August 20, 2026

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Baltimore, MD 21244-8010

Attention: CMS-1850-P

Dear Sir/Madam:

The Association for Diagnostics & Laboratory Medicine (ADLM) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) July 7, 2026 proposed revisions to the Hospital Outpatient Prospective Payment System (OPPS) and Medicare Ambulatory Surgical Center (ASC) Payment System. Within the document the agency recommends the adoption of a new payment policy for software-based medical services used in algorithmic analyses. This provision is the focus of ADLM's comments.

CMS states that existing reimbursement policy for software as a medical service (SaMS) "may create significant vulnerabilities for the Medicare program" because these tests are paid under the Clinical Laboratory Fee Schedule (CLFS) and not "subject to beneficiary cost-sharing or budget neutrality." To address this concern, the agency asserts these services are not clinical diagnostic tests and therefore may be performed by non-CLIA certified entities, allowing CMS to remove them from the CLFS.

ADLM is concerned that this payment-driven approach does not adequately consider the regulatory implications or potential effects of this change on patient care. While we agree that the level of regulatory oversight for these algorithmic services warrants discussion, this payment rule is not the proper venue. ADLM recommends that CMS withdraw the proposal and engage the broader healthcare community in a dialogue on the appropriate regulatory model for these tests.

General Comments

In the proposed rule, CMS suggests that secondary analyses of test results may be performed by non-CLIA laboratories because specimen collection, quality control, testing, result generation, and interpretation have already occurred. CMS views subsequent use of those data to generate patient-care information as distinct from the laboratory testing process and outside CLIA oversight. ADLM believes this characterization is inaccurate as it fails to take into consideration the laboratory's central role in this process. As CMS assesses this proposal, it should consider the following:

- ***All test results, even when measuring the same analyte, are not equivalent –*** many clinical laboratory results are not harmonized. Depending on the method or device used, laboratories may produce different numeric values and reference intervals for the same analyte. Although these results may be reproducible for a specific method, they may not be comparable across devices or platforms. Algorithms that combine or interpret data generated through different methodologies may increase the risk of misdiagnosis and lead to higher, rather than lower, healthcare costs. Many non-laboratorians are not familiar with this limitation.

- ***Laboratory expertise remains essential to interpreting lab-generated data because laboratory physicians and scientists are best positioned to assess the strengths and limitations of test results*** — laboratory professionals use their knowledge of test methodologies, clinical context, and related results to identify aberrations or inconsistencies that algorithmic analysis alone may miss. If unrecognized, these issues can produce inaccurate or harmful outputs. Algorithms can support clinical decision-making, but they cannot replace informed laboratory judgment, particularly when preanalytical or analytical factors may affect downstream analysis or when non-harmonized data is employed.

- ***Appropriate oversight of the data is needed to ensure the results are accurate and meaningful wherever they are generated*** - non-CLIA certified entities do not operate under the same quality standards that clinical laboratories use to ensure the integrity of the testing process, the accuracy of results, and the appropriateness of result interpretation. These safeguards are critical to generating reliable data. Treating all diagnostic data as equivalent, regardless of how it was produced, could lead to unsafe patient care decisions. Laboratorians understand these constraints, while non-laboratorians often are not aware of them or the clinical implications.

Proposed New Technology APC Codes CY 2027

In the proposal, CMS identifies several secondary analyses that it characterizes as non-clinical diagnostic tests, which do not need to be performed by a CLIA-certified laboratory. The agency suggests that once a test result is generated, subsequent computations using those data qualify as "other diagnostic tests" under section 1861(s)(3) of the Social Security Act and are not eligible for CLFS reimbursement.

A review of the data in Table 62 indicates that most analytical methods used for these tests are poorly harmonized, requiring laboratory expertise to align locally generated data with the model's training inputs. For example, digital-pathology morphology and stain intensity have no cross-scanner or cross-stain reference standard and shift measurably with tissue processing, staining, and scanner; most quantitative chemistry and immunoassays yield method-specific

numeric values and reference intervals for the same measurand. In these cases, the computation is not separable from the examination; it is part of it, and the service meets the 493.2 definition of a CLIA laboratory. The image-analysis codes (0512U, 0513U, 0414U, 0418U, 0220U, 0376U) and the functional cell-culture assay (0511U) listed in Table 62 rely upon non-harmonized inputs and remain clinical diagnostic laboratory tests; 0510U is the exception.

Regulatory Oversight of Secondary Analyses

Clinical laboratories operate within a quality-focused regulatory framework designed to protect patients by ensuring that test results are accurate, reliable, and clinically meaningful. Separating algorithmic clinical decision-making from the upstream processes that generate the underlying data—without applying comparable quality management expectations—could increase the risk that patient care decisions are based on incomplete, inconsistent, or unreliable information.

If CMS wants to expand testing of secondary analyses to non-CLIA laboratories, it should first specify how these facilities will be regulated to ensure the accuracy, reliability, and appropriate use of these services, including how these data will be validated, meet quality control standards, monitor performance, report results, and provide meaningful interpretation. ADLM urges CMS to withdraw this provision from the proposed rule and address the oversight and patient care questions before moving forward with changes to the payment system.

Thank you for considering ADLM's comments. If you have any questions, please email Vince Stine, PhD, ADLM's Chief Policy Officer, at vstine@myadlm.org, or Evan Fortman, MPA, ADLM's Manager of Government Affairs, at efortman@myadlm.org.

Sincerely,

Stanley F. Lo, PhD, DABCC, FADLM
ADLM President