ASSOCIATION FOR MOLECULAR PATHOLOGY
Providing global expertise in molecular testing that drives patient care
6120 Executive Boulevard, Suite 700, Rockville, Maryland, 20852
Tel: 301-634-7987 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

September 14, 2026

Mehmet Oz, MD
Administrator
Department of Health and Human Services
Centers for Medicare & Medicaid Services
Attention: CMS-3485-NC
P.O. Box 8013
Baltimore, MD 21244-8013

RE: Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; CMS-1848-P

Submitted electronically via regulations.gov

Dear Administrator Oz:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit comments in response to CMS' proposed rule, Medicare and Medicaid Programs; CY 2027 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program; CMS-1848-P. AMP is an international medical and professional association representing approximately 3,100 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 members are highly involved in the development, validation, and interpretation of molecular diagnostic tests, including biomarker tests for the diagnosis and management of inherited disorders, cancers, rare and infectious diseases. AMP's comments will address the following sections in the proposed rule:

- X. Request for Information (RFI) on Duplicate Laboratory Testing, Imaging, and Result Sharing and Interoperability
- D.3.b.(61) Software as a Medical Service (SaMS) Laboratory Analyses
- H. Current Procedural Terminology (CPT) Request for Information (RFI)
- D.4.b.(9) Request for Revaluation of Physician Work Time Based on Empiric Data (CPT Codes 88305, 88307)

X. Request for Information (RFI) on Duplicate Laboratory Testing, Imaging, and Result Sharing and Interoperability

In the proposed rule, CMS expresses concern that inaccessible, siloed electronic health records (EHRs) may contribute significantly to unnecessary and duplicative laboratory testing by limiting information sharing among treating providers and laboratories. While AMP respects CMS' efforts to ensure appropriate payment is made for medically needed care, **AMP disagrees with CMS' assertions that unnecessary duplicative laboratory testing is widespread.** Laboratory testing, particularly with regard to genetic and molecular pathology testing, is performed within complex clinical workflows, and repeat testing is often medically necessary and appropriate to answer distinct clinical questions, guide treatment decisions, or update prior findings as a disease progresses and alterations

occur. **AMP urges CMS to focus its efforts on improving interoperability and access to relevant clinical data across the healthcare system, before contemplating any payment incentive or penalty policies that would inadvertently restrict access to medically necessary testing. Additionally, AMP strongly recommends that CMS create a narrow and appropriate definition of what an unnecessarily "duplicative" test is, in order to ensure there are no unintended consequences for laboratories, ordering providers, and our patients.**

X.3. Potential Mechanisms for Addressing Duplicative Payment

AMP appreciates CMS' efforts to reduce unnecessary patient testing. However, the proposed potential mechanisms for addressing duplicative payment inappropriately place the burden for reducing testing on the laboratory. Laboratories typically run tests that are first ordered by the treating physician. Moreover, often the laboratory lacks access to the patient's medical record to determine if the test was previously performed. Any proposed CMS mechanism to address potentially duplicative laboratory testing must consider that any payment reductions would likely inappropriately impact laboratories providing the service, not necessarily the treating healthcare provider who ordered the previously performed test.

With this in mind and to achieve its stated goal, AMP recommends CMS establish a clear definition of what the agency considers to be duplicative testing. Innumerable examples of necessary laboratory testing exist that may look duplicative upon initial review but are actually integral to medically necessary and appropriate patient care. We recognize that the intent of reducing duplicative testing is to reduce incomplete or delayed care management, but overly restrictive policies can also result in the same unwanted outcome.

To illustrate AMP's concerns, please consider the following patient scenarios where laboratory testing that could be labeled "duplicative" is needed for accurate patient care.

- Infectious Disease Testing: In infectious disease laboratories, it is typical to run a panel for Flu A/B, RSV and SARS-COV-2 when a patient presents with upper respiratory infection symptoms. However, if a patient tests positive for Influenza A, the laboratory must perform an additional test to determine the subtype to report the information to local regulatory agencies. It is imperative that the second test is run so that agencies can accurately track influenza cases and know what subtypes are in the population.
- Oncology Testing, Solid Tumor Testing: In an oncology solid tumor example, a comprehensive next generation sequencing (NGS) assay may identify a pathogenic variant from the tumor tissue that raises concerns that the alteration may actually be germline in nature. In that setting, additional blood testing for the same genetic alterations is clinically necessary to determine whether the finding is inherited rather than tumor-acquired, which is essential in determining a patient's treatment. While there is likely overlap in the variant or genes being interrogated, the specimens used in the tests are different and the tests answer fundamentally different clinical questions.
- Oncology Testing, Multiple Tumor Specimen Testing: When multiple lesions are biopsied or identified on resection, it is assumed that all sections represent the same neoplasm. However, during the analysis of the sections, differences in morphology or results from ancillary studies may suggest different neoplasms exist. In this case, precision medicine testing of multiple samples, but with the same biomarkers, may be useful to determine whether all lesions are affected by the same drug.

These are relatively rare clinical scenarios, but they are important to individual patients who should not be prevented or delayed from receiving medically necessary testing. The scenarios illustrate the importance of why a targeted, clear, and narrow definition for "duplicative testing" should be determined first. Any definition should not focus solely on overlap in genes, variants, or analytes. **CMS should consider the specimen type, intended use, analytical design and coverage, variant classes assessed, and the distinct clinical question being answered before determining that two molecular tests are duplicative.**

X.4. Laboratory and Imaging Interoperability

While AMP has concerns about restrictive billing solutions, AMP applauds CMS' ongoing commitment to advancing solutions to the significant challenges created by overall inadequate system interoperability across healthcare providers and health systems. We agree with CMS that the data exchange standards between laboratories

and providers, both in regulation and in real world practical application, are inadequate for ensuring patients receive the best and most timely care available. **However, AMP urges CMS to be extraordinarily cautious in adopting and mandating new standards, with any attendant incentives or penalties, given that the available standards themselves are not yet ready for universal application and implementation.** Three significant barriers currently limit the feasibility and scalability of broad interoperability requirements for molecular pathology laboratories: (1) limitations in foundational coding standards such as Logical Observation Identifiers Names and Codes (LOINC); (2) the complexity of exchanging genomic data in structured formats; and (3) the lack of mature, universally implemented standards across laboratory and EHR systems.

Foundational Issues with LOINC

For molecular laboratories, a critical requirement of any interoperability framework is the ability to consume, store, and manage individual genomic variants as discrete data elements in a scalable, standardized, and reliable way. However, current interoperability standards fall short in supporting the structured, computable exchange of complex genomic data across EHRs and laboratory information systems (LIS).

Most federal interoperability standards rely on applying the correct LOINC, a six-part unique code, to a laboratory test. While this comprehensive approach is a step in the right direction, numerous foundational challenges with LOINC persist. First, studies have shown that users of LOINC have a significant error rate in assigning LOINC codes.[1,2] LOINC uses unique, unrelated, and non-hierarchical codes to assign laboratory result names, making it exceedingly difficult to verify whether a LOINC code has been assigned correctly by simply looking at it. Additionally, LOINC's one-unique-code-per-test approach does not always align well with molecular pathology testing needs as highly complex molecular tests may require hundreds of LOINC codes. For example, more than two hundred distinct LOINC codes exist for HIV-related testing, making consistent code selection challenging and increasing the likelihood that similar tests will be mapped differently across laboratories, or even within the same laboratory by different laboratory professionals.

Second, LOINC test descriptions are incapable of accounting for all testing complexity. LOINC currently does not capture units of measure – results with different reference ranges and observed values can have the same LOINC code. This issue is exacerbated when a test result goes to another laboratory. If the second laboratory changes any of the underlying facets of the test (reference range, units of measure, method, etc.), that laboratory has to decide how to maintain the record. The laboratory could keep the original LOINC code, forget to update the LOINC code, or erroneously update the LOINC code such that the results are charted in the wrong location of the structured data. Even when LOINC codes are correctly assigned, differences in units of measure, reference ranges, and test methodologies may limit the comparability of results and increase the risk of clinical misinterpretation.

General Interoperability Concerns for Molecular Pathology Laboratories

Aside from concerns related to LOINC, there are other challenges for molecular pathology laboratories with regard to interoperability. Test results are often delivered to EHRs as PDF reports or unstructured text. This reality makes information contained in these documents difficult to search, aggregate, or compare across time. It also makes it difficult to use these reports for purposes of duplicate test detection, or in clinical decision support (CDS) systems, which require discrete genomic data elements for best test utilization and patient care. Proprietary vendor systems may also limit data portability and standardized data exchange. For laboratories using legacy LIS and EHR platforms, there is often a lack of native support for modern genomic interoperability standards, creating a significant bottleneck in precision medicine. Such older systems were designed for traditional, low-volume data lab results (like blood chemistry panels), versus the massive and complex datasets generated by NGS testing.

---

[1] Stram M, Seheult J, Sinard JH, Campbell WS, Carter AB, de Baca ME, Quinn AM, Luu HS; Members of the Informatics Committee, College of American Pathologists. A Survey of LOINC Code Selection Practices Among Participants of the College of American Pathologists Coagulation (CGL) and Cardiac Markers (CRT) Proficiency Testing Programs. Arch Pathol Lab Med. 2020 May;144(5):586-596. doi: 10.5858/arpa.2019-0276-OA. Epub 2019 Oct 11. PMID: 31603714.

[2] McDonald CJ, Baik SH, Zheng Z, Amos L, Luan X, Marsolo K, Qualls L. Mis-mappings between a producer's quantitative test codes and LOINC codes and an algorithm for correcting them. J Am Med Inform Assoc. 2023 Jan 18;30(2):301-307. doi: 10.1093/jamia/ocac215. PMID: 36343113; PMCID: PMC9846663.

These interoperability challenges are further complicated by the reality that NGS testing is not always interchangeable across laboratories. Assays may differ substantially in gene content, limit of detection, methodology, bioinformatic pipelines,[3] reporting practices, and acceptable specimen types.[4] This is particularly true with NGS testing in oncology. As previously outlined, multiple genomic tests may be clinically appropriate for a single patient because distinct tests can address different diagnostic, prognostic, hereditary risk, monitoring, or therapy-selection questions.

Finally, while FHIR appears to be the solution to many of these concerns, significant implementation barriers remain. Currently under law, only EHRs and third-party applications accessing EHR systems are required to use FHIR. For data interoperability between laboratories and EHRs, EHRs are mandated by law to use HL7 version 2.5.1 for most operations. The differences between HL7 version 2.5.1 and HL7 FHIR are significant in both syntax (how the data is packaged and structured) and semantics (how the data is translated between system). Furthermore, the cost and burden on laboratories and vendors to switch to FHIR for interfaces between laboratory instruments, LIS, and EHRs would also be substantial.

AMP Recommendations to Improve Interoperability
AMP supports the continued development of laboratory and genomic interoperability standards and recognizes their critical role in advancing data sharing, clinical decision support, and overall patient care. However, current HL7 Clinical Genomics and United States Core Data for Interoperability (USCDI) standards continue to evolve and require additional refinement, testing, and implementation experience before they are broadly adopted as normative requirements**.**

AMP recommends that CMS do the following:

- **Work closely with stakeholders and subject matter experts to create more robust or wholly new standards that address how complex laboratory information should be stored, maintained, and shared.**
- **Carefully evaluate the costs and operational burdens that new interoperability requirements, including a transition to HL7 FHIR, would place on laboratories.**
- **Evaluate the limitations of current coding standards, which do not yet consistently support the exchange of complex genomic data. This evaluation should occur after stakeholders establish consensus on the minimum set of discrete data elements needed to accurately represent a genomic variant.**
- **Prioritize standards maturation, successful pilot implementations, and multi-stakeholder collaboration to ensure that future adoption is practical, scalable, and capable of delivering meaningful clinical value while minimizing unintended consequences.**
- **Exercise significant caution in utilizing AI to detect "duplicate" tests, as such tools may not reliably distinguish between assays with different gene content, analytical performance characteristics, specimen requirements, or clinical indications.**

D.3.b.(61) Software as a Medical Service (SaMS) Laboratory Analyses
AMP thanks CMS for proposing a mechanism to address the role of software in the administration of healthcare services in Section D.3.b.(61), "Software as a Medical Service (SaMS) Laboratory Analyses" in the proposed rule. AMP is also supportive of distinguishing "Software as a Medical Service (SaMS)" from "Software as a Service (SaaS) given that software-enabled medical technologies are quickly evolving. **However, as outlined in our**

[3] A bioinformatic pipeline is an analysis workflow that takes input data files in unprocessed raw form through a series of transformations to produce output data in a human-interpretable form (a list of variants or assemble a genome(s)).
[4] Luu, H. S., Campbell, W. S., Cholan, R. A., Edgerton, M. E., Englund, A., Keller, A., Korte, E. D., Mitchell, S. H., Watkins, G. T., Westervelt, L., & Krasowski, M. D. (2024). *Analysis of laboratory data transmission between two healthcare institutions using a widely used point-to-point health information exchange platform: A case report*. *JAMIA Open, 7*(2), ooae032. https://doi.org/10.1093/jamiaopen/ooae032.

response to a similar CMS proposition in the 2027 Hospital Outpatient Prospective Payment System (OPPS), AMP opposes CMS' proposal to remove SaMS laboratory 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, to a contractor price under the Physician Fee Schedule (PFS).

First, 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, or as, a laboratory procedure to clarify or enhance the clinical usefulness of the procedure. Furthermore, AMP has 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.[5] 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 CMS' 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.**

Second, shifting some laboratory codes to another payment system is incongruent with the CLIA regulation's purpose and poses a risk to patient safety. AMP acknowledges CMS' 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. 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.

Lastly, AMP believes changing the payment system for certain laboratory tests is premature. Currently, complex and consequential 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 issued an open request for information (RFI) focused on CLIA updates concurrently with this proposed rule 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.

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

H. Current Procedural Terminology (CPT) Request for Information (RFI)

CMS is seeking comment on the use of Current Procedural Terminology (CPT) codes as the national coding standard for physicians and other health care professional services. AMP has extensive experience with CPT and has submitted numerous molecular laboratory code applications to accurately describe the services provided by our members. **AMP supports CPT as the national standard for describing physician and other health care professional services.** CPT provides a common vocabulary that promotes consistent reporting across the health care system.

AMP is concerned about several assertions in the RFI regarding the CPT code development process. New CPT codes are not introduced by the CPT Advisory Committee; rather, code applications may be submitted by individuals and organizations in response to a need to describe services provided in clinical practice. The CPT Editorial Panel is an independent body of volunteer physicians and other qualified health care professionals with the authority to modify the CPT code set. The Panel considers information and expertise submitted by code applicants and follows established criteria to ensure that codes accurately describe the services they represent. The process also incorporates broad clinical input from stakeholders, including national medical specialty societies. As an active participant in the CPT code change process, AMP brings molecular pathology expertise to the development and maintenance of codes that accurately reflect evolving molecular laboratory services. It is important to preserve the distinction between coding, coverage, and payment. The CPT Editorial Panel develops codes to describe services; it does not determine Medicare coverage, medical necessity, or payment. Medicare payment and coverage determinations are made by CMS through processes that include opportunities for public and stakeholder input.[6]

Molecular pathology laboratories have seen firsthand the challenges created by increasingly complex coding, registration, coverage, and billing requirements. In particular, the requirement in certain circumstances for molecular pathology claims to include DEX Z-codes has added significant administrative complexity and burden. These requirements can be especially costly and disruptive for pathologists and laboratories performing and reporting increasingly complex molecular diagnostic testing.

AMP supports the continued use of CPT as the national coding standard for physicians and other health care professional services. **AMP encourages CMS to work collaboratively with the AMA and medical specialty societies to evaluate the existing framework and identify opportunities to improve the coding process while ensuring that it continues to accurately and efficiently describe evolving health care services, including molecular pathology.**

D.4.b.(9) Request for Revaluation of Physician Work Time Based on Empiric Data (CPT Codes 88305 and 88307)

In the proposed rule, CMS identified a number of CPT codes that are potentially misvalued, including CPT codes 88305 and 88307 (surgical pathology services). Rather than utilizing its customary process for evaluating potentially misvalued codes, CMS proposed revaluation based on a nomination submitted by the Maryland Health Care Commission (MHCC), which identified 88305 and 88307 among eleven other codes for potential misvaluation. MHCC's analysis to identify these codes does not provide a transparent or verifiable basis for its conclusions, making it difficult to assess the accuracy and validity of its findings. Relying on it as a basis for immediate reevaluation would set a concerning precedent for future reevaluations of potentially misvalued codes. **Given all of this, AMP urges CMS not to make any unilateral changes to the surgical pathology service codes 88305 and 88307 for CY 2027.**

The MHCC analysis does not provide an empirically valid estimate of typical time or service intensity and does not establish that the physician time or work relative value unit (RVU) assigned to the typical service is inaccurate. The review also lacks transparency, making it impossible to determine whether it accurately attributed each service to the

[6] CLFS Annual Public Meetings | CMS

rendering physician or assigned professional work to the correct day. **Instead of relying on this single analysis, CMS should follow its previously established valuation framework, which includes the American Medical Association (AMA) and Specialty Society RVS Update Committee (RUC), and the associated public comment process.** Following this process allows physicians with relevant clinical expertise to evaluate the time and intensity required to furnish the typical service.

Making changes based on flawed findings that misrepresent and distort the full clinical realities of these services could compromise access to timely and accurate diagnostic care. **As such, AMP urges CMS to follow the established pathways for addressing potentially misvalued codes, and not to make any changes to the surgical pathology code set for CY 2027.**

Conclusion

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 D. Bossler, MD, PhD
President Association for Molecular Pathology