

When Software Stopped Being a Lab Test: How the CY2027 OPPS Rule's Software as a Medical Service Category, the O1 Status Indicator, and Pulling Lab AI Off the CLFS Reshape Health Tech Investing

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Thoughts on Healthcare Markets & Technology

 **When Software Stopped Being a Lab Test: How the CY2027 OPPS Rule's Software as a Medical Service Category, the O1 Status Indicator, and Pulling Lab AI Off the CLFS Reshape Health Tech Investing**

Medicare just created the first formal reimbursement category for clinical AI. It is called Software as a Medical Service, and it comes with its own payment status indicator: O1. This is bigger than it sounds. Thread...

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Abstract

Scope: the Software as a Medical Service provisions inside CMS-1850-P, the CY2026 OPPS and ASC proposed rule, comments open through August 31, 2026.

The move: CMS retires the term Software as a Service and adopts Software as a Medical Service, or SaMS, and creates a brand new OPPS status indicator, O1, meaning software paid separately under a New Technology APC.

The numbers: 36 HCPCS codes designated as SaMS and parked in New Technology APCs at rates roughly matching CY2026, with certain existing CLFS-paid software-like codes proposed to be handled under OPPS rather than the Clinical Laboratory Fee Schedule.

The logic: once a genomic sequence exists, downstream algorithmic analysis of the data can run an infinite number of times, does not necessarily require a CLIA lab, therefore, in CMS's read, is an other diagnostic test rather than a diagnostic laboratory test.

Why founders should care: this is the birth of a reimbursement category for clinical AI, and first categories are underpriced, band-capped, and up for grabs.

Why it stings: moving from the CLFS to OPPS adds beneficiary coinsurance that did not exist before, plus budget-neutrality pressure, and it strips the CLIA moat that incumbents leaned on.

The open question that decides economics: whether O1 keeps behaving like status indicator S, or flips to something like T and gets hit with multiple-procedure discounting.

The short version for people who skim

Medicare just gave software its own name tag. For years, algorithm-driven diagnosis got shoved into whatever coding closet was closest, sometimes a clinical APC, sometimes a lab code, sometimes a packaged nothing. In this proposed rule CMS is pretending and creates a dedicated category called Software as a Medical Service with a dedicated payment marker called O1. That sounds like bureaucratic housekeeping.

is actually the moment a whole class of AI diagnostics becomes a first-class citizen in the payment system, with all the upside and all the danger that implies. In the same stroke, CMS reaches into the lab world and signals that certain genomics and digital pathology analyses are not really lab tests at all, they are software, and that they should be paid under OPPS rather than the lab fee schedule. If your company sells an algorithm that reads a scan, a slide, an ECG, or a gene panel, your reimbursement story just changed, and the comment window closes at the end of August.

What CMS actually proposed, the SaMS turn and the O1 tag

Start with the vocabulary, because CMS clearly thinks the vocabulary matters. The agency proposes to stop calling these products Software as a Service and start calling them Software as a Medical Service. The stated reason is that SaaS means something generic in every other industry, a cloud delivery model, and CMS wants a term that signals a medical function rather than a hosting arrangement. The term SaMS shows up throughout the document, which is not the frequency of an afterthought. When a payer coins a noun and repeats it that many times, it is building a category it intends to regulate for a decade.

Then comes the mechanism. CMS proposes to designate 36 HCPCS codes as SaMS and to move the ones currently paid separately under clinical APCs into New Technology APCs, choosing bands that roughly match their CY2026 dollars so nobody's rate falls off a cliff on day one. To keep these distinct from every other item that lives in a New Tech APC, CMS invents a new status indicator, O1, defining Software as a Medical Service, paid under OPPS with separate APC payment. Functionally O1 is proposed to behave like the familiar status indicator S, meaning the service gets paid on its own and is not discounted when it shows up alongside other procedures. The named codes are a who's who of the clinical AI landscape, coronary CT fractional flow reserve analysis, coronary plaque quantification, quantitative brain MRI with comparison to prior studies, AI electrocardiogram assessment for low ejection fraction and other cardiac dysfunction, bone-strength finite element analysis from CT, automated retinal imaging, and a noninvasive

prostate cancer estimation map derived from fusion biopsy and pathology. If you watched this space, you can put company names to most of those lines without too much effort. It's not very hard.



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