ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
9650 Rockville Pike. Bethesda, Maryland 20814
Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

March 27, 2014

The Honorable Harry Reid
Majority Leader
United States Senate
522 Hart Senate Office Building
Washington, D.C. 20510

Dear Majority Leader Reid,

On behalf of the Association for Molecular Pathology (AMP), I write to you today to express our grave concern with Section 216, "Improving Medicare Policies for Clinical Diagnostic Laboratories" of H.R. 4302, the "Protecting Access to Medicare Act of 2014." According to the unanimous consent agreement, it is our understanding that the Senate plans to vote on the language passed by the House on March 31st and hence, not allow adequate time to consider stakeholder input on these significant reforms to the Clinical Lab Fee Schedule (CLFS). AMP is very disappointed that these policy changes will be enacted into law without sufficient time to consider the unanticipated consequences and ramifications of these sweeping changes to the CLFS.

AMP is an international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine and the *in vitro* diagnostics industry. AMP is very concerned about the effect Section 216 will have on its members' ability to provide care in the many diverse settings where laboratory testing is performed for the following reasons.

Section 216 Disadvantages Hospital-Based Labs:

H.R. 4302 could have significant unintended consequences for hospital-based labs. It creates a serious un-level playing field that provides significant favor to independent laboratories. First, hospitals lack the infrastructure to collect the data outlined in Section 216, which will make it extremely difficult and overly burdensome for them to comply with these new reporting requirements. Second, there are 244,564 laboratories in the United States, and Medicare pays for clinical laboratory services provided in a variety of settings including the inpatient and outpatient hospital, ambulatory surgery center, dialysis facility, health center, home health agency, skilled nursing facility, pharmacy, and public health laboratory. Many of these tests must be performed in a stat setting, within one hour of being ordered. Medicare's changes to payment rates on the CLFS must take into account the

effect those changes may have on beneficiaries' access to medically necessary testing in the hospital setting, as well as to the varying needs of different types of hospitals. Last, the new weighted median calculations will place a disproportionate burden of the reduced payments on hospital-based labs and favor large volume independent laboratories.

Section 216 Disregards the CPT Code Process:

In 2010, the American Medical Association, with the input of leading molecular pathology experts, developed more than 100 new CPT codes for molecular pathology tests. The creation of these codes led to increased transparency in the payment process as the codes provide sufficient granularity for payors to understand and identify the test ordered. AMP believes that Congress and CMS should encourage the use of CPT codes. Unfortunately, H.R.4302 encourages the use of permanent HCPCS codes for new diagnostics over the creation of CPT codes.

Additionally, H.R. 4302 further disregards the use of CPT codes by establishing a unique identifier system for certain tests for the purposes of tracking and monitoring. The current CPT coding system is more than sufficient for tracking, monitoring, coverage and payment. It is a waste of Medicare resources to build a redundant system. There is no need for further identifiers, which will increase costs and create administrative burdens to both CMS and laboratories.

Section 216 Conflicts with Existing Law:

On page 50, subsection "(2) Designation of One or More Medicare Administrative Contractors for Clinical Diagnostic Laboratory Tests" directly conflicts with existing law. This subsection does not reference or modify Public Law 105-33 enacted on August 5, 1997. The designation of contractors is already outlined in 42 USC 1395u, Section 4554 "Improvements in Administration of Laboratory Tests Benefit" and H.R.4302 will create confusion among CMS, contractors and laboratories. It is not necessary and should be stricken from the language.

Additionally, Medicare legislation and regulations appropriately establish and outline the criteria used for establishing coverage. To avoid conflicts with existing policy, a rule of construction should be added to the end of Section 216 stating that "Nothing in Section 216 will alter the coverage criteria of reasonable and necessary."

Section 216 Creates Confusion Among Stakeholders:

First, the language creates different reporting requirements for laboratories offering advanced diagnostic laboratory tests and those providing other clinical diagnostic laboratory tests. It is not clear why this distinction is necessary and it has the potential to create significant confusion, especially among laboratories offering both types of tests.

Second, laboratory developed tests (LDTs) by definition are tests furnished by a single laboratory and not sold for use by a laboratory other than the original developing laboratory. Therefore, H.R. 4302's definition of advanced diagnostic laboratory test encompasses LDTs that are FDA-approved and molecular-based LDTs that

include multiple biomarkers and an algorithm (regardless of whether they are FDA approved or not). Although, the bill does not reference LDTs directly, which leads to confusion among stakeholders and potentially CMS as to what constitutes an advanced diagnostic laboratory test.

Conclusion:

H.R. 4302 includes Section 216 which results in significant modifications and changes to the CLFS payment policy. Due to the inability to thoroughly vet these changes and consider the ramifications as outlined above, AMP calls on Congress to provide additional oversight as CMS implements this policy. If the GAO report finds evidence demonstrating detrimental effects on laboratories in any setting, beneficiaries, etc., then AMP hopes Congress will act just as swiftly as it has today to repeal or modify this policy.

Thank you for your consideration of AMP's comments and concerns about Section 216 of H.R. 4302. If you have any questions or would like to discuss this further, please contact Mary Williams, AMP Executive Director, at mwilliams@amp.org.

Sincerely,

Elaine Lyon, PhD
President