ASSOCIATION FOR MOLECULAR PATHOLOGY
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August 28th, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1850-P
P.O. Box 8010
Baltimore, MD 21244-8010

RE: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; Including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency (HPT) Data; Prior Authorization; Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA); and Notices of Closure of Teaching Hospitals and Opportunities to Apply for Available Slots; CMS-1850-P

Submitted electronically via www.regulations.gov

Dear Administrator Oz,

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit these comments in response to the CY 2027 Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems proposed rule in Public Docket CMS-1850-P. AMP is an international medical and professional association representing approximately 3,100 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, government, and the in-vitro diagnostics industry.

AMP thanks CMS for proposing a mechanism to address the role of software in the administration of healthcare services in Section X.(B) *OPPS Payments for SaMS Diagnostic Services* of the proposed rule. We appreciate that CMS has outlined some of the issues in determining coding and payment for these tools. However, AMP has serious concerns that this provision would remove ten existing codes from the Medicare Clinical Laboratory Fee Schedule (CLFS) where they have been reviewed by the AMA CPT Editorial Panel for placement and descriptor language and place them temporarily under New Technology Ambulatory Payment Classifications (APCs) on the Hospital Outpatient Prospective Payment System (OPPS). **We strongly oppose this change as proposed and outline our comments and concerns in more detail below.**

X.B: OPPS Payments for SaMS Diagnostic Services

AMP generally supports the move to distinguish "Software as a Medical Service (SaMS)" from "Software as a Service (SaaS) given that software-enabled medical technologies are quickly evolving.

We recognize the challenges the Agency faces in providing a consistent approach to SaMS payment and appreciate that the term SaMS better reflects that they are a part of a healthcare provider's medical practice.

However, AMP does not agree with or support CMS' assertion that SaMS is not an integral part of some laboratory procedures. AMP's long held position is that laboratory analytics, including SaMS, encompass algorithms (i.e., those powered by artificial intelligence or machine learning), software, mathematical formulae, clinical decision support tools, clinical calculations, risk calculations, and other tools that are used with a laboratory procedure to clarify or enhance the clinical usefulness of the procedure. Furthermore, we have advocated for legislation that would further clarify that genomic, molecular, and "dry bench" laboratories should be regulated within the Clinical Laboratory Improvement Amendments (CLIA)'s jurisdiction.[1] Data analysis is an inseparable, professional component of a continuous diagnostic testing service. Even when it is offered as a standalone manufactured product, data analysis should not be fully divorced from operating in a CLIA regulated laboratory nor the initial, "wet-lab" specimen analysis because they are directly contributing to ongoing patient care.

CMS states, "We do not believe it is appropriate to consider these secondary algorithmic analyses to be CDLTs or establish CLFS payment rates for these analyses. Because these secondary algorithmic analyses do not require laboratory services or entities, regulated by CLIA, to perform them." AMP disagrees with this statement and the Agency's conclusion that SaMS used to evaluate data generated from a clinical laboratory test should always be treated differently for payment purposes from a CDLT and, therefore, not paid for under the CLFS. AMP believes such tests should be conducted under the oversight of the CLIA regulations. Specifically, when SaMS is used to generate a reportable laboratory result, is necessary to generate the result, is an integral component of the testing process required to interpret the result, and is related to patient care, a CLIA-certified laboratory should remain responsible for ensuring the validity of the result. **Therefore, AMP urges CMS to clarify the definition of "laboratory" within the CLIA regulations to include facilities that produce and examine information obtained through analysis of such materials derived from the human body.**

Given this position, AMP opposes the proposal to remove certain codes from the CLFS and place them under new technology APC on the OPPS. Shifting them to another payment system is incongruent with the CLIA regulation's purpose and poses a risk to patient safety. **We urge CMS to reject this proposal in the final rule and leave any codes for SaMS that are integral to producing a clinical result on the CLFS.**

AMP acknowledges the Agency's concerns about a lack of transparency into laboratory algorithm costs and lack of beneficiary cost-sharing to increase transparency; however, the Protecting Access to Medicare Act (PAMA) explicitly established a unique system to base CLFS rates on commercial payment data reported by applicable laboratories to CMS, and the system does not include cost-sharing requirements. Since PAMA was enacted, and despite implementation challenges, Congress has maintained the position that benchmarking public Medicare rates for clinical laboratory tests against actual private-sector market rates will drive transparency and lead to appropriate valuation by aligning Medicare with commercial reality. For the first time since 2017, applicable laboratories have reported private-sector data to CMS for rate-setting in CY 2027 and beyond. Making a change to some codes now would likely have the opposite effect and would instead reduce transparency.

Beyond AMP's significant concern that moving clinical laboratory test codes from the CLFS to APC is inappropriate, AMP also asserts this change is premature. Currently, complex and consequential

[1] https://www.amp.org/advocacy/clia/

discussions and actions are taking place at both the executive branch and congressional levels that will shape the broader health policy approach to the use of artificial intelligence (AI) and new software-based technologies for years to come. For example, CMS currently has an open request for information (RFI) focused on CLIA updates which specifically asks about "data-only facilities" that use software-based services. Moreover, as previously noted, the annual coding cycle is underway with clinical laboratories reporting private payor data for codes on the CLFS under the requirements set forth under PAMA for the first time in nine years, and the White House continues to develop a broader policy focused on AI and its use across the spectrum of society, including in healthcare. Changing how clinical laboratory tests using SaMS are paid in the current environment introduces untimely complexity to other conversations and actions within the administration and may ultimately be incongruent with related policy.

Conclusion

The Association for Molecular Pathology strongly opposes the proposed policy to shift SaMS used by laboratories from the CLFS. AMP respectfully requests that CMS:

1. clarify that CLIA includes facilities that produce and examine information obtained through analysis of such materials derived from the human body; and
2. exempt current and future software-based laboratory tests from a SaMS-specific payment structure and continue to include them on the CLFS.

Not only does this approach align with current CLIA regulations but also enables ongoing policymaking on AI to advance enough to inform decisions such as these.

Thank you for the opportunity to provide these comments. If you have any additional questions, please do not hesitate to reach out to Gail M. Reese, JD, Director of Public Policy and Advocacy, at greese@amp.org.

Respectfully,

Aaron Bossler, MD, PhD
President
Association for Molecular Pathology