May 4, 2016

Shaun Donovan, Director
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Medicare Program; Medicare Clinical Diagnostic Laboratory Tests Payment System; Final Rule (CMS-1621-F) 0938-AS74

Dear Director Donovan:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to raise concern about the Center for Medicare and Medicaid Services (CMS) Final Rule on the Medicare Clinical Diagnostic Laboratory Tests Payment System. We are concerned that by excluding hospital and physician office laboratories (POLs) from reporting data that will be used to calculate new payment rates, the agency is not meeting its statutory obligations. Moreover, we are concerned the final rule may not provide sufficient time for clinical laboratories to submit the applicable data required by the Protecting Access to Medicare Act (PAMA), inappropriately exposing them to potentially huge fines.

I. Statutory Framework in Brief
Per the Section 216 of PAMA, beginning on January 1, 2016 and generally every three years thereafter, “applicable laboratories” must report to CMS private payor data (health insurance issuers, group health plans, Medicare Advantage plans, and Medicaid managed care organizations) for more than 1,200 laboratory tests reimbursed under the Clinical Laboratory Fee Schedule (CLFS). Applicable laboratories are those receiving the majority of their Medicare revenues under the CLFS or Physician Fee Schedule (PFS). The data to be reported includes private payor payment rates and the corresponding test volume. CMS will use this data to calculate weighted median payment rates for each test on the CLFS.

II. Definition of an Applicable Laboratory
In its Proposed Rule, CMS proposed to exclude hospital and physician office laboratories from the definition of an applicable laboratory. Such an interpretation of the statute is contrary to congressional intent. In a colloquy between Senators Orrin Hatch (R-UT) and Richard Burr (R-NC), the two senators clearly outlined Congress’s intent as to what sort of laboratories were to be included in the data submission requirements. In that colloquy, Senator Burr asked: “It is my 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” (emphasis added), including independent laboratories and hospital outreach laboratories that receive payment on a fee-for-service basis under the fee schedule.” Senator Hatch responded: “The Senator is correct.”

According to a September 2015 report by the Department of Health and Human Services (HHS) Office of Inspector General (OIG), 57 percent of CLFS payments are made to independent laboratories, 24 percent of payments are made to hospital laboratories, and 19 percent are made to POLs. A NPRM excluding 100 percent of hospital laboratories, 96 percent of POLs, and 52 percent of independent laboratories, while simultaneously prohibiting CMS from considering data submitted from laboratories voluntarily, clearly fails to satisfy congressional intent. We are concerned that by cherry-picking the laboratory market to secure data only from those laboratories with the greatest economies of scale, the resulting fee schedule will be unsustainable for many laboratories.
CMS’s exemption of hospital laboratories rests on its examination of whether hospital laboratories meet the “applicable laboratory” revenue test. PAMA defines an applicable laboratory as “a laboratory (emphasis added) that, with respect to its revenues under this title, a majority of such revenues are from” the PFS, CLFS or new section of the Social Security Act 1834A (See aforementioned note about PAMA).

However, by focusing on the Taxpayer Identification Number (TIN)-level rather than the laboratory’s Clinical Laboratory Improvement Amendments (CLIA) Number, CMS disregards the statute’s clear focus on the “laboratory” and instead looks at the entire hospital’s Medicare revenue. Had Congress intended for CMS to use such an approach, then it would have used a broader term than “laboratory” in the law, but it did not. Given the plain language of the statute plus the Congressional colloquy, it is clear that the appropriate inquiry is from what sources a laboratory’s Medicare revenues are derived. Hence, the final rule should define an applicable laboratory using the CLIA number.

CMS is also proposing that if a laboratory receives less than $50,000 in Medicare revenues in a data collection period, it would be excluded from the definition of an applicable laboratory. ASCP is concerned that for a large number of clinical laboratory services primarily provided in POLs, this dollar threshold exempts too much data from the reporting requirement and could skew payment rates. ASCP believes a lower threshold is appropriate.

III. Extend Timeline for Revaluing CLFS
ASCP is concerned that delays in finalizing regulations may shortchange laboratories with regard to the time available to submit data. Per PAMA, Congress imposed a June 30, 2015 deadline for CMS to finalize its regulations and a January 1, 2016 date to begin accepting data submissions from applicable clinical laboratories. In establishing this timeline for implementation, Congress not only gave the Agency fifteen months (from PAMA’s April 1, 2014 effective date to the June 30, 2015 statutory deadline) to develop regulations, it also provided clinical laboratories with at least six months (from the June 30, 2015 statutory deadline to the January 1, 2016 statutory commencement date) before the data submission window would commence. Because of the immense amount of data that will be required of full-service laboratories, at least six months of time is needed from the date the regulations are finalized to the opening of the reporting commencement date to allow laboratories enough time to collect and report applicable data. Congress’s concern about this issue has been raised in several letters (attached).

Like many of our colleagues in the laboratory community, we are concerned that the requirements imposed on applicable clinical laboratories are complex and extensive. Laboratories will need sufficient time to plan for and test information systems before data collection begins. The requirements will require significant work by laboratories to hire and/or train staff, identify and resolve software issues, and review collected data to ensure its accuracy. ASCP supports the proposed implementation timetable that many clinical laboratory organizations, such as ASCP proposed to CMS in comments on the NPRM.

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<tr>
<th>Initial data collection period</th>
<th>January 1, 2016 – June 30, 2016</th>
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<tr>
<td>Final rule has been published; data collection and reporting guidance has been finalized</td>
<td>By June 2016</td>
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<td>Labs build information systems to collect and report data; period between end of data collection period and beginning of data reporting period</td>
<td>July 2016 – December 2016</td>
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<tr>
<td>Initial data reporting period</td>
<td>January 1, 2017 – March 31, 2017</td>
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<td>CMS publishes preliminary weighted median payment rates</td>
<td>September 2017</td>
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<td>CMS publishes final weighted median payment rates</td>
<td>November 2017</td>
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<td>Weighted median payment rates take effect</td>
<td>January 1, 2018</td>
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IV. Calculation of the Weighted Mean/Burden Reduction

PAMA requires that for each laboratory test the Secretary shall calculate a weighted median. The purpose of the weighted mean is to ensure that new payment rates are an accurate reflection of current market payment rates. This could distort payment rates such that CMS will not be able to calculate a true median price for each laboratory service.

ASCP believes that it is imperative for prices to accurately represent rates everywhere in accordance with their respective market share. Therefore, ASCP respectfully urges CMS to weight the data received in accordance with that laboratory type’s respective market share. If hospital laboratories represent 20 percent of the market for testing services, then the data for these facilities should be weighted to 20 percent. This will help adjust the data to ensure that CMS’s calculated median pricing accurately reflects the true market median price—which is the central goal of PAMA.

In closing, ASCP urges OMB to ensure that the final rule utilizes the CLIA number rather than the TIN for identifying applicable laboratories; to develop a timeline that allows applicable laboratories sufficient time to collect and report data; to allow data submitted voluntarily by non-applicable laboratories, such as POLs, to be included in the calculation of median prices; and to weight the data received in accordance with that laboratory type’s respective market share.

The ASCP is a nonprofit medical specialty society representing more than 100,000 members. Our members are board certified pathologists, other physicians, clinical scientists (PhDs), certified medical laboratory scientists/technologists and technicians, and educators. ASCP is one of the nation’s largest medical specialty societies and is the world’s largest organization representing the field of laboratory medicine and pathology. As the leading provider of continuing education for pathologists and medical laboratory personnel, ASCP enhances the quality of the profession through comprehensive educational programs, publications, and self-assessment materials.

ASCP appreciates the opportunity to present these comments. If we can be of further assistance, please do not hesitate to contact me or Matthew Schulze, Director of ASCP’s Center for Public Policy, at (202) 347-4450.

Sincerely,

David N.B. Lewin, MD, FASCP
President, ASCP