March 13th, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-0057-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

SUBMITTED ELECTRONICALLY VIA http://www.regulations.gov

RE: Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations Proposed Rule (CMS-0057-P)

Dear Administrator Brooks-LaSure:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to provide comments on Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations proposed rule (CMS-0057-P). AMP is an international medical and professional association representing approximately 2,900 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.

Prior authorization is often a barrier to care for patients in receiving laboratory testing, including molecular testing. Laboratories must provide extensive documentation before prior authorization is granted, which can include: a molecular diagnostic clinical history form, a recent pathology report, relevant clinical encounter notes, and other documentation required by the insurer. The process requires laboratories to hire administrative staff to complete the prior authorizations, as often the ordering physician does not submit the prior authorization on behalf of the patient. The time required to assemble this information and wait for approval delays medically necessary testing, which ultimately delays treatment and could negatively impact health outcomes for patients, in addition to affecting the cost of health care.

Therefore, AMP was pleased that CMS proposed requirements for prior authorization timeframes and communications. We recommend that CMS adopt the shorter proposed timeframes for decisions, which include five days for a standard decision. However, in certain circumstances, as described below, a 24-hour timeframe would be beneficial for our patients. Therefore, we request that CMS consider adopting a 24-hour timeframe for expedited requests instead of the 48-hour timeframe that was proposed. Laboratory testing is unique in that for some tests once a patient's specimen has been collected, processing must be performed shortly thereafter in order to preserve sample integrity. Delays such as 48 hours could negatively impact the clinical test results. Often, laboratories will have to move forward with testing before prior authorization is granted. It would be helpful to have a 24-hour turnaround time

when dealing with testing of specimens so that the laboratory could have the approval before starting testing.

Furthermore, genomic sequencing procedures already have long turnaround times, so adding a few days for prior authorization can further delay medical decision making, and ultimately treatment. Often, cancer biomarker testing is done in conjunction with prior authorization, since any delays in testing can impact the medical treatment decisions for patients.

Thank you again for the opportunity to provide feedback on the proposed changes to prior authorization in Medicare Advantage. Please address any questions to Sarah Thibault-Sennet, AMP's Director, Public Policy and Advocacy at sthibaultsennett@amp.org. We look forward to continuing to work with CMS on this important issue.

Sincerely,

Laura Tafe, MD
President, Association for Molecular Pathology