September 10, 2018

Ms. Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
P.O. Box 8016
Baltimore, Maryland 21244-8016

American Clinical Laboratory Association

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2019; Proposed Rule (CMS-1693-P)

Dear Ms. Verma,

The American Clinical Laboratory Association ("ACLA") is pleased to submit these comments on the proposed rule addressing the Medicare Physician Fee Schedule ("PFS") for CY 2019 and other issues ("Proposed Rule").[1] ACLA is a non-profit association representing the nation's leading clinical and anatomic pathology laboratories, including national, regional specialty, end-stage renal disease, hospital, and nursing home laboratories. The clinical laboratory industry employs nearly 277,000 people directly and generates over 115,000 additional jobs in supplier industries. Clinical laboratories are at the forefront of personalized medicine, driving diagnostic innovation and contributing more than $100 billion annually to the nation's economy. ACLA's comments on the Proposed Rule are focused primarily on provisions related to Section 216 of the Protecting Access to Medicare Act of 2014 ("PAMA")[2] and its implementation, and on direct practice expense supply inputs for pathology services.

A. PAMA

1. Statutory and Regulatory Background

Section 216 of PAMA requires most "applicable laboratories" to report information about payments received from private payors and to do so every three years.[3] The weighted medians derived from this "applicable information" become payment rates under the Medicare Clinical Laboratory Fee Schedule ("CLFS") and stay in place for three years, until after the next data collection period and data reporting period. An "applicable laboratory" is defined in the statute as "a laboratory that, with respect to its revenues under this subchapter, a majority of such revenues are from this section, section 1833(h), or section 1848. The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary deems appropriate."[4] CMS's regulatory definition of "applicable laboratory" currently reads:

[1] 83 Fed. Reg. 35704 (Jul. 27, 2018).
[2] Pub. L. 113-93.
[3] 42 U.S.C. § 1395m-1(a)(1). Reporting for advanced diagnostic laboratory tests ("ADLTs") is annual.
[4] 42 U.S.C. § 1395m-1(a)(2). Section 1833(h) of the Social Security Act governs the CLFS, and section 1848 governs the Physician Fee Schedule ("PFS").

> *Applicable laboratory* means an entity that:
>
> (1) Is a laboratory, as defined in § 493.2 of this chapter;
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> (2) Bills Medicare Part B under its own National Provider Identifier (NPI);
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> (3) In a data collection period, receives more than 50 percent of its Medicare revenues, which includes fee-for-service payments under Medicare Parts A and B, Medicare Advantage Payments under Part C, prescription drug payments under Part D, and any associated Medicare beneficiary deductible or coinsurance for services furnished during the data collection period from one or a combination of the following sources:
>
> (i) This subpart G;
>
> (ii) Subpart B of this part.
>
> (4) Receives more than $12,500 of its Medicare revenues from this subpart G…

In the first data reporting period in early 2017, just 0.7 percent of laboratories paid under Medicare Part B in 2015 reported applicable information to CMS – 1,942 out of 261,524 labs.[5] Only 658 independent labs reported applicable information to CMS – 20 percent of all independent labs paid under Medicare Part B. Just over 1,100 physician office labs ("POLs") reported applicable information to CMS – one half of one percent of all POLs paid for lab services under Medicare Part B in 2015. And 21 hospital outreach labs reported applicable information to the agency, representing one percent of all reporting entities and less than one half of one percent of all hospital labs paid under Medicare Part B for lab services in 2015. The volume of applicable information CMS received from independent labs, POLs, and hospital labs was far out of proportion to their respective shares of CLFS volume. Independent labs submit about half of all CLFS claims, yet they submitted more than 90 percent of the applicable information during the first data reporting period. Hospitals, in contrast, submit just over one quarter of CLFS claims, yet they reported only one percent of the applicable information CMS received in 2017.[6]

2. PAMA Provisions in the Proposed Rule

In the Proposed Rule, CMS says it is responding to stakeholder "concern that CY 2018 CLFS payment rates are based on applicable information from only a relatively small number of laboratories" and "because most hospital-based laboratories were not applicable laboratories, and therefore, did not report applicable information during the initial data reporting period, the CY 2018 CLFS payment rates do not reflect their information and are inaccurate."[7] The agency says that one of its objectives is "to obtain as much applicable information as possible from the broadest possible representation of the national laboratory market on which to base CLFS payment

[5] Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payor Rate-Based System ("Summary") at 3, *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf.
[6] *Id*.; 2016 Physician/Supplier Procedure Summary file; 2015 Outpatient Standard Analytic file.
[7] 83 Fed. Reg. 35856.

amounts, for example, from independent laboratories, hospital outreach laboratories, and physician office laboratories, without imposing undue burden on those entities" and that "it is important to achieve a balance between collecting sufficient data to calculate a weighted median that appropriately reflects the private market rate for a [clinical diagnostic laboratory test], and minimizing the reporting burden for entities."[8]

CMS proposes one change to the regulations implementing Section 216 of PAMA that it says would help it achieve its goal, involving removal of Medicare Advantage payments from the denominator of the "majority of Medicare revenues" threshold calculation.[9] CMS also is soliciting comments, but is not making any concrete proposals, on "other approaches that have been requested by some stakeholders who have suggested that such approaches would result in CMS receiving even more applicable information to use in establishing CLFS payment rates."

3. CMS has an opportunity to broaden the number and types of laboratories that report "applicable information" in the upcoming data reporting period, yet its proposed approach would fall far short of this goal.

ACLA agrees with the agency that payment rates under the CLFS should be based on applicable information reported by "the broadest possible representation of the national laboratory market" and that all entities that comprise the laboratory testing marketplace should have their private payor rates and volumes reflected in CLFS rates. Congress intended that all sectors of the laboratory market are to be represented in private payor rates reported to CMS, including hospital outreach laboratories.[10] If Congress meant to exclude all hospitals from the universe of "applicable laboratories," it easily could have done so directly, but it did not. ACLA remains committed to the principles that under the statute, the applicable information reported to CMS should accurately reflect all segments of the clinical laboratory market (independent laboratories, POLs, and hospital outreach laboratories); that all applicable laboratories should report applicable information, as required by law; that CMS should validate the applicable information that has been reported to it; and that the reporting burden on applicable laboratories should be minimized.

The one proposal that CMS has made, and the other concepts it discusses, would do very little to help the agency meet its objective of broadening the range of applicable labs that report applicable information, increasing the amount of applicable information that is reported, and calculating a weighted median for each test that appropriately reflects private market rates. The proposal regarding Medicare Advantage payments' removal from "Medicare revenues" should be implemented, but it is unlikely to move the needle with respect to the inclusion of more hospital outreach laboratories among the entities reporting applicable information. CMS did not make any

[8] *Id*.
[9] *Id*.
[10] 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."

other proposals for how it would achieve its goal of "obtain[ing] as much applicable information as possible from the broadest possible representation of the national laboratory market," and its own comments on other approaches put forth by stakeholders suggest that it is not committed to implementing them.

To collect applicable information that truly reflects the national laboratory market, CMS must correct its regulatory definition of "applicable laboratory" and make the definition consistent with the statutory text. CMS must remove the requirement that only an entity that bills Medicare Part B under its own NPI can qualify as an applicable laboratory. This condition is contrary to the statute, it exempts large numbers of laboratories from their reporting obligations, and it far exceeds CMS's lawful authority. Congress authorized CMS to exclude laboratories from the definition of "applicable laboratory" only in narrow circumstances and through setting a low expenditure or low volume threshold. CMS's approach has the effect of removing virtually all hospital outreach labs from the universe of applicable laboratories, violating the statute and frustrating the agency's stated goal of collecting private payor data from the broadest possible representation of the national laboratory market.

CMS also must implement aggressive education efforts directed at independent laboratories, POLs, and hospital outreach laboratories about how to determine if they qualify as applicable laboratories. And CMS must investigate applicable laboratories that are required to report applicable information but fail to do so, and take appropriate enforcement action against them. As we discuss below, the HHS Office of Inspector General ("OIG") estimated that far more laboratories would report applicable information than the number that actually did so, and it even identified 20 high-volume laboratories that it believes likely were obligated to report applicable information but did not. We agree with the OIG that "complete and accurate data are essential to setting payment rates for lab tests, and CMS should address challenges from 2017 to ensure data quality in the future," including additional outreach and education, and perhaps using its authority to impose civil monetary penalties if labs fail to report data, or if they misrepresent or omit reported data.[11] CMS can and should do more to faithfully implement the statute and make certain that all applicable laboratories that are required to report applicable information do so.

4. Medicare Advantage Payments

a) CMS should exclude Medicare Advantage payments and Part D payments from "Medicare revenues" for purposes of the "majority of Medicare revenues" threshold.

The agency is proposing to amend section (3) of the regulatory definition of "applicable laboratory" to exclude Medicare Advantage payments from the denominator of the "majority of Medicare revenues" test, in part because "it is more logical to not consider Medicare Advantage payments under Part B to be both Medicare revenues for determining applicable laboratory status and private payor rates for purposes of reporting applicable information."[12] ACLA agrees with this assessment. In our comments on the proposed rule to implement Section 216 of PAMA,[13] we

[11] Setting Medicare Payment Rates for Clinical Diagnostic Laboratory Tests: Strategies to Ensure Data Quality, OEI-09-17-00050 (July 2018), *available at* https://oig.hhs.gov/oei/reports/oei-09-17-00050.pdf.
[12] 83 Fed. Reg. 35856.
[13] 80 Fed. Reg. 59386 (Oct. 1, 2015).

urged CMS to exclude Medicare Advantage payments from the denominator because, per the statute, those payments are included among the private payor payments about which applicable laboratories would report applicable information.[14]

CMS also should interpret the statutory phrase as not including "prescription drug payments under Medicare Part D." We agree with CMS that it is reasonable to interpret "Medicare revenues" as not including Medicare Advantage payments received by a laboratory, and it also is reasonable to read the statutory text as not encompassing Part D payments. Part D payments' inclusion is illogical, because there is no circumstance under which such payments would be related to laboratory testing.

b) CMS's "Estimation of Increased Reporting" is flawed.

While we agree with CMS's proposal that "Medicare revenues" is reasonably interpreted as not including Medicare Advantage payments, we disagree conceptually with CMS's "Estimation of Increased Reporting" under the proposal.[15] The agency estimates that excluding Medicare Advantage payments from total Medicare revenue would increase the number of reporting laboratories by 43 percent, resulting in approximately 2,777 laboratories reporting applicable information, up from 1,942 in the 2017 data reporting period. However, according to the OIG's estimates, the number of laboratories that should have reported applicable information in the first data reporting period is far higher than 1,942, and this number should not be used as a baseline to compare the effects of any proposed policy change. Far fewer laboratories reported data than the OIG estimated would be required to report their private payor data. The OIG estimated that five percent of all laboratories paid under Medicare Part B, or about 12,500 laboratories, would qualify as applicable laboratories and would be required to report information to CMS.[16] In reality, only 0.7 percent of laboratories paid under Medicare Part B reported applicable information to CMS.

The OIG identified at least 20 high-volume independent labs that likely met the "majority of Medicare revenues" criterion but did not report their data in 2017.[17] Additionally, 80 TIN-level entities registered to report applicable information but then reported no applicable information. CMS guessed that the reporting entities "may have determined during the process that they do not have component laboratories that meet the definition of applicable laboratory and therefore are not subject to reporting requirements."[18] The agency offered no support for this supposition. It is just as likely that some or all of the 80 TIN-level entities simply failed to meet their legal obligation to report applicable information to CMS.

There is a large discrepancy between the number of applicable laboratories that the OIG estimated would be required to report applicable information to CMS and the number of

[14] 42 U.S.C. § 1395m-1(a)(8)(B).
[15] 83 Fed. Reg. 36047.
[16] Office of Inspector General, Medicare Payments for Lab Tests in 2015: Year 2 of Baseline Data (OEI-09-16-00040) at 7, *available at* https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf.
[17] OEI-09-17-00050 (July 2018).
[18] Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System at 4 (Sept. 22, 2017), *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf.

laboratories that actually reported. CMS still has not said if it investigated whether any of the 80 registered TIN-level entities that did not report applicable information were under an obligation to do so. Nor has CMS said if it made any efforts to identify the more than 10,000 laboratories that the OIG included in its estimate of applicable laboratories that did not report information to CMS, or if it will ask the OIG for information about the 20 high-volume laboratories that most likely qualified as applicable laboratories but failed to report applicable information. It is critical that CMS does so, because receipt of applicable information from all of these laboratories could have had a material effect on the weighted medians CMS calculated, especially for the highest volume test codes.

5. Adjustment of the Low-Expenditure Threshold

Currently, an entity must receive more than $12,500 in CLFS revenues during a data collection period in order to be considered an "applicable laboratory."[19] In the Proposed Rule, CMS offers two conflicting proposals. On one hand, it suggests decreasing the low expenditure threshold to $6,250 because "some physician office laboratories and small independent laboratories that are not applicable laboratories because they do not meet the current low expenditure threshold may still want to report applicable information despite the administrative burden associated with qualifying as an applicable laboratory."[20] On the other hand, it suggests increasing the low expenditure threshold to $18,750 "because many small laboratories may not want the additional administrative burden of data collection and reporting and, because their test volume is relatively low, their data is unlikely to have a meaningful impact on the weighted median of private payor rates."[21] The agency does not state whether it has a preference for one approach or the other.

ACLA does not support increasing the low expenditure threshold because doing so would whittle away at the already low number of reporting laboratories, which is inconsistent with CMS's stated goal of ensuring reporting by "the broadest possible representation of the national laboratory market". ACLA would not oppose decreasing the low-expenditure threshold, but it may not be necessary if CMS adopts other changes ACLA suggests. The agency can accommodate those laboratories that do not meet the low expenditure threshold but that seek to report applicable information by removing the following language from the regulations: "Applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory."[22] The statute authorizes CMS to exempt certain laboratories from the reporting requirements; it does not authorize CMS to prohibit laboratories from reporting information. CMS's prohibition does not appear in the statute, it is not inferable from the statute, and it is detrimental to achieving the goal of acquiring applicable information in the most efficient and effective manner possible. All laboratories that submit Medicare claims for services payable under the CLFS are subject to the rates developed using applicable information, and they should be permitted to report data even if they do not meet the low expenditure threshold.[23] CMS has never said whether or how it would

[19] 42 C.F.R. § 414.502.
[20] 83 Fed. Reg. 35861.
[21] *Id.*
[22] 42 C.F.R. § 414.504(g).
[23] CMS has acknowledged that during the first data reporting period, it received applicable information from laboratories that did not meet the definition of "applicable laboratory" and that it used those laboratories' information in its calculations of weighted medians, indicating that the agency would be comfortable with this approach. *See*

enforce the regulatory prohibition; while the regulatory text includes the possibility of civil monetary penalties for failure to report or for misreporting data, the agency never proposed or finalized any penalties for violating the prohibition. The regulatory prohibition should be removed entirely.

6. Use of 14X Bill Type for "Majority of Medicare Revenues" and "Low Revenues" Threshold

A 14X bill type is used only by a hospital outreach laboratory, the kind of hospital laboratory that functions in the marketplace like an independent laboratory. CMS is seeking input on a revision of the definition of "applicable laboratory" that would account for revenues identified on a 14X bill type, instead of revenues associated with the NPI the laboratory uses, to determine whether a laboratory is an applicable laboratory.

In addition to removing the requirement that an applicable laboratory is an entity that bills Medicare Part B under its own NPI, CMS should amend the definition of "applicable laboratory" to make clear that for the purpose of determining whether an entity receives a majority of its Medicare revenues under the CLFS and/or PFS, "Medicare revenues" means payment for claims submitted on a CMS 1500, a CMS 1450 using a 14X bill type, or their electronic equivalents. A 14X bill type is used only to submit claims for hospital laboratory outreach (non-patient) claims, so this approach would account only for the hospital laboratory business that competes in the marketplace with independent clinical laboratories. The revised definition would not have the effect of excluding from the definition of "applicable laboratory" any laboratory that already reported private payor data to CMS. It also would effectuate Congress' intent to determine whether a majority of Medicare revenues attributable to the laboratory – as opposed to the entire hospital – was from the CLFS and/or PFS.

CMS questions "whether hospitals would have sufficient time after publication of a new final rule that included using the form CMS-1450 14X bill type, and any related subregulatory guidance, to develop and implement the information systems necessary to collect private payor rate data before the start of the next data collection period, that is, January 1, 2019."[24] We believe this is a non-issue, for two reasons. First, the final rule implementing Section 216 of PAMA was not released until June 17, 2016 (less than two weeks prior to the end of the first data collection period), then CMS released subregulatory guidance even after the start of the first data reporting period on January 1, 2017.[25] Yet reporting applicable laboratories managed to "develop and implement the information systems necessary to collect private payor rate data" and to report it, even with this remarkably difficult regulatory schedule. Surely, hospitals could manage gathering private payor data with a regulation finalized two months before the start of the data collection period, if other applicable laboratories could manage to do so with a rule finalized only two weeks before the end of the data collection period. Second, it takes far more time for a hospital laboratory

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"Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule (CLFS) Private Payor Rate-Based Payment System" at 4 (Sept. 22, 2017), *available at* https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ClinicalLabFeeSched/Downloads/CY2018-CLFS-Payment-System-Summary-Data.pdf.

[24] 83 Fed. Reg. 35859.

[25] *See* "Additional Guidance for Clinical Laboratories as Data Reporting Begins" (Jan. 4, 2017), *available at* https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/SE17002.pdf.

to begin submitting claims under its own NPI than it would to develop systems to collect applicable information. Obtaining an NPI itself is not time-consuming. However, the process of re-credentialing with each and every private payor and State Medicaid program under a new NPI can take more than a year and a tremendous amount of administrative resources, and this is a condition precedent to submitting claims and getting paid by private payors for laboratory services. Based on information shared by ACLA hospital members, we believe that for this and other business reasons, very few hospital outreach laboratories would obtain unique NPIs separate from the hospitals', solely so they could report applicable information to CMS. We do not believe that CMS is authorized to impose the requirement that only a laboratory that bills Medicare Part B under its own NPI qualifies as an applicable laboratory in any event, but it also is a far more burdensome process for a hospital laboratory than collecting private payor rate information.

The agency worries that under the 14X bill type proposal, "revenues attributed to the hospital outreach laboratory would have to be calculated in every instance where those services exceeded the low expenditure threshold. This would be true even for a hospital outreach laboratory that performs relatively few outreach services under Medicare Part B." This simply means that hospital outreach laboratories would have the same obligations as every other laboratory that exceeds the low expenditure threshold and that serves non-hospital patients. It appears that CMS's most acute concern with this approach is that it would result in all hospital outreach laboratories meeting the majority of Medicare revenues threshold. This is true for almost all independent laboratories, as well, and hospital outreach laboratories act like independent laboratories and compete with them in the marketplace. It is reasonable that a laboratory whose revenues are derived primarily from the CLFS and/or PFS and that meets the low expenditure threshold should be included in data reporting, regardless if it is a hospital outreach laboratory.

In the Appendix, we have included regulatory language to effectuate our suggestions.

7. Alternate Proposal for Identifying an Applicable Laboratory

In our comments on the proposed rule to implement Section 216 of PAMA, ACLA put forth 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. This would be an alternative to the "14X bill type" proposal for identifying a hospital laboratory's revenue attributable to outreach (non-patients), which we believe is preferable. In the preamble to the final rule implementing Section 216 of PAMA, CMS did not respond to this this approach that ACLA proposed,[26] so we are including it here to give the agency an opportunity to do so.

The statute applies the "majority of Medicare revenues" test to a laboratory's Medicare revenues, not to an entire entity's Medicare revenue where the entity is larger than the laboratory itself, such as a hospital.[27] While it is obvious that hospital laboratory services paid for under the CLFS or PFS are "Medicare revenues" attributable to the laboratory, some form of accounting is necessary to identify laboratory revenues when the laboratory services are included in bundled payments (MS-DRG and APC payments) received by the hospital. But the accounting would not

[26] *See* 81 Fed. Reg. 41036, 41046 (June 23, 2016).
[27] *See* 42 U.S.C. § 1395m-1(a)(2) ("In this section, the term 'applicable laboratory' means *a laboratory* that, with respect to *its revenues* under this title, a majority of such revenues are from this section, section 1833(h), or section 1848.") (emphasis added).

be difficult. A hospital could use a basic calculation to determine what portion of the bundled Medicare payments it receives are attributable to laboratory services. This approach is consistent with the statutory text because it permits a hospital to identify the laboratory's Medicare revenue, to apply the "majority of Medicare revenues" test to that revenue alone, and to ascertain whether the laboratory is an "applicable laboratory."

It is clear that 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.

A hospital could apply its own payment-to-charges ratio to the laboratory services it bills to determine the approximate percentage of Medicare revenues that were paid to it during a data collection period for inpatient and outpatient laboratory services. It would add to this amount its other separately-paid laboratory revenues, such as for services furnished to non-patients, to derive the hospital laboratory's total Medicare revenue for laboratory services during the data collection period. This amount would be the denominator in the "majority of Medicare revenues" calculation; a hospital's total CLFS and PFS revenues would be 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, together with all of its hospital laboratories, would be an "applicable laboratory."

In the alternative, CMS could develop an adjustment factor that a hospital could use in lieu of its own payment-to-charges ratio to determine the amount of the hospital's inpatient and outpatient Medicare revenue that is attributable to the hospital laboratory. ACLA developed such an adjustment factor by taking the laboratory charges included in inpatient and outpatient hospital claims for 2013[28], applying the hospital's specific payment-to-charges ratios to those charges, and totaling the results. Of all inpatient and outpatient services furnished by hospitals to Medicare beneficiaries, 6 percent were hospital laboratory-related Medicare revenues. A hospital could use this "national" adjustment factor, which would be a "safe harbor" for purposes of the "majority of Medicare revenues" determination, instead of calculating its own hospital-specific adjustment factor. CMS could spot-check hospitals for compliance with reporting requirements, as the agency itself would have all the information required to perform the calculation for each hospital. The equation is below:

Hospital Laboratory Revenues from CLFS/PFS

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

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

[28] When ACLA developed this adjustment factor, the 2013 data was the most recent available. CMS could use a more recent year's data to develop the adjustment factor.

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.

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 reasonable approach to implementing the statutory requirements. 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 significant hospital 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 requiring reporting by only those hospitals whose laboratories compete directly with independent laboratories. We urge CMS to adopt this approach for defining which hospitals are "applicable laboratories," if it does not adopt the 14X bill type approach.

8. To reduce the reporting burden on applicable laboratories, CMS should adopt new flexible approaches to reporting applicable information.

a) Manual remittances

A way that CMS can dramatically reduce the reporting burden on applicable laboratories is to allow laboratories to exclude from applicable information those payments on manual (hard-copy) remittances for which test-level payment information is not captured in the laboratory's electronic billing system. These payments comprise a relatively small portion of applicable information overall, yet a laboratory must expend a tremendous amount of resources to manually transcribe the test-level information from the manual remittances into an electronic format.

An applicable laboratory whose manual remittances comprise less than 10 percent of its claim-level remittances in a data collection period should be permitted to exclude manual remittances from the applicable information it reports, but it should not be required to do so. An applicable laboratory should have the option to include manual remittances in applicable information, even if manual remittances comprise a small percentage of its applicable information overall, but an applicable laboratory should not have the option of including manual remittances for some HCPCS codes and not for others or have the option to include only certain manual remittances for a given HCPCS code. When reporting applicable information during a data reporting period, an applicable laboratory would notify CMS whether or not it has included manual remittances, and if it has not, certify to the fact that manual remittances comprised less than 10 percent of its claim-level remittances in the data collection period.

b) Aggregate reporting

In addition, CMS should implement optional aggregate reporting, as authorized by law. Section 1834A(a)(6) of the Social Security Act states:

> (6) ENSURING COMPLETE REPORTING.—In the case where an applicable laboratory has more than one payment rate for the same payor for the same test or more than one payment rate for different payors for the same test, the applicable laboratory shall report each such payment rate and the volume for the test at each such rate under this subsection. Beginning with January 1, 2019, the Secretary may establish rules to aggregate reporting with respect to the situations described in the preceding sentence.

In the first data reporting period in early 2017, applicable laboratories were required to collect and report every private payor rate and the associated volume for each of more than one thousand test codes on the CLFS for tests furnished and paid during the first data collection period. Depending on the number of private payors from which a laboratory received payments, hundreds or even thousands of data points were to be collected and reported for each code on the CLFS. Recognizing the significant burden on applicable laboratories, Congress authorized CMS to reduce this burden by adopting rules for aggregate reporting. CMS should use this authority in the upcoming data collection and reporting periods, and it should solicit input from stakeholders about how applicable information can be aggregated in a way that preserves the integrity of the data while reducing both the data collection and reporting burdens.

B. Pathology Supply Inputs

Section 220(a) of PAMA allows CMS to collect or obtain information from a variety of sources to determine relative value units ("RVUs") under the PFS. The agency engaged StrategyGen, a market research firm, to provide pricing for the medical equipment and supplies found in the PFS direct practice expense ("PE") inputs. StrategyGen used telephone surveys, aggregate database reviews, vendor interviews, market scans, physician substantiation, and statistical analyses to come up with its input recommendations. It also conducted secondary market research for more than two thousand medical equipment and supply items, consulting aggregate health system provider databases, publicly-available vendor resources, the General Services Administration ("GSA") schedule, and information in previous PFS rules.[29] Based on this information, CMS is proposing large adjustments in the direct PE inputs for some of the supplies used to furnish certain pathology services. There would be large shifts in PE RVUs for individual codes with major increases in supply inputs, but changes to codes with sizeable PE RVU decreases would be limited by the requirement to phase in significant reductions in RVUs.[30]

ACLA supports adequate reimbursement for pathology services that accurately reflects the cost of providing the service, and we also value having some measure of predictability and stability in reimbursement for these services. We agree with CMS that it is important to "make use of the

[29] 83 Fed. Reg. 35719; StrategyGen, Direct Practice Expense Input Market Research Report (March 1, 2018), *available at* http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html under CY 2019 Market-Based Supply and Equipment Pricing Update.
[30] *See* 42 U.S.C. § 1395w-4(c)(7).

most current information available for supply and equipment pricing instead of continuing to reply on pricing information that is more than a decade old."[31]

We are concerned that StrategyGen's report does not provide sufficient information about how it arrived at information on commercial prices for supplies and that stakeholders have not had adequate time to analyze the proposed prices to formulate comments. We know from the report that StrategyGen reviewed 310 supplies that "would generally be found in a laboratory," but we do not have sufficient information about what unit of each supply was priced or the sources of the pricing information. For example, StrategyGen says "Commercial prices were gathered from subscription-based benchmark databases for medical supplies and equipment that [are] operated by a non-profit organization that represents more than 5,000 members," but there is little information about the non-profit organization's identity or the content and parameters of the databases.[32] It is difficult for ACLA and other stakeholders to comment on StrategyGen's conclusions without more details on how it reached its conclusions. Moreover, the time allotted to review the proposed prices is not sufficient for stakeholders to offer constructive and meaningful input.

ACLA also is concerned that CMS or the American Medical Association RVS Update Committee ("RUC") could determine that certain test codes are potentially misvalued, based primarily on faulty pricing information yielded by StrategyGen's analysis. This is another reason that CMS should provide more information about StrategyGen's recommendations, and additional time for stakeholders to analyze the proposed supply prices, before proceeding.

CMS should proceed cautiously before finalizing the direct PE inputs included in the Proposed Rule. We agree with the sentiment behind CMS's proposal to phase in its use of new direct PE input pricing over a period of years: to ease the shift to the updated supply and equipment pricing and "to allow interested parties an opportunity to review and respond to the new pricing information associated with their services."[33] However, rather than finalizing the prices now and phasing them in over the next four years, CMS should consider providing stakeholders with more detailed information about StrategyGen's sources and methodologies and providing additional time for stakeholders to offer their feedback before finalizing the prices.

C. Conclusion

Thank you for your consideration of ACLA's comments.

Sincerely,

Julie Khani, President
American Clinical Laboratory Association

[31] 83 Fed. Reg. 35720.
[32] Direct Practice Expense Input Market Research Report at 16.
[33] *Id*.

APPENDIX

The statutory definition of "applicable laboratory" set forth at 42 U.S.C. § 1395m-1(a)(2) is "a laboratory that, with respect to its revenues under [title XVIII] a majority of such revenues are from this section, section 1833(h), or section 1848. The Secretary may establish a low volume or low expenditure threshold for excluding a laboratory from the definition of applicable laboratory under this paragraph, as the Secretary deems appropriate." Additions to the current regulatory language appear in bold type, and deletions are struck through.

42 C.F.R. § 414.502. Definitions.

Applicable laboratory means an entity that:

(1) Is **itself** a laboratory, as defined in § 493.2 of this chapter, **or if it is not itself a laboratory, has at least one component that is a laboratory.**

(2) **With respect to a hospital laboratory, bills Medicare Part B** ~~under its own National Provider Identifier (NPI)~~ **on a CMS 1450 or its electronic equivalent using a 14X Type of Bill.**

(3) In a data collection period, receives more than 50 percent of its Medicare revenues, which ~~includes~~ **means** fee-for-service payments **for claims submitted on a CMS 1500 or its electronic equivalent or on a CMS 1450 or its electronic equivalent using a 14X Type of Bill** under Medicare Parts A and ~~and~~ B, ~~Medicare Advantage payments under Medicare Part C, and prescription drug payments under Medicare Part D~~, and any associated Medicare beneficiary deductible or coinsurance, for services furnished during the data collection period from one or a combination of the following sources:

(i) This subpart G.

(ii) Subpart B of this part.

(4) **In a data collection period,** receives at least $12,500 of its Medicare revenues from this subpart G. Except, for a single laboratory that offers and furnishes an ADLT, this $12,500 threshold—

(i) Does not apply with respect to the ADLTs it offers and furnishes; and

(ii) Applies with respect to all the other CDLTs it furnishes.

* * *

42 C.F.R. § 414.504. Data reporting requirements.

~~(g) Applicable information may not be reported for an entity that does not meet the definition of an applicable laboratory. For a single laboratory that offers and furnishes an ADLT that is not an applicable laboratory except with respect to its ADLT, the applicable information of its CDLTs that are not ADLTs may not be reported.~~