IRONSTREET

REGULATORY INTELLIGENCE FOR HEALTHTECH
FOUNDERS & HEALTHCARE INVESTORS

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The *Signal*

Translating what CMS just changed into what it means for your product, your go-to-market, and your investment thesis — told from the operator's chair, not the consultant's desk.

A NOTE FROM HOWARD GRUVERMAN, CEO & PARTNER

There is a version of this business where you read the trade press, form a view, and advise from a distance. That is not the firm we built. Every partner here has sat on the buyer's side of a mandate like the three in this issue — as health plan executives, as health system operators, as enterprise technology leaders. We have signed the contracts. We have felt the budget pressure. We have watched good companies fail because they did not understand what was changing underneath their buyer.

This month is different from most. CMS has spent years asking how Medicare should pay for clinical software and never answering. In July it started answering — in two proposed rules, in public, with comment windows that close in a matter of days. At the same time it moved to narrow who is permitted to deliver software-enabled services and get paid for them. If your company sells an algorithm, or depends on remote monitoring revenue, the terms of your business are being written right now. We have been through 20+ successful exits valued at over $3 billion in healthtech. We know what a fundable, acquirable company looks like. We know what kills one. This is the kind of moment that decides which one you become.

THE SIGNAL · AUGUST 2026

What Changed *This Month*

Three regulatory developments with direct commercial / operational implications

S1 SOFTWARE REIMBURSEMENT

Medicare Just Gave Clinical Software Its Own Name — *And Its Own Price Tag*

AUG 31	CMS-1850-P: CY 2027 OPPS proposed rule — comment period closes August 31, 2026
SEP 14	CMS-1848-P: CY 2027 Physician Fee Schedule proposed rule — comments close September 14, 2026
JAN 2027	Proposed effective date for the interim SaMS payment framework

WHAT HAPPENED: On July 2, 2026, CMS released the CY 2027 Hospital Outpatient Prospective Payment System proposed rule (CMS-1850-P), followed on July 14 by the CY 2027 Physician Fee Schedule proposed rule (CMS-1848-P). Together they establish a new Medicare payment category: Software as a Medical Service, or SaMS — software that supports clinical decision-making through algorithmic analysis.

The specifics matter. CMS proposes to retire the term "Software as a Service," designate 36 HCPCS codes as SaMS, create a dedicated OPPS status indicator O1 for separately payable software services, and move 21 separately paid codes into New Technology APCs. Separately, it proposes to pull 10 HCPCS codes for algorithm-only analyses of laboratory data — genomic reanalysis, digital pathology, tumor profiling — off the Clinical Laboratory Fee Schedule entirely, on the reasoning that once the lab work is done, downstream computation does not require a CLIA-certified laboratory.

CMS is explicit that CY 2027 is a transitional period and that the proposal is not intended to increase reimbursement. Payment rates would hold near CY 2026 levels while the agency works toward a durable methodology.

> *For years, an algorithm-driven product got filed wherever it fit — a clinical APC, a lab code, or bundled into a procedure and paid nothing separately. CMS has stopped pretending that works. It has given clinical software a name, a status indicator, and a place in the payment architecture.*
>
> *That is a promotion, and it comes with a bill. Moving off the lab fee schedule strips the CLIA moat that incumbent laboratories relied on, and it adds beneficiary coinsurance that did not exist before. The unresolved question decides the economics: whether O1 behaves like status indicator S and escapes multiple-procedure discounting, or gets a T-like treatment and takes a haircut every time the software runs alongside another procedure. CMS is soliciting comment on exactly that.*

FOR FOUNDERS

If your product analyzes a scan, a slide, an ECG, a gene panel, or any clinical data stream, your reimbursement story just changed — and you have days, not months, to influence it. The OPPS window closes August 31.

The strategic shift is larger than the codes. Reimbursement has moved from something you address after commercial traction to something being defined before your product has a code. "We will figure out payment later" is no longer a viable plan, because CMS is deciding now and has said it is not looking to increase payment.

Practical step: identify whether any of the 36 designated codes or the 10 reassigned lab codes touch your product, and file a comment. Being on the regulatory record is cheap, and it is visible to buyers and investors both.

FOR PE/VC INVESTORS

Every AI diagnostic and clinical decision support company in a portfolio is affected by this, whether or not management has raised it. Companies whose economics assume CLFS pricing face a change in payment vehicle and a new coinsurance exposure.

The reimbursement pathway has moved from a diligence footnote to a central valuation question. A company with a designated SaMS code and a durable payment vehicle is a materially different asset than one waiting for a coding decision.

Diligence question to ask every software-based diagnostic target: Which specific HCPCS code does your product bill under today, and does the CY 2027 SaMS proposal move it, reprice it, or leave it unpriced?

S2 REMOTE MONITORING & VIRTUAL CARE

The Staffing Rule That Breaks a *Remote Monitoring Business Model*

SEP 14	CMS-1848-P: comment period on the RPM/RTM staffing restriction closes September 14, 2026
JAN 2027	New telehealth modifiers BB and BC required on platform-affiliated claims

WHAT HAPPENED: Inside the CY 2027 Physician Fee Schedule proposed rule, CMS proposes that remote physiologic monitoring and remote therapeutic monitoring services be payable only when furnished by clinical staff who are direct employees of the billing practitioner's practice. Outsourced clinical staff would no longer qualify for monitoring and treatment management services.

The same rule introduces modifiers BB and BC, required beginning January 1, 2027, on telehealth claims where the billing practitioner contracts with — or has a payment arrangement with — the entity that owns the virtual platform. The modifiers do not change payment. They make platform-affiliated telehealth visible in Medicare claims data for the first time.

CMS also proposes refinements to nine RPM codes covering weight, blood pressure and related measures, and extends non-behavioral telehealth payment protection for Rural Health Clinics and FQHCs through the end of 2027.

> *A large share of the remote monitoring market runs on a staffing model CMS just proposed to defund. The vendor supplies the devices, the software, and — critically — the clinical staff who do the monitoring, and the practice bills. If direct employment becomes the condition of payment, that arrangement stops working in its current form.*
>
> *The modifiers are the quieter and possibly more consequential item. CMS is not changing what it pays platform-affiliated telehealth. It is building a dataset. Nobody creates claims-level visibility into an arrangement they intend to leave alone.*

FOR FOUNDERS

If your revenue depends on supplying clinical labor into a practice that bills RPM or RTM, model the direct-employment scenario this quarter. The answers are a restructured commercial arrangement, a shift to enabling your customer's own staff, or a different revenue line — and all three take longer than the comment window.

If you operate a virtual care platform, the BB and BC modifiers mean your arrangements become legible to CMS in January. Get your contracting structure reviewed before it is reported rather than after.

There is an opening here too. Practices that lose an outsourced monitoring vendor still have the patients and the codes. A product that makes a practice's own staff capable of delivering monitoring at scale is selling into a problem CMS is about to create.

FOR PE/VC INVESTORS

This is the most direct threat to an operating model in this issue. Portfolio companies in RPM, RTM, and monitoring-as-a-service should be asked for a staffing-model impact analysis, not a reassurance.

Revenue quality matters more than revenue growth here. Monitoring revenue that depends on a specific CMS staffing interpretation is lower quality than the same revenue delivered through the customer's own employed staff.

Diligence question: What share of this company's revenue is billed by a customer using clinical staff the company employs — and what happens to that revenue on January 1, 2027 if the direct-employment proposal is finalized as written?

S3 HOSPITAL PAYMENT & MARKET ACCESS

Joint Replacement Goes National — *and the Breakthrough Shortcut Closes*

FINALIZED	CMS-1849-F: FY 2027 IPPS final rule published August 4, 2026, effective October 1, 2026
JAN 2028	Comprehensive Care for Joint Replacement nationalized — mandatory participation
FY 2028	Alternative pathway for new technology add-on payments eliminated for new applications

WHAT HAPPENED: CMS issued the FY 2027 IPPS final rule on July 31, published August 4 and effective October 1, 2026. It finalizes a 2.3% payment update for hospitals that participate in inpatient quality reporting and are meaningful EHR users, an increase of roughly $2.1 billion in hospital payments.

Three provisions matter more than the rate. CMS finalized nationalizing the Comprehensive Care for Joint Replacement model with mandatory participation beginning January 1, 2028. It expanded the Transforming Episode Accountability Model to cover additional spinal fusion episodes and realigned TEAM attribution and quality measures with other CMS programs. And it finalized elimination of the alternative pathway for new technology add-on payments beginning with FY 2028 applications — every technology seeking an add-on payment must now demonstrate substantial clinical improvement against the same standard, breakthrough designation or not. CMS proposed the parallel change for OPPS device pass-through.

One data point worth noting: CMS approved a new technology add-on payment for an AI tool that analyzes CT images and flags urgent findings, at a maximum of $137.53 per case in FY 2027.

> *Two things happened in the same rule and they point in opposite directions. Episode-based accountability is going from selected to universal — TEAM covered 700-plus chosen hospitals, and nationalized CJR means every hospital doing joint replacement is in. That expands the buyer cohort for anything that manages post-acute cost and outcomes from a list to a market.*
>
> *At the same time, the fastest route to incremental Medicare payment for a novel technology just closed. Breakthrough designation no longer buys a shortcut; substantial clinical improvement is the single standard. Read alongside the SaMS proposal in S1, the pattern is consistent — CMS is building a front door for software and closing the side doors.*

FOR FOUNDERS

If your product reduces episode cost, manages care transitions, or prevents readmissions, your addressable market stops being a CMS selection list in January 2028. Build the national version of your pitch now; the hospitals that will be mandated are already modeling it.

If your regulatory strategy assumed breakthrough designation would carry you to an add-on payment, that assumption expires with FY 2028 applications. Clinical

FOR PE/VC INVESTORS

CJR nationalization is a durable tailwind for episode analytics, post-acute coordination, and readmission prevention companies. It is one of the few expansions of addressable market in this issue rather than a constraint.

The add-on pathway change is a repricing event for any device or software company whose model assumed breakthrough-designation reimbursement. Check whether

improvement evidence is now the requirement, and generating it takes longer than a rulemaking cycle.

The AI add-on payment approved in this rule is a useful precedent to cite — and a useful reality check on scale. Roughly $137 per case is a real payment and a modest one.

a portfolio company's financial model contains that assumption and when it was last tested.

Diligence question: Does this company's Medicare payment thesis depend on the alternative add-on pathway — and if so, what clinical improvement evidence exists today rather than on the roadmap?

THE ISA PERSPECTIVE

Three Signals. *One Read.*

CMS is deciding what clinical software is worth and, in the same season, deciding who is permitted to deliver it and get paid. It is building a front door and narrowing the side doors at the same time.

For Founders, the message is that the reimbursement question has moved to the front of the queue. For most of the last decade the healthtech answer to "how does this get paid for" was that it would be worked out after the product found traction. That was a reasonable bet while Medicare had no framework. Medicare is building one now, in public, with comment windows measured in days — and it has said plainly that the exercise is not about paying more. The companies that engage this cycle will enter their next raise with a payment vehicle they can name. The ones that do not will be explaining to investors why a code they assumed would exist does not.

For Investors, the underwriting implication is that reimbursement pathway has become the central diligence question in software-enabled healthcare, not a footnote in the appendix. Two shortcuts closed this quarter: breakthrough designation as a route to an add-on payment, and outsourced clinical labor as a route to monitoring revenue. Any portfolio model still resting on either is carrying an assumption that expired in July. The offsetting opportunity is real — nationalized episode accountability expands a buyer cohort from a list of selected hospitals to a market — but it accrues to companies that can prove cost and outcome impact, not to companies that can describe it.

> *"We've been the buyer, the builder, and the seller — more than twenty times, across more than three billion dollars in healthtech exits. When we say a regulatory change creates a commercial opening, we're not reading a policy brief. We're pattern-matching against deals we've closed."*

BEFORE THE NEXT ISSUE

Three Things *to Do Now*

01

FOUNDERS

Find your codes. Pull the 36 HCPCS codes designated as SaMS and the 10 lab codes proposed for reassignment, and determine whether any of them is how your product gets paid today. If none of them is, that is also an answer — it means your product has no separately payable Medicare pathway, and you should know that before your next investor conversation rather than during it.

02

INVESTORS

Add one question to every software-enabled healthcare diligence this quarter: name the billing code. Not the value proposition, not the pilot results — the code, the payment vehicle, and what the CY 2027 rules do to it. In our experience the quality of that answer separates management teams that understand their market from teams that understand their product.

03

EVERYONE

The OPPS comment period closes August 31, 2026 — days from now. The SaMS framework is the first structural attempt to pay for clinical software as its own category, CMS has said it wants comment on the discounting question that decides the economics, and most of the industry is treating a transitional-year proposal as a future problem. It isn't. The methodology CMS lands on next year will be built on the record created this month.

FROM THE ISA PORTFOLIO

This Is the *Work We Do*

Glytec is FDA-cleared in a market about to fill with software that isn't — and ISA is opening the right doors.

Glytec is the leader in enterprise insulin management — FDA-cleared, cloud-based software that improves glycemic control and reduces adverse drug events. Since January 1, 2026, every acute care hospital in the country has been required to report Severe Hypoglycemia and Hyperglycemia electronic quality measures under the Hospital Inpatient Quality Reporting Program. Hospitals that fail to comply forfeit the full annual Medicare reimbursement update. Against the 2.3% FY 2027 update finalized this month, that is not a compliance line item — it is the margin.

This month's SaMS proposal sharpens the point. As Medicare begins paying for clinical software as its own category, the market will fill with algorithm-driven glucose tools that have no FDA clearance behind them. Clearance stops being a regulatory checkbox and becomes a commercial moat. ISA has been working alongside Glytec's leadership to reach the

hospital executives, chief medical officers, and quality reporting stakeholders who feel this most urgently — and at scale. We know which doors to open and how to frame the conversation at the C-suite level, because we have sat in those chairs, signed those contracts, and felt the pressure of those mandates from the other side of the table.

> *This is not advisory work. This is operators who have been buyers, builders, and sellers — more than twenty times, across more than $3 billion in healthtech exits — actively opening the right doors at the right moment for companies that are ready to walk through them.*

We can help you too.

If your company is navigating a CMS payment decision, a new quality reporting requirement, or an enterprise buyer relationship that needs a different kind of entry point — this is exactly the work ISA does. The three signals in this issue are not abstractions. They are live commercial situations with defined buyers, financial consequences, and deadlines measured in days. We know how to position your company inside them.

FOR FOUNDERS

Ready to pressure-test your go-to-market against what enterprise buyers are actually accountable for right now?

Let's talk before your next raise.

FOR INVESTORS

Want ISA's read on how these mandates affect your current portfolio — or a company you're evaluating?

Let's talk before the window closes.

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