



August 28, 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 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]

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 Outpatient Prospective Payment System ("OPPS") 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

¹ 91 Fed. Reg. 41734 (July 7, 2026) (CY 2027 OPPS/ASC Proposed Rule)

² <https://digitalpathologyassociation.org/>

category of services that use laboratory-generated data, including digital pathology images, alone or in combination with other clinical information, to produce 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 OPPTS Proposed Rule focus specifically on the SaMS analyses performed on laboratory test services and address the agency's proposal to uniformly remove the laboratory diagnostic services from the Clinical Laboratory Fee Schedule (CLFS) and temporarily assign such services to separately payable New Technology APCs. Our detailed comments are presented below.

A. Overview of Proposed Policies

In the Proposed Rule, broadly, CMS proposes a number of 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;
- Redefining the benefit category for algorithm-only LDTs and laboratory SaMD as “other diagnostic tests” rather than “diagnostic laboratory tests”;
- Removing codes describing these services from the Clinical Laboratory Fee Schedule (CLFS) and assigning them to a new technology APC under OPPTS;
- Assigning the new status indicator “O1” to algorithm-only LDTs and laboratory SaMD, which has the same payment specifications as status indicator “S”; and,
- Evaluating whether these procedures should be subject to multiple procedure discounting.

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

B. Response to Proposed Policies

i. Defining the Terminology Software as a Medical Service

In the CY 2027 OPPTS Proposed Rule, CMS proposes to change its terminology from Software as a Service (SaaS) to Software as a Medical Service (SaMS) to avoid confusion with the general-industry use of “SaaS” for cloud computing services. This change would distinguish these services as software-based technologies that provide clinical or diagnostic functionality. While the DPA is supportive of this new term conceptually, CMS should consider incorporating additional specificity into the definition to ensure that technologies with meaningful differences (e.g., algorithm-only LDTs versus laboratory SaMD versus imaging SaMD) are not treated as equivalent.

ii. Coordination of Payment Policy with CLIA Request for Information (RFI)

CMS notes in the Proposed Rule that these SaMS performed on laboratory analyses represent an emerging category of medical technology. As an interim step, CMS has proposed to assign all SaMS procedures (including but not limited to analyses performed on laboratory tests (algorithm-only LDTs and laboratory SaMD)) to new technology APCs while it formalizes its strategy. The DPA appreciates

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.

CMS taking a step-wise approach as it contemplates its broader payment policy, listening to the feedback from stakeholders to date in meetings and through RFI responses in prior rulemaking cycles.

Prior to drafting a broader payment policy though, CMS should also consider the feedback from stakeholders in response to the recently issued RFI on Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations. In this RFI, CMS and the CDC seek input on a number of topics including the appropriate level of CLIA oversight of “dry-lab” facilities that perform different computational analyses without the traditional wet lab component and the use of advanced technology or AI-assisted interpretation in clinical laboratories and the test process. **Given that the Agencies are still defining these types of services and determining how these types of services should be regulated, CMS should hold off on proposed payment policy changes.**

iii. 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 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.

iv. Movement of Services from CLFS to OPFS

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 the APC-based rate-setting under the OPFS 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 was not able to establish a payment rate via crosswalk, the codes were set 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 OPSS, there is limited ability to establish 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 of the codes that CMS has proposed to move off the CLFS were subject to PAMA reporting, further demonstrating that these tests are in fact diagnostic laboratory tests. OPSS – which is based on hospital costs/charges and resource consumption – is less transparent than the CLFS given the disconnect between institutional charges and actual costs. Hospital charges may in fact bear little relationship to the research and development costs that underly the cost of an algorithm.

For laboratory SaMD that may be performed by provider types other than CLIA-certified laboratories, the DPA supports the assignment of these services to the new technology APCs as an interim step. For existing tests priced under the CLFS, the DPA agrees to the assignment to a new tech APC that is reflective of the CLFS rate. For new tests, the new tech APC assignment should reflect the costs that hospital incur for furnishing this service and thus be based on invoice price – consistent with how CMS has determined the appropriate new tech APC band for other SaMS services (e.g., fractional flow reserve and artificial intelligence-guided quantitative coronary computed tomography).

v. 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 LDT may be developed and validated by CLIA-certified clinical laboratories, and are lawfully performed as laboratory developed tests (LDTs). Under current rules, CLIA-certified laboratories can perform and bill for such services under the CLFS.

However, OPSS payment is available only to Medicare-enrolled hospital outpatient departments. If these algorithm-only LDTs performed by laboratories are not billable by CLIA-certified laboratories (that are not hospital based), laboratories would effectively be prohibited from directly billing and receiving payment for the services in the hospital outpatient setting. Leaving independent (not hospital-based) laboratories without a clear pathway to bill and receive payment for these services risks disrupting beneficiary access to these important services.

If only hospitals (or hospital labs) can bill for algorithm-only LDTs, independent laboratories who performed these services would be required to contract with hospitals, and those hospitals would bill for

services they do not actually furnish. This indirect billing arrangement may exacerbate the program integrity concerns that CMS raised by effectively making clinical laboratories a hospital vendor, making the actual cost less transparent than when performing laboratories bill CMS directly.

- **Avoid applying multiple procedure payment reduction for algorithm-only analyses.**

In the Proposed Rule, CMS seeks feedback from stakeholders on whether algorithms should be subject to multiple procedure discounting. This type of discounting may be appropriate for services that share overlapping resources, set up time, or overhead when furnished together in a single encounter (e.g., surgical procedures performed in the same operating room). However, algorithm-only services do not meet these criteria; each algorithm is typically a distinct, independently developed and validated analytic service answering a distinct clinical question. Laboratories furnishing multiple algorithmic analyses do not gain any marginal efficiencies from running a second or third algorithm on the same underlying data.

Discounting multiple, clinically distinct algorithms run on the same underlying laboratory data risks creating financial disincentives for using medically necessary, physician-ordered, validated SaMS analyses performed on laboratory tests, which could compromise patient care and hinder timely access to precision medicine tools that CMS otherwise wants to encourage. For example, discounting the second analysis could cause clinicians to delay orders for medically necessary services.

To the extent that CMS has concerns about performing multiple algorithm-only services without demonstrated clinical value or ones that may be duplicative in nature, the Agency would better address these concerns via other well-established utilization control mechanisms – such as the development of evidence-based local coverage determinations (“LCDs”) and national coverage determinations (“NCDs”) – rather than applying a broad payment policy that penalizes the use of multiple clinically appropriate services.

- **Confirm the appropriate date of service for algorithm-only LDTs and laboratory SaMD.**

The date of service for a clinical laboratory test is the date of specimen collection unless an exception applies.⁴ However, if the algorithm-only services are “other diagnostic tests”, then the laboratory date of service rule is not applicable. The DPA strongly supports CMS clarifying that the date of service for these services is the date the performing provider (recommended to be the laboratory) returns the report – not the date of specimen collection. From a policy perspective, such positioning would be appropriate since the service cannot inform patient care until it is actually run and performed. Typically, this analysis will not occur until after the patient has already been discharged from the outpatient hospital setting – and as such, it would be reasonable to allow the laboratory to bill for the service.

- **For types of SaMS assigned to new tech APCs, establish a streamlined application with faster turnaround time.**

Organizations can apply for assignment of their service or procedure to be assigned to a new technology APC at any point in time during the year, as CMS accepts applications on a quarterly basis. However, decisions on those applications can take upwards of 9 months before the Agency will render a decision. Given the growth in the number of SaMS analyses (not just limited to algorithm-only LDTs and laboratory SaMS), if it proceeds with its policy as proposed, CMS should establish a streamlined application with clear deadlines for when an application should be submitted in order to be included in

⁴ 42 CFR 414.510(a).

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the upcoming rulemaking cycle. CMS should also review and render a decision in a shorter period of time so as to not delay Medicare beneficiary access to clinically appropriate services.

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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 framework for algorithm-only LDTs and laboratory SaMD.

Sincerely,

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

Principal, McDermott+
Consultant, Digital Pathology Association

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