ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
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October 16, 2019

The Honorable Richard Neal
Chairman
House Committee on Ways and Means
1100 Longworth House Office Building
Washington, DC 20515

The Honorable Kevin Brady
Ranking Member
House Committee on Ways and Means
1100 Longworth House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
Chairman
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

The Honorable Greg Walden
Ranking Member
House Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Neal, Chairman Pallone, Ranking Member Brady and Ranking Member Walden:

The Association for Molecular Pathology (AMP) applauds the introduction of H.R. 3584, the Laboratory Access for Beneficiaries (LAB) Act. AMP believes that the bill is an important first step to addressing concerns with implementing parts of the Protecting Access to Medicare Act (PAMA). However, AMP continues to have concerns about additional elements of PAMA implementation beyond those that are addressed in this bill, including and most notably concerns regarding the integrity of data submitted by laboratories to establish market-based pricing for codes on the Clinical Laboratory Fee Schedule (CLFS). We support H.R. 3584 and look forward to working with the Agency and Congress to ensure that clinical laboratories maintain the ability to provide potentially life-saving services to patients.

AMP is an international medical and professional association representing approximately 2,500 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, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

As part of PAMA,[1] Congress directed the Centers for Medicare and Medicaid Services (CMS) to develop a market-based fee schedule for clinical laboratory services. In response to PAMA, CMS has implemented a process for gathering private payor data from laboratories and using it to establish the CLFS fee schedule in a three-year cycle. One complete cycle of data collection and rate setting has been completed. Based on the experience of the first cycle, AMP has significant concerns about both the process and outcomes from the first pricing cycle, which resulted in inaccurate and inequitable pricing. The drastically-reduced reimbursement rates set under PAMA threaten patient access to laboratory testing, including molecular pathology procedures. Of the over two-hundred thirty (230) molecular pathology tests (including oncology, inherited diseases, and infectious diseases) on the CLFS, fifty-seven percent (57%) decreased in value from their 2017 National Limitation Amount (NLA). Ninety (90) molecular tests decreased in value by thirty percent (30%) or more.

[1] Protecting Access to Medicare Act of 2014, H.R. 4302, 113th Congress. (2014).

LAB Act Section 1: Revised Reporting Period for Clinical Diagnostic Laboratory Tests

The LAB Act (H.R. 3584), recently introduced by Rep. Scott Peters (D-CA), Rep. Gus Bilirakis (R-FL), Rep. Bill Pascrell (D-NJ), Rep. Kurt Schrader (D-OR), Rep. Richard Hudson (R-NC) and Rep. George Holding (R-NC) is bipartisan legislation that addresses some of AMP and other stakeholders' concerns with PAMA. H.R. 3584 delays the next round of data reporting by one year and delays the timing for payment reductions under PAMA. These delays are important so that applicable laboratories have time to understand the reporting requirements, make preparations to accurately collect their data, and ensure those data are accurately reported to CMS.

AMP continues to hear from laboratories that are not aware of their obligation to report data to CMS. Therefore, we remain concerned that CMS is not receiving comprehensive or even representative data for most molecular pathology procedures commonly utilized in the Medicare population. Furthermore, in 2019 CMS expanded the domain of laboratories that will have to report under PAMA. This will likely exacerbate the existing issues with the integrity of the data that are reported and used in the second rate setting cycle. While AMP and other stakeholders continue to educate laboratory personnel on PAMA reporting requirements, the expansion of applicable laboratories was implemented at the same time that data collection for the second cycle began. This did not provide hospital laboratories, a group now required to report their data, sufficient time to put needed systems in place to accurately collect data for the first 6 months of 2019. Without delaying reporting, the agency will likely again be working with incomplete and inaccurate data. Section 1 of the LAB Act will allow for extra time will help ensure that laboratories submit the required data accurately.

LAB Act Section II: National Academy of Medicine (NAM) Study and Report

The bill would also direct the National Academy of Medicine (NAM) to conduct a study reviewing the methodology that CMS has implemented for the private payor rate-based clinical laboratory fee schedule. AMP agrees that it is important for an independent body to review the methodology that CMS is using to implement PAMA. Due to the various types of laboratory settings impacted by PAMA, AMP recommends that the NAM study include representatives from all of the different laboratory market segments. Additionally, AMP recommends adding analysis of laboratory capability to perform data collection and reporting as required under PAMA. Ensuring that the NAM study is comprehensive to include all laboratory market segments and analysis of laboratory capability to perform PAMA data collection and reporting is particularly important for laboratories that operate within a hospital or academic medical center. For these laboratories, separating the data required under PAMA from other data contained within the hospital billing system presents a significant and unique challenge. It is crucial that any further recommendations to improve the methodology account for the feasibility for laboratories to report.

AMP Concerns with Data Integrity

While AMP is pleased that the LAB Act would give more time for accurate data reporting, we continue to be concerned with data accuracy, integrity and transparency for future price setting under PAMA. We have shared these concerns with CMS on several occasions, including in our public comments on the CY2019 Physician Fee Schedule Proposed Rule.[2] AMP urged CMS to implement measures to safeguard data integrity in future reporting periods. We also recommended that CMS consider implementing a data aggregation system in future reporting periods. The statute grants CMS authority to implement a data aggregation system after the first reporting period.[3]

[2] AMP Public Comments on the CY2019 Medicare Physician Fee Schedule Proposed Rule. Accessed at https://www.amp.org/AMP/assets/AMP_Comments_PFSCY2019_CMS-1693-P_9-10-2018FINAL.pdf?pass=95.

[3] 42 U.S.C. 1395m-1.

To date, AMP is not aware of CMS having taken any steps to implement this system as authorized. AMP continues to believe that data aggregation is a way to guarantee more complete reporting and expand the ability of laboratories to report more accurate data. We would be happy to discuss ways to incorporate these suggestions into the legislation, or to include as part of the NAM review.

AMP reiterates our support for the bipartisan LAB Act, and appreciate the opportunity to provide feedback and recommendations on the legislation. We look forward to working with Congress to ensure that PAMA is implemented successfully and accurately represents the market rates paid for laboratory tests.

Sincerely,

Victoria M. Pratt, PhD, FACMG
President, Association for Molecular Pathology