May 16, 2014

Ms. Anne Tayloe Hauswald, Director
Division of Ambulatory Services
Center for Medicare
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

Dear Ms. Hauswald:

Thank you for your willingness to meet with representatives of the clinical laboratory community on May 19, 2014 to discuss the Clinical Laboratory Fee Schedule ("CLFS") reform provisions included in Section 216 of the recently-enacted Protecting Access to Medicare Act of 2014 ("PAMA").[1] Our organizations – the American Clinical Laboratory Association ("ACLA"), AdvaMedDx, and the Coalition for 21st Century Medicine – together represent members of the laboratory industry that furnish millions of tests to Medicare beneficiaries each year. Having supported the inclusion of the CLFS reform provision in PAMA, we are supportive of CMS's efforts to implement the law, and we hope to work with you throughout the process to ensure the success of the program.

This is the first major reform of reimbursement methodology under the CLFS since its inception in 1984, and we are certain that you have an appreciation for how complex this undertaking will be for CMS and for the clinical laboratories and other healthcare providers that will be required to collect, aggregate, and report private payor data to CMS as part of that rate-setting. Our organizations and members intend to work very diligently with CMS and with other stakeholders on the front end of the implementation process so that the information technology infrastructure development, data collection and aggregation, private payor rate reporting, Medicare payment amount calculations, coding, and other activities proceed as smoothly as possible.

We are writing in advance of our May 19th meeting to provide you with an overview of the broad topics we would like to discuss with you. Below are our preliminary recommendations, which we hope you will consider as you implement the new program. We look forward to talking about these preliminary recommendations with you in further detail at our meeting.

Rate Reporting and Rate Setting

1. In addition to including independent clinical laboratories, the definition of "applicable laboratory" should include hospital laboratories performing outreach testing and certain physician office laboratories. Like independent clinical laboratories, hospitals and physician office laboratories should report their private payor rates for clinical laboratory tests that are not part of a bundled payment.

[1] Pub. L. 113-93 (codified at 42 U.S.C. § 1395m-1 (2014)).

2. To ensure consistency among reported rates, laboratories should report the final total approved payment rates for covered services during the reporting period, excluding those for which appeals are not fully exhausted and for which final rates are not yet determined. The approved payment rate is the total "Allowable Amount" paid by a private plan, including any copayments, coinsurance, deductible amounts, and other patient cost-sharing.

3. A six month period should be the length of the first data collection period, and this initial data collection period should cover the first six months of 2015.

4. There should be at least six months between the end of the initial data collection period and the date by which applicable laboratories must report data so that laboratories have adequate time to collect, organize, review and verify the data so that they may submit accurate payment rates and volumes to CMS. This also would allow a lab to factor into its reported rates any volume-based discounts, rebates, and price concessions.

5. An electronic reporting mechanism, such as an internet-based portal, should be established for laboratories to test their rate-reporting capabilities and for CMS to test its information technology infrastructure prior to the actual reporting date. The agency also should consider establishing a reporting test period, limited to a small number of codes, and calculate "draft" weighted median Medicare rates so that CMS and applicable laboratories can review the rates that the agency calculates, before the reporting system is used for all clinical laboratory test rates.

6. We urge CMS to ensure that there is sufficient transparency in the rate-calculation and rate-setting processes so that interested stakeholders can validate the payment rates for individual tests.

Advanced Diagnostic Laboratory Tests and Coding

7. For advanced diagnostic laboratory tests ("ADLTs"), the "initial period of three quarters" for rate reporting that is referenced in the statute should begin once a Medicare administrative contractor ("MAC") determines that an ADLT is covered by Medicare and a unique Healthcare Common Procedure Coding System ("HCPCS") code has been issued to identify the test.

8. A process should be developed as soon as possible through subregulatory guidance to issue unique HCPCS codes and publish the payment rates for existing ADLTs and existing clinical laboratory tests that were cleared or approved by the Food and Drug Administration ("FDA") and paid by Medicare as of the date of enactment under a miscellaneous code or otherwise not reported under a uniquely-assigned code.

9. Congress gave CMS the authority, codified in Section 1834A(d)(5)(C) of the Social Security Act, to establish criteria under which tests that do not fit the statutory definition of an ADLT but that are similar to ADLTs may be considered ADLTs. CMS should use that authority to establish a process in rulemaking that allows a laboratory to request that such a test be classified as an ADLT, at the time of submission of clinical evidence for Medicare coverage. Based on the process that CMS establishes in rulemaking and based on criteria that CMS sets forth in guidance, the relevant MAC or MACs may determine whether a requesting lab's test warrants classification as an ADLT.

Clinical Laboratory Expert Advisory Panel

10. A public announcement should be issued regarding the clinical laboratory expert advisory panel, which discusses the types of individuals the agency would expect to serve on the advisory panel and that solicits nominations from the public. CMS should ensure that at least some panel members have recent industry experience with clinical laboratory operations, commercial test development, and diagnostics reimbursement, and it also should account for patient and clinician perspectives. Stakeholders should be afforded an opportunity to provide input on the advisory panel's charter, role, processes, and meetings.

Rulemaking

11. Given how soon laboratories will have to collect data to report to CMS early in 2016, it is important for the agency to proceed with the regulatory implementation process as soon as possible. Therefore, CMS should include information about its proposed process and timeline for PAMA implementation in the CY 2015 Physician Fee Schedule proposed rule and solicit input from interested stakeholders on discrete questions. Also, as part of that rule, CMS should formally withdraw the regulation that appears at 42 C.F.R. § 414.511 regarding adjusting prices on the CLFS based on technological changes, which is based on a statutory provision that Congress eliminated in PAMA.

We are looking forward to a productive meeting with you and with your colleagues on May 19th, and we sincerely hope that it will be the first in a series of opportunities for us to ask questions and raise issues and for the agency to solicit input and hear about how different policy options might affect different sectors of the laboratory industry. Thank you again for the opportunity to meet with you to discuss these issues of critical importance to us.

Sincerely,

Alan Mertz, President
ACLA

Don May, Executive Vice President
Payment & Health Care Delivery Policy
AdvaMed

John Hanna, Chair, Reimbursement & Policy Workgroup
Coalition for 21st Century Medicine

cc: Sean Cavanaugh
Marc Hartstein