June 7, 2017

American Clinical Laboratory Association

CMS Administrator Seema Verma
Office of the Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building, Rm. 314-G
200 Independence Avenue SW
Washington, DC 20201

Dear Administrator Verma,

Thank you for meeting with representatives of the American Clinical Laboratory Association (ACLA) on April 27 for a productive meeting to discuss implementation of Section 216 of the Protecting Access to Medicare Act (PAMA).[1] That section of the law aims to establish Medicare Clinical Laboratory Fee Schedule (CLFS) prices that are based on rates paid by private payors for laboratory tests. We are encouraged by your willingness to work with ACLA and other stakeholders to ensure that Section 216 is implemented in a manner consistent with Congressional intent and to ensure that all sectors of the laboratory market are represented in the data CMS uses to calculate the new CLFS rates.

As we discussed during our meeting, the current regulations effectively remove an entire piece of the laboratory market – hospital outreach laboratories – from data reporting. An "applicable laboratory" is one that bills under its own NPI number, receives a majority of its Medicare revenues under the CLFS and/or Physician Fee Schedule (PFS), and receives more than a certain amount of CLFS revenue in a given period.[2] Only applicable laboratories are required or allowed to report their private payor rates and associated volumes to CMS, yet because of the way CMS defined that term in the final rule, only a very small number of hospitals provided their data to the agency. As a result, the data that CMS will use to calculate CLFS rates is incomplete and not reflective of the entire laboratory market. This is the first major change to the CLFS in more than 30 years, and ACLA believes strongly that this change should not be implemented in a way that results in incorrect rates and that threatens Medicare beneficiary access to laboratory services.

We also are very concerned about difficulties during the recently-completed data reporting period, faced both by CMS in accepting the data and laboratories reporting data. These issues affect the quality and the integrity of the data that CMS has received to date. Despite CMS's best efforts to provide clear direction through the regulations, the final rule's preamble language, webinars, and FAQs, we know from talking with other stakeholders that reporting entities took a variety of approaches to determining which private payor rates and volumes to report. The data CMS will use to calculate CLFS rates is likely to be inconsistent and possibly incomplete.

During our April 27 meeting, you asked ACLA to provide you with specific recommendations for changes that would result in the entire laboratory market being represented in data that CMS uses to calculate new CLFS rates. Since then, ACLA member companies have had numerous meetings to work together toward a viable solution that can be implemented administratively, and we have reached out to other stakeholders, as well. As we worked together

[1] Pub. L. 113-93.
[2] 42 U.S.C. § 1395m-1(a)(2).

to develop a reasonable approach to resolving these issues, we also have been mindful of the agency's own timeline for implementing the law.

We considered a variety of approaches to rectifying the flawed applicable laboratory definition in the final rule and resulting incomplete data collection, and we continue to believe that **CMS should not implement the new CLFS rates until it has collected private payor rates and volumes from all sectors of the laboratory market, including hospital outreach laboratories.** Below, we propose a revised definition of "applicable laboratory" that would include both hospital outreach laboratories and those entities described in the current definition. We also have proposed a revised implementation timeline that would allow CMS to collect this data from hospital outreach laboratories and integrate it into the data it already has collected from other applicable laboratories.

Rather than calculate weighted medians based on incomplete data, CMS should issue an interim final rule to: (1) postpone its calculation and publication of new CLFS rates; (2) amend the definition of "applicable laboratory" to include all hospital outreach laboratories that exceed the minimum CLFS revenue threshold and meet the "majority of Medicare revenues" test; and (3) establish dates for hospital outreach laboratories to report private payor rates to CMS and for publication of the new CLFS rates.

Postpone calculation of new CLFS rates: CMS should not calculate and publish CLFS rates that are based on incomplete data. The agency should issue an interim final rule that delays implementation of new CLFS rates for at least six months, until it has collected private payor data from the remainder of the laboratory market and until it has integrated that data with data that already has been reported. Prior to the effective date of the new CLFS rates, rates for CY 2018 would be determined under Sec. 1833(h) of the Social Security Act, in the same manner as the rates were determined for CY 2017.

Definition of "applicable laboratory": In the final rule, CMS defined "applicable laboratory" at the NPI level, reasoning that a hospital outreach laboratory that already had its own NPI number could qualify as an applicable laboratory, and a hospital outreach laboratory that did not have one could obtain one and then qualify as an applicable laboratory.[3] However, very few hospital outreach laboratories have their own NPI numbers – almost all bill under the NPI number used by the entire hospital. As a practical matter, a hospital outreach laboratory will not obtain its own NPI number voluntarily solely for the purpose of qualifying as an applicable laboratory. We have no evidence that any hospital outreach laboratories proactively sought separate NPI numbers since issuance of the final rule.

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 the PFS, "Medicare revenues" means payment for claims submitted on a CMS 1500, a CMS 1450 using a 14X Type of Bill, or their electronic equivalents.[4] A 14X Type of Bill 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

[3] 81 Fed. Reg. 41036, 41045 (Jun. 23, 2016).
[4] The appendix includes proposed regulatory language for a revised definition of "applicable laboratory."

from the definition of "applicable laboratory" any laboratory that already has 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.

Timeline for data reporting and new rate implementation: The data collection period for hospital outreach laboratories that qualify as applicable laboratories under the revised definition should be January 1 through June 30, 2016, the same data collection period as other applicable laboratories. CMS then would have a complete "snapshot" of the national laboratory market in its data. Hospital outreach laboratories would report their applicable information to CMS between November 1, 2017 and January 31, 2018. CMS would calculate weighted medians from data reported during the just-completed data reporting period and data reported by newly-eligible hospital outreach laboratories. The new CLFS rates, representing the weighted medians of the entire clinical laboratory testing market, would be effective starting July 1, 2018 or a later date. In recognition of hospital outreach laboratories reporting their data in 2018, CMS should consider postponing the next data reporting period from 2020 to 2021 for all applicable laboratories, to give hospital outreach laboratories a reasonable interval between reporting periods. The implementation schedule for this approach is summarized below:

> Aug. 2017: CMS issues an interim final rule delaying calculation and publication of new CLFS rates, setting forth a new definition of "applicable laboratory", and revising the implementation timeline.
>
> Nov. 1, 2017 – Jan. 31, 2018: Data reporting period for newly-eligible applicable laboratories (reporting data for the period Jan. 1 – June 30, 2016).
>
> Mar. 31, 2018: CMS publishes preliminary CLFS rates that include hospital outreach laboratory data, for a 30 day comment period.
>
> May 31, 2018: CMS publishes final CLFS rates, taking stakeholder comments into account.
>
> July 1, 2018: New CLFS rates are effective (or a later date, if this date is not feasible).

* * * * *

In the final rule implementing Sec. 216 of PAMA, CMS said: "We believe that it is important not to prevent private payor rates from being reported for hospital outreach laboratories so that we may have a broader representation of the national laboratory market to use in setting CLFS payment amounts."[5] The approach set forth above would allow the agency to have and to use information from all parts of the national laboratory market to set new CLFS rates. All entities submitting claims under the CLFS will be subject to the new rates, and all sectors of the laboratory market should be represented in the data used to develop those rates.

We sincerely appreciate your willingness to work with ACLA and other stakeholders to address this issue, and we look forward to our continued collaboration with you.

[5] 81 Fed. Reg. 41045.

Sincerely,

Julie Khani, President
American Clinical Laboratory Association

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." Below is a proposed regulatory definition of "applicable laboratory" that would include hospital outreach laboratories. 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) Bills Medicare Part B under its own National Provider Identifier (NPI)**, or bills Medicare Part B 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~~ 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.