UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION, Plaintiff, v. XAVIER BECERRA, Secretary, United States Department of Health and Human Services, Defendant.	Civil Action No. 17-2645 (ABJ)

MEMORANDUM OPINION

In this case, plaintiff American Clinical Laboratory Association challenged a regulation issued by the Secretary of the U.S. Department of Health and Human Services[1] governing the reporting of the pricing information used to set Medicare reimbursement rates for clinical diagnostic laboratory services. Plaintiff is a trade association that represents clinical and anatomic pathology laboratories, Compl. [Dkt. # 1] ¶ 18, and the challenged regulation implements section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"), which established a new scheme for setting Medicare reimbursement rates for these laboratory tests.

The parties have filed cross-motions for summary judgement and for the reasons set forth below, the Court will dismiss this case as moot.

1 The newly appointed Secretary, Xavier Becerra, has been substituted as defendant pursuant to Federal Rule of Civil Procedure 25(d).

BACKGROUND

Clinical diagnostic laboratory tests are tests performed on specimens of bodily fluids or tissue that are used to monitor, diagnose, and treat patients, and they range from routine blood tests to sophisticated genetic and molecular tests. Compl. ¶ 1. The federal Medicare program, which is administered by the Department of Health and Human Services ("HHS" or "the Department") and pays for healthcare for elderly and disabled individuals, is the nation's largest purchaser of clinical laboratory services. *See* 42 U.S.C. § 1395 *et seq*.; *Am. Clinical Lab'y Ass'n. v. Azar*, 931 F.3d 1195, 1199 (2019).

How Medicare reimburses laboratories for clinical diagnostic laboratory tests depends on the setting in which they are provided. These services may be provided in hospitals on an inpatient or outpatient basis, in nursing facilities, or at a doctor's office. Compl. ¶ 22. If a Medicare beneficiary receives these laboratory tests at a hospital, Medicare pays for *all* of the services the hospital provides to the beneficiary – medications, room and board, laboratory, and all other services – in one bundled payment pursuant to either the Inpatient Prospective Payment System ("IPPS") or the Outpatient Prospective Payment System ("OPPS"). *See* 42 U.S.C. §§ 1395ww(d), 1395l(t); *Appalachian Reg'l Healthcare, Inc. v. Shalala*, 131 F.3d 1050, 1051, 1053 (D.C. Cir. 1997) (explaining that the IPPS 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 separate services a patient received from the hospital). In contrast, if a beneficiary receives laboratory tests outside of a hospital setting, such as at a doctor's office or from an independent laboratory, Medicare pays the laboratory for each test performed based on the Clinical Laboratory Fee Schedule ("CLFS") or the

Physician Fee Schedule ("PFS").[2] *See* 81 Fed. Reg. 41,036, 41,038 (June 23, 2016); J.A. [Dkt. # 38].[3]

Some hospital laboratories provide services not only to hospital patients, but also externally, to individuals who are not patients of the hospital. For example, the blood sample taken at a doctor's office may be sent to a hospital laboratory for analysis. Such hospital laboratory services provided to non-hospital patients are referred to as "outreach services," and Medicare pays for them as it would for an independent laboratory: on a fee-for-service basis based on the CLFS or the PFS. *Id.*, citing 42 U.S.C. §§ 1832, 1833(a), (b), (h), 1861.

I. Protecting Access to Medicare Act of 2014

In 2014, Congress passed the Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, 128 Stat. 1040, to overhaul Medicare payments for laboratory services. Before PAMA, Medicare's fee schedule for clinical laboratory services was set by the Secretary based on a "regional, statewide, or carrier service area basis," with adjustments for differences in wages. 42 U.S.C. § 1395*l*(h)(1)(B)–(C), (h)(4)(A). In 2013, the Department's Office of Inspector General found that Medicare was paying eighteen to thirty percent more for laboratory tests than private insurers were paying. *Am. Clinical Lab'y Ass'n*, 931 F.3d at 1199. Congress passed PAMA in an effort to make Medicare's reimbursement rates comparable to those paid by private insurers for the same laboratory tests. *Id.*; *see also* 160 Cong. Rec. S2860 (May 8, 2014) (stating Congress sought to "ensure that Medicare rates reflect true market rates for laboratory services").

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2 Generally speaking, tests that require both a professional and technical component to provide the test results are paid under the PFS, and those that require no interpretation by a physician or professional are paid under the CLFS. *See* 42 C.F.R. § 414.40(b)(2).

3 Citations to the Joint Appendix refer to the Bates numbers appearing at the bottom right of each page of the appendix.

PAMA established a market-based approach for setting payment rates based on the amounts private payors pay for these tests. *See* 42 U.S.C. § 1395m-1. Section 216 of PAMA requires "applicable laborator[ies]" to report to the Department every three years the amounts and volume of payments they receive from private insurers, 42 U.S.C. § 1395m-1(a),[4] exempting certain "low volume or low expenditure" laboratories from the requirement. *Id.* § 1395m-1(a)(2). It requires the Secretary to compile the reported data to calculate Medicare's reimbursement rates for laboratory tests. *Id.* § 1395m-1(b) (requiring the Secretary to calculate a weighted median for each laboratory test "by arraying the distribution of all payment rates reported for the period for each test weighted by volume for each payor and each laboratory").

PAMA defines "applicable laboratory" to mean "a laboratory that, with respect to its revenues under this subchapter, a majority of such revenues are from this section, section 1395l(h) of this title, or section 1395w–4 of this title." *Id.* § 1395m-1(a)(2). In other words, a laboratory must receive the majority of its Medicare revenues from the CLFS or the PFS – the payment mechanisms covering non-hospital settings – rather than the inpatient or outpatient payment mechanisms, to be obligated to report its private payor data to the Secretary. *Id.*

II. Rulemaking and Litigation History

As required by the statute, the Secretary promulgated a rule in June of 2016 to implement PAMA's provisions, including its data collection requirements. *See* 42 U.S.C. § 1395m-1(a)(12); 81 Fed. Reg. 41,036 (June 23, 2016); J.A. at 0001, 0004–17 ("2016 Rule"). The 2016 Rule included its own definition for "applicable laboratory": a laboratory that "bills Medicare Part B under its own NPI." 81 Fed. Reg. at 41,047. The NPI, or National Provider Number, is a unique

4 In the case of advanced diagnostic laboratory tests, laboratories must report this information annually. 42 U.S.C. § 1395m-1(a).

billing number assigned by the Department to health care providers to use when submitting claims for Medicare reimbursement. 81 Fed. Reg. at 41,042, citing 45 C.F.R. § 162.406 (2004); 80 Fed. Reg. 59,386, 59,392 (Oct. 1, 2015); J.A. at 00075.

Plaintiff filed this lawsuit on December 11, 2017, challenging the Secretary's regulatory definition of "applicable laboratory." Compl. [Dkt. #1] ¶¶ 3–4. According to plaintiff, defining the term to mean only laboratories that bill Medicare under their own NPIs excluded significant numbers of hospital laboratories that provide outreach services from the Secretary's data collection; this is because most hospital laboratories bill under their hospitals' NPIs, rather than their own. *See id.* ¶ 44 (alleging the Secretary improperly "treated the entire hospital as a laboratory for purposes of evaluating whether the statutory revenue requirements are satisfied" and "effectively carved out hospital laboratories from the statutory requirements," ensuring the reporting obligations would be imposed primarily on only independent and physician-office laboratories). At the end of the day, less than one percent "of the total number of laboratories that currently serve Medicare beneficiaries" reported data to the Secretary in 2016. *Id.* ¶ 7.

The Court did not reach the merits of plaintiff's claim that this narrowing of the definition was arbitrary and capricious. A motion to dismiss was filed, and in light of a provision Congress included in PAMA, the Court concluded that judicial review was precluded, and it dismissed the case for lack of subject matter jurisdiction. Order (Sept. 21, 2018) [Dkt. # 46]; Mem. Op. [Dkt. # 47]. Plaintiff appealed the ruling. Notice of Appeal [Dkt. # 48].

Two months later, on November 23, 2018, the Secretary promulgated another rule that amended the definition of "applicable laboratory" to address the problem plaintiff had identified. 83 Fed. Reg. 59,452 (Nov. 23, 2018) ("2018 Rule"). The 2018 Rule revised the definition to add "hospital outreach laboratories" that "bill[ ] Medicare Part B on the CMS 1450 under bill type 14x," a claim form used by hospitals for non-patient laboratory services. *Id.* at 60,074; *see also*

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