

Congress of the United States
House of Representatives
Washington, DC 20515-0552

March 10, 2020

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Verma:

We are writing to stress the importance of proper implementation of payment reform to the Clinical Laboratory Fee Schedule (CLFS) under *the Protecting Access to Medicare Act of 2014* (PAMA) (Sec. 216 of P.L. 113-93). In light of the recent passage of *the Laboratory Access for Beneficiaries (LAB) Act* (Sec. 105 of P.L. 116-94), it is critical that CMS work with stakeholders to ensure that private payor data accurately reflects all segments of the clinical laboratory market, as Congress intended.

As you are aware, PAMA requires CMS to develop one national fee schedule for clinical laboratory tests based on private payor data collected from all applicable laboratories. According to a July 2018 OIG report, fewer than 1 percent of laboratories reported data in the first round of PAMA and many large segments of the laboratory market, including hospital outreach and physician office labs, were significantly underrepresented. As a result, reimbursement reductions to the CLFS from the first round of PAMA far exceed CBO's original projections. These cuts of nearly \$10 billion are unsustainable and threaten beneficiary access, particularly in medically-underserved and rural areas.

As a first step in addressing these implementation challenges, Congress passed the LAB Act in December 2019 to delay the next round of PAMA data reporting by one year and require a study by the Medicare Payment Advisory Commission (MedPAC) to identify steps to improve PAMA data collection and rate-setting methodology.

We were encouraged by recent agency actions to improve market representation in PAMA data reporting, including CMS' expansion of reporting requirements to a broader scope of hospital laboratories under the 14x type of bill. However, we remain concerned that many hospital outreach labs are unaware of their obligation to participate in PAMA and are not equipped to collect and report in the next data round.

To help ensure that this additional year is used effectively and results in a more robust and representative data set for CMS to update Medicare reimbursement rates during the next cycle, we ask the agency respond to the following questions within thirty days of receipt of this letter:

1. What outreach and education efforts have been undertaken by CMS to ensure that all applicable labs—including hospital outreach labs and physician office labs—are aware of data collection and data reporting requirements and deadlines?
2. What outreach and education efforts will CMS be conducting in 2020 to ensure more robust compliance by all applicable laboratories with data collection and data reporting requirements and deadlines, including hospital outreach labs and physician office labs?
3. What measures have been established by CMS to assess the effectiveness of its outreach and education efforts, particularly in reaching hospital outreach and physician office laboratories and helping them to prepare for their new reporting obligations?

In order for the LAB Act to be successful, it is imperative that CMS utilize the one-year delay period to promote PAMA participation, particularly among newly applicable hospital outreach labs. We strongly urge CMS to work with stakeholders from all sectors of the laboratory market, including independent, physician, and hospital labs, to encourage complete and accurate data reporting.

Laboratory payment reform is a highly complex task with significant implications far beyond the Medicare program. We look forward to your responses and working with you to ensure proper implementation of PAMA and the LAB Act in line with congressional intent so that beneficiaries can maintain access to critical laboratory services.

Sincerely,



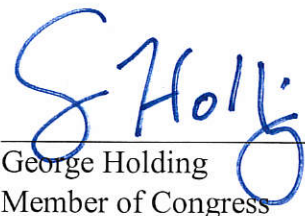
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Bill Pascrell Jr.
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