

United States Senate

WASHINGTON, DC 20510

December 22, 2017

The Honorable Seema Verma
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

We write today to raise concerns with the recent announcement from the Centers for Medicare and Medicaid Services (CMS) finalizing payment rates for the Clinical Laboratory Fee Schedule (CLFS) as required by Section 216 of the Protecting Access to Medicare Act (PAMA). The CLFS has long been in need of reform, and for this reason, PAMA allowed for a more dynamic, market-based system to develop payment rates that better reflect the commercial market for clinical laboratory services.

Clinical laboratory services continue to evolve as new and innovative diagnostics come to market and manufacturers improve existing tests to better inform the care of all Americans, including Medicare beneficiaries. The CLFS should foster this innovation and reflect the evolving market. We are concerned, however, that the recently finalized cuts to the CLFS payment rates may stifle this innovation and ultimately decrease access to tests that may help to save and improve the lives of Medicare beneficiaries across the country.

In order to create a CLFS system nimble enough to adjust for this innovation, Congress intended for the reforms to CLFS to be a dynamic process in which Medicare reimbursement rates are determined based on the reporting of private market rates by clinical laboratories. For this reason, it is critical that the CLFS accurately reflect all sectors of the laboratory market. Absent the inclusion of all sectors of the laboratory industry as a part of these reporting requirements, such as independent labs, hospital labs and larger physician office labs, reimbursement rates may not reflect the true market rates, as designed by Congress.

Though we welcome these reforms, we are concerned with the quality of the data currently available at CMS, and the effect these decreased rates may have on Medicare beneficiaries' access to these services. For example, CMS indicates that only 21 hospital labs have reported their private market rates, reflecting only 1% of the market. It is our concern that these types of quality issues may result in permanently lower reimbursement rates across the board as private payors follow rates set by CMS in a manner that is not consistent with PAMA's intent. For this reason, we respectfully ask CMS to respond to the following questions about the data and accompanying documents provided by CMS finalizing the CLFS rates:

Reporting Process and Accountability

1. The Congressional Budget Office initially scored the reforms to the CLFS as saving \$100 million in the first year of implementation.¹ However, CMS estimates indicate that the savings will generate almost \$700 million in the first year alone. How does CMS account for such a drastic increase in the savings to the program while still meeting the limitation of a 10% reduction in payment rates in the first year?
2. CMS has stated that over 4.9 million records of applicable information were used to inform the final CLFS rates. What is the system through which CMS reviews this data and checks for reporting errors, and what is the agency's protocol for correcting these errors should they be found?
3. Does CMS have the capability to address data discrepancies on a line by line or itemized basis? If so, how did CMS address data inconsistencies for reporting entities? If not, what are the quality controls in place to confirm the accuracy of the data submitted?
4. In advance of the reporting requirements outlined under PAMA, the Health and Human Services Office of the Inspector General (HHS OIG) provided an overview of the laboratory market.²
 - a. Can CMS explain the discrepancy between the number of applicable laboratories paid under Medicare Part B in 2015 that HHS OIG estimated would be required to report (12,547 labs) and the number of labs that actually reported (994 labs)?
 - b. What is the effect of this discrepancy on providing a full picture of the laboratory market when HHS OIG estimated that 12,547 labs paid under Medicare Part B in 2015 would qualify as applicable laboratories and would be required to submit their data to CMS?
5. The definition of an applicable laboratory promulgated by CMS may result in fewer labs deciding to report. What authorities does CMS have, if any, to ensure that the laboratories captured by the applicable laboratory definition today are reporting?
6. In the comments submitted by the American Clinical Laboratory Association (ACLA), the organization states that "more than 99 percent of laboratories that were paid for laboratory services under Medicare Part B in 2015 reported no data to CMS" with less than 1% of all labs reporting this information to the agency.³
 - a. Does CMS believe that the preliminary rates are capturing a full and fair picture of the clinical laboratory market when, according to stakeholders, less than 1% of the market is reporting data to calculate the weighted median of private payor rates?
 - b. If so, how has CMS worked to address these stakeholder concerns?

CMS Data Questions

7. On page 4 of the CMS document titled "Summary of Data Reporting for the Medicare Clinical Laboratory Fee Schedule Private Payor Rate-Based Payment System", the agency states that "37

¹ <https://www.cbo.gov/sites/default/files/113th-congress-2013-2014/costestimate/house-introduced-protecting-access-medicare-act-2014-march-26-20140.pdf>

² <https://oig.hhs.gov/oei/reports/oei-09-16-00040.pdf>

³ http://www.acla.com/wp-content/uploads/2017/10/ACLA-Comments-on-PAMA-Preliminary-Rates-October-2017_AY.pdf

percent of the applicable laboratories for which applicable information was reported...might not meet the definition of an applicable laboratory.” Yet, because the laboratories decide for themselves whether or not they meet the applicable laboratory definition, the data submitted by these laboratories was included in the calculation for private payor rate weighted medians. Why does CMS believe the data used to calculate the weighted medians accurately captures the market given the inconsistency mentioned above?

8. On page 6 of the document, during the discussion of the outliers in the reported data, it is stated that the statistical outliers were not removed from the calculation of the weighted median of private payor rates as their “impact on the weighted median should be minimal.” Based on the numbers provided, the outliers would make up 7% (using the total of 994 reporting entities and a total of 69 outliers, from pages 4 and 6, respectively) of the reported data.
 - a. What are the reasons that CMS concluded that 7% of the reported data would not influence the overall findings?
 - b. How did CMS choose when to accept and include certain data and when to exclude other data?
9. One of the reporting metrics of an applicable lab is “each private payor rate for the test described by that HCPCS code for which final payment has been made...” What information does CMS request as a part of the reporting process to account for variation in commercial market rates? What mechanisms does CMS have in place to ensure proper oversight of private payor amounts that an applicable lab reports?

Participation Simulations

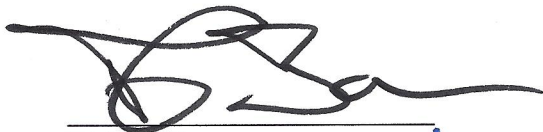
10. As you know, CMS received data from 1,942 applicable laboratories. As a part of the CLFS data collection process, CMS ran three simulations of alternative data collecting scenarios – a larger volume of hospital laboratories reporting, a larger volume of physician office laboratories reporting, and increased participation of all laboratories. CMS concluded that “there would be no significant impact on projected CLFS spending...” should these simulations have been true.
 - a. Did CMS use only reported data to inform these simulations?
 - b. If so, how does CMS account for any discrepancies given the extrapolation of existing data?
 - c. If not, what other supplemental data was CMS able to utilize as a part of these simulations?
11. According to ACLA’s analysis of CMS data, hospital labs accounted for 26% of Medicare payments for lab tests in 2016.⁴ However, CMS indicates that only 1% of reporting National Provider Identifiers (NPI) were hospital labs as a part of their data collection. Why did CMS decide not to include a simulation reflecting the current composition of the market, such as the example listed above?
12. The simulation section of the report concluded that “there would be no significant impact on projected CLFS spending...” In the case of the hospital laboratory scenario, how did CMS

⁴ http://www.acla.com/wp-content/uploads/2017/10/ACLA-Comments-on-PAMA-Preliminary-Rates-October-2017_AY.pdf

determine that a ten-fold increase in reporting hospital laboratories would only lead to a difference of about 1% in payment rates when compared to the baseline?

Again, thank you for your time and attention to this important matter. We look forward to continuing to work with you on the successful implementation of reforms to the CLFS as required by PAMA. If implemented according to Congressional intent, the changes to the CLFS should result in Medicare rates that will allow for the continued innovation of clinical laboratory tests and provide Medicare beneficiaries with access to these critical services.

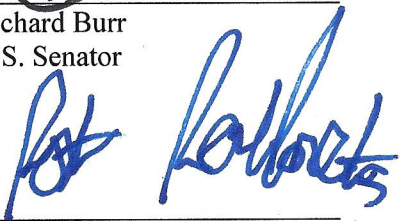
Sincerely,



Richard Burr
U.S. Senator



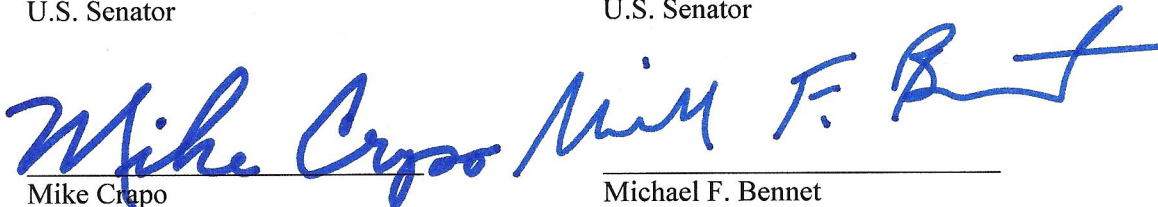
Bill Nelson
U.S. Senator



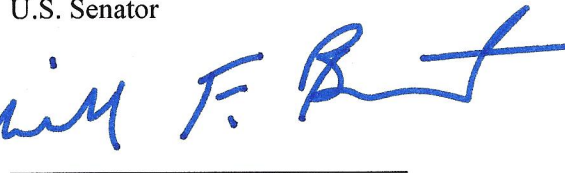
Pat Roberts
U.S. Senator



Sherrod Brown
U.S. Senator



Mike Crapo
U.S. Senator



Michael F. Bennet
U.S. Senator



Robert Menendez
U.S. Senator