



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

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December 31, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1720-P
Baltimore, MD 21244

Joanne Chiedi
Acting Inspector General
Office of Inspector General
Department of Health and Human Services
Attention: OIG-0936-AA10-P
330 Independence Ave SW
Washington, DC 20201

RE: Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations (CMS-1720-P) and Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements (OIG-0936-AA10-P)

Dear Administrator Verma and Acting Inspector General Chiedi:

The Association of Molecular Pathology (AMP) appreciates the opportunity to provide comments on the Modernizing and Clarifying the Physician Self-Referral Regulations (CMS-1720-P) and the Revisions To Safe Harbors Under the Anti-Kickback Statute (OIG-0936-AA10-P). 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. Our membership includes professionals from academic medicine, hospital-based and private clinical laboratories, the government, and the in vitro diagnostics industry.

AMP supports the Centers for Medicare & Medicaid Services' (CMS) and the Department of Health and Human Services Office of Inspector General (OIG) efforts to remove regulatory barriers to the expansion of care coordination and value-based care. We commend HHS efforts to modernize and revise the physician self-referral law and the anti-kickback regulations. Clinical laboratory services play an important role in value-based care and as such, AMP would like to provide comments to ensure any changes made by the agency recognize and support the role laboratories play in coordinating and managing care for patients.

The Value of Clinical Laboratories in Patient Care

AMP agrees with CMS and OIG on the importance of patient care coordination and management to improve patients' health outcomes. We understand that CMS and OIG requested comment on the role that laboratories play in care coordination and believe that clinical laboratories are absolutely necessary to foster care coordination for patients through their delivery of high value to medical care. For example, laboratories play a vital role in decision-making as test results are essential for determining diagnoses and managing disease. In

fact, 60-70 percent of clinical decisions depend on laboratory testing results.¹ As the Medicare program and healthcare system place a greater emphasis on precision medicine, the role of clinical laboratories in value-based care will continue to grow. Already molecular pathology testing plays a key role in identifying the most appropriate treatments for patients with non-small cell lung cancer and cancer patients with a suspected family history.

AMP members are experts in the role of molecular pathology and molecular genetic testing. Most such testing is performed in laboratory settings where molecular pathologists oversee the performance of the ordered test. When testing is done locally, molecular pathologists provide a further and even more valuable role assisting in care coordination by interpreting the test results and assisting with diagnosis, treatment, and management of care decisions.

Laboratory medicine can support value-based health care and foster outcomes-based payment arrangements. By providing important clinical diagnostic data, laboratory medicine assists in population health initiatives that target improved short- and long-term patient outcomes and drive cost-effective care.² Using longitudinal clinical data from laboratories has the potential to identify disease specific information related to patients' progression to support disease management and improve the health of individuals with chronic health conditions that drive increasing health care costs, such as diabetes and kidney disease. One example of a value-based health care model based on laboratory data that is already taking place is Clinical Laboratory 2.0.³

For these reasons, it is important that molecular pathology services be appropriately reimbursed. Compensating laboratories and molecular pathologists for their services is critical to insure patients have access to timely results and coordinated care. Adequate payment is essential for laboratories to continue to be able to foster growth and key advances – both technological and medical – in the field. Unfortunately today, due to the changes in the clinical laboratory fee schedule (CLFS), including effects from the Protecting Access to Medicare Act of 2014 (PAMA), reimbursement for clinical diagnostic laboratory tests is expected to be cut by as much as 30% by 2020 and potentially 45% by 2023.⁴ These cuts are especially damaging in the rapidly advancing area of molecular pathology, for which testing for academic and specialty hospital outpatients continues to be directly paid at CLFS rates.

Preventing Abusive Financial Arrangements

We understand that CMS and OIG are concerned with potentially abusive relationships between clinical laboratories and providers and for this reason did not propose to include clinical laboratories in the Stark and Anti-Kickback exceptions proposed in this rule. AMP shares CMS' concerns about fraud and abuse. However, given the central role of laboratory medicine in health care, we urge CMS and OIG to examine this issue more closely.

¹ Rohr UP, Binder C, Dieterle T, Giusti F, Messina CG, Toerien E, et al. The Value of In Vitro Diagnostic Testing in Medical Practice: A Status Report. PLoS One. 2016;11:e0149856.

² Swanson K, Dodd MR, VanNess R, Crossey, M. Improving the Delivery of Healthcare through Clinical Diagnostic Insights: A Valuation of Laboratory Medicine through "Clinical Lab 2.0". The Journal of Applied Laboratory Medicine Nov 2018, 3 (3) 487-497; DOI: 10.1373/jalm.2017.025379

³ Crawford JM, Shotorbani K, Sharma G, Crossey M, Kothari T, Lorey TS, et al. Improving American healthcare through "Clinical Lab 2.0": a project Santa Fe report. Acad Pathol 2017;4:1–8

⁴ Centers for Medicare & Medicaid Services. Medicare clinical diagnostic laboratory tests payment system final rule. <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-06-17.html>

It is important to monitor value-based arrangements between participating entities not only to ensure the absence of fraud and abuse, but also to ensure that such arrangements provide value to patients. However, in some situations it may be appropriate to include clinical laboratories in the proposed Stark and Anti-Kickback exclusions without causing undue risks of fraud and abuse. We request that CMS and OIG work with stakeholders to identify any such situations and incorporate them in the revised regulations.

Thank you again for the opportunity to comment on this proposed rule. We are happy to be of assistance in providing additional clinical or other information to assist you with the final rule. If you have any further questions, please direct your correspondence to Tara Burke, AMP Senior Director of Public Policy and Advocacy at tburke@amp.org.

Sincerely,

Karen E. Weck, MD, FCAP
President, Association for Molecular Pathology