IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION,
1100 New York Avenue, N.W., Suite 725W
Washington, D.C. 20005

Plaintiff,

v.

ALEX M. AZAR,
In His Official Capacity as Secretary of Health and Human Services,
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Defendant.

Civil Action No. 1:17-cv-2645 (ABJ)

PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Plaintiff American Clinical Laboratory Association hereby moves for summary judgment in its favor on the claims asserted in its Complaint for the reasons explained in the accompanying Memorandum of Points and Authorities in Support of Plaintiff's Motion for Summary Judgment. There are no disputed issues of material fact. The administrative record demonstrates that the final rule of Defendant Alex M. Azar, acting in his official capacity as Secretary of Health and Human Services, as set forth in *Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; Final Rule*, 81 Fed. Reg. 41,036 (June 23, 2016); *see also* 42 C.F.R. § 414,502, violates the Administrative Procedure Act because it is arbitrary and capricious, an abuse of discretion, and contrary to any reasonable interpretation of the statutory requirements. *See* 5 U.S.C. § 706(2).

WHEREFORE, and as set forth more fully in the accompanying memorandum, summary judgment for Plaintiff is warranted under the Administrative Procedure Act, 5 U.S.C. § 706 and the Social Security Act, 42 U.S.C. § 1395m-1.

Respectfully submitted,

Dated: October 14, 2019

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MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF
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INTRODUCTION AND SUMMARY OF ARGUMENT

This case returns to this Court because the United States Court of Appeals for the D.C. Circuit has held that no jurisdictional bar applies and, as a result, this Court has jurisdiction to consider the merits of the challenge to the Secretary's final rule brought by the American Clinical Laboratory Association ("ACLA"). *See Am. Clinical Lab Ass'n v. Azar*, 931 F.3d 1195 (D.C. Cir. 2019). The question now before the Court is whether the Secretary's final rule violates the requirements of the Administrative Procedure Act. *See* 5 U.S.C. § 706(2).

The statutory provision at the center of this case is section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA"). *See* Pub. L. No. 113093, § 216, 128 Sta. 1040, 10552 (2014), codified at 42 U.S.C. § 1395m-1. Congress enacted PAMA to ensure that Medicare payments received by laboratories for providing clinical diagnostic services better reflect the full range of payments received in the commercial market. To this end, PAMA mandates that all "applicable laboratories" report to the Secretary confidential information regarding private-sector laboratory services payments. 42 U.S.C. § 1395m-1(a)(1)–(2). Because many different types of laboratories exist — including thousands of laboratories located in hospitals, physician offices, independent facilities, and other settings — Congress took care to specify which laboratories would be required to report data: *any* laboratory that receives a majority of *its* Medicare revenues from certain specified fee schedules. *See* 42 U.S.C. § 1395m-1(a)(2).

The Secretary's final rule unlawfully rewrites the statutory definition of "applicable laboratory." The rule defines "applicable laboratory" to include any entity with a National Provider Identifier ("NPI") that is either a laboratory itself *or has a laboratory as one of its components*. 42 C.F.R. § 414.502(b). That change is significant with respect to the thousands of laboratories that are located in hospitals, which compete with other laboratories to provide

services to non-hospital patients. Because nearly all hospital laboratories bill under their hospitals' general NPIs, the Secretary's rule sweeps into the denominator of the statute's "majority of Medicare revenues" equation massive amounts of Medicare revenue received by the hospitals as a whole for non-laboratory services. Instead of comparing the *laboratory's* total revenues from the relevant fee schedules with the *laboratory's* total Medicare revenues, as the statute directs, the Secretary's rule compares the laboratory's total revenues from the relevant fee schedules with the total Medicare revenues of *the hospital as a whole* (the entity with the NPI). The rule effectively reads the majority of Medicare revenues requirement out of the statute for hospital laboratories, exempting virtually all hospital laboratories from the data reporting requirements, even when a majority of *their* Medicare revenues are from the fee schedules that Congress specified.

This rewrite of the definition of "applicable laboratory" — exempting an entire category of market participants from the data-reporting requirements — dramatically undermines Congress's mandate that the Secretary collect private-sector information reflecting the full range of payments received in the commercial market. In 2016, hospital laboratories received approximately 26 percent of the payments made under Medicare for providing laboratory services to non-hospital patients. But out of the approximately 7,000 hospital laboratories that billed Medicare for services provided to non-hospital patients on a fee-for-service basis, no more than 21 reported information to the Secretary — less than half of one percent of all hospital laboratories in the country. Hospital laboratories often receive higher private-sector payments for the testing services they provide — as much as 1.5 to 4 times higher than the rates paid to large independent laboratories — so the Secretary's final rule ensures that, contrary to Congress's intent, the information collected by the Secretary does not reflect the private-sector

market as a whole. Indeed, the Secretary has since effectively acknowledged the problems with its final rule, adopting a new rule in 2018 that requires hospital laboratories to report data. 83 Fed. Reg. 59,452, 60,074 (Nov. 23, 2018); *see also Am. Clinical Lab Ass'n v. Azar*, 931 F.3d at 1202. But the Secretary's new rule does not take effect until 2021, and the Secretary has refused to remedy the errors that infect the 2016 final rule that is before this Court.

If the Secretary's errors are not corrected, the consequences will be severe. Because the data-collection parameters imposed by the final rule have resulted in the Secretary establishing payment rates that are far below private-sector rates, some laboratories face a serious threat of being forced out of business, others are being forced to scale back essential services, and patients are being deprived of the services they need. Instead of modernizing the Medicare program to better reflect the private sector market and to protect access to Medicare, the Secretary's statutory rewrite has subverted Congress's reforms.

The Secretary's final rule should be vacated for at least two reasons. *First*, the Secretary's rule is arbitrary, capricious, an abuse of discretion, and contrary to law because it violates the clear terms of the statute and is an unreasonable construction of Congress's directives. *Second*, the Secretary's rule is arbitrary, capricious, an abuse of discretion, and contrary to law because the Secretary failed to follow required rulemaking procedures and has not meaningfully responded to comments. The Secretary's only stated reason for exempting hospital laboratories from the statutory reporting requirements — the agency's administrative convenience — cannot justify its failure to comply with the statute that Congress enacted. The Court should therefore set aside the final rule.

STATEMENT OF FACTS

A. Procedural History

ACLA represents the nation's leading clinical and anatomic pathology laboratories, including national, regional, specialty, end-stage renal disease, hospital, and nursing home laboratories. Doc. 1, Compl. ¶ 18. Its members perform tens of millions of tests each year that are reimbursed under the Medicare program. *Id.* ¶ 2.

ACLA filed a complaint in this case on December 11, 2017. *See* Doc. 1. In early 2018, the parties exchanged briefing on cross-motions for summary judgment. *See* Docs. 13, 27, 29, and 32. On September 21, 2018, this Court held that, while "plaintiff's arguments on the merits raise important questions," the case should be dismissed for want of subject matter jurisdiction under 42 U.S.C. § 1395m-1(h)(1). *See* Doc 47, Mem. Op. at 1, 13.

ACLA appealed to the D.C. Circuit. On July 30, 2019, the D.C. Circuit reversed, holding that the statute's jurisdictional bar does not apply. *See Am. Clinical Lab Ass'n v. Azar*, 931 F.3d 1195 (D.C. Cir. 2019). As the Court explained, "[i]n view of PAMA's text, its structure, and the distinct nature of the processes of data collection and establishment of payment rates, we cannot conclude that the bar against reviewing the 'establishment of payment amounts' also prevents our review of the rule setting up a new and detailed process for collecting data on market rates that private insurers pay to laboratories." *Id*. at 1208. In other words, the jurisdictional bar set forth in 42 U.S.C. § 1395m-1(h)(1) does not prevent this Court from reviewing the merits of ACLA's claims.

In reaching that conclusion, the D.C. Circuit rejected the Secretary's suggestion that ACLA might lack standing. *See id.* at 1203 (noting that although the Secretary "scarcely challenges standing on appeal," the Court had an independent obligation to consider the issue).

The D.C. Circuit held that ACLA has established associational standing, in that "at least one of its members" "suffered a concrete and particularized injury that is fairly traceable to the challenged conduct and is likely to be redressed by a favorable decision." *Id.* (citing *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560–61 (1992); *Am. Library Ass'n v. FCC*, 401 F.3d 489, 492 (D.C. Cir. 2005)). In addition, the D.C. Circuit declined to hold that the Secretary's actions met the high bar to be struck down as *ultra vires*, which would have "obviate[ed] any need to remand" to this Court for further proceedings, explaining that "[*u*]*lra vires* review 'is intended to be of extremely limited scope,' and it 'represents a more difficult course . . . than would review under the [Administrative Procedure Act ("APA")].'" *Id.* at 1208 (citing *Trudeau v. Fed. Trade Comm'n*, 456 F.3d 178, 190 (D.C. Cir. 2006)); *see also DCH Regional Medical Ctr. v. Azar*, 925 F.3d 503, 509 (D.C. Cir. 2019) (noting that *ultra vires* review is "very limited" in scope and is not permitted when an alternative procedure exists for reviewing a statutory claim) (citations and quotations omitted).

ACLA's challenge now returns to this Court "to consider in the first instance whether the rule comports with the APA" — that is, whether the rule is arbitrary, capricious, an abuse of discretion, or contrary to law. *Id.* at 1198–99; *see also* 5 U.S.C. § 706(2).

B. Statutory and Regulatory Background

Clinical diagnostic laboratory services are tests performed on specimens from the body, such as blood or urine, that are used to monitor, diagnose, and treat patients. They range from routine blood tests to ground-breaking genetic and molecular tests.

The Medicare Program. Through the federal Medicare program, the Centers for Medicare & Medicaid Services ("CMS") is the nation's largest purchaser of clinical laboratory services. Medicare beneficiaries receive laboratory services in different contexts, including as a

registered inpatient or outpatient of a hospital, as a resident of a skilled nursing facility, or when visiting a doctor's office. Unless the doctor's office has an on-site laboratory, the beneficiary will typically have the tests performed at a local laboratory — either an independent laboratory or a hospital laboratory that serves individuals who are not hospital patients (providing what are known as "outreach" services).

For payment purposes, Medicare distinguishes the different contexts in which beneficiaries receive laboratory services. When a hospital laboratory performs tests for a registered hospital patient, payment is typically bundled with other provided services and billed under the Inpatient Prospective Payment System or the Outpatient Prospective Payment System. *See* 42 U.S.C. §§ 1395ww(d), 1395*l*(t). The bundled Medicare payment covers all services provided by the hospital, including (for example) laboratory services, radiology services, operating room services, pharmacy services, and room and board. In contrast, when a non-hospital patient visits a hospital laboratory for ordered services, Medicare makes payment on a fee-for-service basis under either the Clinical Laboratory Fee Schedule or the Physician Fee Schedule. *See id.* §§ 1395*l*(h)(1)(B), 1395w-4(a)(1). Both hospital laboratories providing these outreach services and independent laboratories are paid this way, with each receiving a significant portion of Medicare payments under the Clinical Laboratory Fee Schedule. *See* Office of Inspector General ("OIG"), Medicare Payments for Clinical Diagnostic Laboratory Tests in 2016: Year 3 of Baseline Data, OEI-09-16-00140 (Sept. 2017) at 2, *available at* https://oig.hhs.gov/oei/reports/oei-09-17-00140.pdf ("OIG 2016 Data Report) (in 2016, independent laboratories received 55 percent of Clinical Laboratory Fee Schedule payments; hospital outreach laboratories received 26 percent). Hospital laboratories providing outreach services compete directly with independent laboratories and other laboratories. *See*, *e.g.*, CMS,

Medicare Claims Processing Manual (Pub. No. 100-04), Ch. 16, § 10, *available at* https://www.cms.gov/Regulations-and-guidance/Guidance/Manuals/Downloads/clm104c16.pdf ("When a hospital laboratory performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory").

Before PAMA, clinical laboratory services provided on a fee-for-service basis were reimbursed the lesser of (1) the laboratory's charge or (2) the local amount under the Clinical Laboratory Fee Schedule, which varied based on a "regional, statewide, or carrier service area basis." 42 U.S.C. §§ 1395*l*(h)(1)(B)–(C), (h)(4)(B); *see also id*. § 1395*l*(a)(1)(D)(i)(I). The system resulted in differing reimbursement amounts in different parts of the country. OIG, Variation in the Clinical Laboratory Fee Schedule, OIE-05-08-00400 (July 2009) at 1, *available at* https://oig.hhs.gov/oei/reports/oei-05-08-00400.pdf. Any given laboratory test could have multiple payment amounts on the Clinical Laboratory Fee Schedule depending on where the test occurred. *See id*. Variations were not tied to geographic differences in wages or other factors, *id.* at 9, and "may . . . not have reflected real differences in cost," *id.* at 11.

PAMA Requirements. In 2014, Congress enacted PAMA, the most extensive reform of the Medicare Clinical Laboratory Fee Schedule since it was established in 1984 under the Deficit Reduction Act of 1984, Pub. L. No. 98-369, § 2303(d), 98 Stat. 494, 1064 (1984). *See* PAMA § 216, amending 42 U.S.C. § 1395m-1. Through PAMA, Congress sought to modernize Medicare reimbursements by "ensur[ing] that Medicare rates reflect true market rates for laboratory services." 160 Cong. Rec. S2860 (May 8, 2014) (statement of Sen. Richard Burr, affirmed by Sen. Orrin Hatch); *see also Am. Clinical Lab. Ass'n*, 931 F.3d at 1199 ("A central goal of the Act is to set Medicare reimbursement rates for laboratory tests at approximately the price private insurers pay for the same tests.").

Intending for "all sectors of the laboratory market [to] be represented in the reporting system," 160 Cong. Rec. S2860, Congress defined "applicable laboratory" to include any "laboratory" that receives a "majority of" its Medicare revenues from the Clinical Laboratory Fee Schedule or the Physician Fee Schedule. 42 U.S.C. § 1395m-1(a)(2); *see also id.* § 1395*l*(h) (establishing the Clinical Laboratory Fee Schedule); *id.* § 1395w-4 (establishing the Physician Fee Schedule). Congress selected this definition to obtain accurate information about prices in the private commercial market, recognizing that some types of laboratories tend to receive higher payments in the private sector, while others tend to receive lower payments. *See* Doc. 1-2, Decl. of John Kolozsvary ¶ 16; Doc. 1-3, Decl. of Dermot Shorten ¶ 14.

Congress gave the Secretary only limited authority to exempt laboratories from the statutory requirements, permitting the Secretary to "establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory." 42 U.S.C. § 1395m-1(a)(2). Apart from that narrow exception, Congress provided the Secretary with no discretion to exempt applicable laboratories from the statute's data-reporting requirements. Instead, consistent with its goal of obtaining accurate market data, PAMA reflects Congress's intent that the Secretary would collect data from *all* "applicable laboratories." *Id.* § 1395m-1(a)(1). "Applicable laboratories that fail to report accurate data face monetary penalties of up to $10,000 per day." *Am. Clinical Lab. Ass'n*, 931 F.3d at 1199 (citing 42 U.S.C. § 1395m-1(a)(9)).

In a separate provision, Congress instructed the Secretary to use the data reported by applicable laboratories to establish new market-based payment amounts. 42 U.S.C. § 1395m-1(b)(1)(A); *see generally Am. Clinical Lab. Ass'n*, 931 F.3d at 1199. Specifically, the Secretary must 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." 42 U.S.C. § 1395m-1(b)(2). The new payment amounts "shall continue to apply until the year following the next data collection period," *id.* § 1395m-1(b)(4)(A), and "shall not be subject to any adjustment (including any geographic adjustment, budget neutrality adjustment, annual update, or other adjustment)," *id.* § 1395m-1(b)(4)(B).

The Secretary's Rulemaking. On October 1, 2015, the Secretary issued a proposed rule setting out the "parameters for data collection." *Id.* § 1395m-1(a)(12); *see also* 80 Fed. Reg. 59,386 (Oct. 1, 2015). Instead of applying the statutory definition of "applicable laboratory," the Secretary solicited comments on a new definition of "applicable laboratory that would include any entity with one or more national provider identifiers ('NPIs') that is either a laboratory *or has a laboratory as one of its components*." 80 Fed. Reg. at 59,392 (emphasis added). An NPI is a unique 10-digit billing number, issued by CMS to healthcare providers, that is used in transactions with commercial and government health plans.

The Secretary indicated that in applying the "majority of" Medicare revenues test, the agency would consider total Medicare revenues of any entity with one or more NPIs (even if the laboratory was just one component of that larger entity), and not limit his consideration to only the Medicare revenues received by the laboratory itself, as the statute directs:

> [F]or the entity evaluating whether it is an applicable laboratory, the "majority of Medicare revenues" determination would be based on the collective amount of its Medicare revenues received during the data collection period, whether the entity is a laboratory under [42 C.F.R.] § 493.2 or is not, but has at least one component that is. We proposed that the determination of whether an entity is an applicable laboratory would be made across the entire entity, including all component NPI entities, and not just those NPI entities that are laboratories.

80 Fed. Reg. at 59,393; *see also Am. Clinical Lab. Ass'n*, 931 F.3d at 1201–02.

In response to the proposed rule, the Secretary received nearly 1,300 comments — most of them heavily critical of the Secretary's proposal. *See* CMS, Public Comments on Medicare Clinical Diagnostic Lab. Test Payment Syst. CMS-1621-P, *available at* https://www.regulations.gov/docketBrowser?rpp=25&so=DESC&sb=commentDueDate&po=0&dct=PS&D=CMS-2015-0109. ACLA submitted extensive comments to the agency and, both before and after the Secretary published his final rule, met with CMS to explain its concerns. *See* Doc. 1-4, Khani Decl. ¶¶ 11–61; *see also* Doc. 38, Joint Appendix reflecting Administrative Record (A.R.) 03392–424. ACLA's significant engagement with CMS included 22 in-person meetings, 14 letters, 1 presentation at a public meeting, 3 telephone conferences, and 2 rounds of comments submitted through the rulemaking process. *See* Doc. 1, Compl. ¶ 12.

ACLA and other commenters explained that these statutory departures impermissibly and unreasonably carve out hospital outreach laboratories from Congress's data-reporting requirements. A.R. 4095–97. Although the Secretary proposed evaluating an entity's revenue based on its NPI, there is no requirement that a hospital laboratory have its own NPI to bill the Medicare program. A.R. 4096. In fact, it is almost always the case that a hospital laboratory will bill for services under the Clinical Laboratory Fee Schedule or Physician Fee Schedule using the NPI of the larger hospital, of which the laboratory is only one small component. *See id.*; *see also Am. Clinical Lab. Ass'n*, 931 F.3d at 1202.

Using the same NPI as the hospital laboratory, a hospital will receive a tremendous amount of Medicare revenues for non-laboratory services, such as oncology services, radiology services, and surgeries, that are not paid under the Clinical Laboratory Fee Schedule or Physician Fee Schedule. Because the Secretary proposed to consider the revenues of the entire hospital, including revenues unrelated to laboratory tests, when setting the denominator of the statute's

"majority of Medicare revenues" equation, hospital laboratories providing outreach services to non-hospital patients that do not have a separate NPI will never meet the "majority of" Medicare revenues test. A.R. 4095–97. For those hospitals, overall Medicare revenues — which include revenues attributable to services provided and billed by other parts of the hospital — will inevitably far exceed the Medicare revenues of the hospital outreach laboratory under either the Clinical Laboratory Fee Schedule or the Physician Fee Schedule.

The Secretary issued his final rule in June 2016. 81 Fed. Reg. 41,036 (June 23, 2016). In response to comments, the Secretary acknowledged that to comply with Congress's directives, "it was important . . . [to] define laboratory broadly enough to encompass every laboratory type that is subject to the [Clinical Laboratory Fee Schedule]." 81 Fed. Reg. at 41,042. The Secretary also agreed that "hospital outreach laboratories should be accounted for" and that it was "important" for hospital outreach laboratories to report data "so that [the Secretary] may have a broader representation of the national laboratory market." 81 Fed. Reg. at 41,045.

Despite these acknowledgments, the Secretary's final rule did the opposite, rewriting the statutory definition of "applicable laboratory" to read:

> (1) Is a laboratory, as defined in § 493.2 of this chapter;
>
> (2) Bills Medicare Part B under its own [NPI];
>
> (3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, Medicare Advantage payments under Medicare Part C, prescription drug payments under Medicare Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period [from the Physician Fee Schedule or Clinical Laboratory Fee Schedule];
>
> (4) Receives at least $12,500 of its Medicare revenues [under the Clinical Laboratory Fee Schedule] . . . .

81 Fed. Reg. at 41,098, as codified at 42 C.F.R. § 414.502; *see also* 81 Fed. Reg. at 41,099 ("Applicable information may not be reported for an entity that does not meet the [regulatory] definition of an applicable laboratory"). The new requirement that the entity bill Medicare Part B under its own NPI sweeps into the "majority of Medicare revenues" test an enormous amount of hospital revenues that have nothing to do with laboratory services and, as a result, exempts almost all hospital outreach laboratories from the statutory reporting requirements, no matter how much of a laboratory's revenue is from the relevant fee schedules.

The final rule does not accomplish Congress's objective that the Secretary use data from all sectors of the laboratory market to calculate payment rates. Using 2015 data, the OIG estimated that the final rule would require only 5 percent of all laboratories that service Medicare beneficiaries to report their data. *See* OIG, Medicare Payments for Clinical Laboratory Tests in 205: Year 2 of Baseline Data, OEI-09-16-00040 (Sept. 2016), at 3, 7, *available at* https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf ("OIG 2015 Data Report"). The actual reported data was even more abysmal. The Secretary received private payor data from less than 0.7 percent of the laboratories that currently serve Medicare beneficiaries — only 1,942 NPI-level entities, including only 658 independent laboratories, 1,106 physician office laboratories, 157 "other" entities, and just 21 hospital laboratories (out of approximately 7,000 hospital laboratories). *Compare* OIG 2015 Data Report at 8, *with* CMS, Summary of Data Reporting for Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System at 3, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf ("CMS Reporting Summary").

The reported data is not representative of the different types of laboratories that compete in the private market, contrary to the Secretary's acknowledgment of the need to include "a wide variety of laboratories." 81 Fed. Reg. at 41,402. In 2016, independent laboratories received 55 percent of Medicare Clinical Laboratory Fee Schedule payments but made up more than 90 percent of the reported laboratory test volume collected by the Secretary. *Compare* OIG 2016 Data Report at 2, *with* CMS Reporting Summary at 3. In contrast, hospital laboratories received 26 percent of the Clinical Laboratory Fee Schedule payments in 2016, but the mere 21 hospital laboratories that reported data make up just 1 percent of the reported laboratory test volume. *Id.*

In November 2018, the Secretary effectively acknowledged his error and published a new rulemaking that changed the regulatory definition of "applicable laboratory." 83 Fed. Reg. 59,452, 60,074 (Nov. 23, 2018) (amending the definition at 42 C.F.R. § 414.502 to also include "[f]or hospital outreach laboratories — bills Medicare Part B on the CMS 1450 under bill type 14x," a claim form used by hospitals for non-patient laboratory services). Under the 2018 rule, "[hospital] laboratories providing outreach services" must "report data using the CMS-1450 14x TOB — a billing form used only by hospital outreach laboratories." *Am. Clinical Lab. Ass'n*, 931 F.3d at 1202. The Secretary made this change to require "more hospital outreach laboratories to report data for calculating [Clinical Laboratory Fee Schedule] rates" so that the collected "dataset . . . is a more robust representation of the laboratory testing market." 83 Fed. Reg. at 59,674.

The Secretary recognized that under his 2016 final rule's definition of "applicable laboratory," most hospital outreach laboratories are excused from their statutory data-reporting obligations because they do not have separate NPIs to bill for clinical laboratory tests. *Id.* at 59,675. The Secretary also conceded that hospital outreach laboratories that receive a majority

of their Medicare revenues from the relevant fee schedules "should not be exempt from reporting the applicable data merely due to their shared use of a billing entity with a hospital." *Id.*

Despite these concessions, the Secretary has done nothing to remedy the harmful consequences of his unlawful 2016 final rule. The new 2018 rule will not result in any change in payment amounts until at least 2021. *See id.* at 59,667. In the meantime, the Secretary's 2016 final rule continues to harm ACLA's members and the patients they serve.

JURISDICTIONAL STATEMENT

This Court has jurisdiction because ACLA is challenging the Secretary's final rule as arbitrary, capricious, an abuse of discretion, and contrary to law under the APA. *See* 5 U.S.C. § 706(2); *see also* 42 C.F.R. § 414.502; 80 Fed. Reg. at 41,036. The Secretary's rule is quintessential final agency action for purposes of judicial review under the APA. *See Ctr. for Law & Educ. v. U.S. Dep't of Educ.*, 209 F. Supp. 2d 102, 110 n.9 (D.D.C. 2002) ("final agency action" with regard to an agency rulemaking is "typically the promulgation of the final rule"); *see also* 5 U.S.C. §§ 702, 704.

The jurisdictional issues previously raised by the Secretary have been resolved on appeal. The D.C. Circuit held that no jurisdictional bar applies under 42 U.S.C. § 1395m-1(h)(1). *See Am. Clinical Lab. Ass'n*, 931 F.3d at 1208. The D.C. Circuit also concluded that ACLA has standing because its members are directly regulated by, and subject to, the requirements of the Secretary's final rule. *See id.* at 1203–04. There is no question that ACLA and certain of its identified members have suffered concrete, particularized injuries as a result of the Secretary's failure to comply with Congress's mandates and that a judgment in ACLA's favor will redress that injury. *See* Doc. 1-1, Decl. of Peter Gudaitis ¶¶ 22–23; Doc. 1-2, Kolozsvary Decl. ¶¶ 27, 30; Doc. 1-3, Shorten Decl. ¶¶ 16, 20–30; *see also* Doc. 1, Compl. ¶ 72.

The Secretary did not raise and wisely abandoned on appeal its earlier, unsupported suggestion that ACLA failed to meet the necessary presentment and exhaustion requirements. *See Williamsburg Wax Museum, Inc. v. Historic Figures, Inc.*, 810 F.2d 243, 250 (D.C. Cir. 1987) (noting that party waives challenges not raised on appeal). Sections 405(h) and 405(g) of the Medicare statute, which require the "channeling" of claims through an agency's administrative review process, are inapplicable here because there is no viable avenue for administratively reviewing the data-reporting obligations imposed by the Secretary's final rule. *See Council for Urological Interests v. Sebelius*, 668 F.3d 704, 708 (D.C. Cir. 2011) ("section 405(h) is inapplicable where the Medicare Act offers no avenue for review of a particular category of statutory or constitutional claims").

Even if sections 405(h) and 405(g) did apply, their jurisdictional requirements have been satisfied. At least one of ACLA's members submitted its objections to CMS in the context of a claim for payment. *See*, *e.g.*, Exhibits A, B, and C (seeking redetermination, reconsideration, and an Administrative Law Judge hearing). That claim has been rejected at both the first and second level of administrative appeal on grounds that "the challenge to the validity of the" final rule is not appealable through the administrative process and that expedited access to judicial review applies under 42 C.F.R. § 405.990. *See* Exhibit B at 6–7; Exhibit C at 8–14. Moreover, ACLA's objections were repeatedly presented to the agency, both in comments and in other correspondence, and the agency declined to correct its final rule. *See* Doc. 1-4, Khani Decl. ¶ 12. Under these circumstances, there is no reason to require any further exhaustion because any proceedings before the agency would be futile. *See Tataranowicz v. Sullivan*, 959 F.2d 268, 274 (D.C. Cir. 1992); *Nat'l Ass'n for Home Care & Hospice, Inc. v. Burwell,* 77 F. Supp. 3d 103, 110 (D.D.C. 2015) ("Futility may serve as a ground for excusing exhaustion, either on its own or in

conjunction with [] other factors"). The pure legal question posed by this case can and should be resolved by this Court.

STANDARD OF REVIEW

ACLA pleads claims under the APA, 5 U.S.C. § 706, and the Social Security Act, 42 U.S.C. § 1395m-1. "[W]hen a party seeks review of agency action under the APA, the district judge sits as an appellate tribunal," and "[t]he 'entire case' on review is a question of law." *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001). Under the APA, agency action must be set aside if it is "in excess of statutory jurisdiction, authority, or limitations[.]" 5 U.S.C. § 706(2)(C). Agency action is also invalid if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law[.]" 5 U.S.C. § 706(2)(A).

When agency action is contrary to any reasonable interpretation of a governing statute, it cannot stand. It is an "essential function of the reviewing court . . . to guard against bureaucratic excesses by ensuring that administrative agencies remain within the bounds of their delegated authority." *Bensman v. Nat'l Park Serv.*, 806 F. Supp. 2d 31, 40 (D.D.C. 2011). When the agency's interpretation is "in conflict with the statute's plain language" and not "consistent with the statutory purpose," the agency's decision receives no deference and should be reversed. *Coal Emp't Project v. Dole*, 889 F.2d 1127, 1131 (D.C. Cir. 1989); *see also Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984).

The APA also imposes certain procedural safeguards on agency action. An agency must "examine the relevant data and articulate a satisfactory explanation for its action including a 'rational connection between the facts found and the choice made.'" *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). In addition, the agency must consider "alternative[s]" that are "neither frivolous nor out of bounds" and explain its rejection of those

alternatives. *Chamber of Commerce v. SEC*, 412 F.3d 133, 145 (D.C. Cir. 2005). "[A]n agency's 'failure to respond meaningfully' to objections raised by a party renders its decision arbitrary and capricious." *PSEG Energy Res. & Trade LLC v. FERC*, 665 F.3d 203, 208 (D.C. Cir. 2011) (quoting *Canadian Ass'n of Petroleum Producers v. FERC*, 254 F.3d 289, 299 (D.C. Cir. 2001)).

ARGUMENT

I. The Secretary's Final Rule Violates the Administrative Procedure Act Because It Is Arbitrary and Capricious, an Abuse of Discretion, and Contrary to the Statute's Requirements.

When "Congress has directly spoken to the precise question at issue," both the agency and this Court must give effect to Congress's stated intent. *Chevron*, 467 U.S. at 842–43. It is a "core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate." *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2446 (2014); *see also Landstar Exp. Am., Inc. v. Federal Martime Com'n*, 569 F.3d 493, 498 (D.C. Cir. 2009). A court "must reject a statutory interpretation — and surely one merely serving administrative convenience — when it flouts a legislative edict." *Mullins v. Andrus*, 664 F.2d 297, 309 (D.C. Cir. 1980).

A court may defer to an agency's interpretation of an ambiguous statutory provision only if the interpretation falls within the "bounds of reasonableness." *Goldstein v. SEC*, 451 F.3d 873, 881 (D.C. Cir. 2006). A "reasonable statutory interpretation must account for both 'the specific context in which . . . language is used' and 'the broader context of the statute as a whole.'" *Util. Air Regulatory Grp.*, 134 S. Ct. at 2442 (quoting *Robinson v. Shell Oil Co.*, 519 U.S. 337, 341 (1997)). Agency interpretation that is "'inconsisten[t] with the design and structure of the statute as a whole, . . . does not merit deference.'" *Id.* (quoting *University of Tex. Sw. Med. Ctr. v.*

Nassar, 133 S. Ct. 2517, 2529 (2013)). "And beyond context and structure, the Court often looks to 'history [and] purpose' to divine the meaning of language." *Gundy v. United States*, 139 S. Ct. 2116, 2126 (2019) (quoting *Maracich v. Spears*, 570 U.S. 48, 76 (2013)).

The Secretary's final rule satisfies none of these canons of statutory construction. His exclusion of one of the largest groups of laboratory service providers is an unreasonable interpretation of the statute, arbitrary and capricious, and an abuse of discretion. *See Am. Bar Ass'n v. FTC*, 430 F.3d 457, 468 (D.C. Cir. 2005) (holding that agency action in excess of its statutory authority is both impermissible and unreasonable).

The Secretary's Rule Contravenes the Statutory Language. In PAMA, Congress directed the Secretary to collect data from any *laboratory* that receives a majority of its Medicare revenue from the Clinical Laboratory Fee Schedule and Physician Fee Schedule. 42 U.S.C. § 1395m-1(a)(2); 83 Fed. Reg. at 59,675 (acknowledging that the Secretary cannot "exclude[] laboratories that meet the majority of Medicare revenues threshold from potentially qualifying as an applicable laboratory"). The Secretary's final rule is invalid because it rewrites PAMA's definition of "applicable laboratory" in a way that unreasonably eliminates the majority-of-the-revenues requirement when applied to hospital laboratories, therefore exempting most hospital laboratories from the mandatory data-reporting obligations that Congress imposed. *See SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1355 (2018) ("Where a statute's language carries a plain meaning, the duty of an administrative agency is to follow its commands as written, not to supplant those commands with others it may prefer.").

Congress set clear boundaries for the Secretary to determine which laboratories are "applicable laboratories" under the statute:

(1.) The Secretary is to compare a laboratory's revenues from the Clinical Laboratory Fee Schedule and the Physician Fee Schedule (the numerator) against its overall total Medicare revenues (the denominator). *Id.* §§ 1395m-1(a)(1)–(2).

(2.) If a laboratory's revenues from the relevant fee schedules are more than fifty percent of its total Medicare revenues, the Secretary must treat the laboratory as an "applicable laboratory" that must report data. *Id.*

(3.) The Secretary may make *limited* exceptions related to low volume or low expenditures. *See id.* § 1395m-1(a)(2).

Instead of undertaking the inquiry that Congress required, the Secretary's final rule requires a comparison of a laboratory's total revenues from the relevant fee schedules against the total Medicare revenues of *any entity* with an NPI (of which the laboratory is often only a small component). For hospital laboratories, the final rule takes account of massive amounts of Medicare revenues received by the hospital as a whole that are unrelated to the outreach services that the hospital laboratory provides. Nothing in the statute authorizes the Secretary to inflate the denominator by including unrelated Medicare revenues for services attributable to a much larger entity (the hospital) of which the laboratory is only a small component part. To the contrary, as the Secretary has now conceded, "[t]he statute specifically directs [the Secretary] to identify applicable 'laboratories' and not 'providers' or 'suppliers.'" 83 Fed. Reg. at 59,675; *see also* 42 U.S.C. § 1395x(u) (a hospital is a "provider").

The Secretary's departure from the statute is depicted in the following equations when applied to hospital laboratories:

Equation as required by PAMA:

$$\frac{\text{Laboratory's Revenues from Fee Schedules (CLFS|PFS)}}{\textit{Laboratory's}\text{ Total Medicare Revenues}}$$

Equation as rewritten in the Secretary's final rule:

$$\frac{\text{Laboratory's Revenues from Fee Schedules (CLFS|PFS)}}{\textit{Hospital's}\text{ Total Medicare Revenues (revenues from the laboratory }\textit{and}\text{ other hospital components)}}$$

The Secretary's rewrite is unreasonable because it drains all meaning from the "majority of Medicare revenues" requirement as applied to hospital laboratories. *See Nat'l Ass'n of Mfrs. v. Dep't of Def.*, 138 S. Ct. 617, 632 (2018) ("[T]he Court rejects an interpretation of the statute that would render an entire subparagraph meaningless."). It is undisputed that almost every hospital laboratory uses the hospital's overall NPI to bill Medicare, thus ensuring that the *hospital's* overall revenues are considered for purposes of determining whether the *laboratory* must report data under the Secretary's final rule. GAO Report at 14; Doc. 1-4, Khani Decl. ¶32; A.R. 496. Because a hospital's total Medicare revenues will always dwarf the revenues of the laboratory itself, the final rule exempts hospital laboratories without their own NPIs from the data-reporting requirements, even if a majority of the hospital laboratory's Medicare revenues are from the relevant fee schedules. Even the Secretary admits that "such laboratories . . . should not be exempt from reporting the applicable data merely due to their shared use of a billing entity with a hospital." 83 Fed. Reg. at 59,675.

The Secretary's Rule Contravenes the Statutory Purpose. Excluding hospital laboratories from the data-reporting requirements is also unreasonable because it cannot be

reconciled with Congress's stated overarching purpose of requiring the Secretary to collect private-payor information to ensure that reimbursement under Medicare's Clinical Laboratory Fee Schedule is comparable to payments made in the private sector. *See* 81 Fed. Reg. at 41,046 (acknowledging "that the purpose of the revised Medicare payment system is to base [Clinical Laboratory Fee Schedule] payment amounts on private payor rates"). Indeed, Congress specifically designed the majority-of-revenues tests to ensure that the Secretary would receive data from hospital laboratories providing outreach services. Because independent laboratories and physician office laboratories bill for their laboratory services almost exclusively under the Clinical Laboratory Fee Schedule and the Physician Fee Schedule, it is a foregone conclusion that virtually all of their revenues will be derived from those two schedules.

The "majority of" Medicare revenues requirement is therefore most relevant in distinguishing between different types of hospital laboratories — on one hand, those hospital laboratories that still receive a majority of Medicare revenues from serving registered hospital patients and, on the other hand, those with more significant outreach business. Congress could have easily worded the statute differently if it had intended to grant hospital laboratories a blanket exclusion from the data-reporting requirements. *See Knight v. Comm'r of Internal Revenue*, 552 U.S. 181, 188 (2008) (noting principle that "fact that [Congress] did not adopt" a "readily available and apparent alternative" "strongly" suggests that the alternative should be rejected); *see also SAS Inst.*, 138 S. Ct. at 1355–56. Instead, it expressed a clear intent that *all* laboratories — including hospital laboratories — would be subject to the same statutory test for determining their reporting obligations.

The Secretary's rewrite is also contrary to Congress's design because, by omitting a large segment of the market, the final rule can only lead to payments that are inconsistent with private-

sector payments. Hospital outreach laboratories received approximately 26 percent of Medicare's Clinical Laboratory Fee Schedule payments in 2015. *See* OIG 2016 Data Report at 2.oig Despite over 7,000 hospitals providing outreach services under the Clinical Laboratory Fee Schedule, OIG 2015 Data Report at 8, the Secretary only collected data from 21 hospitals, far less than 1 percent of all hospital laboratories nationwide. This absurd result, leaving thousands of hospital laboratories out of the equation, is so far from what Congress intended that it should have prompted the Secretary to select an alternative approach. *See Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) (statutory interpretations that "would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available").

The Secretary Has No Reasoned Justification for His Rule. The Secretary's final rule provides no explanation why the *statute* reasonably permits him to exclude all hospital laboratories that do not bill Medicare under their own NPI from the data-reporting requirements. The final rule provides no textual analysis to justify its conclusions that "the statute supports the effective exclusion of hospital laboratories," 81 Fed. Reg. at 41,045, and that "the statute supports limiting reporting to primarily independent laboratories and physician office laboratories," *id.* at 41,046. Instead, the Secretary appears to have relied entirely on an assertion of administrative convenience — that Medicare payments for hospital outpatients and inpatients bundle all services, including laboratory services, and it is "unclear" how Medicare "revenues from" laboratory services provided to hospital patients "would be determined for the denominator of the ratio" called for under the statute. *Id.* at 41,046; *see also id.* (rejecting approach to focus on revenues attributable to the hospital laboratory because of "the difficulties

many hospitals would have in determining whether their laboratories are applicable laboratories").

But an agency is not free to "throw up its hands" when confronted with challenges in complying with a statute's commands. *Cobell v. Salazar*, 573 F.3d 808, 813 (D.C. Cir. 2009); *see also Schurz Commc'ns, Inc. v. FCC*, 982 F.2d 1043, 1050 (7th Cir. 1992) (agency cannot just "throw[] up [its] hands" and "split[] the difference" with "unprincipled compromises"). Nor does an agency have any authority to disregard "clear statutory terms that turn out not to work in practice." *Util. Air Regulatory Grp.*, 134 S. Ct. at 2446. As the Supreme Court has recognized, an agency cannot "resolve the practical problems" caused by a statutory requirement "by eliminating [the requirement] altogether." *Comm'r of Internal Revenue v. Engle*, 464 U.S. 206, 227 (1984). Even if "simpler to administer," an agency has no authority to adopt an interpretation that is unreasonable in light of the statute's language and overall purpose. *Id.*

The Secretary's Approach Is Irrational. The Secretary's final rule appears to assume that hospital laboratories with significant outreach programs are likely to have separate NPIs, and thus would be likely to be required to report their private-payor data. But nothing in the statute or regulation requires a hospital to obtain a separate NPI for its laboratory, and most do not undertake this voluntary and burdensome task. *See, e.g.*, Doc. 1-4, Khani Decl. ¶ 32. The Secretary has acknowledged as much. *See* 83 Fed. Reg. at 59,673 ("defining applicable laboratory at the NPI level . . . provides flexibility for hospital outreach laboratories to not obtain a unique billing NPI, which may be burdensome, particularly where a hospital outreach laboratory performs relatively few outreach services under Medicare Part B.").

A hospital billing under a separate NPI therefore says nothing about the amount of outreach services provided by the laboratory as compared to services provided to hospital

patients and thus is not an accurate indicator of whether the hospital laboratory meets PAMA's majority-of-Medicare-revenues requirement. The NPI is therefore an unreasonable and arbitrary proxy because it does not (and cannot) reliably identify which hospital laboratories provide most of their services on an outreach basis. *Cf. Exxon Co., U.S.A. v. FERC*, 182 F.3d 30, 42 (D.C. Cir. 1999) (concluding that the goal of "administrative efficiency" does not "free [an] agency from the requirement that" its "chosen proxy" must bear a "rational relationship" to the statutory market-valuation requirements). And because obtaining a separate NPI is entirely voluntary, the Secretary has effectively made PAMA's reporting obligations optional for hospital laboratories, but not for independent or physician office laboratories that meet the statutory requirements.

In his most recent regulations, the Secretary has effectively conceded that his final rule does not comply with the statutory requirements. *See* 83 Fed. Reg. at 59,674. He has acknowledged that Congress did not grant him authority to exempt applicable laboratories from the statutory requirements. Doc. 27, Gov't Cross Mot. at 29–30 (Mar. 23, 2018). And he has conceded that Congress intended for him to collect data from "a wide variety of laboratories," 81 Fed. Reg. at 41,042, and "it is important not to prevent private payor rates from being reported for hospital outreach laboratories so that we may have a broader representation of the national laboratory market to use in setting [Clinical Laboratory Fee Schedule] payment amounts," 81 Fed. Reg. at 41,045. His new approach confirms that, contrary to the final rule, PAMA does not permit him to "exclude[] laboratories that meet the majority of Medicare revenues threshold from potentially qualifying as an applicable laboratory." 83 Fed. Reg. at 59,675.

II. The Secretary's Final Rule Is Arbitrary, Capricious, an Abuse of Discretion, and Contrary to Law Because it is Procedurally Invalid.

The Secretary's final rule is also arbitrary and capricious because the Secretary failed to follow required rulemaking procedures. The Secretary has not reasonably responded to serious

objections to his approach. Nor has he articulated a "rational connection" between the facts and his rewrite of the statutory definition. His only purported reason for rewriting the statute — the administrative challenges of asking hospitals to track Medicare revenues attributable to the laboratory services they provide — is an unexplained abuse of discretion.

Dozens of commenters, including ACLA and its members, repeatedly objected that the Secretary's rule would exclude hospital laboratories from reporting applicable information and urged the Secretary to adopt an approach that would require hospital laboratories to comply with the statute's data-reporting requirements. *See, e.g.*, A.R. 121–122; 123–124; 127; 129–130; 182–183; 1473–74; 1580–81; 1949–50; 1977–79; 1990–92; 2287; 2292–93; 2359–61; 2372; 2407–08; 2581–82; 2765–66; 2780–81; 3256–57; 3393–94; 3396–98; and 3862, 3864–66. Commenters also urged the Secretary to adopt an approach that would require hospital laboratories to determine what portion of a hospital's overall Medicare revenues are attributable to clinical diagnostic services provided by the laboratory (and not by other components of the hospital). *See* 81 Fed. Reg. at 41,046; A.R. 3392–3424 (ACLA Comments), 4092–4123 (ACLA Correspondence). Among other suggestions, a commenter suggested that a hospital could "establish an adjustment factor based on its payment-to-charges ratio" to determine what portion of the hospital's overall Medicare revenues are attributable to the hospital laboratory. 81 Fed. Reg. at 41,046; *see also* A.R. 3399, 4098.

The Secretary did not reasonably respond to these comments and offered no reasoned explanation for rejecting the alternative approaches that commenters urged. *See PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005) ("An agency's failure to respond meaningfully to objections raised by a party renders its decision arbitrary and capricious.") (internal quotation marks omitted). Instead, while the Secretary purported to

understand the importance of collecting market data from hospitals that provide outreach services to non-hospital patients, he asserted, without any reasoned explanation, that "it is [not] necessary to establish a hospital adjustment factor to enable hospital outreach laboratories to be applicable laboratories." 81 Fed. Reg. at 41,046. In the Secretary's view, the NPI requirement is adequate because it allows hospital laboratories *in their discretion* to become "applicable laboratories" by obtaining a separate NPI. *Id.*; *see also* 83 Fed. Reg. at 59,673.

That response is wholly inadequate. The statute does not permit laboratories to opt in and out of the mandatory reporting requirements based on whether they choose to obtain a separate laboratory NPI. Nor is it rational for those requirements to be optional, where Congress's intent was to obtain data from the market as a whole and imposed penalties for non-compliance. *See Am. Clinical Lab. Ass'n*, 931 F.3d at 1199 (citing 42 U.S.C. § 1395m-1(a)(9)). The burden was on the Secretary to provide some reasoned basis for not adopting an approach that would do the job that Congress directed him to do — determine which hospital laboratories satisfy the "majority of" Medicare revenues requirement that Congress imposed. *See Nat'l Treasury Employees Union v. Horner*, 654 F. Supp. 1159, 1164 (D.D.C. 1987) (noting that agency's "self-serving" claim of "impracticability" was not entitled to deference). The Secretary has not come close to meeting that burden.

The Secretary's failure to comply with Congress's directives imposes an unfair and arbitrary data-reporting burden on only some laboratories, and the Secretary has never justified why hospital laboratories should be exempt from the burdens imposed on their competitors, which do not have the ability to opt in or out of the data-reporting requirements. *See* 81 Fed. Reg. at 41,093 (recognizing "there could be substantial costs associated with" complying with the data-reporting requirements); *see also Hall v. McLaughlin*, 864 F.2d 868, 872 (D.C. Cir.

1989) ("[r]easoned decisionmaking requires treating like cases alike"). As the Secretary recognized, the statute's data-reporting obligations were significant and costly. *See* 81 Fed. Reg. at 41,093 (In discussing the "Cost of Data Collection and Reporting Activities" for laboratories, the Secretary stated that "there could be substantial costs associated with compliance with [42 U.S.C. § 1395m-1]."). Collecting the data required under the statute is a "difficult, resource-intensive, and burdensome task" that cost some companies millions of dollars to complete. Doc. 1-3, Shorten Decl. ¶ 21; *see also id*. ¶¶ 20–30. There is no reason some laboratories should be burdened with these substantial costs and the risk of civil penalties, while their competitors are arbitrarily exempt. *See id.* ¶ 30.

The Secretary also has no reasoned response to the serious objection that, as a result of his final rule, Medicare payment amounts for clinical diagnostic tests will not be based on private-payor rates, but instead will be based on data collected from a small segment of the market with private-payor rates that are dramatically lower than the market as a whole. *See* A.R. 2081, 2407, 2447 (expressing concerns that Secretary's approach will artificially reduce Medicare payments and result in systematic underpayments); *see also Int'l Fabricare Inst. v. EPA*, 972 F.2d 384, 389 (D.C. Cir. 1992) (an agency "is required to give reasoned responses to all significant comments in a rulemaking proceeding").

The Secretary's final rule will likely force some laboratories out of business and deprive patients of ready access to essential services, especially in remote rural areas. *See, e.g.*, A.R. 4407–08 (expressing concern that some laboratories could be forced "to either scale back or discontinue their test," with "significant ramifications for patient access to testing, particularly in rural and other underserved areas"); A.R. 4409 (expressing concerns that some community or regional laboratories could be forced "out of business altogether"); Doc. 1-2, Kolozsvary Decl.

¶ 27; Doc. 1-1, Gudaitis Decl. ¶ 28–31; Doc. 1-3, Shorten Decl. ¶¶ 14–19. At a minimum, the Secretary should have addressed these grave concerns. His failure to do so is a quintessential example of arbitrary and capricious agency action.

The only individual likely to benefit from the Secretary's final rule appears to be the agency itself. *Cf. Alabama Power Co. v. FERC*, 993 F.2d 1557, 1570 n.8 (D.C. Cir. 1983) (no deference due to agency when a proposed interpretation serves only the agency's own interests). By failing to comply with Congress's mandate, the Secretary has set the stage to dramatically reduce the payments that Medicare makes for laboratory services. He has also avoided doing the work that Congress intended the agency to do. Collecting data from a small, cherry-picked sample of laboratories may be easier for the Secretary but it does not come close to completing the task that Congress assigned. The Secretary's refusal to comply with Congress's mandate should not be tolerated. Instead, the Court should strike down the Secretary's final rule.

* * * *

The Secretary had hoped to avoid defending the merits of his final rule on the theory that the statute barred this Court from considering them. But the D.C. Circuit has now rejected that gambit and dispensed with the Secretary's other jurisdictional objections. With those issues brushed aside, there is nowhere left to hide. The Secretary's final rule is not a permissible or reasonable interpretation of the statutory requirements and, even if it were, the Secretary has not complied with his obligations to respond to comments or justified his decision to exempt a major category of market participants from the statute's data-reporting obligations. The Court should grant summary judgment in ACLA's favor, vacate those portions of the Secretary's final rule that impermissibly narrow the definition of "applicable laboratory," and direct the Secretary to implement the statute as Congress intended. The Court should also direct the Secretary to take

whatever steps are necessary to remedy the serious harms that are resulting from the Secretary's statutory violation.

CONCLUSION

The Court should grant summary judgment to ACLA and set aside the Secretary's final rule rewriting the statutory definition of "applicable laboratory."

Respectfully submitted,

/s/ Ashley C. Parrish
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Attorneys for Plaintiff
American Clinical Laboratory Association

Dated: October 14, 2019

CERTIFICATE OF SERVICE

I hereby certify that on October 14, 2019, I electronically filed the foregoing with the Clerk of Court using the CM/ECF system, which will send a notice of electronic filing to all counsel of record who have consented to electronic notification.

/s/ Ashley C. Parrish
D.C. Bar No. 464683
KING & SPALDING LLP

Exhibit A

BioReference
LABORATORIES
an OPKO Health Company

March 1, 2018

VIA U.S. EXPRESS MAIL TRACKING NO. EL 839482985 US AND FAX

Medicare Appeals
Novitas Solutions
Medicare Part B – New Jersey Part B
P.O. Box 3031
Mechanicsburg, PA 17055-1803

Re: **REQUEST FOR REDETERMINATION**

Appellant/Supplier: **BIOREFERENCE LABORATORIES, INC.**
Tax I.D. (last 5 digits): 05059
Medicare PTAN: 301910
NPI: 1134277494
Beneficiaries: Multiple (Attachment 1)

To Whom It May Concern:

In accordance with 42 C.F.R. §§ 405.940-405.946, this letter constitutes a request by BioReference Laboratories, Inc. ("BioReference") for a redetermination relating to the claims listed in **Attachment 1** ("Request"). BioReference furnished certain clinical laboratory services to the beneficiaries identified at Attachment 1, and Attachment 1 lists the name, Medicare health insurance claim number, services or items, claim number and dates of service for each Medicare beneficiary whose claims are the subject of this appeal. The claims set forth at Attachment 1 are aggregated for purposes of this Request as they all share the same issue as set forth below.

Under Section 216(a) of the Protecting Access to Medicare Act ("PAMA"), the Secretary of HHS is required to collect information regarding commercial payment rates for clinical diagnostic laboratory services from "applicable laboratories." *See* 42 U.S.C. § 1395m-1(a). PAMA defines an "applicable laboratory" as any laboratory that receives a majority of its Medicare revenue from the Clinical Lab Fee Schedule or the Physician Fee Schedule. *Id.* § 1395b-1(a)(2). Section 216(b) of PAMA requires the Secretary to use the information collected from "applicable laboratories" to determine future payment rates for clinical diagnostic services. *Id.* § 1395m-1(b). These rates apply to clinical diagnostic services provided on or after January 1, 2018.

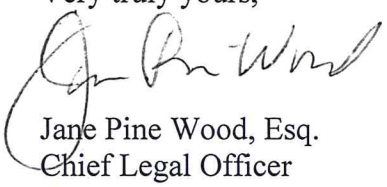
The Secretary has adopted a regulatory definition that conflicts with PAMA 216(a) by limiting "applicable laboratories" to those that separately bill the Medicare program using their own National Provider Identifier ("NPI"). 42 C.F.R. § 414.502(b). The purpose and effect of this definition is to exclude numerous applicable laboratories from PAMA 216's reporting requirement. BioReference challenges the Secretary's regulation on the basis that it is arbitrary

and capricious, violates the Medicare statute, and exceeds the authority granted to the Secretary by Congress.

There are no material facts in dispute in this appeal. The only factor precluding a decision favorable to BioReference is a determination of the invalidity of 42 C.F.R. § 414.502(b). Medicare Administrative Contractors, Qualified Independent Contractors and Administrative Law Judges are bound by the Secretary's regulation and cannot provide that relief. BioReference respectfully requests prompt action on this appeal so that it may file a request for Expedited Access to Judicial Review pursuant to 42 C.F.R. § 405.990 at the earliest juncture.

For the foregoing reasons, BioReference respectfully requests redetermination of the claims set forth at Attachment 1.

Very truly yours,



Jane Pine Wood, Esq.
Chief Legal Officer
BioReference Laboratories, Inc.
481 Edward H. Ross Drive
Elmwood Park, NJ 07407
Email: jwood@bioreference.com
Office: 800-229-5227 ext.7800

29313

MEDICARE PART B REDETERMINATION AND CLERICAL ERROR REOPENING REQUEST FORM

FAX to: 1-888-541-3829

***EACH FIELD OF THE FORM MUST BE FILLED OUT TO AVOID HAVING YOUR REQUEST DISMISSED**

Do not complete this form for the following situations: Shade Circles like this ● Not like this ⊗ ✓

1. If you received a Medicare Redetermination Notice (MRN) on this claim DO NOT use this form to request further appeal. Your next level of appeal is a Reconsideration by a Qualified Independent Contractor (QIC) (https://www.novitas-solutions.com/partb/forms/pdf/rrf/pdf).
2. If you received a message MA-130 on the Medicare Remittance Notice for this claim, no appeal or reopening rights are available. Please submit a NEW claim with the appropriate corrections.

If this request is due to a Prior-Authorization denial select from the drop down:

***Please select one of the following jurisdictions and select YES or NO to the questions below:**

○ AR ○ CO ○ DCMA ○ DE ○ LA ○ MD

○ MS ● NJ ○ NM ○ OK ○ PA ○ TX/IHS/ Veterans

1. Does your appeal involve the Recovery Auditor (RA) decision? ○ Yes ● No
2. Does your appeal involve a 935 overpayment decision? ○ Yes ● No
3. Does the claim you are appealing involve Medicare Secondary Payer (MSP)? ○ Yes ● No

***Please select one of the choices below to identify the category which the request pertains to:**

○ Procedure Codes 00100-69999 ● Procedure Codes 70000-89999 ○ Chiropractic Services

○ Procedure code beginning with "J" or "G" or 90000-99999 or Ambulance Services ○ Other

***Please fill in the information below in all UPPERCASE letters:**

Provider Transaction Access No (PTAN):	NPI *(10 digits):*	Tax Identification Number *(last 5 digits):*
301910	1134277494	05059

Provider Name: BIOREFERENCE LABORATORIES, INC.

Beneficiary First Name:	Beneficiary Last Name:
SEE ATTACHMENT 1	SEE ATTACHMENT 1

Beneficiary Medicare Number *(11 digits):*	Claim Number *(13 digits):*
SEE ATT. 1	SEE ATT. 1

Date(s) of Service	Procedure Code(s) in Question
SEE ATTACHMENT 1	SEE ATTACHMENT 1
Requestor's Name *(Printed)* JANE PINE WOOD	Requestor's Relationship to Provider VP, Legal
Requestor's Signature Jane Pine Wood	Telephone Number and Extension 800-229-5227 ext.7800

***Reason for Redetermination or Clerical Error Reopening Request:**

BioReference challenges the validity of 42 C.F.R. Section 414.502(b) for the reasons explained in detail in the attached letter and seeks redetermination of the claims set forth in Attachment 1.

Attachment 1

Attachment 1 is an excel spreadsheet that identifies hundreds of Medicare claims for clinical laboratory services. Plaintiff American Clinical Laboratory Association has redacted this information in full because it consists almost entirely of protected health information that does not have any direct relevance to the issues in this case. If the Court decides that it would like to review the information, however, ACLA will file it under seal upon the Court's request.

Exhibit B

Plaintiff American Clinical Laboratory Association has redacted certain information from the reconsideration request and redetermination decision in Exhibit B because it consists of protected health information that does not have any direct relevance to the issues in this case. If the Court decides that it would like to review this information, however, ACLA will file it under seal up the Court's request.

BioReference
LABORATORIES
an OPKO Health Company

September 26, 2018

VIA FEDEX OVERNIGHT DELIVERY

C2C Innovative Solutions, Inc.
Part B North Reconsiderations
301 W Bay St., Sixth Floor
Jacksonville, FL 32202-5100
FedEx Overnight Delivery Tracking No. 8130 3180 0985

Re: **REQUEST FOR RECONSIDERATION**
Novitas Reference No. [redacted]

Appellant/Supplier: **BIOREFERENCE LABORATORIES, INC.**
Tax I.D. (last 5 digits): 05059
Medicare PTAN: 301910
NPI: 1134277494
Beneficiaries: Multiple Including [redacted] **and Beneficiaries Identified at Attachment 2**

To Whom It May Concern:

In accordance with 42 C.F.R. § 405.960, this letter constitutes a request by BioReference Laboratories, Inc. ("BioReference") for a reconsideration relating to the Novitas Solutions, Inc. Medicare Appeal Decision available at **Attachment 1** and the claims listed in **Attachment 2** ("Request"). BioReference furnished certain clinical laboratory services to the beneficiaries identified at Attachments **1** and **2**, and Attachment **2** lists the name, Medicare health insurance claim number, services or items, claim number and dates of service for each Medicare beneficiary whose claims are the subject of this appeal. The claims set forth at Attachment **2** are aggregated for purposes of this Request as they all share the same issue as set forth below.

Under Section 216(a) of the Protecting Access to Medicare Act ("PAMA"), the Secretary of HHS is required to collect information regarding commercial payment rates for clinical diagnostic laboratory services from "applicable laboratories." *See* 42 U.S.C. § 1395m-1(a). PAMA defines an "applicable laboratory" as any laboratory that receives a majority of its Medicare revenue from the Clinical Lab Fee Schedule or the Physician Fee Schedule. *Id.* § 1395b-1(a)(2). Section 216(b) of PAMA requires the Secretary to use the information

collected from "applicable laboratories" to determine future payment rates for clinical diagnostic services. *Id.* § 1395m-1(b). These rates apply to clinical diagnostic services provided on or after January 1, 2018.

The Secretary has adopted a regulatory definition that conflicts with PAMA 216(a) by limiting "applicable laboratories" to those that separately bill the Medicare program using their own National Provider Identifier ("NPI"). 42 C.F.R. § 414.502(b). The purpose and effect of this definition is to exclude numerous applicable laboratories from PAMA 216's reporting requirement. BioReference challenges the Secretary's regulation on the basis that it is arbitrary and capricious, violates the Medicare statute, and exceeds the authority granted to the Secretary by Congress.

There are no material facts in dispute in this appeal. The only factor precluding a decision favorable to BioReference is a determination of the invalidity of 42 C.F.R. § 414.502(b). Medicare Administrative Contractors, Qualified Independent Contractors and Administrative Law Judges are bound by the Secretary's regulation and cannot provide that relief. BioReference respectfully requests prompt action on this appeal so that it may file a request for Expedited Access to Judicial Review pursuant to 42 C.F.R. § 405.990 at the earliest juncture.

For the foregoing reasons, BioReference respectfully requests reconsideration of the claims set forth at Attachments **1** and **2**.

Very truly yours,

Jane Pine Wood 15/ jmm

Jane Pine Wood, Esq.
Chief Legal Officer
BioReference Laboratories, Inc.
481 Edward H. Ross Drive
Elmwood Park, NJ 07407
Email: jwood@bioreference.com
Office: 800-229-5227 ext.7800

Attachment 1

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Medicare Part B

MEDICARE APPEAL DECISION

March 26, 2018

BIO-REFERENCE LAB INC
481 EDWARD H ROSS DRIVE
ELMWOOD PARK NJ 07407-3118

[redacted]

Dear Bio-Reference Laboratories, Inc.,

This letter is to inform you of the decision on your Medicare Appeal. An appeal is a new and independent review of a claim. You are receiving this letter because you requested an appeal for the diagnostic laboratory service.

The appeal decision is unfavorable. The Medicare payment is correct.

More information on the decision is provided below. If you disagree with the decision, you may appeal to a Qualified Independent Contractor (QIC). Your appeal of this decision must be made in writing and received by the QIC within 180 days of receipt of this letter. You are presumed to have received this decision five days from the date of the letter unless there is evidence to show otherwise. However, if you do not wish to appeal this decision, you are not required to take any action. For more information on how to appeal this decision, see the section of this letter entitled, "Important Information About Your Appeal Rights."

A copy of this letter was also sent to [redacted] Novitas Solutions was contracted by Medicare to review your appeal.

Summary of the Facts

A claim was submitted for the [redacted]. An initial determination on this claim was made on January 23, 2018. The service was allowed and paid. On March 02, 2018, we received a request for a redetermination. The request included a redetermination request letter and a spreadsheet containing multiple claims for appeal.

Decision

Bio-reference Lab INC [redacted]

submitted with the request for reconsideration. All evidence must be presented before the reconsideration decision is issued. If all additional evidence as indicated above and/or otherwise is not submitted prior to issuance of the reconsideration decision, you will not be able to submit any new evidence to the Administrative Law Judge or the Medicare Appeals Council unless you can demonstrate good cause for withholding the evidence from the Qualified Independent Contractor (QIC).

NOTE: You do not need to resubmit documentation that was submitted as part of the redetermination. The information will be forwarded to the QIC as part of the case file utilized in the reconsideration process.

Contact Information

If you have questions, write or call:

Novitas Solutions
P.O. Box 3031
Mechanicsburg, PA 17055-1803

Beneficiary: 1-800-MEDICARE (1-800-633-4227)
Nationwide TTY Number-1-877-486-2048
Provider: 1-877-235-8073
Nationwide TTY Number-1-877-235-8051

Sincerely,

B. Snauffer

B. Snauffer
Novitas Solutions
Appeals

cc: [redacted]

IG60/R20

Attachment 2

Attachment 2 is an excel spreadsheet that identifies hundreds of Medicare claims for clinical laboratory services. Plaintiff American Clinical Laboratory Association has redacted this information in full because it consists almost entirely of protected health information that does not have any direct relevance to the issues in this case. If the Court decides that it would like to review the information, however, ACLA will file it under seal upon the Court's request.

Exhibit C

KING & SPALDING

Mark D. Polston
Partner
King & Spalding LLP
1700 Pennsylvania Avenue, NW
Suite 200
Washington, DC 20006-4707
Direct Dial: (202) 626-5540
Fax: (202) 626-3737
mpolston@kslaw.com

Juliet M. McBride
Partner
King & Spalding LLP
1100 Louisiana Street, Suite 4000
Houston, Texas 77002-5213
Direct Dial: (713) 276-7448
Fax: (713) 751-3290
jmcbride@kslaw.com

January 30, 2019

VIA UPS OVERNIGHT DELIVERY TRACKING NO. 1Z 26W 446 01 5872 6197

Attachments Contain Confidential Protected Health Information

HHS OMHA
Centralized Docketing
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

Re: **REQUEST FOR ALJ HEARING**
QIC Medicare Appeal Number: 1-7911115006
Beneficiaries: Multiple (Attachments 1 and 2)

Appellant: **BIOREFERENCE LABORATORIES, INC.**
481 Edward H Ross Drive
Elmwood Park, NJ 07407
Tax I.D. (last 5 digits): 05059
Medicare PTAN: 301910
NPI: 1134277494
Beneficiaries: Multiple, See Attachments 1 and 2

To Whom It May Concern:

In accordance with 42 C.F.R. § 405.1000 *et seq*., this letter and attachments constitute a timely request by BioReference Laboratories, Inc. ("BioReference"), a Medicare-certified clinical laboratory, for an in-person hearing before an Administrative Law Judge ("ALJ") ("Request for Hearing") for a *de novo* review of the claims denied by C2C Innovative Solutions, Inc., the Qualified Independent Contractor ("QIC"), in the unfavorable Medicare Reconsideration Decision, dated November 27, 2018 ("Reconsideration"), available at **Attachment 1**. Enclosed with **Attachment 1** is the QIC's individual claims spreadsheet of the aggregated claims subject to this appeal identifying the Medicare beneficiary claim number,

redacted Health Insurance Claim number, beneficiary name, date of service, procedure code, and QIC decision and explanation. **Attachment 2** includes the aggregated listing of claims at issue originally filed with BioReference's request for redetermination and request for reconsideration; notably, however, this listing should overlap with and be duplicative of the QIC's individual claims spreadsheet available at **Attachment 1**.

This Request for Hearing satisfies the requirements set forth at 42 C.F.R. § 405.1002 and § 405.1014. This request is made within sixty (60) days of receipt of the notice of the Reconsideration.[1] The claims set forth at **Attachments 1** and **2** are aggregated for purposes of this Request for Hearing as they all share the same issue as set forth below, and the amount in controversy exceeds $160.00. *See* 42 C.F.R. §§ 405.1002(a)(2), 405.1006.

BioReference has appointed the undersigned King & Spalding attorneys as its representatives: Mark D. Polston, King & Spalding LLP, 1700 Pennsylvania Avenue, N.W., Suite 200, Washington, DC 20006-4707; and Juliet M. McBride, King & Spalding LLP, 1100 Louisiana Street, Suite 4000, Houston, TX 77002-5213. A completed form CMS-1696 for each representative attorney is included with this Request for Hearing at **Attachment 3**.

This appeal relates to a Medicare payment methodology. Under Section 216(a) of the Protecting Access to Medicare Act ("PAMA"), the Secretary of HHS is required to collect information regarding commercial payment rates for clinical diagnostic laboratory services from "applicable laboratories." *See* 42 U.S.C. § 1395m-1(a). PAMA defines an "applicable laboratory" as any laboratory that receives a majority of its Medicare revenue from the Clinical Lab Fee Schedule or the Physician Fee Schedule. *Id.* § 1395b-1(a)(2). Section 216(b) of PAMA requires the Secretary to use the information collected from "applicable laboratories" to determine future payment rates for clinical diagnostic services. *Id.* § 1395m-1(b). These rates apply to clinical diagnostic services provided on or after January 1, 2018.

The Secretary has adopted a regulatory definition that conflicts with PAMA 216(a) by limiting "applicable laboratories" to those that separately bill the Medicare program using their own National Provider Identifier ("NPI"). 42 C.F.R. § 414.502(b). The purpose and effect of this definition is to exclude numerous applicable laboratories from PAMA 216's reporting requirement. BioReference challenges the Secretary's regulation on the basis that it is arbitrary and capricious, violates the Medicare statute, and exceeds the authority granted to the Secretary by Congress.

There are no material facts in dispute in this appeal. The only factor precluding a decision favorable to BioReference is a determination of the invalidity of 42 C.F.R. §

---

[1] 42 C.F.R. § 405.1002(a)(1) establishes a 60-day timeframe for parties to file a request for an ALJ hearing. The period of 60 calendar days begins from the date on which the party *received* the notice of reconsideration. There is a rebuttable presumption established by § 405.1002(a)(3) that a party received the notice of reconsideration five days after the notice was dated. The QIC's notice of reconsideration was dated November 27, 2018, therefore, receipt of this notice is presumed to be on December 2, 2018. However, December 2, 2018 was a Sunday and the notice of reconsideration was actually received by BioReference's representatives on December 3, 2018. Therefore, BioReference has until February 1, 2019 to file this Request for Hearing.

414.502(b). Medicare Administrative Contractors, Qualified Independent Contractors and Administrative Law Judges are bound by the Secretary's regulation and cannot provide that relief. BioReference respectfully requests prompt action on this appeal so that it may file a request for Expedited Access to Judicial Review pursuant to 42 C.F.R. § 405.990 at the earliest juncture.

For the foregoing reasons, BioReference respectfully requests an ALJ hearing to address the claims set forth at Attachments **1** and **2**.

Very truly yours,

Mark D. Polston

Juliet M. McBride

Enclosures

cc: Jane Pine Wood, Esq.
Chief Legal Officer
BioReference Laboratories, Inc.
481 Edward H. Ross Drive
Elmwood Park, NJ 07407
Email: jwood@bioreference.com

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office of Medicare Hearings and Appeals

REQUEST FOR ADMINISTRATIVE LAW JUDGE (ALJ) HEARING OR REVIEW OF DISMISSAL

Section 1: Which Medicare Part are you appealing (if known)? (*Check one*)

☐ Part A ☒ Part B ☐ Part C (*Medicare Advantage*) or Medicare Cost Plan ☐ Part D (*Prescription Drug Plan*)

Section 2: Which party are you, or which party are you representing? (*Check one*)

☐ The Medicare beneficiary or enrollee, or a successor (such as an estate), who received or requested the items or services being appealed, or is appealing a Medicare Secondary Payer issue.

☒ The provider or supplier that furnished the items or services to the Medicare beneficiary or enrollee, a Medicaid State agency, or an applicable plan appealing a Medicare Secondary Payer issue.

☐ Other. *Please explain*:

Section 3: What is your (the appealing party's) information? (*Representative information in next section*)

Name (*First, Middle Initial, Last*)	Firm or Organization (*if applicable*)		
Jane Pine Wood, Esq., Chief Legal Officer	BioReference Laboratories, Inc.		
Address where appeals correspondence should be sent	City	State	ZIP Code
481 Edward H. Ross Drive	Elmwood Park	NJ	07407
Telephone Number	Fax Number	E-Mail	
1-800-229-5227 ext. 7800		jwood@bioreference.com	

Section 4: What is the representative's information? (*Skip if you do not have a representative*) See Attachment 3

Name	Firm or Organization (*if applicable*)		
Mark D. Polston	King & Spalding LLP		
Mailing Address	City	State	ZIP Code
1700 Pennsylvania Avenue, N.W., Suite 200	Washington	DC	20006-4707
Telephone Number	Fax Number	E-Mail	
202-626-5540	202-626-3737	mpolston@kslaw.com	

Did you file an appointment of representation (form CMS-1696) or other documents authorizing your representation at a prior level of appeal?

☒ No. *Please file the document(s) with this request.* See Attachment 3

☐ Yes

Section 5: What is being appealed? *Submit a separate request for each Reconsideration or Dismissal that you wish to appeal. If the appeal involves multiple beneficiaries or enrollees, use the multiple claim attachment (OMHA-100A).*

Name of entity that issued the Reconsideration or Dismissal (*or attach a copy of the Reconsideration or Dismissal*)	Reconsideration (Medicare Appeal or Case) Number (*or attach a copy of the Reconsideration or Dismissal*)		
C2C Innovative Solutions, Inc., See Attachment 1	1-7911115006		
Beneficiary or Enrollee Name	Health Insurance Claim Number		
See Attachments 1 and 2	See Attachments 1 and 2		
Beneficiary or Enrollee Mailing Address	City	State	ZIP Code
See Attachments 1 and 2	See Attachments 1 and 2	See Attachments 1 and 2	
What item(s) or service(s) are you appealing? (*N/A if appealing a Dismissal*)		Date(s) of service being appealed (*if applicable*)	
See Attachments 1 and 2		See Attachments 1 and 2	
Supplier or Provider Name (*N/A for Part D appeals*)		Supplier or Provider Telephone Number (*N/A for Part D appeals*)	
BioReference Laboratories, Inc.		1-800-229-5227 ext. 7800	
Supplier or Provider Mailing Address (*N/A for Part D appeals*)	City	State	ZIP Code
481 Edward H. Ross Drive	Elmwood Park	NJ	07407

Section 6: For appeals of prescription drugs ONLY (*Skip for all other appeals*)

Part D Prescription Drug Plan Name	What drug(s) are you appealing?

Are you requesting an expedited hearing?
(*An expedited hearing is only available if your appeal is not solely related to payment (for example, you do not have the drug) and applying the standard time frame for a decision (90 days) may jeopardize your health, life, or ability to regain maximum function*)

☐ No. ☐ Yes. *On a separate sheet, please explain or have your prescriber explain why applying the standard time frame for a decision (90 days) may jeopardize your health, life, or ability to regain maximum function.*

PSC Publishing Services (301) 443-6740. EF

Section 7: Why do you disagree with the Reconsideration or Dismissal being appealed? (*Attach a continuation sheet if necessary*)

BioReference challenges the validity of 42 C.F.R. Section 414.502(b) for the reasons explained in detail in the attached letter and seeks an ALJ hearing of the claims set forth in Attachments 1 and 2.

Section 8: Are you submitting evidence with this request, or do you plan to submit evidence?

☒ I am not planning to submit evidence at this time. (*Skip to Section 9, below*)

☐ I am submitting evidence with this request.

☐ I plan to submit evidence. Indicate what you plan to submit and when you plan to submit it:

Was the evidence already submitted for the matter that you are appealing?

☐ No. *Part A and Part B appeals only. If you are a provider or supplier, or a provider or supplier that is representing a beneficiary, you must include a statement explaining why the evidence is being submitted for the first time and was not submitted previously.*

☐ Yes.

Section 9: Is there other information about your appeal that we should know?

Are you aggregating claims to meet the amount in controversy requirement? (*If yes, attach your aggregation request. See 42 C.F.R. § 405.1006(e) and (f), and 423.1970(c) for request requirements.*)	☐ No	☒ Yes	See attached letter
Are you waiving the oral hearing before an ALJ and requesting a decision based on the record? (*If yes, attach a completed form OMHA-104 or other explanation. N/A if requesting review of a dismissal.*)	☒ No	☐ Yes	
Does the request involve claims that were part of a statistical sample? (*If yes, please explain the status of any appeals for claims in the sample that are not included in this request.*)	☒ No	☐ Yes	

Section 10: Certification of copies sent to other parties (*Part A and Part B appeals only*)

If another party to the claim or issue that you are appealing was sent a copy of the Reconsideration or Dismissal, you must send a copy of your request for an ALJ hearing or review of dismissal to that party.

Indicate the party (or their representative) to whom and address where you are sending a copy of the request, and when the copy will be sent (*attach a continuation sheet if there are multiple parties*).

Name of Recipient		
Mailing Address		
City	State	ZIP Code
Date of Mailing		

☒ Check here if no other parties were sent a copy of the Reconsideration or Dismissal.

Section 11: Filing instructions

Your appealed claim must meet the current amount in controversy requirement to file an appeal. See the Reconsideration or Dismissal or visit www.hhs.gov/omha for information on the current amount in controversy. Send this request form to the entity in the appeal instructions that came with your reconsideration (for example, requests for hearing following a Part C reconsideration are generally sent to the entity that conducted the reconsideration). If instructed to send to OMHA, use the addresses below.

Beneficiaries and enrollees, send your request to:	**For expedited Part D appeals, send your request to:**	**All other appellants, send your request to:**
OMHA Centralized Docketing Attn: Beneficiary Mail Stop 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316	OMHA Centralized Docketing Attn: Expedited Part D Mail Stop 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316	OMHA Centralized Docketing 200 Public Square, Suite 1260 Cleveland, Ohio 44114-2316

We must receive this request within 60 calendar days after you received the Reconsideration or Dismissal that you are appealing. We will assume that you received the Reconsideration or Dismissal 5 calendar days after the date of the Reconsideration or Dismissal, unless you provide evidence to the contrary. *If you are filing this request late, attach a completed form OMHA-103 or other explanation for the late filing.*

PRIVACY ACT STATEMENT

The legal authority for the collection of information on this form is authorized by the Social Security Act (section 1155 of Title XI and sections 1852(g)(5), 1860D-4(h)(1), 1869(b)(1), and 1876 of Title XVIII). The information provided will be used to further document your appeal. Submission of the information requested on this form is voluntary, but failure to provide all or any part of the requested information may affect the determination of your appeal. Information you furnish on this form may be disclosed by the Office of Medicare Hearings and Appeals to another person or governmental agency only with respect to the Medicare Program and to comply with Federal laws requiring the disclosure of information or the exchange of information between the Department of Health and Human Services and other agencies.

If you need large print or assistance, please call 1-855-556-8475

Attachment 1

Medicare Appeal Number:
1-7911115006

[edicare
econsideration
ecision

NOVEMBER 27, 2018

JANE PINE WOOD ESQ
BIOREFERENCE LABORATORIES INC
481 EDWARD H ROSS DRIVE
ELMWOOD PARK NJ 07407

RE:
Beneficiary: See Attached List
Appellant: BioReference Laboratories, Inc.

Dear Jane Pine Wood, Esq.:

This letter is to inform you of the decision on your Medicare Appeal. An appeal is a new and independent review of a claim. You are receiving this letter because you requested an appeal for the services shown under the Analysis section.

The appeal decision is UNFAVORABLE. The Qualified Independent Contractor's (QIC) decision is that Medicare will make no additional payment. More information on the decision is provided on the next pages. You are not required to take any action. If you disagree with the decision, you may appeal to an Administrative Law Judge (ALJ). You must file your appeal, in writing, within 60 days of receipt of this letter. For more information on how to appeal, see the page entitled "Important Information about Your Appeal Rights." The amount still in dispute is estimated to be equal to or over $160. However, the ALJ will determine if your appeal case meets the $160 amount in controversy requirement for an ALJ hearing.

If this appeal is partially favorable or unfavorable, and it originated from an overpayment, recoupment will begin 31 days from the date of this letter in the absence of an acceptable request for an Extended Repayment Schedule (ERS). Please refer to the original demand letter for information regarding the collection process, interest accrual, and requesting an ERS.

How to get Information?

If you want a status on your appeal and you are the beneficiary, please contact – 1-800 MEDICARE. If you are a provider, please visit Q2A.com

If you have questions about your appeal other than status or post decision issues, contact:

C2C Innovative Solutions, Inc.
Medicare Part B North
QIC Contractor
P.O. Box 45258
Jacksonville, FL
32232-5258

For non-status inquiries dial:
904-224-7426

Who we are:
We are a Qualified Independent Contractor (QIC). Medicare has contracted with us to review your file and make an independent decision.

A copy of this letter was also sent to the parties shown below. C2C Innovative Solutions, Inc. was contracted by Medicare to review your appeal.

Sincerely,

Wanda Y. Foston

Wanda Y. Foston, LPN, CPC
QIC Part B North Operations Manager

CC: Novitas Solutions, Inc.

Summary of Facts

From January 2, 2018, through January 4, 2018, BioReference Laboratories, Inc. (Appellant) provided laboratory testing for multiple Medicare beneficiaries. Appellant submitted claims for these services to Novitas Solutions, Inc. (Novitas), the Medicare Administrative Contractor (MAC). The MAC paid the claims.

On March 1, 2018, Appellant submitted multiple Redetermination Requests to the MAC. The MAC received the Redetermination Requests on March 2, 2018. From March 14, 2018, through March 26, 2018, the MAC issued Redetermination Decisions, which upheld the initial payment amount.

On September 27, 2018, C2C Innovative Solutions, Inc. (C2C), the QIC, received multiple Reconsideration Requests dated September 26, 2018. Appellant is dissatisfied with the payment rate for the provided laboratory services. The sole reason for the appeal is to challenge the validity of 42 Code of Federal Regulations (CFR) § 414.502(b).

The QIC review is a *de novo* review of the case based on the provided information from all prior level of review and Appellant. The responsibilities of the QIC include rendering a decision only on the coverage or payment issues raised by the review request.

Key records contained in the case file included:

- Reconsideration Requests dated September 26, 2018
- Redetermination Decision Letters dated March 14, 2018, through March 26, 2018
- Redetermination Requests dated March 1, 2018

Explanation of Decision

A licensed health care professional reviewed the documentation in this case and made these decisions.

Laws, Regulations, and Applicable Policies

Law, regulations and policy that pertain to this case are identified below. An analysis of findings and the decision rendered will follow in the QIC's Decision Analysis section.

Actions That Are Not Initial Determinations

Actions that are not initial determinations and are not appealable under this subpart include, but are not limited to the following:

(a) Any determination for which the Centers for Medicare and Medicaid Services (CMS) has sole responsibility, for example one of the following:
  (1) If an entity meets the conditions for participation in the program.
  (2) If an independent laboratory meets the conditions for coverage of services.
  (3) Determination under the Medicare Secondary Payer provisions of Section (§) 1862(b) of the Act of the debtor for a particular recovery claim.

(b) The coinsurance amounts prescribed by regulation for outpatient services under the prospective payment system.
(c) Any issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule set forth in part 414 of this chapter, or an inherent reasonableness adjustment pursuant to § 405.502(g), and any issue regarding the cost report settlement process under Part A. [42 CFR § 405.926]

Right to a Reconsideration

(a) A person or entity that is a party to a redetermination made by a contractor as described under § 405.940 through § 405.958, and is dissatisfied with that determination, may request a reconsideration by a QIC in accordance with § 405.962 through § 405.966, regardless of the amount in controversy. [42 CFR § 405.960]

Authority of the QIC

With regard to authority of the QIC, 42 CFR 405.968(b) provides:
(1) National coverage determinations (NCDs), CMS Rulings, and applicable laws and regulations are binding on the QIC.
(2) QICs are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but give substantial deference to these policies if they are applicable to a particular case. A QIC may decline to follow a policy, if the QIC determines, either at a party's request or at its own discretion, that the policy does not apply to the facts of the particular case.
(3) If a QIC declines to follow a policy in a particular case, the QIC's reconsideration explains the reasons why the policy was not followed.
(4) A QIC's decision to decline to follow a policy under this section applies only to the specific claim being reconsidered and does not have precedential effect.
(5) A QIC may raise and develop new issues that are relevant to the claims in a particular case provided that the contractor rendered a redetermination with respect to the claims. [42 CFR § 405.968(b)]

Medicare Clinical Laboratory Fee Schedule (CLFS) Protecting Access to Medicare Act Regulations

The CLFS final rule entitled "Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System" (CMS-1621-F) was published in the Federal Register on June 23, 2016. The final CLFS rule implements § 216 of the PAMA of 2014.

Under the final rule, laboratories, including physician office laboratories, are required to report private payor rate and volume data if they:
- have more than $12,500 in Medicare revenues from laboratory services on the CLFS and
- they receive more than 50 percent of their Medicare revenues from laboratory and physician services during a data collection period.

Laboratories will collect private payor data from January 1, 2016, through June 30, 2016, and report it to CMS by March 31, 2017. We will post the new Medicare CLFS rates (based on weighted median private payor rates) in November 2017 that will be effective on January 1, 2018.

C2C Innovative Solutions, Inc.
P.O. Box 45258, Jacksonville, Florida 32232-5258

[https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/PAMA-Regulations.html]

Expedited Access to Judicial Review (EAJR)

A party can request EAJR with respect to a question of law or regulation for a specific matter in dispute in an appeal. The request for EAJR must—

(1) Allege that there are no material issues of fact in dispute and identify the facts that the requestor considers material and that are not disputed; and

(2) Assert that the only factor precluding a decision favorable to the requestor is—

i. A statutory provision that is unconstitutional, or a provision of a regulation or national coverage determination and specify the statutory provision that the requestor considers unconstitutional or the provision of a regulation or a national coverage determination that the requestor considers invalid, or

ii. A CMS Ruling that the requester considers invalid;

(3) Include a copy of any QIC Reconsideration and of any ALJ hearing decision that the requester has received;

(4) If any QIC Reconsideration or ALJ hearing decision was based on facts that the requestor is disputing, state why the requestor considers those facts to be immaterial; and

(5) If any QIC Reconsideration or ALJ hearing decision was based on a provision of a law, regulation, national coverage determination or CMS Ruling in addition to the one the requestor considers unconstitutional or invalid, a statement as to why further administrative review of how that provision applies to the facts is not necessary. [42 CFR § 405.990]

Analysis

The following service is at issue for Reconsideration:

84443 Thyroid stimulating hormone (TSH)

Brief Procedural History

As noted above, Appellant provided laboratory testing services to multiple Medicare beneficiaries. Claims for these services were paid by the MAC.

The MAC's denial reason stated:

- Effective January 1, 2018, the CLFS rates will be based on weighted median private payer rates as required by the PAMA of 2014. The 2018 CLFS fee for the thyroid stimulating hormone (84443) is $20.75. The allowance was then reduced an additional 2% based on the Sequestration – Mandatory Payment Reductions in the Medicare Fee-for-Services Program. The 2% sequestration reduction is not appealable to Medicare. Therefore, no additional payment can be made. CMS 2018 CLFS and the Budget Control Act of 2011 were used to make this decision.

The following Laws, Regulations, and Applicable Policies were cited by the prior levels of review:

- CMS 2018 CLFS

C2C Innovative Solutions, Inc.
P.O. Box 45258, Jacksonville, Florida 32232-5258

- The Budget Control Act of 2011 the Budget Control Act of 2011

Multiple Reconsideration Requests were submitted to the QIC. The QIC's claims review findings are detailed under section, "Claims Review" and claims detailed spreadsheet is attached under section, "Individual Claims Spreadsheet". In the following paragraphs, the QIC will address Appellant's Reconsideration Request.

Claim Review

Below is the text of Appellant's Reconsideration Requests:

> "In accordance with 42 CFR § 405.960, this letter constitutes a request by BioReference Laboratories, Inc. ("BioReference") for a reconsideration relating to the Novitas Solutions, Inc. Medicare Appeal Decision available at Attachment 1 and the claims listed in Attachment 2 ("Request"). BioReference furnished certain clinical laboratory services to the beneficiaries identified at Attachments 1 and 2, and Attachment 2 lists the name, Medicare health insurance claim number, services or items, claim number and dates of service for each Medicare beneficiary whose claims are the subject of this appeal. The claims set forth at Attachment 2 are aggregated for purposes of this Request as they all share the same issue as set forth below."
>
> "Under § 216(a) of the Protecting Access to Medicare Act (PAMA), the Secretary of Health and Human Services (HHS) is required to collect information regarding commercial payment rates for clinical diagnostic laboratory services from "applicable laboratories." See 42 USC § 1395m-1(a). PAMA defines an "applicable laboratory" as any laboratory that receives a majority of its Medicare revenue from the Clinical Lab Fee Schedule or the Physician Fee Schedule. *Id.* § 1395b-1(a)(2). Section 216(b) of PAMA requires the Secretary to use the information collected from "applicable laboratories" to determine future payment rates for clinical diagnostic services. *Id.* § 1395m-1(b). These rates apply to clinical diagnostic services provided on or after January 1, 2018."
>
> "The Secretary has adopted a regulatory definition that conflicts with PAMA 216(a) by limiting 'applicable laboratories' to those that separately bill the Medicare program using their own National Provider Identifier ("NPI"). [42 CFR § 414.502(b)] The purpose and effect of this definition is to exclude numerous applicable laboratories from PAMA 216's reporting requirement. BioReference challenges the Secretary's regulation on the basis that it is arbitrary and capricious, violates the Medicare statute, and exceeds the authority granted to the Secretary by Congress."
>
> "There are no material facts in dispute in this appeal. The only factor precluding a decision favorable to BioReference is a determination of the invalidity of 42 CFR § 414.502(b). MACs, QICs, and ALJs are bound by the Secretary's regulation and cannot provide that relief. BioReference respectfully requests prompt action on this appeal so that it may file a request for Expedited Access to Judicial Review pursuant to 42 CFR § 405.990 at the earliest juncture."

In response, as noted, the claims at issue are for the clinical laboratory service reported with procedure code 84443. All services were rendered in 2018, following implementation of new Medicare CLFS rates. The authority for the change is the CLFS final rule entitled "Medicare Program: Medicare Clinical Diagnostic Laboratory Tests Payment System" (CMS-1621-F). This rule was published in the Federal Register on June 23, 2016, and implements § 216 of the PAMA of 2014.

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P.O. Box 45258, Jacksonville, Florida 32232-5258

The QIC notes the 2017 allowance for the code at issue was $23.05. This allowance was adjusted in 2018; the new allowed amount is $20.75. The services at issue were rendered in 2018. The appeal spreadsheet submitted reveals all services were allowed at the 2018 amount of $20.33. The QIC finds that Appellant was paid in accordance with the 2018 allowance.

Further, as noted in 42 CFR § 405.926(c), any issue regarding the computation of the payment amount of program reimbursement of general applicability for which CMS or a carrier has sole responsibility under Part B such as the establishment of a fee schedule set forth in part 414 of 42 CFR § 405.926, or an inherent reasonableness adjustment pursuant to § 405.502(g), and any issue regarding the cost report settlement process under Part A is not considered to be an initial determination and is therefore not appealable.

The QIC finds the challenge to the validity of regulations upon which the payment was made is not appealable in this venue. As such, the QIC must render an unfavorable Reconsideration Decision. The QIC refers Appellant to 42 CFR § 405.990, which provides regulatory guidance for expedited access to judicial review. It is in this venue that Appellant can challenge the validity of § 414.502(b).

The QIC's conclusion is denoted with code D1 on the attached Individual Claim Spreadsheet. Finally, the QIC has determined that the request for Beneficiary R. Pace, Internal Claim Number 0218016478370, is a duplicate submission of a request received under Medicare Appeal Number 1-7477778144. Please refer to the previously issued Reconsideration decision letter.

Conclusion

The decision of the QIC is unfavorable and finds the services were not appealable in accordance with 42 CFR § 405.926(c).

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Plaintiff American Clinical Laboratory Association has redacted the claims spreadsheet in this Reconsideration Decision in full because it consists almost entirely of protected health information that does not have any direct relevance to the issues in this case. If the Court decides that it would like to review the information, however, ACLA will file it under seal upon the Court's request.

Who is Responsible for the Bill?

The provider is responsible for being aware of how to correctly bill Medicare for services provided. Providers who bill Medicare must be familiar with coverage provisions that apply to the services that are rendered. The regulation in 42 CFR § 405.926 notes the services at issue were not appealable to the QIC. The provider cannot bill the patient for the difference in the allowed amount.

Other Important Information

If you appeal this decision the ALJ will not consider new evidence unless you show good cause for not presenting the evidence to the QIC. This requirement does not apply to beneficiaries, unless a provider or supplier represents the beneficiary.

For information on how to appeal this decision, refer to the page titled "Important Information about Your Appeal Rights." If you need more information or have any questions, please call 1-800-Medicare (1-800-633-4227) [TTY/TDD: 1-800-486-2048] or the phone number listed on page one.

You can receive copies of statutes, regulations, policies, and/or manual instructions we used to arrive at this decision. For instructions on how to do this, please see 'Other Important Information' on the page entitled "Important Information about Your Appeal Rights." The request must be submitted in writing to this office.

IMPORTANT INFORMATION ABOUT YOUR APPEAL RIGHTS

Your Right to Appeal this Decision

If you do not agree with this decision, you may file an appeal. The next level of appeal is an ALJ Hearing at the Office of Medicare Hearings and Appeals (OMHA). At this hearing, you or your representative may present your case to an ALJ.

As of January 1, 2018, you must have $160.00 in dispute to appeal to an ALJ. A claim can be combined ("aggregated") with others to reach this amount if: (1) the other claims have also been decided by a QIC; (2) all of the claims are listed on your request for hearing; (3) your request for hearing is filed within 60 days of receipt of all of the QIC reconsiderations being appealed; and (4) you explain why you believe the claims involve similar or related services.

You can find more information about your right to an ALJ hearing at www.hhs.gov/omha or by calling 1-855-556-8475. This is a toll free call.

How to Appeal

To exercise your right to appeal, you must file a written request for an ALJ hearing within **60 days** of receiving this letter.

When preparing your request for hearing, please use **Form CMS-20034 A/B**, available at: www.hhs.gov/omha/forms/index.html

If you do not use the form, your request for hearing must include the following:

1. The Beneficiary's name, address, and Medicare health insurance claim number;
2. The name and address of the person appealing, if the person is not the beneficiary;
3. The representative's name and address, if any;
4. The Medicare appeal number listed on the front page of this Reconsideration notice;
5. The dates of service for the claims at issue;
6. The reasons why you disagree with the QIC's Reconsideration; and
7. A statement of any additional evidence to be submitted and the date it will be submitted.

Please **do not attach evidence to your hearing request.** If you have evidence to submit, please submit the evidence directly to the ALJ when your case is assigned.
Mail your hearing request to (tracked mail is suggested):

HHS OMHA Central Operations
200 Public Square, Suite 1260
Cleveland, OH 44114-2316

If you are a Medicare beneficiary filing a request for an ALJ hearing, please also include "**Attn: Beneficiary Mail Stop**" in the address above.

If your request for hearing is being filed late, you must explain why your request is being filed late.

The ALJ will require proof that you sent a copy of the request for hearing to the other parties who received a copy of the QIC Reconsideration (for example, the beneficiary or provider/supplier). Please **do not** send a copy of your hearing request to the QIC that issued the Reconsideration or to the Medicare Administrative Contractor that issued the Redetermination.

Please **do not** submit multiple requests for hearing for the same QIC Reconsideration.

For additional filing tips, go to www.hhs.gov/omha or call 1-855-556-8475 for a copy.

Who May File an Appeal

You or someone you name to act for you (your **appointed representative**) may file an appeal. You can name a relative, friend, advocate, attorney, doctor, or someone else to act for you.

If you want someone to act for you, you and your appointed representative must sign, date a statement naming that person to act for you and send it with your request for hearing. Call 1-800-MEDICARE (1-800-633-4227) to learn more about how to name a representative.

Help With Your Appeal

You can have a friend or someone else help you with your appeal. If you have any questions about payment denials or appeals, you can also contact your State Health Insurance Assistance Program (SHIP). For information on contacting your local SHIP, call 1-800-MEDICARE (1-800-633-4227). Information about the ALJ hearing process can also be found at www.hhs.gov/omha or by calling 1-855-556-8475.

Other Important Information

If you want copies of statutes, regulations, and/or policies we used to arrive at this decision, please write to us and attach a copy of this letter, at:

C2C Innovative Solutions, Inc.
A Medicare Contractor
P.O. Box 45258
Jacksonville FL 32232-5258

If you have questions, please call us at the phone number provided on the front of this notice.

Other Resources To Help You

1-800-MEDICARE (1-800-633-4227),
TTY/TDD: 1-800-486-2048

Attachment 2

Attachment 2 is an excel spreadsheet that identifies hundreds of Medicare claims for clinical laboratory services. Plaintiff American Clinical Laboratory Association has redacted this information in full because it consists almost entirely of protected health information that does not have any direct relevance to the issues in this case. If the Court decides that it would like to review the information, however, ACLA will file it under seal upon the Court's request.

Attachment 3

Department of Health and Human Services
Centers for Medicare & Medicaid Services

Form Approved OMB No.0938-0950

Appointment of Representative

Name of Party	Medicare Number (beneficiary as party) or National Provider Identifier (provider or supplier as party)
BioReference Laboratories, Inc.	NPI: 1134277494

Section 1: Appointment of Representative

To be completed by the party seeking representation (i.e., the Medicare beneficiary, the provider or the supplier):
I appoint this individual, Mark D. Polston, to act as my representative in connection with my claim or asserted right under Title XVIII of the Social Security Act (the Act) and related provisions of Title XI of the Act. I authorize this individual to make any request; to present or to elicit evidence; to obtain appeals information; and to receive any notice in connection with my claim, appeal, grievance or request wholly in my stead. I understand that personal medical information related to my request may be disclosed to the representative indicated below.

Signature of Party Seeking Representation		Date
[signature], VP Legal, BioReference		01/30/19
Street Address 481 Edward H. Ross Drive		Phone Number (with Area Code) 800-229-5227 ext. 7800
City Elmwood Park	State New Jersey	Zip Code 07407
Email Address (optional) jwood@bioreference.com		

Section 2: Acceptance of Appointment

To be completed by the representative:
I, Mark D. Polston, hereby accept the above appointment. I certify that I have not been disqualified, suspended, or prohibited from practice before the Department of Health and Human Services (HHS); that I am not, as a current or former employee of the United States, disqualified from acting as the party's representative; and that I recognize that any fee may be subject to review and approval by the Secretary.
I am a / an Attorney (Partner) with King & Spalding LLP
(Professional status or relationship to the party, e.g. attorney, relative, etc.)

Signature of Representative		Date
[signature]		01/30/19
Street Address 1700 Pennsylvania Avenue, NW, Suite 200		Phone Number (with Area Code) 202-626-5540
City Washington	State DC	Zip Code 20006
Email Address (optional) mpolston@kslaw.com		

Section 3: Waiver of Fee for Representation

Instructions: This section must be completed if the representative is required to, or chooses to, waive their fee for representation. (Note that providers or suppliers that are representing a beneficiary and furnished the items or services may not charge a fee for representation and must complete this section.)
I waive my right to charge and collect a fee for representing _____ before the Secretary of HHS.

Signature	Date

Section 4: Waiver of Payment for Items or Services at Issue

Instructions: Providers or suppliers serving as a representative for a beneficiary to whom they provided items or services must complete this section if the appeal involves a question of liability under section 1879(a)(2) of the Act. (Section 1879(a)(2) generally addresses whether a provider/supplier or beneficiary did not know, or could not reasonably be expected to know, that the items or services at issue would not be covered by Medicare.) I waive my right to collect payment from the beneficiary for the items or services at issue in this appeal if a determination of liability under §1879(a)(2) of the Act is at issue.

Signature	Date

Charging of Fees for Representing Beneficiaries before the Secretary of HHS

An attorney, or other representative for a beneficiary, who wishes to charge a fee for services rendered in connection with an appeal before the Secretary of HHS (i.e., an Administrative Law Judge (ALJ) hearing or attorney adjudicator review by the Office of Medicare Hearings and Appeals (OMHA), Medicare Appeals Council review, or a proceeding before OMHA or the Medicare Appeals Council as a result of a remand from federal district court) is required to obtain approval of the fee in accordance with 42 CFR 405.910(f).

The form, "Petition to Obtain Representative Fee" elicits the information required for a fee petition. It should be completed by the representative and filed with the request for ALJ hearing, OMHA review, or request for Medicare Appeals Council review. Approval of a representative's fee is not required if: (1) the appellant being represented is a provider or supplier; (2) the fee is for services rendered in an official capacity such as that of legal guardian, committee, or similar court appointed representative and the court has approved the fee in question; (3) the fee is for representation of a beneficiary in a proceeding in federal district court; or (4) the fee is for representation of a beneficiary in a redetermination or reconsideration. If the representative wishes to waive a fee, he or she may do so. Section III on the front of this form can be used for that purpose. In some instances, as indicated on the form, the fee must be waived for representation

Approval of Fee

The requirement for the approval of fees ensures that a representative will receive fair value for the services performed before HHS on behalf of a beneficiary, and provides the beneficiary with a measure of security that the fees are determined to be reasonable. In approving a requested fee, OMHA or Medicare Appeals Council will consider the nature and type of services rendered, the complexity of the case, the level of skill and competence required in rendition of the services, the amount of time spent on the case, the results achieved, the level of administrative review to which the representative carried the appeal and the amount of the fee requested by the representative.

Conflict of Interest

Sections 203, 205 and 207 of Title XVIII of the United States Code make it a criminal offense for certain officers, employees and former officers and employees of the United States to render certain services in matters affecting the Government or to aid or assist in the prosecution of claims against the United States. Individuals with a conflict of interest are excluded from being representatives of beneficiaries before HHS.

Where to Send This Form

Send this form to the same location where you are sending (or have already sent) your appeal if you are filing an appeal, grievance or complaint if you are filing a grievance or complaint, or an initial determination or decision if you are requesting an initial determination or decision. If additional help is needed, contact 1-800-MEDICARE (1-800-633-4227) or your Medicare plan. TTY users please call 1-877-486-2048.

You have the right to get Medicare information in an accessible format, like large print, Braille, or audio. You also have the right to file a complaint if you believe you've been discriminated against. Visit https://www.cms.gov/about-cms/agency-information/aboutwebsite/cmsnondiscriminationnotice.html, or call 1-800-MEDICARE (1-800-633-4227) for more information.

Department of Health and Human Services
Centers for Medicare & Medicaid Services

Form Approved OMB No.0938-0950

Appointment of Representative

Name of Party	Medicare Number (beneficiary as party) or National Provider Identifier (provider or supplier as party)
BioReference Laboratories, Inc.	NPI: 1134277494

Section 1: Appointment of Representative

To be completed by the party seeking representation (i.e., the Medicare beneficiary, the provider or the supplier):

I appoint this individual, Juliet M. McBride, to act as my representative in connection with my claim or asserted right under Title XVIII of the Social Security Act (the Act) and related provisions of Title XI of the Act. I authorize this individual to make any request; to present or to elicit evidence; to obtain appeals information; and to receive any notice in connection with my claim, appeal, grievance or request wholly in my stead. I understand that personal medical information related to my request may be disclosed to the representative indicated below.

Signature of Party Seeking Representation		Date
[signature], VP Legal, BioReference		01/30/19
Street Address 481 Edward H. Ross Drive		Phone Number (with Area Code) 800-229-5227 ext. 7800
City Elmwood Park	State New Jersey	Zip Code 07407
Email Address (optional) jwood@bioreference.com		

Section 2: Acceptance of Appointment

To be completed by the representative:

I, Juliet M. McBride, hereby accept the above appointment. I certify that I have not been disqualified, suspended, or prohibited from practice before the Department of Health and Human Services (HHS); that I am not, as a current or former employee of the United States, disqualified from acting as the party's representative; and that I recognize that any fee may be subject to review and approval by the Secretary.

I am a / an Attorney (Partner) with King & Spalding LLP

(Professional status or relationship to the party, e.g. attorney, relative, etc.)

Signature of Representative		Date
Juliet M. McBride		01/30/19
Street Address 1100 Louisiana Street, Suite 4000		Phone Number (with Area Code) 713-276-7448
City Houston	State Texas	Zip Code 77002
Email Address (optional) jmcbride@kslaw.com		

Section 3: Waiver of Fee for Representation

Instructions: This section must be completed if the representative is required to, or chooses to, waive their fee for representation. (Note that providers or suppliers that are representing a beneficiary and furnished the items or services may not charge a fee for representation and **must** complete this section.)

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Approval of Fee

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Conflict of Interest

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Send this form to the same location where you are sending (or have already sent) your: appeal if you are filing an appeal, grievance or complaint if you are filing a grievance or complaint, or an initial determination or decision if you are requesting an initial determination or decision. If additional help is needed, contact 1-800-MEDICARE (1-800-633-4227) or your Medicare plan. TTY users please call 1-877-486-2048.

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

AMERICAN CLINICAL LABORATORY ASSOCIATION,
1100 New York Avenue, N.W., Suite 725W
Washington, D.C. 20005

Plaintiff,

v.

ALEX M. AZAR,
In His Official Capacity as Secretary of Health and Human Services,
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Washington, D.C. 20201

Defendant.

Civil Action No. 1:17-cv-2645 (ABJ)

ORDER GRANTING PLAINTIFFS' MOTION FOR SUMMARY JUDGMENT

THIS CAUSE comes before the Court upon Plaintiff's Motion for Summary Judgment, filed on October 14, 2019.

UPON CONSIDERATION of the Motion, the pertinent portions of the administrative record, and being otherwise fully advised in the premises, it is

ORDERED AND ADJUDGED that Plaintiff's Motion for Summary Judgment is GRANTED on all counts of the Complaint. Any pending motions are hereby DENIED AS MOOT.

IT IS FURTHER ORDERED that the Secretary of Health and Human Service's definition of "applicable laboratory" in 42 C.F.R. § 414.502 is invalid because it does not comport with the requirements of Section 216 of the Protecting Access to Medicare Act of 2014, Pub. L. No. 113-93, § 216, 128 Stat. 1040, 1053 (2014).

IT IS FURTHER ORDERED that (1) the Secretary must withdraw or suspend his final rule, *Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; Final Rule*; 81 Fed. Reg. 41,036 (June 23, 2016); *see also* 42 C.F.R. § 414.502, until such time as it can be brought into compliance with the statute, and (2) the Secretary must withhold applying the new Clinical Laboratory Fee Schedule until such time as the Secretary has made appropriate revisions to the final rule.

DONE AND ORDERED in Chambers in Washington, District of Columbia, this ____ day of _____, 2019.

_____
AMY BERMAN JACKSON
UNITED STATES DISTRICT JUDGE