



September 13, 2026

VIA Electronic Submission to <https://regulations.gov>

The Honorable Mehmet Oz, M.D.
Administrator
Department of Health and Human Services
Centers for Medicare & Medicaid Services
7500 Security Blvd
Baltimore, MD 21244-1850

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]

Dear Administrator Oz:

On behalf of the Digital Pathology Association (DPA), we are pleased to submit these comments in response to the above-captioned CY 2027 Physician Fee Schedule ("PFS") Proposed Rule with comment period (the "Proposed Rule").¹

The Digital Pathology Association is a global community of over 4,500 pathologists, scientists, technologists, and industry leaders dedicated to the evolution of modern medicine. Founded in 2009, our mission is to facilitate awareness, education, and adoption of digital pathology-enabled AI applications across healthcare and life sciences. By sharing best practices and demonstrating the efficiencies of new technologies, we empower our members to enhance pathology/laboratory workflows and, ultimately, improve patient care. The DPA comprises a diverse international membership which seeks to (1) promote and support reimbursement and regulatory pathways for digital pathology-enabled technologies, (2) establish and disseminate industry standards for clinical development of those technologies including analytical and clinical validation, (3) provide education to promote the understanding, adoption, and scientific advancement of digital pathology, and (4) facilitate collaboration and alignment among members and stakeholders.²

In the Proposed Rule, CMS uses the terminology – software as a medical service (SaMS) – to broadly describe "software-based technologies with novel functionalities, including artificial intelligence, to support clinical decision-making in the outpatient and physician office settings." This terminology serves as an umbrella term to describe these types of technologies used across specialties (e.g., cardiology, radiology, pathology / clinical laboratory). Even within pathology, this terminology describes a diverse category of services that use laboratory-generated data, including digital pathology images, alone or in combination with other clinical information, to produce

¹ 91 Fed. Reg. 43842 (July 16, 2026) (CY 2027 PFS Proposed Rule)

² <https://digitalpathologyassociation.org/>

clinically actionable information. A subset of these services are software analyses that are furnished using FDA-regulated services as a medical device (collectively referred to as laboratory SaMD) while other software analyses have been furnished in a CLIA-certified clinical laboratory, lawfully offered as a laboratory developed tests (collectively referred to as algorithm-only LDTs).³

Our comments on the CY 2027 PFS Proposed Rule address the agency's proposal to remove software as a medical service (SaMS) algorithm-only laboratory developed tests from the Clinical Laboratory Fee Schedule (CLFS) and contractor price these services under the PFS. The DPA also provides feedback on two Requests for Information (RFI) that CMS published in the Proposed Rule specific to CPT and duplicate laboratory services. Our detailed comments are presented below.

SOFTWARE AS A MEDICAL SERVICE FOR LABORATORY TESTS

A. Overview of Proposed Policies

In the Proposed Rule, CMS proposes the following payment policies impacting SaMS analyses performed on laboratory tests:

- Using new terminology – SaMS – as opposed to Software as a Service (SaaS) to identify software-based technologies that provide clinical or diagnostic functionality;⁴
- Redefining the benefit category of algorithmic-only laboratory services as “other diagnostic tests” rather than “diagnostic laboratory tests”;⁵
- Removing codes describing these services from the Clinical Laboratory Fee Schedule (CLFS) and contractor pricing them under the Physician Fee Schedule;

These proposed policies are specific to both algorithm-only LDTs and laboratory SaMD.

B. Response to Proposed Policies

i. Categorization as Laboratory Services

Should CMS proceed with its broader SaMS proposed policies this year, the DPA requests that specifically algorithm-only LDTs should remain on the CLFS, which is the applicable payment system for clinical diagnostic laboratory tests. While there is no existing statutory or regulatory definition for clinical diagnostic laboratory tests, CMS has defined the term “laboratory” in the CLIA regulations:

Laboratory means a facility for the biological, microbiological, serological, chemical, immunohematological, hematological, biophysical, cytological, pathological, or other examination of materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings.

Algorithm-only LDTs (and laboratory SaMD) meet this definition in that the analysis is based on the output from the underlying wet lab component that involved the in silico examination of “materials

³ Algorithm-only LDT in this comment letter is defined as SaMS analyses performed on laboratory tests, offered as an LDT in a CLIA-certified laboratory. Laboratory SaMD refers to analyses on laboratory tests that received FDA clearance, approval or authorization.

⁴ For detailed discussion, see 91 Fed. Reg. 41734 (July 7, 2026) (CY 2027 OPPTS/ASC Proposed Rule).

⁵ Ibid.

derived from the human body". Furthermore, the analysis is inextricably linked to the underlying wet laboratory procedure and cannot be performed absent from the original, specimen-based procedure. The timing of when the analysis is performed on the inputs should not be relevant to defining whether it is a laboratory service.

Finally, algorithm-only LDTs identified in the Proposed Rule are ones developed in and furnished by a CLIA-certified laboratory and are reported under codes subject to CLIA edits. Recently, CMS acknowledged that it "has received inquiries on whether... data-only facilities require a CLIA certificate", and explicitly asked for more information regarding the activities these facilities perform to generate, or to help generate, test results and interpretations. Given that CMS is actively considering whether CLIA certification is required to furnish these tests, it would be premature for CMS to conclude that, at a minimum, algorithm-only LDTs are not "laboratory" tests for purposes of payment.

ii. Movement of Tests from CLFS to MPFS

The DPA acknowledges the challenges with pricing these services and understands the concerns related to the perceived lack of transparency under the current CLFS crosswalk/gapfill process. However, the CLFS methodology is better suited for rate-setting of algorithm-only LDTs than contractor pricing under the MPFS for the following reasons:

- *Experience with pricing algorithm-only laboratory services.* For many years, CMS has priced services that incorporate algorithms (e.g., multianalyte assays with algorithmic analysis (MAAAs) as well as algorithm-only services reported under Proprietary Laboratory Analyses) on the CLFS. Where CMS has been unable to establish a payment rate via crosswalk, the codes were sent to gapfill which requires the disclosure of additional details on costs (e.g., cost of goods sold, direct and indirect costs, private payer reimbursements).
- *Openness to improving transparency under existing CLFS process.* CPT code descriptors offer some degree of insight into key characteristics appropriate for public discussion, such as inputs (e.g., number and type of analytes) and outputs (e.g., risk score, qualitative categorization). To the extent CMS needs additional data points to inform initial rate-setting (e.g., type of algorithm, complexity of algorithm, R&D costs spent training and validating algorithm performance), CMS could consider asking manufacturers or laboratories to provide this information to CMS in a confidential setting, to protect from the disclosure of proprietary or trade secret information in a public setting.
- *Under MPFS, RVU-based rate-setting does not appropriately capture payment rates based on clinical value.* PAMA requires CMS to set rates for CLFS services at the volume-weighted median of reported private payer rates, which reflect the actual, current market value of a proprietary algorithm. Many codes that CMS has proposed to move off the CLFS were subject to the most recent PAMA reporting cycle (which concluded as of July 31, 2026), further demonstrating that these tests are in fact diagnostic laboratory tests. The PFS – which is based on physician work, other clinician labor, equipment, and supplies – is a poor fit for algorithm-only laboratory services, which have a substantive research and development cost, on-going costs for bioinformatics, cloud hosting, and system updates, and non-physician work for clinical laboratory personnel.
- *Under MPFS, contractor pricing can lead to inconsistency in payment rate establishment and potential delays in access to care.* Contractor pricing can cause confusion, inconsistency in payment rate and cost sharing amounts, and potential delays in access for Medicare beneficiaries. When rate-setting is determined by the MACs, it can take many

months for a MAC to publish a contractor (or carrier) priced code. In many cases, codes newly assigned to contractor pricing will have no published payment rate on the effective date. As such, providers (or laboratories with respect to algorithm-only LDTs) have no insight into the payment rate prior to claim submission.

Once established, often the initial rates set are too low due to a lack of understanding regarding the test, and must be adjusted to adequately cover provider costs – a process that, if successful, can take months if not years. These on-going rate-setting challenges result in delays in patient access as providers are not likely to offer such services to Medicare beneficiaries, if the rates are insufficient to cover their costs.

The DPA suggests that instead of implementing a potentially temporary reassignment from the CLFS to contractor pricing under the MPFS, which would introduce substantial uncertainty for manufacturers, laboratories, providers, and Medicare beneficiaries, CMS should maintain pricing under the CLFS as it develops a more permanent approach for SaMS more broadly that may better align payment with clinical outcomes.

iii. Address Outstanding Operational Questions Stemming from Proposed Policy

Should CMS move forward with these proposed payment policies for algorithm-only LDTs and laboratory SaMD, we ask the Agency to make the following changes to minimize disruption to patient access to these clinically appropriate services.

- **Permit algorithm-only laboratory services to be billed by laboratories when lawfully offered as laboratory developed tests.**

These algorithm-only laboratory services, as discussed above, may be developed and validated by CLIA-certified clinical laboratories, and are lawfully performed as LDTs. Under current rules, CLIA-certified laboratories can perform and bill for such services under the CLFS. However, it remains unclear if these algorithm-only LDTs performed by laboratories are billable by CLIA-certified laboratories under the PFS. There is existing precedent for CLIA-certified laboratories submitting claims for services paid under the PFS (e.g., codes for immunohistochemistry⁶ and in situ hybridization⁷). If the Agency finalizes its policy as proposed to move the algorithm-only LDTs to the PFS, the DPA urges CMS to confirm that these services remain billable by the CLIA-certified laboratory that performs them.

If laboratories are unable to bill for these services under the PFS, laboratories would effectively be prohibited from directly billing and receiving payment for the services they perform. Leaving laboratories without a clear pathway to bill and receive payment for these services risks disrupting beneficiary access to these important services. The only options that would remain for laboratories would be either an indirect billing arrangement with hospitals or requiring CLIA-certified clinical laboratories to enroll as a different provider type (i.e., Independent Diagnostic Testing Facility (IDTF)) with difference requirements solely to bill Medicare.

An indirect billing arrangement with hospitals may exacerbate the program integrity concerns that CMS raised in the OPPS, effectively making clinical laboratories a hospital vendor and thus having less cost transparency than when performing laboratories bill CMS directly. Enrolling as an IDTF is a multi-step, multi-month process from meeting any Medicare as well as state and local

⁶ Currently reported under codes such as 88341, 88342, 88344, 88360 and 88361.

⁷ Reported under 88120 and 88121 (fluorescence in situ hybridization) and 88364, 88365, and 88367.

requirements to undergoing the review and approval process by CMS. Should CMS finalize this policy in the PFS Final Rule on or around November 1, 2026, laboratories would be unable to complete enrollment as an IDTF by January 1, 2027, denying patients access to clinically appropriate services supported by published peer-reviewed evidence and guideline support.

For these reasons, should CMS move forward with the proposed policy to move payment from the CLFS to the PFS, the DPA urges CMS to either permit laboratories to bill algorithm-only LDTs as labs under PFS. If the Agency moves forward and requires enrollment as an IDTF (as it is not permitting labs to bill for these services), CMS should delay the proposed policy for at least one year in order to allow laboratories to make operational and billing adjustments (required as an IDTF) without compromising patient access to care.

- **Establish national pricing for the algorithm-only LDTs and laboratory SaMD.**

If CMS moves forward with proposed policy to pay for these tests under the PFS, the DPA urges CMS to establish national pricing for these services rather than rely on contractor pricing, for the reasons discussed above. To determine the RVUs, the DPA recommends that the Agency crosswalk to the New Technology APC band to which these codes have been proposed. This approach is not precedent-setting as CMS has taken this approach with other services in the last few years.⁸

REQUESTS FOR INFORMATION

A. AMA CPT and RUC Processes

In the Proposed Rule, CMS seeks feedback from stakeholders on the current processes and potential challenges with AMA CPT and RUC processes, as well as input on potential coding alternatives and the different coding processes, including use of the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD-10-PCS).

Coding is a key pillar in establishing a pathway for reimbursement for any product or service. It is critical to have clear, transparent and objective processes and pathways in place for the pursuit of new coding. For this reason, the DPA does not support a major change in the coding environment, particularly one that would remove the AMA from the process. The AMA maintains thousands of codes across all specialties, supported by extensive coding guidance and institutional knowledge. Rebuilding a code set from the ground up would be an incredibly complex task that would take multiple years (if done correctly) and would be incredibly disruptive to patient access in the interim. The ICD-10-PCS in its current state is not an appropriate alternative to CPT because this coding set does not have a specific section for laboratory services. As a result, payers and providers would not have the granularity required for claims processing, payment, and coverage and as such, it would not allow for distinguishing between tests that are clinically different, reducing transparency for CMS and MACs.

While the existing code set is the optimal coding pathway particularly in the absence of a clear alternative, the DPA agrees that the AMA could implement meaningful changes to make the process more transparent and objective. The AMA has taken a number of steps in the past few years to improve processes and increase transparency, steps that are acknowledge and appreciated. Taking into consideration the role of coding in the reimbursement decision, the focus

⁸ See the rate-setting approach taken by CMS in the CY 2026 rulemaking for the remote monitoring codes. See methodology leverage for establishment of national payment rate for fractional flow reserve in CY 2022 PFS rulemaking (see 86 Fed. Reg. 65041).

should be on how to successfully obtain a code rather than how to navigate the barriers to coding success. To that end, the DPA highlights a few areas for improvement to the CPT process:

- Representation from other stakeholders, beyond the physician organizations, who are involved in the latest innovations in clinical diagnostics and would bring an additional perspective during the review of code change applications;
- Increased transparency on the different criteria and rules contemplated when reviewing code change applications and greater consistency in the application of those rules;
- Improved engagement through stakeholder participation – particularly with respect to pathology (clinical diagnostics) – in meetings (e.g., Pathology Coding Caucus and Molecular Pathology Advisory Group) prior to the CPT Editorial Panel meeting; and
- Partner with developers and stakeholders of algorithm-only clinical software services as establishing a new code set that accounts for the proprietary nature of these services and the different regulatory pathways. Engagement should be on-going and should be a bi-directional discourse between the AMA CPT Editorial Panel and the relevant stakeholders.

The DPA looks forward to discussing these recommendations and others in greater detail with the AMA.

B. Duplicate Laboratory Testing, Imaging, and Result Sharing and Interoperability

The DPA supports the goal of the Agency to eliminate unnecessary and duplicative laboratory and imaging services. However, in the Proposed Rule, CMS does not give a clear definition of what type of service would be viewed as “duplicative” in nature. It is important for CMS to focus on avoidable and unnecessary duplicative testing, not clinically appropriate serial, repeat or complementary testing.

A test should not be viewed as unnecessary or duplicative solely because the test is for the “same condition” – or because the test is reported by the same CPT code multiple times in a particular period. For example, advanced laboratory tests that share a CPT code may differ substantively in the genes, methods, specimen type, clinical purpose, and/or intended use. Conversely, tests with different CPT codes but focused on the same condition may address overlapping clinical questions. The DPA urges CMS to ensure that any future definition of duplicative testing does not serve as a barrier to clinically appropriate and medically necessary laboratory tests.

In the patient workflow, the lab receives a test requisition form from the ordering provider, detailing the specific tests that the provider wants performed for the patient. It is not operationally feasible or realistic to put the burden on the laboratory to determine if the order received was clinically appropriate and not a duplicative service. Once the laboratory test is ordered, the lab must perform the test consistent with that order. If the objective underlying this RFI is to eliminate duplicative and unnecessary laboratory and imaging services, then CMS should focus on the ordering provider. It would not be appropriate to penalize a laboratory for performing the service as requested by the physician. Should CMS move forward with developing a policy based on stakeholder feedback to this RFI, the DPA urges CMS to focus upstream on the ordering, not the performing of laboratory (or imaging) tests.

The Digital Pathology Association appreciates the opportunity to comment on these proposed policies and is willing to serve as a resource for CMS as it continues to develop a reimbursement

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framework for SaMS under the Physician Fee Schedule.

Sincerely,

A handwritten signature in cursive script that reads "Deborah R. Godes".

Consultant, Digital Pathology Association

Cc: Michael Rivers, Co-Chair, DPA Reimbursement Taskforce
Jennifer Archer, Co-Chair, DPA Reimbursement Taskforce