September 6, 2022
The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1770-P
P.O. Box 8016
Baltimore, MD 21244

Submitted electronically via http://www.regulations.gov

RE: CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies (CMS-1770-P)

Dear Administrator Brooks-LaSure:

The Association for Molecular Pathology (AMP) appreciates the opportunity to provide comments on the Medicare Physician Fee Schedule (MPFS) proposed rule for Calendar Year (CY) 2023. AMP is an international medical and professional association representing approximately 2,600 physicians, doctoral scientists, and medical laboratory scientists (technologists) who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government, and the in vitro diagnostics industry. AMP looks forward to working closely with CMS as the agency implements this proposed rule and offers the following comments on the topics of interest to our members.

**Clinical Laboratory Fee Schedule: Revised Data Reporting Period and Phase-in of Payment Reductions**

AMP supports the proposed technical changes to the Clinical Laboratory Fee Schedule (CLFS), to update the definitions of both the “data collection period” and “data reporting period”. We appreciate CMS providing clarity that the CY2024 and CY2026 payment rates will be based on the applicable data collected during the data collection period of January 1, 2019 through June 30, 2019 and reported to CMS during the data reporting period of January 1, 2023 through March 31, 2023. These changes are aligned with the revisions to the Protecting Access to Medicare Act of 2014 (PAMA) that were included in the Protecting Medicare and American Farmers from Sequester Cuts Act (the Act) of December 2021. AMP also supports the changes made in the Act to revise the payment reductions required by statute, so that for CY 2022, payment was not to be reduced by more than 0 percent compared to the amount established in CY 2021, and for CY 2023-2025, payment may not be reduced by more than 15 percent compared to the amount established the preceding year. AMP continues to support revisions to PAMA to ensure appropriate reimbursement for laboratory tests and protect patient access to testing.

**Proposals for Specimen Collection Fees and Travel Allowance for Clinical Diagnostic Laboratory Tests**

AMP supports CMS’ proposal to codify longstanding specimen collection fee policies by including a new section that would specify that in addition to the payment amounts provided for Clinical Laboratory Diagnostic Tests (CDLTs), new CDLTs, and new Advanced Diagnostic Laboratory Tests (ADLTs), CMS will pay a specimen collection fee and travel allowance. AMP has been supportive of the payment for laboratory specimen
collection and travel allowance since CMS established these policies in CY 2021, and we believe that these payments should continue following the conclusion of the public health emergency.

During the COVID-19 pandemic, laboratories have been forced to scale up personnel and services offered. This has allowed laboratories to offer services that enhance patient care while also offering a high standard of safety to employees. Telehealth adoption has also increased significantly during the pandemic, which has led laboratories to need to travel to patients for specimen collection to provide patients with the full range of necessary care.

COVID-19 and its many variants are becoming endemic in the United States, and although the public health emergency will one day end, the virus will continue to be communicable and pose a threat to community health. The continuance of this payment is necessary for laboratories to continue providing these much-needed services both to address COVID-19 and future viruses. AMP appreciates that CMS will maintain the $3 nominal specimen collection fee amount and we support the proposed specimen collection requirements.

Thank you for the opportunity to provide these comments. Should you have any questions, please do not hesitate to contact Sarah Thibault-Sennett, Director, Public Policy & Advocacy at sthibaultsennett@amp.org.

Sincerely,

Daniel E. Sabath, MD PhD
President, Association for Molecular Pathology