Proposed Rule on Revisions to the CY 2019 Physician Fee Schedule: Summary of PAMA Related Sections

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On July 12, CMS released proposed changes to the Physician Fee Schedule and Quality Payment Program, which is the fee schedule under which physicians and other providers are paid under Medicare. The proposed rule includes a few sections that directly address PAMA and Medicare's Clinical Laboratory Fee Schedule (CLFS), and CMS is specifically soliciting public comment on areas related to PAMA. **Comments are due on September 10**, and AAB and NILA will work to develop a response to the laboratory related sections. Below is a summary of the key concepts on which CMS would like to gather public feedback:

1. *Low Expenditure Threshold Component of the Applicable Laboratory Definition Under the Medicare Clinical Laboratory Fee Schedule (page 378; Section II. K)*

   In 2014 under PAMA, CMS established a definition of an applicable laboratory to determine reporting entities that are required to submit private payor data to help reset the rates on the Clinical Laboratory Fee Schedule (CLFS). One component of this definition includes a low expenditure threshold that requires an eligible laboratory to receive at least $12,500 of its Medicare revenue from the CLFS for clinical laboratory diagnostic tests (this excludes tests that are categorized as advanced diagnostic laboratory tests) within the data collection period.

   The low expenditure threshold is set to achieve a balance between collecting sufficient data while minimizing the reporting burden for laboratories that do not have significant revenue from the CLFS. As a result of this low expenditure threshold, CMS claims that many physician office laboratories and small independent laboratories are excluded from the data collection.

CMS seeks public comment on two aspects related to the low expenditure threshold:

- Decreasing the low expenditure threshold by 50%, from $12,500 to $6,500 in order to increase the data reported by physician office laboratories and small independent laboratories;
- Increasing the low expenditure threshold by 50% from $12,500 to $18,750.

2. *Proposed Change to the Majority of Medicare Revenues Threshold in Definition of Applicable Laboratory (page 402; Section III. A. 3)*

   As discussed above, CMS requires applicable laboratories to report data during a specific data collection period to reset the rates on the CLFS. One of the defining factors of whether a laboratory is required to report data is if it receives more than 50% of its Medicare revenue from the CLFS and/or the Physician Fee Schedule (PFS), establishing a majority of Medicare revenues threshold. CMS defines revenues as payments received from Medicare, including fee-for-service payments under Medicare Parts A and B; Medicare Advantage (MA) payments under Medicare Part C; 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.

   CMS seeks public comment on the majority of Medicare revenues threshold:

   - CMS proposes removing MA plan payments under Part C from the revenues that would be considered Medicare revenues for purposes of the applicable laboratory definition in order to broaden the representation of the laboratory industry that may qualify as applicable laboratories.

3. *Solicitation of Public Comments on Other Approaches to Defining Applicable Laboratory (page 410; Section III. A. 4)*

   CMS seeks public comment on two other approaches to defining an applicable laboratory:

   - *Form CMS-1450 14x bill type*: currently, an applicable laboratory is outlined at the NPI level. In order to increase the number of hospital outreach laboratories reporting data, CMS is proposing to determine whether a laboratory meets the majority of Medicare revenues threshold and low expenditure threshold using only the revenues from services reported on the Form CMS-1450 14x bill type instead of revenues associated with the NPI. This 14x bill type is only used by hospital outreach laboratories.

     This approach would revise the definition of applicable laboratory to permit revenues identified on the CMS-1450 14x bill type instead of the laboratory's NPI.

     CMS seeks public comment on:

     - Utilizing the CMS-1450 14x bill type to determine whether the hospital outreach laboratory meets the majority of Medicare revenues threshold and the low expenditure threshold;
     - Whether hospitals would have sufficient time after the final rule is published to develop and implement the information systems necessary to collect data prior to the next data collection period starting January 1, 2019;
     - By using the CMS-1450 14x bill type, virtually all hospital outreach laboratories would meet the majority of Medicare revenue threshold. CMS believes that the MA statute intended to exclude hospital outreach laboratories and seeks comment on whether this approach would be inconsistent with the statute.

- *Using CLIA Certificate to Define Applicable Laboratories*

  Finally, CMS proposes that another alternative approach to defining an applicable laboratory is to use the laboratory's CLIA certificate instead of NPI. CMS feels that using CLIA certificates to define an applicable laboratory is overly inclusive and could include all hospital laboratories, not just hospital outreach laboratories, and does not give any indication of Medicare revenue since CLIA is not associated with Medicare billing.

CMS seeks public comment on:

- Whether applicable laboratories should be defined by CLIA certificate and if this would be an appropriate way to determine the majority of Medicare revenues threshold and low expenditure threshold components;

- Potential drawbacks of using CLIA certificates to define an applicable laboratory when one certificate is assigned to a hospital's entire laboratory business that includes tests performed for hospital patients and non-patients.

This document is intended to provide a summary of the proposed changes CMS is seeking public feedback. Please refer to the CMS-1693-P for the full proposed rule. Comments are due through www.regulations.gov by **5:00 p.m. on September 10, 2018**. AAB and NILA will work to develop an organization-wide response to CMS' proposed changes. For more information, please contact Mark S. Birenbaum, Ph.D., at birenbaumm@birenbaum.org.