January 29, 2015

The Honorable Joe Pitts
Chairman
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Gene Green
Ranking Member
Subcommittee on Health
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, D.C. 20515

Dear Chairman Pitts and Ranking Member Green:

The American Clinical Laboratory Association (ACLA) commends you for holding the recent hearing entitled: "A Permanent Solution to the SGR: The Time is Now," examining many of the critical policy issues involved with the existing Medicare physician reimbursement methodology and potential paths forward, including possible funding offsets.

ACLA is a not-for-profit association representing the nation's leading providers of clinical laboratory and anatomic pathology services, including national, regional, and esoteric laboratories. We commend the Subcommittee for holding this important hearing, given that Medicare provided reimbursement for at least 650 million individual laboratory test services in 2013.

As the Subcommittee continues to consider policies to permanently repeal the Sustainable Growth Rate, ACLA offers our views on several potential offsets, which if used to fund this effort, could negatively impact Medicare beneficiary access to clinical laboratory services.

Cuts to the Clinical Laboratory Fee Schedule

Cuts and freezes to the Clinical Laboratory Fee Schedule (CLFS) have been used repeatedly as offsets for SGR patches over the past decade. Most recently, the February 2012 *Middle Class Tax Relief and Job Creation Act* (P.L. 112-96), enacted a two percent rebasing cut to the CLFS, a full 15% of all the Medicare offsets included in the Act. In addition, savings from a complete rewrite of the CLFS were utilized as a pay-for in the *Protecting Access to Medicare Act of 2014* (P.L. 113-93) (PAMA) in April 2014.

ACLA believes that not only have these cumulative reductions to the CLFS been disproportionate, as lab services make up less than two percent of Medicare spending, but also fail to take into account the critical role clinical laboratory testing plays in *reducing* Medicare spending. Clinical lab services provide clinicians with the critical data necessary to diagnose and treat acute and chronic conditions, which saves the program and the nation's health care system overall from unnecessary downstream costs.

Furthermore, as mentioned previously, the clinical laboratory sector is preparing for landmark CLFS reforms enacted last year in PAMA. The new law repealed the technological change adjustment authority granted to the Centers for Medicare & Medicaid Services (CMS) under the CY 2014 Physician Fee Schedule Rule, which would have allowed indiscriminate cuts to the CLFS, and replaced it with a process

altering reimbursement cyclically based on market rates for clinical laboratory services. Importantly, the legislation also provided greater predictability in Medicare laboratory reimbursement for several years, provided a per test phase-in of reductions in reimbursement, and created a payment adjustment to allow laboratories to continue to serve the most vulnerable Medicare beneficiaries. ACLA worked diligently with Congress on this legislation, and continues to work closely with CMS to ensure implementation is consistent with congressional intent, and results in a process that reflects the broad scope of the laboratory market, recognizes the value of laboratory services, and protects access for Medicare beneficiaries.

We are extremely concerned that any additional cuts targeting the CLFS would be duplicitous, undermine these deliberate reform efforts, and harm the ability of clinical laboratories to serve Medicare beneficiaries.

Cost-Sharing

Imposing additional beneficiary cost-sharing also has been discussed as a possible means to generate savings for SGR reform. ACLA does not support the addition of either Medicare beneficiary copayments or coinsurance for Part B laboratory services. Collecting beneficiary cost-sharing is uniquely difficult for labs because, unlike other health care providers, labs typically do not have a face-to-face encounter with patients. A Medicare beneficiary's specimen is typically collected at another location, such as a physician's office, and sent to the lab.

Implementation of cost-sharing for lab services would result in a staggering increase in paperwork – estimated at over 143 million new Medicare claims each year. Approximately half of these new claims would be for $5.00 or less. In fact, in almost 40% of cases, a laboratory's cost to collect and process a claim would be more than the actual coinsurance, assuming a $3.50 cost of collection and a 20% coinsurance rate. And yet, a laboratory is obligated to attempt collection of coinsurance under federal fraud and abuse statutes. Not surprisingly, the Institute of Medicine has stated, "Cost-sharing [for laboratory services] is unlikely to significantly reduce overuse or increase the detection of fraud and abuse; it could create barriers to access for the most vulnerable Medicare beneficiaries; and it would be financially and administratively burdensome for laboratories, patients, and the Medicare program."

Moreover, increasing the beneficiary's out-of-pocket expenses for lab services likely will provide a financial disincentive, leading patients to delay or forgo critical clinical lab services altogether. Clinicians depend on these tests both for monitoring existing chronic conditions, such as diabetes and cardiovascular disease, and for diagnosing and treating newly-appearing conditions, such as cancer. Medicare patients should not be forced to choose between lifesaving diagnostic information and other financial expenses.

Competitive Bidding

ACLA is opposed to the extension of competitive bidding to clinical laboratory services. Through the passage of PAMA, Congress provided clear direction on reforming the CLFS by basing Medicare reimbursement on private payor rates. Therefore, the express intent of competitive bidding, which is to integrate market efficiencies to ensure that Medicare expenditures are not out of sync, has already been achieved.

History has also shown that competitive bidding for clinical laboratory services is unworkable. In 2004, CMS initiated a demonstration project for laboratory competitive bidding, which was halted by a federal court injunction. In light of this, Congress repealed the authority for the demonstration project in *The Medicare Improvements for Patients and Providers Act of 2008* (P.L. 110-275).

This congressional action stemmed from the recognition there are significant differences between clinical laboratory services and durable medical equipment (DME), which are currently subject to competitive bidding. Unlike DME, clinical laboratory services are time-sensitive services, since blood, tissue, or

other biological specimens obtained from the patient must be transported to a laboratory expeditiously as these samples degrade quickly. The lab then performs the testing service using complex equipment and highly trained personnel, and reports testing results to the prescribing clinician. For the vast majority of laboratory tests, physicians receive the results in 24 hours or less.

Additionally, the laboratory sector is extremely segmented and specialized. There are thousands of different tests prescribed by clinicians for beneficiaries, performed by more than 100,000 independent, hospital, and physician office laboratories. While many laboratories perform routine tests, they often send out more complex tests to a reference lab. Notably, for certain high-complexity tests, only a handful of labs or even just a single lab in some instances, can perform them, and thus not every lab is able to perform every test needed by beneficiaries. Clearly, these testing services cannot be treated as commodities through competitive bidding. Given the nature of lab services, the statutory history, and the value to beneficiaries, ACLA believes competitive bidding is an unworkable policy.

Conclusion

Thank you for the opportunity to share our views. ACLA commends the Subcommittee for holding this important hearing, and looks forward to continuing to work with you on Medicare policies that do not have a negative impact on clinical laboratories as well as the clinicians and patients served every day.

Sincerely,

Alan Mertz
President