November 23, 2015

Mr. Andrew Slavitt, Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue SW
Washington, DC 20201

American Clinical Laboratory Association

RE: Medicare Program; Medicare Clinical Diagnostic Laboratory Test Payment System (CMS-1621-P)

Dear Mr. Slavitt,

Please accept the comments of the American Clinical Laboratory Association ("ACLA") on the above-referenced proposed rule.[1] ACLA is an association representing clinical laboratories throughout the country, including local, regional, and national laboratories. As providers of millions of clinical diagnostic laboratory services for Medicare beneficiaries each year, ACLA member companies have a direct stake in ensuring that prices for laboratory testing services are developed openly and rationally and that the pricing levels represent reasonable compensation for developing and providing the services.

Since Congress passed the Protecting Access to Medicare Act of 2014 ("PAMA") and President Obama signed it into law, ACLA has been actively engaged in discussions with the Centers for Medicare and Medicaid Services ("CMS") about implementation of Section 216 of the law. That section revamps the way that clinical laboratory tests are to be priced on the Clinical Laboratory Fee Schedule ("CLFS"), the first major overhaul of the fee schedule in three decades. All ACLA members will be impacted greatly by implementation of this law, and we appreciate the opportunity to share our thoughts, concerns, and suggestions.

Summary of ACLA's Comments

"Applicable laboratory". For purposes of determining which entities are "applicable laboratories" and are required to report private payor data to CMS, ACLA believes that the agency should define the term in a way that includes all laboratories that derive a majority of their Medicare revenues from the CLFS and Physician Fee Schedule ("PFS"). For this reason, ACLA strongly disagrees with CMS's current proposal to define an "applicable laboratory" as the taxpayer identification number-level ("TIN-level") entity with which all of its National Provider Identifier ("NPI") entities are associated. A TIN-level definition by itself would not capture all such laboratories or result in CLFS rates that reflect the market for laboratory tests in the United States, which was the underlying purpose of Section 216 of PAMA. In 2014, fully one quarter of Medicare Part B spending on clinical laboratory tests was for tests performed by hospital laboratories, yet CMS's proposal would have the effect of excusing virtually all hospitals from reporting their private payor data. CMS itself has recognized that hospital laboratories are acting as independent laboratories when providing outreach services, and

[1] 80 Fed. Reg. 59386 (Oct. 1, 2015).

hospital laboratories performing outreach testing will be paid at the new prices that CMS establishes, so CMS should ensure that such hospital laboratories are included among "applicable laboratories" for purposes of PAMA's reporting requirements. Since each laboratory is identified by a CLIA number, we believe that it is the best approach for defining "applicable laboratory". It would allow the "majority of Medicare revenues" test to be applied to the laboratory's Medicare revenue, rather than to the entire entity's Medicare revenue. As an alternative, ACLA recommends an approach that would allow a hospital to determine what portion of its overall Medicare revenues are attributable to the hospital laboratory and to determine whether or not the hospital laboratory itself derives a majority of its Medicare revenues from the CLFS and/or PFS.

Data collection period and data reporting period. Because of the delay in issuance of the proposed rule to implement PAMA, and because it is unlikely that CMS will issue a final rule until sometime well into 2016, the agency should amend its timeline for the initial data collection period, initial data reporting period, and the date on which the weighted median payment rates first take effect. ACLA recommends an initial data collection period that spans the first six months of 2016 (January 1 through June 30) and an initial data reporting period from January 1, 2017 through March 31, 2017. The weighted median rates that CMS calculates should take effect on January 1, 2018. This would provide applicable laboratories sufficient notice of their obligation to collect and report applicable information to CMS and adequate time to collect and report the information, and it would give CMS enough time to process the information and calculate new rates and to publish the new rates at least 60 days prior to their effective date. Subsequent data collection periods also should span six months, which we believe will provide CMS with sufficient data to calculate weighted median rates that accurately reflect the private payor market. There should be six months in between each data collection period and data reporting period to allow applicable laboratories time to extract the information from their billing systems and verify the accuracy of the data.

"Applicable information". An applicable laboratory should report information about tests both that it furnishes during the data collection period and for which it receives final payments during the data collection period, from the first day of the data collection period to the last day of the data collection period. The private payor rates that an applicable laboratory reports should be the final total approved payment rates for tests furnished during the reporting period, excluding information on those services for which appeals are outstanding and for which final rates are not yet determined. Certain payments should be excluded from "applicable information," such as hard copy (manual) remittances, payments made in error, payments that do not reflect specific HCPCS code-level amounts, secondary insurance payments, and other similar payments. CMS should allow a measure of flexibility regarding the entity that reports applicable information on behalf of an applicable laboratory and allow applicable information to be reported at the TIN-level, the NPI-level, or the CLIA number-level.

ADLTs. ACLA disagrees with the definition that CMS has proposed for an advanced diagnostic laboratory test ("ADLT") because it does not reflect the text of the statute or Congress' intent. We have provided alternatives to CMS's proposals to define a "single laboratory" as one with a single CLIA certificate, to disqualify protein-based biomarker tests

from qualifying as ADLTs, and to require that an ADLT be a test that provides new clinical information that cannot be derived from any other test or procedure currently available. We believe that an application to qualify as an ADLT should require only publicly-available information, which would be sufficient for CMS to make a determination about whether a test is an ADLT. With regard to payment for new ADLTs, ACLA believes that the start of the "initial three quarters" during which a laboratory offering and furnishing an ADLT is paid the actual list charge for the test should be the first calendar quarter after the first day that Medicare pays for the ADLT, rather than the calendar quarter after the first day that the new ADLT is performed. Under CMS's proposal, a laboratory offering and furnishing a new ADLT likely would have very few payments from private payors to report to CMS by the end of the second quarter, and in many cases, the laboratory would never be paid at the actual list charge by Medicare.

Coding. A unique HCPCS code should be assigned for an ADLT or an FDA-cleared or -approved test if a laboratory or manufacturer requests a unique code, but CMS should not automatically issue a new code for every distinct existing ADLT or FDA-cleared or -approved test. ACLA prefers for the American Medical Association's ("AMA's") Common Procedural Terminology ("CPT") Editorial Panel to assign HCPCS codes to ADLTs and FDA-cleared or -approved tests, instead of CMS assigning HCPCS codes to the tests, because G-codes are viewed as Medicare-only codes by other payors and generally are not accepted.

Data integrity. CMS should create a certification form for applicable laboratories to submit with information they report that includes the following language: "All information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith." Given that most laboratory Presidents, CEOs, and CFOs are not personally familiar with the volume and private payor rates for each laboratory test their labs offer, a laboratory officer should be expected to certify only to his or her good-faith belief in the data's integrity and that he or she does not have any information to the contrary.

Subregulatory guidance. ACLA believes that it is impermissible for CMS to issue subregulatory guidance interpreting the various provisions in PAMA until the agency has issued the final rule. Much of the subregulatory guidance by necessity requires resolution in the final rule of certain issues, such as the meanings of "applicable laboratory," "applicable information," and "private payor rate." CMS cannot resolve those issues until it has had the opportunity to review all stakeholder comments and publish a final rule. Until all terms are defined and other issues are resolved, it is not appropriate for CMS to issue subregulatory guidance.

ACLA's Comments

I. Definition of "Applicable Laboratory"

As defined in the statute, an "applicable laboratory" means a laboratory that receives a majority of its Medicare revenues under the new section 1834A of the Social Security Act, the CLFS, or the PFS.[2] CMS proposes that an "applicable laboratory" would mean an entity that reports tax-related information to the Internal Revenue Service under a TIN with which all of the

[2] 42 U.S.C. § 1395m-1(a)(2).

NPIs in the entity are associated. An applicable laboratory either itself would be a laboratory, as defined in 42 C.F.R. § 493.2, or, if it is not itself a laboratory, would have at least one component that is. In a data collection period, an applicable laboratory would receive, collectively with its associated NPI entities, more than 50 percent of its Medicare revenues from either the CLFS or PFS.[3]

A. CMS's Proposal for Identifying an "Applicable Laboratory"

Under the proposed rule, an "applicable laboratory" would be a TIN-level entity that derives more than 50 percent of its entire Medicare revenues from the CLFS or PFS. ACLA strongly disagrees with this proposed definition of "applicable laboratory" because, in its current form, it is inconsistent with the statutory definition and would not result in CLFS rates that reflect the market for laboratory tests in the United States, which was the underlying purpose of Section 216 of PAMA. The proposed definition, coupled with the proposed low-revenue threshold, would remove the overwhelming majority of hospital laboratories and physician office laboratories from the entities reporting private payor rates, and it would remove more than half of all independent laboratories from reporting.

We vehemently disagree with CMS's inaccurate assumption that "the statute intends to limit reporting primarily to independent laboratories and physician offices…and not include other entities (such as hospitals, or other health care providers)…" Rather, Congress intended that all sectors of the laboratory market are to be represented in private payor rates reported to CMS, including hospital outreach laboratories.[4] If Congress meant to exclude all hospitals from the universe of "applicable laboratories," it easily could have done so directly, but it did not. It is reasonable for hospital laboratories with robust outreach programs to report private payor data to CMS because, as CMS itself has noted, "when a hospital laboratory performs laboratory tests for nonhospital patients, the laboratory is functioning as an independent laboratory."[5] Since hospital outreach laboratories are competing directly with independent laboratories, it is appropriate to include them among the entities reporting private payor data so CMS can obtain information about the entire laboratory market.

By not including hospitals among "applicable laboratories," CMS would exclude a significant part of the laboratory market. The Department of Health and Human Services Office of Inspector General ("OIG") found that in 2014, fully one quarter of Medicare Part B spending on clinical laboratory tests was for tests performed by hospital laboratories, and an independent analysis for ACLA by the Moran Company of 2013 Medicare CLFS expenditures reached the

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[3] 80 Fed. Reg. 59394.

[4] *Id*. at 59393. Congress's intent was made explicit in a colloquy between Sen. Richard Burr (R-NC), a member of the Senate Finance Committee, and Sen. Orrin Hatch (R-UT), Ranking Member of that committee. *See* 160 Cong. Rec. S2860 (daily ed. May 8, 2014). Sen. Burr noted that it was his understanding that "the intent of this provision is to ensure that Medicare rates reflect true market rates for laboratory services, and as such, that all sectors of the laboratory market should be represented in the reporting system, including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis under the fee schedule." Sen. Hatch agreed, stating that "commercial payment rates to all sectors of the lab market should be represented, including independent laboratories and hospital outreach laboratories."

[5] Medicare Claims Processing Manual, Pub. No. 100-04, Ch. 16, § 10.1.

same conclusion about the share of expenditures for services furnished by hospital laboratories and paid under the CLFS.[6] Significantly, the statute specifically applies the payment rates that CMS calculates to hospitals providing outreach services.[7] It is reasonable that these hospital laboratories should be included among "applicable laboratories" for purposes of PAMA's reporting requirements.

CMS suggests in the proposed rule that even though its TIN-level definition of "applicable laboratory" would prohibit reporting of private payor rates by the vast majority of hospital laboratories, physician office laboratories, and independent laboratories, its definition would be appropriate because the majority of Medicare spending for and utilization of laboratory services still would be represented by those laboratories required to report. But CMS's proposal completely misses the point of Section 216 of PAMA, which is to calculate new CLFS rates based on the weighted medians of the broad spectrum of price points in the private market. The fact that laboratories required to report under CMS's proposal may represent the majority of Medicare spending and utilization of laboratory services says nothing about the spectrum of price points in the market that those reporting laboratories would represent.

CMS also considered using the NPI as a criterion for defining an "applicable laboratory." ACLA disagrees with this approach for the same reasons that it disagrees with CMS's proposal for identifying an "applicable laboratory" at the TIN-level. Since HIPAA covered entities have significant flexibility in how they enumerate their organizations with NPIs, not all laboratories are identified separately by an NPI. Very few hospital laboratories have laboratory-specific NPIs – even those with robust laboratory outreach programs – and they generally submit claims under the hospital's NPI. Defining "applicable laboratory" at the NPI level would lead to the same result in most cases as defining the term at the TIN-level, as proposed: the "majority of Medicare revenues" test would be applied to the entire entity's revenue, rather than to the laboratory's revenue.

Determining the source of a majority of a laboratory's Medicare revenue need not – and should not – include an analysis of an entire entity's Medicare revenue, because Medicare revenue outside of the laboratory is not relevant to whether a laboratory is an "applicable laboratory" under the statute. As crafted, CMS's proposal to apply the "majority of Medicare revenues" test at the TIN level would result in reviewing the source of Medicare revenue received by portions of the entity that are far removed from laboratory services. For example, a hospital identified by a TIN may have as one component a laboratory with a robust laboratory outreach program, a significant portion of whose test volume is reimbursed under the CLFS. While a large portion of the hospital laboratory's revenue will be derived from the CLFS and/or

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[6] *See* Medicare Payments for Clinical Laboratory Tests in 2014: Baseline Data (OEI-09-15-00210) at 4, *available at* http://oig.hhs.gov/oei/reports/oei-09-15-00210.pdf; *see also* Appendix A. In the CY 2016 Hospital Outpatient Prospective Payment System ("OPPS") final rule, CMS recognized that a large volume of hospital laboratory tests is paid under the CLFS. It said that because hospital laboratory expenditures under the CLFS in CY 2014 were $1 billion more than the agency anticipated, it would include a two percent cut in the conversion factor in 2016 to offset those expenditures.

[7] 42 U.S.C. § 1395m-1(b)(1)(B) ("The payment amounts established under this section shall apply to a clinical diagnostic laboratory test furnished by a hospital laboratory if such test is paid for separately and not as part of a bundled payment under section 1833(t).").

PFS, a TIN-level analysis of the hospital's Medicare revenue will include significant reimbursement that is not relevant to the laboratory's reimbursement under the CLFS (*e.g.*, surgery, radiology, oncology, intensive care). Under CMS's proposed TIN-level analysis, the agency would not be able to determine whether a majority of the laboratory's Medicare revenue is derived from the CLFS and/or PFS, as called for in the statute.

B. ACLA's Proposal for Identifying an "Applicable Laboratory"

We believe that defining "applicable laboratory" as a facility that is identified by a CLIA number would be the most accurate reflection of Congress' intent: to receive information about private payor rates for those laboratories that derive a majority of their Medicare revenues from the CLFS and/or PFS. Every laboratory is identified by a CLIA number, and CMS recognized the utility of the CLIA number when it proposed to define "laboratory" by reference to the definition in regulations implementing CLIA, which focuses on the laboratory facility itself and not the larger entity of which it may be a part. While a "CLIA-number" approach would allow an analysis of a laboratory's Medicare revenues at the most granular level, ACLA understands that this approach may be problematic to the agency.

In the event that CMS decides not to define "applicable laboratory" as a facility identified by a CLIA number, ACLA proposes an alternative approach that would facilitate an analysis of a hospital laboratory's Medicare revenues to determine whether a majority of such revenues are derived from the CLFS and/or PFS. Naturally, independent laboratories and physician office laboratories derive the majority of their Medicare revenues from the CLFS and/or PFS, but it may be less obvious when a hospital laboratory derives a majority of its Medicare revenues from those sources. To determine whether a majority of a hospital laboratory's Medicare revenues are from the CLFS and/or PFS, first it is necessary to identify the "universe" of Medicare revenues paid to the hospital for laboratory services. These are:

1. Laboratory services furnished to inpatients, which are paid as part of the hospital's Medicare Severity-Diagnosis Related Group ("MS-DRG") payments;

2. Laboratory services furnished to outpatients, which are paid as part of the hospital's Ambulatory Payment Classification ("APC") payments, with certain exceptions;

3. Laboratory services furnished to non-patients, which are paid under the CLFS or PFS, as applicable; and

4. Laboratory services furnished to outpatients who receive only those laboratory services on the date of service, which are paid under the CLFS or PFS, as applicable.

In the last two circumstances above, a hospital laboratory acts as an independent laboratory: when it furnishes services to non-patients, and when it furnishes services to outpatients who receive no other hospital services on the same day. In one circumstance, the services are identical to services furnished by an independent laboratory. In the other

circumstance, an outpatient goes to a hospital for a blood draw and the testing is performed there; this is analogous to a physician directing a patient to get blood drawn at an independent laboratory's patient service center, which then forwards the specimen to the laboratory for testing. In both circumstances, the hospital receives separate payment under the CLFS or PFS, as applicable, for the services. Hospital laboratories with many such services have significant laboratory outreach businesses, compete directly with independent laboratories, and should be required to report their private payor rates to CMS.

The statute applies the "majority of Medicare revenues" test to a laboratory's Medicare revenues,[8] rather than to an entire entity's revenue. While it is obvious that hospital laboratory services paid for under the CLFS or PFS are "Medicare revenues" to the laboratory, it is more difficult to identify laboratory revenues when the laboratory services are included in bundled payments (MS-DRG and APC payments) received by the TIN-level entity. ACLA proposes that CMS should require hospitals to use a basic calculation to determine what portion of the bundled Medicare payments received at the TIN-level are attributable to laboratory services.

Working with the Moran Company, we developed an approach to determine the portion of a hospital's overall Medicare revenues that is attributable to laboratory services. We applied the national hospital payment-to-charges ratio to the laboratory services billed by all hospitals to determine the approximate percentage of revenues paid to hospital for all inpatient and outpatient hospital laboratory services. (We used the 2013 data for this calculation because it was the most recent and complete data set available.)[9] We added other separately-paid laboratory revenues, such as for services furnished to non-patients. That gave us the total amount paid for laboratory services for hospitals in 2013. We then divided that number by the total Medicare expenditures for hospital services to determine what percentage of total hospital Medicare revenues are hospital laboratory-related Medicare revenues. Based on the Moran Company's analysis, this percentage is 6 percent.[10]

To determine whether a hospital is an "applicable laboratory" for purposes of PAMA, the hospital would determine what portion of its total hospital laboratory Medicare revenues were represented by its outreach services (CLFS and PFS services). First it would determine its hospital laboratory Medicare revenues by multiplying its total inpatient and outpatient Medicare revenues by 6 percent,[11] and it then would add that revenue to its Medicare revenue for individually-paid laboratory services (the "denominator"). It then would total its CLFS and PFS revenues (the "numerator"). It would divide the sum of its CLFS and PFS revenues by the total hospital laboratory Medicare revenues. If the result is 50 percent or greater, the hospital,

[8] 42 U.S.C. § 1395m-1(a)(2) ("[T]he term 'applicable laboratory' means a laboratory that, with respect to its revenues under this title, a majority of such revenues are from this section, [the CLFS, or the PFS].").
[9] CMS could use the same process to determine the adjustment factor using 2014 data if it is available when the final rule is issued.
[10] A more detailed description of this methodology is shown in Appendix B.
[11] For an explanation of why this should not include Medicare Advantage payments under Medicare Part C or prescription drug payments under Medicare Part D, please see Section I.D, below.

together with all of its hospital laboratories identified by CLIA numbers, would be an "applicable laboratory."[12] The equation is below:

Hospital Laboratory Revenues from CLFS/PFS

$$\frac{\text{CLFS revenues + PFS revenues}}{\text{(0.06 * (MS-DRG and APC payments)) + CLFS revenues + PFS revenues}} = \text{\% of Medicare rev. from CLFS + PFS}$$

The following is an illustration of how this equation would be applied to a hospital laboratory's Medicare revenues.

Example: XYZ Hospital

Inpatient revenues	$125 million	Apply 6 % adjustment factor	$7.5 million
Outpatient revenues	$50 million	Apply 6 % adjustment factor	$3 million
Non-patient lab revenues	$8 million		$8 million
Non-bundled outpatient laboratory revenues	$4 million		$4 million
Total outreach services (CLFS + PFS)			$12 million
Total hospital lab revenues			$22.5 million
Percentage of total laboratory Medicare revenues from CLFS and PFS			53 %

In this example, because more than 50 percent of XYZ Hospital's laboratory Medicare revenues are from the CLFS and PFS, it would be considered an "applicable laboratory" and would report its private payor rates to CMS.

We recognize that this analysis requires the development of an adjustment factor to determine hospital laboratory Medicare revenues. Therefore, a hospital would be permitted to use its actual revenues and payment-to-charges ratio to show that its Medicare revenues from the CLFS and/or the PFS were more or less than 50 percent of the hospital laboratory's total

[12] This is consistent with CMS's proposal that the determination of whether an entity is an "applicable laboratory" would be made across the entire entity. *See* 80 Fed. Reg. 59393.

Medicare revenues or it could use the 6 percent adjustment factor, which would be a "safe harbor" for purposes of this calculation. A hospital also could show that it did not meet the low Medicare revenue threshold and is excluded from reporting. CMS could spot-check hospitals for compliance with reporting requirements, as the agency would have all the information required to perform the calculation itself.

ACLA believes that under this approach, many hospitals would not qualify as applicable laboratories, but the calculation would capture those hospitals with significant laboratory outreach programs. We believe this approach is a good compromise and serves all stakeholders' needs. It reflects Congress' intent to capture data from all laboratories with a majority of their Medicare revenues coming from the CLFS and/or PFS, including hospitals with significant laboratory outreach programs. It is consistent with the purpose of the statute, in that it would lead to reporting by all significant participants in the laboratory market. It is fair to hospitals, including in reporting only those hospitals whose laboratories compete directly with independent laboratories. We strongly urge CMS to adopt this approach for defining which hospitals are "applicable laboratories."

C. Low Medicare Revenue Threshold

CMS has proposed that an entity that otherwise would be an applicable laboratory, but that has less than $50,000 in Medicare revenues from the CLFS during a 12-month data collection period, would not be required to report (the amount would be $25,000 for the first six month data collection period). With one exception, ACLA does not object to this low revenue threshold. This low revenue threshold should not apply to those applicable laboratories that offer and furnish new ADLTs. Under PAMA, a laboratory with a new ADLT is paid at an "initial list price" for a period of three quarters and then at the weighted median of reported prices. A laboratory offering a new ADLT must report its prices prior to the end of the second quarter. It may be that the laboratory will have less than $50,000 in Medicare CLFS revenues by the time it must report private payor rates. If it is excluded from reporting by the low revenue threshold, then the new ADLT may be priced through crosswalking or gapfilling and negate the very intention of the law. Given that Congress clearly intended for new ADLTs to be priced based on reported private payor rates, it would be inappropriate to exclude a laboratory offering a new ADLT if it did not meet the low revenue threshold. It is more reasonable simply not to apply the low revenue threshold to applicable laboratories offering and furnishing new ADLTs.

If CMS does apply a low revenue threshold to laboratories offering and furnishing new ADLTs, it should be consistent with the low revenue threshold for the initial data collection period ($25,000 in Medicare revenues under the CLFS), as each of those data collection periods are just six months long, rather than a year.

D. Medicare Revenues

In the preamble to the proposed rule, CMS said it would define "Medicare revenues" as "payments received from the Medicare program, which would include fee-for-service payments under Medicare Parts A and B, as well as Medicare Advantage payments under Medicare Part C, and prescription drug payments under Medicare Part D, and any associated Medicare beneficiary

deductible or coinsurance amounts for Medicare services furnished during the data collection period."[13]

CMS should remove from its proposed definition "Medicare Advantage payments under Medicare Part C," because those payments are included among the private payor payments about which applicable laboratories would report applicable information.[14] These payments cannot be both "Medicare revenues" and "private payor" payments at the same time. CMS also should remove from the proposed definition "prescription drug payments under Medicare Part D" because under no circumstances would such payments be related to laboratory testing.

E. Prohibition on Reporting

Oddly, the agency proposes to prohibit any entity that does not meet the definition of "applicable laboratory" from reporting applicable information, a prohibition that does not appear in the statute, that is not inferable from the statute, and that could be detrimental to achieving the goal of acquiring applicable information in the most efficient and effective manner possible. CMS does not say whether or how it would enforce this prohibition; while the regulatory text includes the possibility of civil monetary penalties ("CMPs") for failure to report or for misreporting data, there are no penalties proposed for violating this "prohibition." A laboratory that does not have to report private payor data to CMS and have an officer of the company certify to the accuracy and completeness of the data is extremely unlikely to do so, but in the event that such laboratories may be subject to the new CLFS rates resulting from this process, they should not be prohibited from contributing to the data on which such new rates are to be based. Further, an entity that is not itself an applicable laboratory, but that can report applicable information from any applicable laboratories it owns or controls more efficiently and effectively than the applicable laboratories themselves, should be permitted to do so. CMS should remove this language from the proposed regulatory text at 42 C.F.R. § 414.504(g).

F. End Stage Renal Disease Laboratories

CMS should use its authority under 42 U.S.C. § 1395m-1(a)(2) to establish a low-volume threshold that would exclude end-stage renal disease ("ESRD") laboratories – dialysis specialty laboratories – from the definition of "applicable laboratory." ESRD laboratories provide services primarily for patients receiving chronic renal dialysis treatments in ESRD facilities. Approximately 85 percent of patients with ESRD are covered under the Medicare ESRD benefit. These dialysis specialty laboratories receive a small minority of their Medicare revenues from the CLFS. This is because almost all ESRD-related laboratory testing is bundled into a per-patient payment that Medicare pays directly to the dialysis facility, and the ESRD laboratory is paid by the dialysis facility for the bundled laboratory services they furnish to Medicare beneficiaries. The only Medicare revenues ESRD laboratories receive directly are for laboratory tests that are not related to renal disease. Because of the anomaly in the way ESRD laboratories are paid, the non-ESRD-related laboratory tests they furnish would be their only "Medicare revenues," as CMS has proposed defining that term. This minority of non-ESRD-related

[13] 80 Fed. Reg. 59392.
[14] *See* 42 U.S.C. § 1395m-1(a)(8)(B).

laboratory tests that they furnish to Medicare beneficiaries would result in them being considered "applicable laboratories," although they have little private payor data to report.

The statute does not establish any parameters for the type of low-volume threshold that CMS may establish to exclude a laboratory from the definition of "applicable laboratory." It leaves it up to the agency's discretion to determine what threshold is appropriate. CMS would be acting within its authority if it established a low-volume threshold that excludes specialty laboratories like ESRD laboratories that furnish laboratory services to only certain types of patients and that receive a small amount of "Medicare revenues" from the CLFS.

II. Data Collection Period and Data Reporting Period

The statute calls for the Secretary to define a "data collection period", and it calls for an applicable laboratory to report applicable information for the data collection period "beginning January 1, 2016."[15] The statute also calls for CMS to have issued a final rule to implement data collection and reporting by June 30, 2015. CMS did not issue a proposed rule until several months after that deadline, and ACLA believes that it is virtually impossible for the agency to issue a final rule by January 1, 2016, which was supposed to be the start of the initial data reporting period. In light of this, we comment specifically on the timing of the first data collection period and first data reporting period, and more generally on subsequent data collection periods and data reporting periods.

A. Initial Data Collection Period and Initial Data Reporting Period

CMS proposes that the first data collection period would be six months long, running from July 1, 2015 through December 31, 2015. It proposes that the first data reporting period would be three months long, starting on January 1, 2016 and running through March 31, 2016.[16] The agency proposes to "specify the form and manner for reporting applicable information in guidance prior to the first data reporting period" and that "applicable information must be reported in the form and manner specified by CMS."[17]

Some aspects of CMS's proposed data collection and reporting schedule may have been achievable if the agency had issued a final rule by the June 30, 2015 deadline set by Congress in Section 216 of PAMA. However, because CMS did not issue even a proposed rule by the June 30, 2015 deadline, the agency's proposed timeline is unrealistic. Laboratories should not bear the burden of the agency's failure to meet the statutory deadline.

The agency has stated that in determining what the data collection and reporting periods should be, its objectives were to "(1) Provide applicable laboratories sufficient notice of their obligation to collect and report applicable information to CMS; (2) allow applicable laboratories enough time to collect and report applicable information; (3) give CMS enough time to process applicable information to determine a CLFS payment rate for each laboratory test; and (4)

[15] 42 U.S.C. § 1395m-1(a)(1).
[16] 80 Fed. Reg. 59400.
[17] *Id*. at 59401.

publish new CLFS payment rates at least 60 days in advance of January 1 so laboratories will have sufficient time to review the data used to calculate CLFS payment rates and prepare for implementation of the new CLFS payment rates on January 1."[18] ACLA agrees with these objectives, and as such, we are recommending the schedule below that will enable all stakeholders to accomplish these objectives in a reasonable timeframe. As discussed in more detail below, for the initial data collection period and data reporting period, ACLA recommends the following:

Initial data collection period	January 1, 2016 – June 30, 2016
Final rule has been published; data collection and reporting guidance has been finalized	June 2016
Labs build information systems to collect and report data; period between end of data collection period and beginning of data reporting period	July 2016 – December 2016
Initial data reporting period	January 1, 2017 – March 31, 2017
CMS publishes preliminary weighted median payment rates	September 1, 2017
CMS publishes final weighted median payment rates	November 1, 2017
Weighted median payment rates take effect	January 1, 2018

Final rule and data collection and reporting guidance: The comment period for the proposed rule does not close until November 24, 2015, and it seems impossible for CMS to have issued a final rule by January 1, 2016 (the proposed start of the initial data reporting period). ACLA's recommended timeline is based on the reasonable assumption that CMS will not have published a final rule and final guidance on data collection and reporting until sometime well into 2016.

There is some suggestion in the proposed rule that CMS intends to issue subregulatory guidance prior to the issuance of a final rule, and it may even require applicable laboratories to report private payor rates prior to publication of the final rule, based on such subregulatory guidance. To be clear, ACLA believes that it is impermissible for CMS to issue subregulatory guidance interpreting various aspects of PAMA until it has issued the final rule. Much of the subregulatory guidance by necessity requires resolution in the final rule of certain issues, such as the meanings of "applicable laboratory," "applicable information," and "private payor rate." CMS cannot resolve those issues until it has had the opportunity to review all stakeholder comments and publish a final rule. Until all terms are defined and other issues are resolved, it is not appropriate for CMS to issue guidance on reporting and it certainly would not be possible for laboratories to comply. In the absence of a final rule and subregulatory guidance that reflects the substance of the final rule, laboratories cannot know whether they are required to report private payor data, what data they are to report to CMS, for what time period, and in what format.

[18] *Id.* at 59399.

It is reasonable to assume that it will take CMS until well into 2016 to complete the final rule and any subregulatory guidance. It is difficult to see how the new payment rates could go into effect on January 1, 2017. We recognize that this will mean that the schedule set out in the statute will not be met, owing primarily to the delay in the issuance of the proposed rule. This should not result in any serious legal consequences, as more time is necessary to implement the law than Congress may have anticipated.[19]

Period between final rule and initial data reporting period: The agency seeks to "provide applicable laboratories sufficient notice of their obligation to collect and report applicable information to CMS" and "allow applicable laboratories enough time to collect and report applicable information." To meet these objectives, laboratories need a period of at least six months between publication of the final rule and the start of the initial data reporting period. Congress contemplated this six month gap when it called for CMS to issue a final rule by June 30, 2015 and for data reporting to begin on January 1, 2016.[20] It will take time for laboratories to read and understand the final rule and their obligations under it, determine what "applicable information" they are required to collect, design and program internal information collection systems that meet the requirements of the final rule, troubleshoot, extract the information from their billing systems, and verify the accuracy of the data. Larger laboratories may be challenged by the sheer volume of data they must collect and report for each payor and test code, while smaller and medium-sized laboratories may have yet to develop information technology, coding, and/or billing resources equal to the task. We emphasize that the programming tasks associated with extracting the required information will be monumental, and those tasks must be completed while companies also are using their computer systems for routine functions such as submitting claims and posting and reconciling payments. Further, although many laboratories have begun to design the necessary programs to extract the required information from their billing systems, nothing can be finalized until CMS issues a final rule and any subregulatory guidance. In short, it is not reasonable for the data reporting period to start immediately after the release of a final rule (and certainly not before a final rule and any subregulatory guidance are released), as is envisioned in the proposed rule.

Initial data collection period: Given the amount of time it typically takes to finalize a rule this complex and ACLA's proposal for an initial data reporting period that begins at least six months after a final rule, we believe the initial data collection period should be January 1, 2016 through June 30, 2016. ACLA supports CMS's proposal that the first data collection period would span six months, both for clinical diagnostic laboratory tests ("CDLTs") and ADLTs. As we have conveyed to CMS in the past, we believe the agency should require laboratories to

[19] For example, Congress directed CMS to implement the Inpatient Rehabilitation Facility Prospective Payment System, effective for cost reporting periods beginning on or after October 1, 2000, yet CMS did not issue a final rule until August 7, 2001, and the rule was not effective until January 1, 2002. *See* 66 Fed. Reg. 41316 (Aug. 7, 2001). Another example is the Inpatient Psychiatric Rehabilitation Facility Prospective Payment System ("IPF PPS"), which Congress said was to be effective for cost reporting periods beginning on or after October 1, 2002. In the final rule, issued more than two years after the statutory implementation deadline, CMS said, "With respect to the creation of the IPF PPS, more lead time than usual was necessary" due to the complexity of the issues involved, and the payment system ultimately become effective for cost reporting periods starting on or after January 1, 2005. *See* 69 Fed. Reg. 66922 (Nov. 15, 2004).

[20] *See* 42 U.S.C. §§ 1395m-1(a)(1), 1395m-1(a)(12).

report as much data as the agency needs to calculate accurate market-based Medicare payment rates, but it should not require laboratories to report any more than necessary. When ACLA members evaluated their payment experience for six months of test claims, compared with 12 months of test claims, the resulting median payment amounts generally were consistent with each other. We believe that CMS is able to capture the data it needs, regardless of a test's volume or frequency, by requiring laboratories to report data for tests furnished and paid for in a six month period. Congress also contemplated a data collection period that would be six months or shorter for new ADLTs, indicating it viewed that amount of time as sufficient to gather relevant information on private payor rates.[21]

Initial data reporting period: ACLA recommends that the initial data reporting period should run from January 1, 2017 through March 31, 2017. We believe that if laboratories have adequate time between issuance of a final rule, including all subregulatory guidance, and the start of the reporting period, three months will be a sufficient amount of time to report applicable information.

In the first round of reporting applicable information, it is not reasonable for CMS to propose a data reporting period that begins immediately after the close of the data collection period. (And, as we discuss below, it is not a reasonable approach for subsequent data reporting periods, either.) Laboratories will be required to collect and report thousands, and in some cases hundreds of millions, of data points that include payors, rates, and volume. Expecting a designated official of the laboratory to attest to the completeness and accuracy of such a report, and expecting any laboratory to be able to report such information within 90 days of the close of a data collection period, is not realistic. It makes even less sense when CMS has proposed that the initial reporting period would begin before a final rule is issued.

CMS should amend the proposed regulation at 42 C.F.R. § 414.504(a) to read:

> (a) *General Rule.* In a data reporting period, an applicable laboratory must report applicable information for each CDLT furnished during the corresponding data collection period, as follows—
>
> > (1) For CLDTs that are not new CDLTs, every 3 years beginning January 1, 2017.
> >
> > (2) For ADLTs that are not new ADLTs, every year beginning January 1, 2017.

Preliminary weighted median rates: CMS should publish the preliminary weighted median rates around September 1, 2017, and CMS also should give stakeholders an opportunity to request that CMS review potentially inaccurate rates. Given the large amount of data that CMS will collect, it is reasonable to expect that errors will occur due to information management challenges and/or inaccurate calculations, especially with respect to the initial data reporting period. While the law precludes administrative or judicial review of payment amounts, it does

[21] 42 U.S.C. § 1395m-1(d)(2).

not prohibit CMS from establishing a process to accept requests for review of proposed rates.[22] Such systems already exist in other contexts in the Medicare program (*e.g.*, the PFS and the Hospital Outpatient Prospective Payment System ("OPPS")). Reporting preliminary rates sometime around September 1, 2017 would give the agency approximately five months to process applicable information to determine a Medicare payment rate for each laboratory test.

Final weighted median rates: We agree with CMS's proposal to publish final weighted median payment rates approximately 60 days in advance of their effective date. Our recommendation is that CMS should publish the rates initially around November 1, 2017 for a January 1, 2018 effective date. CMS should amend the proposed regulation at 42 C.F.R. § 414.507(a) to read: "Except as provided in paragraph (d) of this section, and § 414.508 and § 414.522, the payment rate for a CDLT furnished on or after January 1, 2018 is equal to the weighted median for the test…"

B. Subsequent Data Collection Periods and Data Reporting Periods

Data collection periods: CMS proposes that after the initial data collection period, subsequent data collection periods would be a full year, rather than six months.[23] For the reasons outlined above, ACLA believes that six months of data is sufficient, both for CDLTs and ADLTs. The weighted median rates derived from six months of private payor data has been found to be consistent with the weighted median rates derived from a full year of data. Continuing to base weighted median rates on six months of data also would mitigate laboratories' reporting burden. Further, a data collection period should be the first six months of the year prior to the year during which the data reporting period falls. This would provide laboratories with sufficient time during the second six months of the year to determine final total approved payment rates for each payor and test, prior to the data reporting period, which may include relevant discounts, rebates, coupons, and other price concessions applied annually by a payor.

CMS should amend its proposed definition of "data collection period" at 42 C.F.R. § 414.502 to read: "*Data collection period* is the first six months of the calendar year that precedes the year in which a data reporting period occurs."

Data reporting periods: CMS proposes that, like the initial data reporting period, subsequent data reporting periods would span the period between January 1 and March 31. ACLA does not object to a three month data reporting period, as long as there is a period of six months between the conclusion of a data collection period and the start of the data reporting period. Laboratories will continue to need time between the conclusion of a data collection period and the start of a data reporting period to go through the process of collecting final payment rates and assembling data.

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[22] *See* 42 U.S.C. § 1395m-1(h)(1). This refers to a formal review by an administrative law judge and to review of final administrative action in a federal court.
[23] 80 Fed. Reg. 59399.

CMS should amend its proposed definition of "data reporting period" at 42 C.F.R. § 414.502 to read: "*Data reporting period* is the initial 3-month period of the calendar year following the year in which a data collection period occurs and is the period during which an applicable laboratory reports applicable information to CMS."

Publication of preliminary and final weighted median rates: Each time CMS calculates weighted median rates from data that is collected and reported by applicable laboratories, it should publish preliminary weighted median rates in September of the data reporting period year, allow laboratories to request review of possibly erroneous weighted medians, and publish final weighted median rates around November 1 in the year before the rates are to take effect.

We expect that as CMS and laboratories gain experience during the initial data collection and data reporting periods, both the agency and stakeholders may develop proposals for how to adjust data collection and reporting schedules to decrease burdens while still yielding weighted median rates that accurately reflect the private payor market. This may include aggregated reporting in subsequent data collection and reporting periods, as authorized in the statute.[24] ACLA hopes to maintain an open dialogue with CMS about these issues in the coming years, and we hope that the agency is amenable to making adjustments, if needed, in future rulemakings.

III. Definition of "Applicable Information"

The statute requires an applicable laboratory to report "applicable information…for each clinical diagnostic laboratory test that the laboratory furnishes during [a data collection] period."[25] As defined in the statute, "applicable information" means "with respect to a laboratory test for a data collection period, the following: (i) the payment rate (as determined in accordance with paragraph (5)) that was paid by each private payor for the test during the period; (ii) the volume of such tests for each such payor for the period."[26] Paragraph 5, in turn, states that payment rates shall reflect "all discounts, rebates, coupons, and other price concessions…"[27] CMS's proposed definition at 42 C.F.R. § 414.502 reads: "*Applicable information* means, with respect to each CDLT for a data collection period—(1) Each private payor rate. (2) The associated volume of tests performed corresponding to each private payor rate. (3) The specific HCPCS code associated with the test. (4) Does not include information about a test for which payment is made on a capitated basis." Following are ACLA's recommendations for defining "applicable information."

A. Tests about which Applicable Information is to be Reported

1. Furnished and Paid During a Data Collection Period

When addressing "applicable information", the statute refers in one place to a test that a laboratory furnishes during a data collection period, and in another place, it refers to the payment

[24] 42 U.S.C. § 1395m-1(a)(6).
[25] 42 U.S.C. § 1395m-1(a)(1).
[26] 42 U.S.C. § 1395m-1(a)(3).
[27] 42 U.S.C. § 1395m-1(a)(5).

rate that was paid during the collection period. CMS's own definition for "applicable information" refers to "each CDLT for a data period," but the agency does not clarify in the preamble whether a "CDLT for a data period" is one that is furnished during the data period or paid during the data period or both.

The truest interpretation of the statute is that applicable information is to be reported about a test that an applicable laboratory both furnishes during the data collection period and for which the laboratory receives a final payment during the data collection period. In the statute, under the heading "In general", Congress directs applicable laboratories to report applicable information about "each clinical diagnostic laboratory test that the laboratory *furnishes during*" the data collection period.[28] Then, in the definition of "applicable information," Congress requires an applicable laboratory to report the payment rate "that was paid by each private payor for the test *during the period*."[29] Taken together, this indicates that the set of tests about which an applicable laboratory is to report applicable information are those that are furnished during a data collection period and that are fully paid during a data collection period.

This is the only truly workable solution. As CMS is aware, a laboratory is not paid by a private payor on the same day that it furnishes a test. By limiting the data set to those tests both furnished and paid during a data collection period, each applicable laboratory will be able to identify a discreet set of laboratory services about which it is to report information to CMS. Requiring information about tests that are furnished during a data collection period, regardless of when they are paid, would result in an applicable laboratory not being able to "close the data set" until the very last day of the data reporting period. This is because it would never know whether it was going to receive payment for a test and, consequently, whether it would need to change the volume of tests paid at a particular rate or add a new payment rate for a payor. Failing to establish a payment cut-off date also would make it impossible for a laboratory to develop and run a billing system query that captures all applicable information. Given the potentially serious consequences in the form of civil monetary penalties for an omission in reporting information to CMS, it is important that the data set be finite.

2. HCPCS Codes

Well in advance of a data reporting period, CMS should publish a list of HCPCS codes for which it expects applicable laboratories to report information. For various reasons, some tests that are offered by laboratories do not appear on the CLFS, especially if the test is contractor-priced or if no codes are available for the test. Presumably, these tests now would receive unique codes. Nevertheless, to avoid confusion, CMS should publish a list of those codes on which it expects laboratories to report applicable information.

B. Private Payor Rates

CMS must be clear what constitutes a "private payor rate." The proposed definition at 42 C.F.R. § 414.502 is: "*Private payor rate*, with respect to applicable information: (1) Is the

[28] 42 U.S.C. § 1395m-1(a)(1) (emphasis added).
[29] 42 U.S.C. § 1395m-1(a)(3)(A)(i) (emphasis added).

amount that was paid by a private payor for a CDLT after all price concessions were applied; (2) Includes any patient cost-sharing amounts if applicable." In most cases, the rates that private payors set for laboratory tests account not only for the amount that the insurer will pay, but also the patient's obligation. Patients also sometimes have deductibles to meet, meaning that a private payor may be involved in the rate-setting for a particular service, but the payor may shift responsibility for payment to the insured individual, depending on the structure and application of a deductible. In addition, some patients may have multiple payors on a claim (including a primary and secondary payor) that may have different rates allowed for the same claim.

To ensure consistency among reported rates, laboratories should report the final total approved payment rates for tests furnished during the reporting period, excluding information on those services for which appeals are outstanding and for which final rates are not yet determined. The approved payment rate should be the total "allowed amount", as that term is understood in the context of HIPAA 5010 transactions, and should include any copayment or coinsurance amounts, deductible amounts, and any other patient cost-sharing amounts. It appears that CMS intended to include all patient cost-sharing within the definition, and we recommend including "deductible amounts," as it was missing from the itemized list in the proposed rule.

CMS should amend its proposed definition of "private payor rate" to read:

> *Private payor rate*, with respect to applicable information:
>
> (1) is the allowed amount indicated on a remittance described at 45 C.F.R. § 162.1102(b)(2)(iii); and
>
> (2) includes any patient cost-sharing and deductible amounts, if applicable.

C. Exclusions from Reporting

CMS should amend its proposed regulation to allow a laboratory to exclude information about certain tests from its data reporting. It will be virtually impossible for a laboratory to ensure that it has captured every single test performed and every private payor rate for each test. Just as other Medicare reporting systems allow for the exclusion of certain data, we believe similar policies are necessary for reporting under PAMA. Removing information about certain claims from reporting would not have a material effect on the weighted medians that are calculated but would reduce the burden on applicable laboratories. Examples of payments that CMS should allow a laboratory to exclude from reporting are:

- Hard copy (manual) remittances where HCPCS-level payment data is not captured or the formatting of the hard copy remittance advice is not conducive to optical character recognition ("OCR") scanning;

- Manual remittances where the payor has grouped test-level payments into an encounter-level (claim-level) payment;

- Payments that were made in error, which oftentimes are corrected months after the incorrect payment was received;
- Bulk settlements;
- Payments that include post-payment activity such as recoupments;
- Payments from secondary payors;
- Payments that do not reflect specific HCPCS code-level amounts; and
- Other similar payments.

Due to the complexity and difficulty of reporting these rates and their associated volumes, and due to their minimal impact on the private payor market for laboratory tests, CMS should permit applicable laboratories to exclude these types of payments, should they occur, from reporting if the laboratories so choose. CMS should include language in the proposed definition of "applicable information" at 42 C.F.R. § 414.502 that reflects these exclusions and that allows some measure of flexibility for an applicable laboratory to exclude from reporting those payments where the administrative burden of discerning the payment rates and volume exceeds the value to CMS. The agency should issue subregulatory guidance after publication of the final rule to specify the information that laboratories may exclude from reporting.

D. Reporting Mechanism

The mechanism for reporting applicable information is a totally separate issue from the definition of "applicable laboratory" and should be flexible enough to meet the needs of a wide variety of applicable labs with vastly different sizes and structures. CMS should allow the entity reporting applicable information to be: (a) an applicable laboratory reporting its own applicable information, (b) a TIN-level entity that owns multiple applicable laboratories reporting in a single report on behalf of all of its applicable laboratories, or (c) a TIN-level entity reporting on behalf of its TIN-level subsidiaries and all of its subsidiaries' applicable laboratories, whether in a single report or at the subsidiary level. In each case, each applicable laboratory would be identified by its CLIA number, and CMS would get the same information about the volume of laboratory tests furnished at each private payor rate regardless of the entity reporting the applicable information.

Nothing in the statute prohibits this flexible approach, and efficiency demands it. While the statute requires applicable laboratories to report applicable information, it does not specify the manner in which such reports are to be made, and therefore it permits flexibility in the reporting mechanism, such as allowing entities that own or control multiple applicable laboratories to report the applicable information of those applicable laboratories on their behalf. Such consolidated reporting may be necessary for entities with centralized billing systems where the applicable laboratories themselves currently do not have the capability to report applicable information directly to CMS themselves. To demand them to do so would be prohibitively expensive, and would multiply unnecessarily the number of reports that CMS would have to

receive and analyze. The definition of "applicable laboratory" determines whose applicable information is to be reported, not who will report the applicable information. As long as the right data is reported, it should not matter who reports it to CMS.

E. Summary of Recommendations on "Applicable Information"

In sum, CMS should revise the proposed definitions at 42 C.F.R. § 414.502 to read:

> *Applicable information* means, with respect to each CDLT furnished and paid during a data collection period—
>
> (1) Each private payor rate.
>
> (2) The associated volume of tests that are furnished and paid during the data collection period that corresponds to each private payor rate.
>
> (3) The specific HCPCS code associated with the test.
>
> The following shall not be applicable information—
>
> (1) Information about a test for which payment is made on a capitated basis.
>
> (2) Information about a test for which CMS has determined that the administrative burden of collecting information outweighs the value of that information in determining private payor rates.
>
> (3) Information about a test for which appeals are outstanding or for which a final private payor rate has not been determined.
>
> *Private payor rate*, with respect to applicable information:
>
> (1) is the allowed amount indicated on a remittance described at 45 C.F.R. § 162.1102(b)(2)(iii); and
>
> (2) includes any patient cost-sharing and deductible amounts, if applicable.

IV. Advanced Diagnostic Laboratory Tests

A. Definition of an ADLT

Congress defined an ADLT as a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner) and that meets one of the following criteria: (1) The test is an analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm to yield a single patient-specific result; (2) the test is cleared or approved by the FDA; (3) the test meets other similar criteria established by the Secretary. We address CMS's interpretation of, and proposal for, each segment of this definition below.

1. Single Laboratory

CMS should change its proposed definition of "single laboratory" at 42 C.F.R. § 414.502. ACLA vehemently disagrees with CMS's proposal that "a single laboratory" offering and furnishing an ADLT would be one with a single CLIA certificate and that "an entity with multiple CLIA certificates would not be a single laboratory."[30]

The agency's proposal does not comport with the reality of how laboratories operate, and it would be an insurmountable barrier for many laboratories whose tests Congress meant to include among ADLTs. As you know, a separate CLIA certificate is required for each laboratory location.[31] There are several reasons why an ADLT developer may have more than one CLIA certificate, none of which is relevant to whether a laboratory sells the ADLT for use by another laboratory. For example, a laboratory may have a CLIA certificate for the laboratory facility where the ADLT service is performed and another CLIA certificate for a different facility that performs activities wholly unrelated to the ADLT service, such as research. Or, a laboratory may have a CLIA certificate for a laboratory facility where an ADLT service is performed, and due to higher-than-expected demand for its testing, it may have to open a new laboratory facility next door that then then is required to obtain its own CLIA certificate, simply because of its different mailing address or location. Or, a laboratory that developed, offers, and furnishes an ADLT may merge with another laboratory company that has its own CLIA certificate, creating a company with multiple CLIA certificates. Or, a laboratory may have multiple sites, each with its own CLIA certificate, but it furnishes the ADLT at only one of those sites. So long as the offering and furnishing laboratory does not sell the test for use by another laboratory, then the number of CLIA certificates the entity holds should not be relevant to whether a test can qualify as an ADLT.

CMS says that it believes the statute intends "to award special payment status to the one laboratory that is expending the resources for all aspects of the test—developing it, marketing it to the public, performing it, and selling it."[32] One laboratory may expend resources for all aspects of the test, but that "laboratory" is not necessarily an entity that holds only one CLIA certificate. It is possible for CMS to determine that a test is an ADLT without resorting to a cramped definition for "single laboratory" that is based on whether the ADLT developer holds more than one CLIA certificate.

The agency should amend the definition of a "single laboratory" to read: "*Single laboratory*, for purposes of an ADLT, means a laboratory and its parent corporation, wholly-owned subsidiaries, and other entities under common ownership, as applicable."

2. "Offered and Furnished" vs. "Marketed and Performed"

The statute says that an ADLT is one that is "offered and furnished" by a single laboratory. The words "offered and furnished" are sufficiently clear that CMS does not need to

[30] 80 Fed. Reg. 59396.
[31] 42 C.F.R. § 493.43(a).
[32] 80 Fed. Reg. 59396.

redefine them as "marketed and performed", and the terms "offered and furnished" are well-understood in the Medicare program. Furthermore, the words "offered and furnished" when read in the context of the statutory definition for an ADLT, indicate that the single laboratory furnishes the test and does not sell it as a kit to another laboratory so that the other laboratory may offer it and furnish it. It is not uncommon for a small laboratory to contract with a third party to provide marketing support while still performing and billing for its tests because of resource constraints. Some may misconstrue the proposed language as disqualifying a test offered by such a laboratory from ADLT status. This is not what Congress intended, and CMS should not complicate the definition by needlessly substituting its own words for those of Congress.

3. Multiple Biomarkers of DNA, RNA, or Protein

When it defined the term "ADLT" in Section 216 of PAMA, Congress could not have been clearer that a laboratory test can meet the first of the three criteria set forth above when it is an "analysis of multiple biomarkers of DNA, RNA, or proteins combined with a unique algorithm…" CMS has interpreted this simple phrase to mean that "a test must be a molecular pathology analysis of DNA or RNA" and that "an ADLT could include assays in addition to the biomarker assays," such as "a component that analyzes proteins" but that an analysis of multiple biomarkers of proteins combined with a unique algorithm cannot meet Congress's definition.

CMS must change the proposed regulation at 42 C.F.R. § 414.502 to comport with the statutory text. Proteins are included in the statute in the same way and in the same phrase as DNA and RNA. CMS has not offered any support for its interpretation that the statute requires that a "test analyze, at a minimum, biomarkers of DNA or RNA" and that the criterion is limited to molecular pathology analyses.[33] It cannot be that Congress included the words "or protein" in its definition of ADLT but intended that the words be ignored by CMS.

At its October 19, 2015 meeting, the Advisory Panel on Clinical Diagnostic Laboratory Tests ("Advisory Panel") discussed CMS's confounding omission of proteins from the definition, and it made a unanimous formal recommendation to CMS that the regulation should reflect the statutory text and include "DNA, RNA, or proteins".[34] During the meeting, the Advisory Panel moderator stated that CMS interpreted the word "advanced" in the statutory definition of ADLT to preclude the inclusion of a test made up of multiple biomarkers of proteins without analysis of biomarkers of DNA or RNA, as well. Several Advisory Panel members spoke in great detail about why protein testing is "advanced" and may even provide more information than DNA or RNA testing. Unlike DNA testing, which shows the "blueprint" for a patient's disease, protein testing can show how the body is acting upon this blueprint. The Advisory Panel issued a unanimous formal recommendation to CMS that the regulation should reflect the statutory langue and should not require the inclusion of a DNA or RNA marker and

[33] *Id*. at 59397.
[34] *See* Advisory Panel on Clinical Diagnostic Laboratory Tests, Voting results and recommendations as recorded from written ballots, Oct. 19, 2015, at 7, *available at* https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/Downloads/2015-10-19-Lab-Panel-Results.pdf.

exclude protein-only tests. The notion that protein-based tests cannot be "advanced" is unfounded.

It is not helpful that CMS states in the preamble to the proposed rule that it "would not disqualify a test from ADLT status consideration" if the test analyzes DNA or RNA and it also analyzes proteins.[35] Of course, there are tests that analyze only proteins and apply a unique algorithm to the analysis. There is no basis in the statutory text for CMS to disqualify such a test from consideration as an ADLT.

CMS must amend the relevant portion of the proposed definition of an ADLT to read: "Must be an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins…"

4. Patient-Specific Result

CMS has interpreted the requirement that an ADLT that is not FDA-cleared or –approved must "yield a single patient-specific result" to mean that the test must be diagnostic of a certain condition, a prediction of the possibility of an individual developing a certain condition or conditions, or the probability of an individual's response to a particular therapy or therapies.[36]

CMS should amend the proposed regulation so that it reflects the text of the statute. That is, the proposed regulation at 42 C.F.R. § 414.502 should read: "(ii) when combined with a unique algorithm, yields a patient-specific result." The Advisory Panel on CLDTs reached the same conclusion and recommended that the definition reflect the text of the statute. "Single patient-specific result" is sufficiently clear that it does not require further interpretation by CMS, and it is unwise for the definition of ADLT to be overly prescriptive in a way that may prevent otherwise qualified tests from being considered ADLTs in the future.

5. New Clinical Diagnostic Information

CMS should remove from its proposed definition of an ADLT the requirement that the test must "provide new clinical diagnostic information that cannot be obtained from any other existing test on the market or combination of tests." In the preamble to the proposed rule, CMS says that this proposed policy derives from its "view that ADLTs that meet the criterion are innovative tests that are new and different from any prior test already on the market and provide the individual patient with valuable genetic information to predict the trajectory of the patient's disease process or response to treatment of the patient's disease that could not be gained from another test or tests on the market."[37]

While the statute describes an ADLT's algorithm as unique, Congress did not intend that the information that comes from the test must be new and otherwise unobtainable. Additionally, CMS should encourage development of multiple diagnostic tools that seek to answer the same clinical answer using different methods in order to foster competition among test developers.

[35] 80 Fed. Reg. 59398.
[36] Proposed 42 C.F.R. § 414.502.
[37] 80 Fed. Reg. 59398.

ACLA objects to the inclusion of this additional criterion, which is more suitable for a coverage determination than for a determination of whether a test qualifies as an ADLT.

6. Definitions

In sum, CMS should revise its proposed definitions of "advanced diagnostic laboratory test" and "single laboratory" to read:

> *Advanced diagnostic laboratory test* means a CDLT covered under Medicare Part B that is offered and furnished only by a single laboratory and not sold for use by a laboratory other than the original developing laboratory (or a successor owner of that laboratory) and meets one of the following criteria:
>
> (1) The test—
>
> (i) must be an analysis of multiple biomarkers of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), or proteins;
>
> (ii) is combined with a unique algorithm to yield a single patient-specific result; and
>
> (iii) may include other assays.
>
> (2) The test is cleared or approved by the Food and Drug Administration.
>
> *Single laboratory*, for purposes of an ADLT, means a laboratory and its parent corporation, wholly-owned subsidiaries, and other entities under common ownership, as applicable.

B. Application to Qualify as an ADLT

The agency proposes to establish, through subregulatory guidance, a process through which a laboratory may apply for its test to qualify as an ADLT, and it proposes to do so prior to January 1, 2016. As a threshold matter, CMS should not issue subregulatory guidance to implement any aspect of the rule until after the rule has been finalized. CMS cannot create an application format or provide instructions to applicants about the standards for information they submit in an application for an ADLT because the definition of "ADLT" has not been finalized.

The statutory definition of an ADLT is straightforward, and the application process should be equally straightforward to minimize the administrative burden on CMS. Just as a laboratory's President, CEO, or CFO must attest to the completeness and accuracy of private payor data reported to CMS, one of these individuals should be required to attest to the information provided in an ADLT application. The attestation will be key to determining whether a test is offered and furnished by a single laboratory. The President, CEO, or CFO of the laboratory should be asked to attest that to the best of his or her knowledge, the laboratory is the only laboratory to offer and furnish the test and that the test is not sold for use by another laboratory. Supplying information in an application about the type(s) of biomarkers (DNA, RNA, and/or proteins), the number of biomarkers, the patient population, and application of the

score or patient-specific result will assist the agency in its determination of whether an applicant is the only laboratory offering and furnishing a test.

Only public information should be required to support an ADLT application. Published clinical data provides sufficient detail to support an ADLT application and show that the test is an analysis of biomarkers of DNA, RNA, or proteins combined with an algorithm that yields a single patient-specific result. A full review of the clinical and analytical validity and clinical utility of a test is unnecessary for an ADLT application, as a full technical review is conducted during the coverage process. Other publicly-available information also may be useful to support an ADLT application, such as patents and evidence of FDA-clearance or -approval. Congress clearly did not intend for a laboratory's confidential information to be necessary to determine whether a test meets the definition of an ADLT, as it did not confer protection from disclosure under the Freedom of Information Act to information included in an ADLT application. If a laboratory wishes to include in an ADLT information trade secrets or other confidential information, it should be allowed to do so, but it is not necessary for CMS to require any such information in an ADLT application.

C. Payment for New ADLTs

The statute says that for a new ADLT for which payment was not made under the CLFS as of the date of enactment of PAMA, during the "initial period of three quarters," the payment amount is based on the actual list charge for the laboratory test.[38] A laboratory is to report private payor data for an ADLT no later than the last day of the second quarter, and market rates are to apply after the initial three quarters.[39] We address aspects of the statutory requirements below.

1. New ADLT

CMS proposes to define a "new ADLT" as one for which payment has not been made under the CLFS prior to January 1, 2017. ACLA agrees with this proposal.

2. "Actual List Charge"

The statute defines the "actual list charge" as the "publicly-available rate on the first day at which the test is available for purchase by a private payor."[40] CMS expands upon this and proposes a definition at 42 C.F.R. § 414.502 for "actual list charge," meaning "the publicly available rate on the first day the new [ADLT] is obtainable by a patient who is covered by private insurance, or marketed to the public as a test a patient can receive, even if the test has not yet been performed on that date." CMS should not finalize its proposed definition. Instead, CMS should adopt the definition that Congress included in the statute, which is clear and gives laboratories sufficient guidance.

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[38] 42 U.S.C. § 1395m-1(d)(1)(A).
[39] 42 U.S.C. § 1395m-1(d)(2-3).
[40] 42 U.S.C. § 1395m-1(d)(1)(B).

3. "Initial Period of Three Quarters"

CMS proposes that the "initial period of three quarters" would begin on the first day of the first full calendar quarter following the first day on which an ADLT is "performed."[41] CMS should amend this proposal so that the "initial period of three quarters" begins on the first day of the first full calendar quarter following the first day on which the ADLT is paid for by Medicare. ACLA has several reasons for making this recommendation to CMS.

Congress did not say to which "initial three quarters" it was referring. Because the issue is payment for a new ADLT by Medicare, the date on which the test is performed on a commercially-insured patient or in a clinical trial is not relevant. Payment for an ADLT by Medicare will not come until after CMS designates a test as an ADLT, the agency assigns the ADLT a unique code, and a Medicare Administrative Contractor makes a coverage determination, which can come long after a test first is "performed." Indeed, if the clock starts to run on the first day the test is offered to the public, the entire three quarters may pass before a test is covered and paid by Medicare. In that case, the entire reporting process for new ADLTs would be irrelevant, which is an unreasonable result, given Congress' explicit directions on this issue.

Further, not long after the start of the first of the "initial three quarters," a laboratory will have to report private payor data to CMS for the new ADLT. If the "initial three quarters" begins at the start of the quarter after the day when test first is performed, the laboratory may not have sufficient private payor data to report, which will not give CMS adequate data to develop a truly market-based rate. By starting the "initial three quarters" after the date that an ADLT is paid for by Medicare, CMS is likely to get more private payor data in the initial reporting period for the ADLT and be able to calculate a weighted median payment rate that more accurately reflects the private payor market.

CMS should amend the proposed regulation at 42 C.F.R. § 414.504(c) to read: "A laboratory seeking a new ADLT status for its test must, in its new ADLT application, attest to the actual list charge." Because the "initial three quarters" will start on the first day when the ADLT is paid for by Medicare, it is not necessary for the laboratory to attest to "the date the new ADLT is first performed." Information will be readily available to the agency about the first day the test is paid for by Medicare, making an attestation regarding that fact unnecessary.

V. Coding

The statute requires the Secretary to adopt temporary HCPCS codes (effective up to two years) to identify new ADLTs and new laboratory tests that are cleared or approved by the Food and Drug Administration. For an existing ADLT or FDA-cleared or –approved test (paid under Medicare Part B before April 1, 2014) that does not have a unique HCPCS code, the Secretary is

[41] 80 Fed. Reg. 59408.

to assign a unique HCPCS code for the test and publicly report the payment rate for the test.[42] CMS proposes to assign a unique G-code to each such test.

CMS no longer can meet the deadline set forth in the statute to assign unique HCPCS codes to existing ADLTs and FDA-cleared or –approved tests by January 1, 2016.[43] The agency currently does not have information about the universe of existing FDA-cleared or –approved tests that may require new codes. Therefore, CMS cannot include the codes and payment amounts on the electronic CLFS payment file it makes available prior to January 1, 2016, as proposed in the preamble, and it should not do so until after a final rule is issued.

A unique HCPCS code should be assigned for an ADLT or an FDA-cleared or –approved test if a laboratory or manufacturer requests a unique code, but CMS should not automatically issue a new code for every distinct existing ADLT or FDA-cleared or -approved test. Automatically assigning new codes to all such tests would generate a tremendous number of new codes that would have to be crosswalked to existing CPT codes.

The statute does not specify whether the HCPCS codes must be Level I or Level II HCPCS codes. ACLA prefers for the American Medical Association's ("AMA's") Common Procedural Terminology ("CPT") Editorial Panel to assign HCPCS codes to ADLTs and FDA-cleared or –approved tests, instead of CMS assigning HCPCS Level II G-codes to the tests. As you know, G-codes are viewed as Medicare-only codes by other payors and generally are not accepted, and using them can be an administrative burden for laboratories and other healthcare providers, particularly if the purpose is to collect private payor rates for purposes of rate-setting. We are encouraged by the AMA CPT Editorial Panel's efforts to craft a solution to the problem posed by assignment of G-codes, and we are looking forward to hearing the details of any such potential solution.

VI. Data Integrity

A. Civil Monetary Penalties

The statute allows the Secretary of HHS to impose a civil monetary penalty ("CMP") for an applicable laboratory's failure to report or for misrepresentation or omission in reporting applicable information. CMS proposes regulatory language to implement this provision of the law that is similar to the regulation at 42 C.F.R. § 414.806 on CMPs for misrepresentations by pharmaceutical manufacturers reporting Average Sales Price for drugs covered under Medicare Part B. As we have recommended with other parts of the law, CMS should not issue any clarifying guidance on this provision until after publication of a final rule.

The severity of the proposed CMP – $10,000 per day per violation – warrants the agency's reconsideration. If left unchanged, the proposed timeline could expose many laboratories unfairly to draconian punishment for failure to comply with reporting requirements, even though the compressed reporting schedule would not be the laboratories' own fault.

[42] 42 U.S.C. § 1395m-1(e).
[43] 42 U.S.C. § 1395m-1(e)(2).

B. Certification

To implement the provision of the statute requiring an officer of an applicable laboratory to certify the accuracy and completeness of applicable information reported by the lab, CMS proposes that the President, CEO, or CFO of an applicable lab may sign such a certification statement, or it may be signed by an individual who has been delegated authority to sign for, and reports directly to, one of those officers. The certification would be that the applicable information provided is "accurate, complete, and truthful, and meets all the reporting parameters."[44] CMS proposes to provide additional parameters for such a certification in subregulatory guidance before January 1, 2016.

CMS should create a certification form for applicable laboratories to submit with information they report, similar to the form used for reporting Medicare Part B ASP information.[45] Like the ASP certification form, the applicable information form should include the following language: "All information and statements made in this submission are true, complete, and current to the best of my knowledge and belief and are made in good faith." Given that most laboratory Presidents, CEOs, and CFOs are not – and cannot be – personally familiar with the volume and private payor rates for each laboratory test their labs offer, a laboratory officer should be expected to certify only to his or her good-faith belief in the data's integrity and that he or she does not have any information to the contrary.

VII. Local Coverage Determinations and Medicare Administrative Contractors

When PAMA became law in 2014, we were encouraged that it included language to ensure that local coverage determinations ("LCDs") henceforth are to be developed according to the process already spelled out in Section 1869 of the Social Security Act and implementing regulations. Coverage policies for clinical diagnostic laboratory tests have been issued recently through less formal processes, such as articles, without following the existing notice-and-comment requirements of the Social Security Act. We are disappointed that CMS does not make any proposals for implementing or enforcing this section of the statute.

PAMA also permits the Secretary to designate one or more (not to exceed four) Medicare Administrative Contractors ("MACs") to establish coverage policies or establish coverage policies and process claims for CDLTs. Of utmost importance to us is the fairness and transparency of coverage and payment processes, rather than the number of MACs that are involved. We agree with CMS's approach, which is to proceed cautiously before making any such changes, and to determine the feasibility and desirability of assigning coverage and claims processing functions for laboratory tests to fewer MACs. We also agree with CMS about the potential problems with a smaller number of MACs making coverage determinations that then would have to be implemented by other A/B MACs. ACLA hopes to continue a dialogue with CMS about this in the future and to work with the agency on implementation, if CMS and stakeholders determine that it would be appropriate.

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[44] 80 Fed. Reg. 59402.

[45] Average Sales Price Data Addendum B, *available at*: https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Part-B-Drugs/McrPartBDrugAvgSalesPrice/Downloads/aspdata_addendumb.pdf.

VIII. Subregulatory Guidance

CMS plans to issue subregulatory guidance to implement many important provisions of the law, and the details of many of those provisions can have a material impact on how Medicare pays for clinical laboratory tests and on applicable laboratories' operations. These include the method for reporting applicable information, the application for ADLT status, certification to the accuracy and completeness of reported data, and the imposition of civil monetary penalties. As we have stated throughout our comments on the proposed rule, we do not believe that CMS should issue any subregulatory guidance to implement any portion of the reporting system until after it has published a final rule addressing all substantive issues, including those identified in these comments. When CMS does issue subregulatory guidance, as part of the agency's ongoing collaboration with laboratories and other interested stakeholders on implementation of PAMA, the agency should issue the guidance in draft form first, to allow interested stakeholders to provide input and suggestions before guidance is finalized.

* * * * *

Thank you for your consideration of ACLA's comments on the proposed rule to implement Section 216 of PAMA. It is of utmost importance to ACLA's members, and ultimately to Medicare beneficiaries, that CMS implements the law in a way that results in fair and accurate market-based prices for clinical laboratory tests and that causes the least disruption to the clinical laboratories reporting data to the agency. We look forward to our continued work with CMS and remain available to assist the agency in any way we can.

Sincerely,

Alan Mertz, President
American Clinical Laboratory Association

APPENDIX A

	$ Expenditures	% Non-Patient Expenditures	% Total CLFS
A. Independent Laboratories	$ 3,769	53%	41%
B. Physician Office Laboratories and Other	$ 1,263	18%	14%
C. Hospital Non-Patient*			
1. Non-Patient Carrier Claims	$ 133		
2. Non-Patient OPPS Excluded (lab svc. only)	$ 1,474		
3. Non-Patient Inst. Claim (14X bill type)	$ 508		
Hospital Non-Patient Total	$ 2,115	30%	23%
Total Non-Patient CLFS Spending	**$ 7,147**	**100%**	**78%**
D. Hospital OPPS Patient Excluded (includes non-lab services)**	$ 1,993		22%
Total CLFS Spending	**$ 9,140**		**100%**
E. Hospital Packaged Laboratory Services			
1. IPPS (imputed)	$ 5,570		
2. OPPS (imputed)	$ 199		
Total Hospital Packaged Laboratory Spending	**$ 5,769**		

*Non-Patient is a patient where no non-laboratory outpatient or inpatient services were filed on the same day claim.

**OPPS Excluded claims, which include non-lab services, moved from CLFS spending to the OPPS bundles beginning with 2014 claims.

APPENDIX B

As discussed in Section I.A., to calculate a hospital's total laboratory Medicare revenues, it is necessary to develop an adjustment factor that a hospital can apply to its inpatient and outpatient Medicare revenues to determine the percentage that is attributable to laboratory services. The Moran Company calculated this percentage based on the information in the table in Appendix A.

As the table in Appendix A shows, in certain situations (line C.2), hospitals furnished only laboratory services to outpatients; in 2013, hospitals were paid $1.474 billion for this type of service. In other situations (line C.3), hospitals furnished laboratory services to non-patients; hospitals were paid $508 million in 2013 for this type of service. In both of these situations, hospitals competed directly with independent laboratories. Thus, $1.982 billion of Part B laboratory services were provided by hospitals in situations where they acted as independent laboratories.

The Moran Company determined what percentage of inpatient and outpatient bundled Medicare payments were attributable to laboratory services. The Moran Company took the laboratory charges included in inpatient and outpatient Medicare claims and applied the hospitals' specific payment-to-charges ratios to the amounts shown and totaled the results. Based on the analysis, the Moran Company determined that of all inpatient and outpatient services furnished by hospitals to Medicare beneficiaries, $5.769 billion was for laboratory services (line E.1 plus line E.2). That is the amount that the Medicare program paid for laboratory services that were part of inpatient and outpatient Medicare bundled payments.

Then, the Moran Company determined the share of all hospital services that were represented by laboratory services to develop the "adjustment factor". That calculation is shown below.

A	B	C	D	E	F
Description of services	Payments for outpatient hospital services	Payments for inpatient hospital payments (excluding DSH and IME payments)	Total inpatient and outpatient payments (Col. B + C)	Payments from hospital lab services*	Hospital lab service payments/total inpatient and outpatient services (Col E/D)
OPPS/IPPS claims	40.88	121.95	162.83	9.744	6%

* *Total of lines C.2, C.3, D., E.1, and E.2.*

To determine whether a hospital is an "applicable laboratory" under the "majority of Medicare revenues" test, the hospital would calculate the "denominator" by applying the adjustment factor of 6 percent to its inpatient and outpatient bundled Medicare revenues and then adding its other separately-paid laboratory revenues (payments made under the CLFS and PFS). The "nominator" would be the sum of the hospital laboratory's Medicare revenues under the

CLFS and PFS. If more than 50 percent of the hospital laboratory's total Medicare revenues is from the CLFS and PFS, the hospital would be considered an "applicable laboratory."