UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. ALEX M. AZAR, II *Secretary, United States Department of Health and Human Services,* Defendant.	)	Civil Action No. 17-2645 (ABJ)

MEMORANDUM OPINION

Plaintiff American Clinical Laboratory Association, a trade association that represents clinical and anatomic pathology laboratories, Compl. [Dkt. # 1] ¶ 18, has challenged a regulation issued by the Secretary of the U.S. Department of Health and Human Services, Alex M. Azar, II. The regulation at issue implements Section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA") by requiring certain laboratories to report pricing information to the agency for use in establishing Medicare rates. Plaintiff contends that the definition of the term "applicable laboratory" in the regulation violates PAMA and the Administrative Procedure Act ("APA"). In response, defendant asserts that in the statute, Congress expressly precluded judicial review of issues such as these, and the Court has no jurisdiction to hear the case. While the Court acknowledges that plaintiff's arguments on the merits raise important questions, it agrees with defendant that it cannot resolve this dispute, and it will dismiss this matter for lack of subject matter jurisdiction.

STATUTORY FRAMEWORK

The federal Medicare program, established by Title XVIII of the Social Security Act, provides health insurance to the elderly and disabled. *Amgen, Inc. v. Smith*, 357 F.3d 103, 105 (D.C. Cir. 2004). The program is administered by the Department of Health and Human Services ("HHS"), and the Secretary of the Department is authorized to "giv[e] content to the broad outlines of the Medicare statute." *Dialysis Clinic, Inc. v. Leavitt*, 518 F. Supp. 2d 197, 199 (D.D.C. 2007), quoting *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 506–07 (1994). Part A of Medicare covers inpatient hospital stays and related services, while Part B covers outpatient treatment and services, such as doctor's visits and laboratory tests. *See Abington Crest Nursing & Rehab. Ctr. v. Sebelius*, 575 F.3d 717, 718 (D.C. Cir. 2009).

This case concerns laboratory tests paid for under Medicare Part B – specifically, clinical diagnostic laboratory tests, which are performed on specimens, such as blood or urine, and are used in monitoring, diagnosing, and treating patients. Pl.'s Corrected Mem. of P. & A. in Supp. of Pl.'s Mot. for Summ. J. [Dkt. # 31-1] ("Pl.'s Mem.") at 4. They can range from routine blood work to sophisticated genetic and molecular tests. Pl.'s Mem. at 4.

Since 1984, Medicare has paid for these tests based on a fee schedule. *See* Medicare Program; Medicare Clinical Diagnostic Lab. Tests Payment Sys.; Final Rule, 81 Fed. Reg. 41,036, 41,036 (June 23, 2016) ("Final Rule") (codified at 42 C.F.R. §§ 414.500–414.522). In 2014, Congress passed the Protecting Access to Medicare Act of 2014, which, among other things, revised the payment scheme for diagnostic tests by substituting a market-based approach for the Clinical Laboratory Fee Schedule. Pub. L. No. 113-93, § 216, 128 Stat. 1040, 1053 (2014) (codified at 42 U.S.C. § 1395m-1).

Section 216 of PAMA provides that Medicare payments for clinical diagnostic laboratory tests will be based upon what private payors pay laboratories for these tests. *See* 42 U.S.C.

§ 1395m-1(a); *see also* Thomas C. Fox *et al.*, *Health Care Fin. Transactions Man.* § 21:21 (2018). To calculate the appropriate payment amounts, the Secretary is authorized to gather data, and Section 216 requires "applicable laborator[ies]" to report to HHS the amounts and volume of private sector payments they receive for tests, 42 U.S.C. § 1395m-1(a), which the Secretary will then use to calculate Medicare's payment rates for the tests. *Id.* § 1395m-1(b).

The statute defines "applicable laboratory" to mean a laboratory for which a majority of the revenues it receives from Medicare "are from this section, section 1395*l*(h) of this title, or section 1395w–4 of this title" – in other words, that they are from Medicare's Clinical Laboratory Fee Schedule or its Physician Fee Schedule. *Id.* § 1395m-1(a)(2); *see also* Pl.'s Mem. at 8.

The statute also requires the Secretary to issue rules about how these applicable laboratories would report the amounts and volume of private sector payments they receive to the agency. *Id.* at § 1395m-1(a)(12). So in 2016, after publishing a preliminary rule and providing a public notice-and-comment period, the Secretary issued a final rule implementing Section 216. *See* Final Rule. In it, the Secretary further defined an "applicable laboratory" to mean one that "[b]ills Medicare Part B under its own National Provider Identifier (NPI)." 81 Fed. Reg. at 41,098; 42 C.F.R. § 414.502. Plaintiff objects to the additional gloss on the statute.

PROCEDURAL HISTORY

On December 11, 2017, plaintiff filed this lawsuit, challenging the definition of "applicable laboratory" set forth in the Final Rule. Compl. [Dkt. # 1]. Pending before the Court are the parties' cross-motions for summary judgment. Pl.'s Mot. for Summ. J. [Dkt. # 13]; Def.'s Cross-Mot. for Summ. J. & Opp. to Pl.'s Mot. for Summ. J. [Dkt. # 27] ("Def.'s Cross-

Mot. & Opp.").[1] The motions are fully briefed, *see* Pl.'s Combined Opp. to Def.'s Mot. and Reply in Supp. of Pl.'s Mot. for Summ. J. [Dkt. # 29] ("Pl.'s Opp."); Def.'s Reply in Supp. of Cross-Mot. for Summ. J. [Dkt. # 34-1].[2] The Court received four amicus briefs,[3] and the administrative record [Dkt. # 38] was filed on May 4, 2018.

STANDARD OF REVIEW

Federal courts are courts of limited jurisdiction, and the law presumes that "a cause lies outside this limited jurisdiction." *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994); *see also Gen. Motors Corp. v. EPA*, 363 F.3d 442, 448 (D.C. Cir. 2004) ("As a court of limited jurisdiction, we begin, and end, with an examination of our jurisdiction."). "[B]ecause subject-matter jurisdiction is 'an Art[icle] III as well as a statutory requirement . . . no action of the parties can confer subject-matter jurisdiction upon a federal court.'" *Akinseye v. District of Columbia*, 339 F.3d 970, 971 (D.C. Cir. 2003), quoting *Ins. Corp. of Ir., Ltd. v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982). Under Rule 12(b)(1), the plaintiff bears the burden of establishing jurisdiction by a preponderance of the evidence. *See Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992); *Shekoyan v. Sibley Int'l Corp.*, 217 F. Supp. 2d 59, 63 (D.D.C. 2002).

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1 Defendant's motion is styled as a motion for summary judgment, but defendant also asks the Court to dismiss of plaintiff's claims on jurisdictional and other grounds. *See* Def.'s Cross-Mot. at 1, 2.

2 On April 20, 2018, this matter was reassigned to the undersigned judge.

3 *See* Br. of Amicus Curiae Nat'l Assoc. for the Supp. of Long Term Care in Supp. of Pl. [Dkt. # 21]; Br. of the Advanced Med. Tech. Assoc. as Amicus Curiae in Supp. of Pl.'s Mot. [Dkt. # 22]; Br. of Amicus Curiae Am. Assoc. of Bioanalysts in Supp. of Pl.'s Mot. [Dkt. # 23]; and Amicus Curiae Br. of the Coll. Of Am. Pathologists in Supp. of Pl.'s Mot. [Dkt. # 25]. Because these briefs address only the merits of the case and not subject matter jurisdiction, the Court need not address their arguments.

When considering a motion to dismiss for lack of jurisdiction, unlike when deciding a motion to dismiss under Rule 12(b)(6), the court "is not limited to the allegations of the complaint." *Hohri v. United States*, 782 F.2d 227, 241 (D.C. Cir. 1986), *vacated on other grounds*, 482 U.S. 64 (1987). Rather, "a court may consider such materials outside the pleadings as it deems appropriate to resolve the question [of] whether it has jurisdiction to hear the case." *Scolaro v. D.C. Bd. of Elections & Ethics*, 104 F. Supp. 2d 18, 22 (D.D.C. 2000), citing *Herbert v. Nat'l Acad. of Scis.*, 974 F.2d 192, 197 (D.C. Cir. 1992); *see also Jerome Stevens Pharms., Inc. v. FDA*, 402 F.3d 1249, 1253 (D.C. Cir. 2005).

ANALYSIS

Plaintiff challenges the Secretary's definition of "applicable laboratory" on the grounds that it is contrary to the language of PAMA and therefore, promulgated in violation of the APA. It asserts that by defining the term to mean only a laboratory that bills Medicare Part B under its own NPI, the Secretary improperly excluded "virtually all" hospital laboratories from PAMA's data-reporting requirements. Pl.'s Mem. at 2 (stating that most hospital laboratories do not have their own NPIs but bill Medicare using their hospitals' NPI). It contends that the definition is contrary to PAMA's plain text, is unreasonable, and is arbitrary and capricious because it improperly excludes a large body of relevant data and does not reflect private-sector market prices for diagnostic tests. Pl.'s Mem. at 3.

Defendant asserts that the Court does not have subject matter jurisdiction over plaintiff's lawsuit because the Final Rule is not subject to judicial review, and even if it were, plaintiffs do not have standing, and they did not exhaust their administrative remedies. Def.'s Cross-Mot. & Opp. at 1–2.

There is a "strong presumption that Congress intends judicial review of administrative action," *Bowen v. Mich. Acad. of Family Physicians*, 476 U.S. 667, 670 (1986), and the APA

provides for a "basic presumption of judicial review" of administrative actions. *Tex. All. for Home Care Servs. v. Sebelius*, 681 F.3d 402, 408 (D.C. Cir. 2012), quoting *Banzhaf v. Smith*, 737 F.2d 1167, 1169 (D.C. Cir. 1984) (en banc); *see also* 5 U.S.C. § 701(a)(1). Congress may, however, preclude judicial review of an administrative action by statute. *Tex. All.*, 681 F.3d at 408, citing *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 349 (1984) (holding that the presumption in favor of judicial review can be overcome by "specific language" in the statute that is a "reliable indicator" of Congress's intent to preclude review).

To determine "[w]hether and to what extent a particular statute precludes judicial review," courts consider its "express language, . . . the structure of the statutory scheme, its objectives, its legislative history, and the nature of the administrative action involved." *Block*, 467 U.S. at 345. In conducting this analysis, "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." *Fla. Health Scis. Ctr., Inc. v. Sec'y of Health & Human Servs.*, 830 F.3d 515, 521 (D.C. Cir. 2016) (emphasis in original).

Section 216 of the Protecting Access to Medicare Act, entitled "Improving policies for clinical diagnostic laboratory tests," consists of eight subsections, (a) through (i). 42 U.S.C. § 1395m-1. Subsection (a) of Section 216 requires laboratories to report certain data about payments they receive from private payors for laboratory tests they perform, and subsection (b) requires the Secretary to use the data to calculate Medicare payment rates for laboratory tests. *Id.* § 1395m-1(a), (b). Subsections (c) through (g) and (i) have no bearing on the case at hand, but subsection (h)(1) of Section 216 precludes "administrative or judicial review . . . of the establishment of payment amounts under this section." 42 U.S.C. § 1395m-1(h)(1).

The words "this section" obviously apply to Section 216 as a whole.[4] But plaintiff argues that subsection (a) and the Final Rule issued under that provision relate only to the reporting of payment information, and do not involve the "the establishment of payment amounts under this section." Pl.'s Opp. at 4. So, according to plaintiffs, they are not covered by the preclusion provision in subsection (h). Pl.'s Opp. at 4–5 (arguing that the Final Rule does not purport to establish payment amounts but only parameters for data collection). But this reading of the judicial review provision is not consistent with the text and structure or the purpose of the statute.

The Court's research uncovered no substantive legislative history on Section 216, and the parties cite to none.[5] But there is no dispute that the purpose of the provision was to change how the amount of Medicare payments for laboratory tests will be determined. *See* Pl.'s Mem. at 7; Def.'s Cross-Mot. & Opp. at 5–6; *see also* Final Rule, 81 Fed. Reg. at 41,036 (stating that Section 216 made "extensive revisions to the Medicare payment, coding, and coverage

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4 Plaintiff contends that the preclusion provision appears in "a separate provision of PAMA," and it invokes the principle set forth in *Dean v. United States*, 556 U.S. 568 (2009), that "[w]here Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." Pl.'s Mem. at 20–21, quoting 556 U.S. at 573. But the principle is inapplicable because plaintiff's description of the statute is plainly incorrect.

PAMA is comprised of two titles. Title I contains twelve sections, Pub. L. No. 113-93, §§ 101–112, and Title II contains twenty-five sections, including Section 216. *Id*. §§ 201–225. The two provisions at issue in this case, the data reporting provision in Section 216(a) and the preclusion provision in Section 216(h), both appear in a single section of PAMA, along with seven other subsections, that together establish a single system for how payment amounts will be calculated for clinical diagnostic laboratory tests.

5 Plaintiff's reference to the statements of two Senators about Section 216 made after PAMA was enacted, Pl. Mot. at 8, 26, citing 160 Cong. Rec. S2860 (daily ed. May 8, 2014), is "inherently entitled to little weight." *Cobell v. Norton*, 428 F.3d 1070, 1075 (D.C. Cir. 2005); *Verizon v. FCC*, 740 F.3d 623, 639 (D.C. Cir. 2014) (stating that subsequent legislative history is an unreliable guide to legislative intent).

requirements" for clinical diagnostic laboratory tests); Fox *et al.*, *supra*, § 21:21 (describing Section 216 as amending Medicare payments to clinical laboratories for diagnostic tests from a fee schedule approach to a market approach, using rates based on what private payors pay for the tests).

And a review of Section 216 shows that subsection (a) is part of the larger scheme set out in the section as a whole. *See King v. St. Vincent's Hosp.*, 502 U.S. 215, 221 (1991) (stating that "a statute is to be read as a whole"). Section 216(a) calls for laboratories to report payment data to the agency. 42 U.S.C. § 1395m-1(a). Section 216(b), titled "Payment for clinical diagnostic laboratory tests," governs the "[u]se of private payor rate information to determine medicare payment rates." *Id.* § 1395m-1(b), (b)(1). It requires that "the payment amount under this section shall be equal to the weighted median determined for the test under paragraph (2) for the most recent data collection period," *id.* § 1395m-1(b)(1)(A), and specifies that for each laboratory test for "which information is reported under *subsection (a)* for a data collection period, the Secretary shall calculate a weighted median for the test for the period," setting forth how that weighted median is to be calculated. *Id.* § 1395m-1(b)(2) (emphasis added). Subsection (b) is the only provision in Section 216 that makes any use of the data collected from laboratories. *See id.* § 1395m-1. Thus, it is clear from the statute that the data gathered under subsection (a) is gathered specifically for the purpose of calculating payment rates for clinical diagnostic laboratory tests under subsection (b).

Indeed, subsection (a) is titled "Reporting of private sector payment rates *for establishment of medicare payment rates*." *Id.* § 1395m-1(a) (emphasis added). So the header of the provision that plaintiff asserts does *not* concern "the establishment of payment amounts under this section" expressly states that it does. *See United States v. Villanueva-Sotelo*, 515 F.3d

1234, 1243 (D.C. Cir. 2008), quoting *Almendarez-Torres v. United States*, 523 U.S. 224, 234 (1998) ("[T]he title of a statute and the heading of a section are tools available for the resolution of a doubt about the meaning of a statute."). Given this, the statute's text supports the conclusion that subsection (a) is part and parcel "of the establishment of payment amounts under this section," which Congress shielded from judicial review. 42 U.S.C. § 1395m-1(h)(1).

Plaintiff emphasizes that it is not challenging the amounts to be paid for laboratory tests, only the Secretary's data reporting rules. *See* Pl.'s Opp. at 4. But given that the data reported under subsection (a) feeds directly into the payment calculation in subsection (b), and it is not being accumulated for any other purpose, the data is "inextricably intertwined" with the establishment of Medicare payments under Section 216. *Fla. Health*, 830 F.3d at 519. Under those circumstances, the Court is bound to take note of the D.C. Circuit's opinion in *Florida Health*, which "rejected the categorical distinction between inputs and outputs" when analyzing whether a particular agency action is covered by a statutory preclusion provision. *Id.*

Although it involves a different preclusion provision in the Medicare statute, the ruling in *Florida Health* provides clear guidance that is instructive here. The case involved a challenge to the Secretary's "estimate" of a hospital's uncompensated care, a number that is factored in the determination of the payment a hospital will ultimately receive. *Id*. at 517–18. In making the estimate, "the Secretary used the number of Medicaid and Medicare SSI patients as a proxy for the population of uninsured low-income patients." *Id.* at 519. The plaintiff challenged the Secretary's choice of the data used to formulate that estimate, arguing that she had used inappropriate data in using data from March 2013 instead of April 2013. *Id.* at 518–19. Faced with a statutory provision barring judicial review of "[a]ny estimate of the Secretary," the plaintiff characterized the challenge as limited simply to the Secretary's reliance on inappropriate

data, not her methodology for "estimating" uncompensated care. *Id.* at 519. The defendant maintained that the statute prohibited any judicial review.

After the case was dismissed for lack of jurisdiction, Florida Health appealed. The D.C. Circuit pointed to the provision in the statute precluding review, which bars "administrative or judicial review" of "[a]ny estimate of the Secretary" or "[a]ny period selected by the Secretary" to determine each hospital's payment. *Fla. Health*, 830 F.3d at 518, quoting 42 U.S.C. § 1395ww(r)(3) (alterations in original). It explained that the applicability of such a provision turns on the relationship between the challenged decision and the agency action shielded from review, and that it "could not review a decision that was 'indispensable' or 'integral' to, or 'inextricably intertwined' with, the unreviewable agency action." *Id*. at 519, quoting *Tex. Alliance*, 681 F.3d at 409–11. It ruled that the Secretary's decision to use a particular data set to estimate the number of uninsured low-income patients a hospital served was not reviewable because "[n]o other data factored into the Secretary's estimate of uncompensated care." *Id.*

The Court finds plaintiff's challenge here to be comparable to the challenge in *Florida Health* because it concerns which data the Secretary will use in establishing payment amounts. To be sure, *Florida Health* did not involve a rule about how the Secretary would obtain the data needed to make the estimate, like this case does. But that is because the Secretary did not need to collect additional data for that particular calculation; it already received the information from hospitals. *Id.* at 517 ("Hospitals keep track of the number of Medicaid patients served by submitting annual reports to HHS.").

Here, in moving from a fee schedule regime to a market-based one, the agency needed to collect information that it was not already receiving from laboratories. So the statute required

the Secretary to establish "parameters for data collection." 42 U.S.C. § 1395m-1(a)(12). The Secretary's determination about which laboratories would report their private payor payment is analogous to the determination about which time frame the Secretary would use in making the estimate in *Florida Health*: there was a universe of data the Secretary could use, and the Secretary identified the subset to be used in both cases.

Thus, the decision of which laboratories must report data is "indispensable" and "integral" to, and "inextricably intertwined" with, the agency action's calculation of payment amounts based on that data and "the establishment of payment amounts under" Section 216. Therefore, it is not subject to judicial review. *Fla. Health*, 830 F.3d at 519; *see also Tex. All.*, 681 F.3d at 409, 411 (holding that where "awarding of contracts" was protected from judicial review, the financial standards regulation that determined eligibility for contracts was also protected); *Knapp Med. Ctr. v. Hargan*, 875 F.3d 1125, 1129 (D.C. Cir. 2017) (holding that where "the process" of a hospital's application to the agency for an particular exemption was precluded from suit, the agency's final "determination" on the application was also barred).

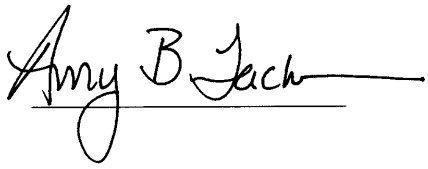
According to the plaintiff, because subsection (a) requires the agency to take some affirmative action related to laboratories other than just the establishment of rates, it falls outside the scope of the preclusion provision in a way that, for example, subsection (c), which expressly relates to the establishment of payments for newly developed tests would not. *See* Pl.'s Opp. at 4. And plaintiff argues that the fact that Congress required the agency to undergo notice-and-comment rulemaking when developing rules to implement subsection (a) but not subsection (c) reinforces this interpretation. *Id.* But these circumstances do not alter the Court's conclusion given the text and structure of the statute.

Plaintiff argues that the Congressional requirement in subsection (a) that the Secretary promulgate regulations using notice-and-comment rulemaking, along with the establishment of civil penalties for the failure to report data, reflects that Congress understood that the Secretary was regulating the "primary conduct" of laboratories. Pl.'s Opp. at 6. So, plaintiff argues, it must have intended the regulation to be subject to judicial review to protect the interests of the regulated entities. *See* Pl.'s Mem. at 6 ("It would raise constitutional concerns of the highest order if Congress were to require the Secretary to promulgate substantive legislative regulations that directly regulate primary conduct on threat of civil penalties but then attempt to insulate those regulations, as well as the Secretary's enforcement of them, from any form of judicial review.").

But the purpose and effect of the Final Rule is not to regulate the work of laboratories but, rather, to ensure that HHS is equipped with the data it needs to calculate Medicare payment amounts. That does not constitute regulation of the laboratories' "primary conduct." *See Nat'l Park Hosp. Ass'n v. Dep't of Interior*, 538 U.S. 803, 810 (2003) (explaining that a regulation does not affect a party's "primary conduct" when the party is "free to conduct its business as it sees fit"); *contra Abbott Labs. v. Gardner*, 387 U.S. 136, 153 (1967), *abrogated by Califano v. Sanders*, 430 U.S. 99 (1977) (holding that judicial review must be permitted "where a regulation requires an immediate and significant change in the plaintiffs' conduct of their affairs with serious penalties attached to noncompliance, . . . absent a statutory bar or some other unusual circumstance"). While Section 216 does provide for civil penalties for failing to report data or making misrepresentations or omissions in reports, 42 U.S.C. § 1395m-1(a)(9), the Court finds that the challenged regulation does not affect the primary conduct of clinical laboratories, and it is not subject to judicial review in light of the statutory bar in subsection (h).

CONCLUSION

For the reasons stated above, this matter is DISMISSED for lack of subject matter jurisdiction pursuant to Federal Rule of Civil Procedure 12(b)(1). Plaintiff's motion for summary judgment [Dkt. # 13] is DENIED, and defendant's motion for summary judgment on the merits is [Dkt. # 27] as DENIED AS MOOT.



AMY BERMAN JACKSON
United States District Judge

DATE: September 21, 2018