in the Final Rule a definition of "applicable laboratory" to require data from entities 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. The Florida Hospital Association, for example, "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." AR 01474. Likewise, the Biotechnology Industry Association commented that the agency should use the NPI to identify applicable laboratories, because it "offers greater accuracy in identifying those laboratories that should report pricing data to CMS for the purpose of calculating the true market value." *See* AR 02293. Similar recommendations were made by healthcare associations, trade groups, and other commenters. *See also* AR 01979, 02318, 02322, 02361, 02603, 03487. At bottom, the agency thoughtfully considered objections to the proposed use of TINs in defining "applicable laboratory," as well as comments in favor of using NPIs, and accordingly adopted a definition that used NPIs instead, for the express purpose of enabling hospital outreach laboratories to qualify as applicable laboratories. This decision was neither arbitrary nor capricious.

1. The Final Rule Collected Data As Intended By the Statute

In arguing to the contrary, Plaintiff raises three arguments. First, Plaintiff urges that the Final Rule is unreasonable because it does not collect sufficient data from hospitals and therefore results in Medicare payment rates that are not comparable to private payor rates. The gist of Plaintiff's argument is that the definition caused the collection of data from too few hospital

laboratories, which was an "absurd result" and should have prompted the Secretary to select a different, albeit unspecified, "alternative approach." Pl.'s Mot. at 22.

This argument echoes Plaintiff's deficient standing contentions. That is, in arguing that the definition of "applicable laboratory" collected data from too few hospital laboratories, 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 expenditure threshold. Absent any specific facts concerning the number of hospitals that should have reported data, and to what extent that data would have resulted in higher payment rates, Plaintiff cannot show that the Final Rule caused insufficient data collection and resulted in inaccurate payment rates.

Furthermore, it was entirely reasonable for the agency to conclude that the statute "limit[ed] reporting primarily to independent laboratories and physician offices," AR 00011; 81 Fed. Reg. at 41,045, because "[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*. Thus, far from being unintended, the agency explicitly and reasonably determined that the statute meant for the vast majority of data collection to come from independent laboratories and physician offices, rather than hospital laboratories.

Thus, 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.'s Mot. at 12. Instead, Congress included the specific and unique 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 prospective payment systems. In one of the alternative definitions of "applicable laboratory" Plaintiff suggested during the comment period, Plaintiff conceded that including the majority of Medicare revenues test in the definition meant that "many hospitals would not qualify as applicable laboratories." Khani Decl. at 162. Accordingly, 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 by Medicare under the CLFS or PFS.

2. The Final Rule Reasonably Adopted a Bright-Line Requirement

Plaintiff's cursory second and third arguments are related and may be addressed together. That is, Plaintiff claims that the use of an NPI was improperly supported by a claim of administrative convenience, and in any event failed to capture reporting from all hospital laboratories with outreach programs. But the NPI criterion was not adopted solely for administrative convenience or to distinguish between hospitals with varying levels of outreach. Rather, in using NPIs in the definition of "applicable laboratory," the agency sought to determine the entity, applicable across the entire market, which could reasonably be described as a "laboratory" that received Medicare revenues. *See* 81 Fed. Reg. at 41046 (explaining that in using NPIs to define "applicable laboratory," "[u]nder this approach, the criteria for being an applicable laboratory would be applied by each laboratory with an NPI").

And to the extent considerations of administrative convenience supported this determination, that reasoning further supports upholding the Final Rule. The D.C. Circuit has repeatedly and consistently held that "[a]gencies generally do not violate the APA's deferential arbitrary-and-capricious standard when they employ bright-line rules for reasons of

administrative convenience, so long as those rules fall within a zone of reasonableness and are reasonably explained." *Emily's List v. Fed. Election Comm'n*, 581 F.3d 1, 22 n. 20 (D.C. Cir. 2009); *see also Actavis Elizabeth LLC v. U.S. Food & Drug Admin.*, 625 F.3d 760, 766 (D.C. Cir. 2010) (same). As Plaintiff notes, the agency found it entirely unclear how hospitals could determine the relevant Medicare revenues associated with a given hospital laboratory, absent an identifier "associated with Medicare billing" such as an NPI, "with which revenues for specific services can be easily identified." *See* 81 Fed. Reg. at 41046.

Notably, in its initial briefing and once again here, Plaintiff fails to offer any suggestion as to how the agency should have resolved this quandary. But unlike Plaintiff here, the agency did not simply "throw up its hands," Pl.'s Mot. at 23, when faced with this dilemma, and rather adopted a bright-line rule that was reasonable, supported by many commenters, grounded in the statute, and that would be simple for regulated entities to understand and administer. Given the agency's thorough explanations as to how its definition would work in practice and why it was supported by the statute, Plaintiff cannot show it to be arbitrary and capricious.

C. HHS Appropriately Responded to Critical Comments

In its final swing, Plaintiff argues that the Final Rule is arbitrary and capricious because the "Secretary has not reasonably responded to serious objections to his approach." Pl.'s Mot. at 24-25. 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.*

The Final Rule exhaustively responded to all significant comments. Plaintiff is simply incorrect in claiming that the Secretary did not "reasonably respond" to commenters that urged a change from the proposed rule, so as to include more hospital laboratories in the data collection for rate setting. Pl.'s Mot. at 25. In fact, the Secretary specifically noted this "particular concern" by commenters and responded at length. *See* 81 Fed. Reg. at 41045. The agency said, among other things, that "the statute supports the effective exclusion of hospital laboratories by virtue of the majority of Medicare revenues criterion," because "[m]ost hospital laboratories will not meet the majority of revenues threshold." *Id*. At the same time, the agency agreed that "hospital outreach laboratories," those that are "enrolled in Medicare separately from the hospital of which they are a part" and therefore have identifiable revenues, should be "accounted for in the new CLFS payment rates," which the agency sought to do in part by use of an NPI. *Id.* Thus, there can be no plausible dispute that the Secretary considered and responded to the concerns of these commenters.

Nor can Plaintiff reasonably argue that the Secretary "offered no reasoned explanation for rejecting the alternative approaches that commenters urged." Pl.'s Mot. at 25. 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; Khani Decl. 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; Khani Decl. 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 more than 50% of the revenues for their laboratory services were received from the CLFS and PFS. *Id*. The agency also considered and rejected this proposal.

In the Final Rule CMS 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."[6] *City of Portland, Oregon v. EPA*, 507 F.3d 706, 714 (D.C. Cir. 2007).

[6] 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 proposed definition of "applicable laboratory" to address the genesis of those concerns. *See Tex. Mun.*

Notably, Plaintiff does not appear to support the use of an "adjustment factor" any longer. When recently asked by the agency to propose specific changes to the Final Rule, Plaintiff in fact did not rely upon its proposed "adjustment factor." Khani Decl. at 260. The agency should not be faulted for rejecting a proposal that Plaintiff itself has disowned.

CONCLUSION

For the reasons set forth above, this Court should grant Defendant's Cross-Motion for Summary Judgment, deny Plaintiff's Motion, and enter judgment for Defendant.

Dated: November 22, 2019

Respectfully submitted,

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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.").

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