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CMS Proposes a New Reimbursement Path for Algorithm-Based Laboratory Services

What the CY 2027 OPPS Proposal Could Mean for Laboratories and Revenue Cycle Management
As diagnostic medicine becomes increasingly driven by artificial intelligence, digital pathology, genomics and advanced algorithms, CMS is beginning to reconsider a fundamental question: When does a laboratory test stop being a laboratory service and become a software service?

In the CY 2027 Hospital Outpatient Prospective Payment System (OPPS) [section: X. B.2. SaMS Analyses Performed on Laboratory Tests] proposed rule, CMS introduced a new concept, Software as a Medical Service (SaMS), for software-based technologies that use algorithmic analysis to provide clinical or diagnostic information. More importantly for laboratories, CMS proposes removing 10 algorithm-driven HCPCS/CPT services currently paid under the Clinical Laboratory Fee Schedule (CLFS) and paying them instead through New Technology Ambulatory Payment Classifications (APCs) under OPPS.

Why CMS Is Proposing the Change
CMS is drawing a distinction between the laboratory work that generates patient data and software that subsequently analyzes those data.

Under CMS' interpretation, genomic sequencing, pathology imaging, immunoassays and similar services may require a CLIA-certified laboratory. However, a subsequent stand-alone algorithm analyzing previously generated data may not. CMS therefore proposes treating certain downstream analyses as "other diagnostic tests" rather than clinical diagnostic laboratory tests.

This distinction could have implications well beyond the 10 codes currently identified.

CMS has indicated that future SaMS laboratory-analysis codes could also be assigned to New Technology APCs rather than the CLFS, potentially creating a new Medicare reimbursement pathway for algorithm-based diagnostics.

The Revenue Cycle Impact Could Be Significant
From an RCM perspective, this proposal should be viewed as much more than a fee-schedule change.

- Payment methodology changes. Instead of receiving a test-specific CLFS rate, affected services would be assigned to New Technology APC cost bands. CMS intends initial payments to approximate current CLFS reimbursement, but they will not necessarily be identical. CMS provides an example in which a HCPCS code paid $430.17 under the CLFS would be assigned to New Technology APC 1506 ($401–$500), with a standardized payment rate of $450.50.
- Patient financial responsibility could change. Medicare clinical laboratory services generally do not carry beneficiary coinsurance. OPPS services, however, generally involve Part B cost-sharing. Reclassification could therefore alter both reimbursement mechanics and the patient billing experience.

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- Billing responsibility may shift. Independent laboratories traditionally bill Medicare directly for qualifying CLFS services. Moving services into an OPPS framework raises important questions regarding whether the hospital, laboratory, software developer or another entity will ultimately submit the claim and receive payment.
- Commercial payers may follow CMS' lead. CMS policy frequently influences commercial payer reimbursement and medical-policy development. Laboratories should therefore monitor whether payers eventually distinguish between the underlying laboratory procedure and the downstream algorithmic analysis.

Industry Concerns Remain

Laboratory organizations have questioned whether CMS is drawing the line too broadly. The College of American Pathologists has urged CMS to keep algorithm-based laboratory services within the CLFS while a more comprehensive long-term payment policy is developed. ADLM has similarly argued that many algorithmic services remain inseparable from laboratory methodology, quality systems and professional oversight.

The larger issue is important: an algorithm may operate digitally, but the clinical validity of its output can still depend heavily on how the underlying specimen was processed, measured, stained, scanned or sequenced.

What Laboratories Should Do Now

RCM and laboratory leaders should begin identifying services that combine laboratory testing with stand-alone algorithmic interpretation and model the financial consequences of both CLFS and alternative payment structures. Organizations should also review payer contracts, billing workflows, CLIA responsibilities, patient cost-sharing processes and hospital relationships to understand how a future separation of the laboratory component from the software component could affect revenue.

The immediate proposal involves only 10 codes, but the broader policy direction is much more significant. CMS appears to be laying the groundwork for a distinct reimbursement pathway for certain software-driven diagnostic services. For laboratory and pathology organizations, the RCM implications extend beyond reimbursement rates to coding, billing responsibility, payer contracts, patient cost-sharing and potentially even the structure of future diagnostic offerings.

If you have questions about how these proposed changes may impact your practice, please reach out to your APS Practice Manager. We are here to help you protect your revenue and navigate these changes with confidence.