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

September 11, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1676-P
P.O. Box 8016
Baltimore, MD 21244-8013

RE: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018; Medicare Shared Savings Program Requirements; and Medicare Diabetes Prevention Program (CMS-1676-P)

Dear Administrator Verma:

The Association for Molecular Pathology (AMP) appreciates the opportunity to comment on the CY2018 Physician Fee Schedule proposed rule. 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, private and hospital-based clinical laboratories, and the in vitro diagnostics industry. We look forward to working closely with CMS as this proposed rule moves toward implementation and offer the following response to your solicitation of comments on data collection and reporting periods for the Clinical Diagnostic Laboratory Tests Payment System.

Solicitation of Public Comments on Medicare Clinical Diagnostic Laboratory Tests Payment System Initial Data Collection and Reporting Periods

AMP appreciates that CMS is attempting to better understand applicable laboratories' experiences with the data reporting, data collection, and other compliance requirements for the first data collection and reporting periods under the new pricing system authorized by the Protecting Access to Medicare Act (PAMA). We welcome the opportunity to work with the agency to ensure that PAMA is implemented successfully and the resulting pricing accurately reflects the current private payer market.

However, the experiences of many laboratories during the initial data collection and reporting period lead us to question the potential accuracy of data reported. Our concern is bolstered by the fact that CMS either received no data or insufficient data for 60 codes on the Clinical Laboratory Fee Schedule (CLFS). CMS's suggestion that these codes be removed because of perceived lack of data during the reporting period is also worrisome as the final rule makes no mention that codes be removed from the CLFS should no/minimal data be submitted. The regulatory requirements for the reporting of highly granular payment data may have made it difficult or impossible for applicable laboratories in a hospital and small or physician-owned laboratory

setting to properly collect data in time for the data reporting deadline. Concerns have also been raised regarding the functionality of the agency's data collection system, and operational problems from the 2016 test phase that remain unresolved and hamper the ability of laboratories to submit data.

We understand that CMS finds itself working within a tight timeline to make pricing determinations for January 1, 2018, as mandated by section 216 of PAMA for the first time. However, the combination of onerous reporting requirements and unresolved systemic problems leaves room for grave concern that final pricing will not accurately reflect payer market rates and could harm Medicare beneficiaries by reducing patient access and choices in testing, decreasing innovation, inhibiting research, and resulting in inaccurate payment rates. CMS should make every effort to address the concerns surrounding data collection and integrity as the new pricing structure is implemented. Specifically regarding the codes for which insufficient or questionable data or no data was submitted, we request that for CY2018 CMS maintain the existing pricing. Given the low volume of the tests there is unlikely to be substantial financial impact to CMS by this decision and retaining existing pricing is the least disruptive to laboratories who perform and potentially financially depend on the tests. Further, as communicated to CMS earlier this year, we recommend that CMS pursue recommendations by adding these codes to the agenda list for the next public meeting for the CLFS in 2018. We believe this will allow all interested stakeholders to provide meaningful input on the re-pricing of these codes and is within the discretion of CMS when data is insufficient.

Thank you for the opportunity to provide these comments. If you require any further information or require additional information, please contact Tara Burke, PhD, AMP Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Federico A. Monzon, MD
President, Association for Molecular Pathology