November 12, 2013

The Honorable Dave Camp                   The Honorable Sander Levin
Chairman                    Ranking Member
House Ways & Means Committee     House Ways & Means Committee
Washington, DC 20515            Washington, DC 20515

The Honorable Fred Upton                   The Honorable Henry Waxman
Chairman                    Ranking Member
House Energy & Commerce Committee     House Energy & Commerce Committee
Washington, DC 20515            Washington, DC 20515

The Honorable Max Baucus                   The Honorable Orrin Hatch
Chairman                    Ranking Member
Senate Finance Committee      Senate Finance Committee
Washington, DC 20510            Washington, DC 20510

Subject: Clinical Laboratory Community Supports Negotiated Rulemaking to Reform the Clinical Diagnostic Laboratory Fee Schedule

Dear Chairmen and Ranking Members:

We are writing on behalf of the clinical laboratory community to strongly urge the Congress to consider legislation requiring the Centers for Medicare and Medicaid Services (CMS) to enter into negotiated rulemaking with stakeholders in the clinical laboratory community to refine and develop an updated clinical laboratory fee schedule.

Action is warranted by Congress to establish such a negotiated rulemaking process. The fee schedule for clinical diagnostic laboratory tests under Part B of the Medicare program was developed in 1984 based on the local prevailing fees charged in 1983. The cost of clinical diagnostic laboratory tests, laboratory equipment, supplies, and medical professional staff has increased exponentially in recent years. Clinical laboratories are currently reimbursed at levels below those provided in 1984 when adjusted for inflation. The fee schedule for clinical diagnostic laboratory tests is the last Medicare fee schedule that has not been made reliant on prospective payment or relative value as the primary payment methodology. Clinical laboratories provide vital information that influences all major diagnostic, treatment and prognostic patient-care decisions.

As CMS considers reform of the clinical laboratory fee schedule, the agency must take into consideration the impact changes will have on access by all individuals enrolled in Part B to quality laboratory services in all settings. In addition, the agency must establish a mechanism to periodically revise the fee schedule for years subsequent to the first year in which the updated fee schedule is implemented. It should also establish a mechanism to provide for annual inflationary updates to the fee schedule for each year after the first year for which the updated fee schedule is implemented. The
complexities of these tasks require the input of stakeholders representing the beneficiary, the clinical laboratory community, clinicians and the agency to achieve an efficient, cost-effective, accessible, quality process.

We realize that other proposals outline across the board reductions to the fee schedule. While such reductions might be handled by many of the large laboratory service companies which rely on Medicare clinical laboratory test reimbursement for only about 15% of their revenue, hospital and community laboratory services which care for 45-55% of Medicare beneficiaries will not be able to absorb arbitrary cuts such as the one being proposed.

The need to modernize the clinical laboratory fee schedule is apparent. Now is the time for Congress to instruct CMS to engage stakeholders in the process of negotiated rulemaking. For more information on this issue, please contact Patrick Cooney at 202-347-0034 x101 or via email at patrick@federalgrp.com. Thank you for your consideration.

Sincerely,

American Society for Clinical Laboratory Science
American Medical Technologists
American Society for Clinical Pathology
American Society for Microbiology
Clinical Laboratory Management Association