A R C L I G H T  I N S I G H T S ™

*Policy White Paper*

# Pricing Spike to Spiral:

## How Medicare's Skin Substitute Payment Architecture Created a Crisis and How the 2026 Reset Risks Creating Another

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April 2026

**AUDIENCE: Congressional Offices | CMS | Industry Stakeholders | Healthcare Policy Organizations**

# Executive Summary

Between 2019 and 2024, Medicare Part B spending on skin substitutes, a category of cellular and tissue-based products (CTPs) used to treat chronic wounds, grew from $252 million to more than $10 billion. That is a nearly forty-fold increase in five years. A single product, Membrane Graft/Wrap, generated over $1 billion in Medicare payments in 2024 alone. One patient's records showed $279,000 in annual CTP expenditures.

This did not happen because wound care became dramatically more complex or because breakthrough therapies swept the market. It happened because Medicare's payment design sent the wrong signal and no one adjusted the signal quickly enough.

The Centers for Medicare & Medicaid Services (CMS) paid most skin substitutes in the physician-office setting as Part B biologicals at Average Sales Price (ASP) plus 6 percent. When manufacturers failed to report ASP data, a widespread noncompliance documented by the HHS Office of Inspector General (OIG) in 2023, payment fell back to Wholesale Acquisition Cost (WAC) or invoice-based rates.

Either way, Medicare's reimbursement was anchored to prices that manufacturers could directly influence and manipulate. The incentive was straightforward: raise your stated price, raise your Medicare payment. Some manufacturers raised them to more than $4,000 per square centimeter by 2025.

CMS received clear warning signals as early as 2022 and proposed structural reform in the 2023 Physician Fee Schedule rulemaking cycle, but then backed away. The OIG published its findings in March 2023 and urged fast action. MedPAC documented escalating spending in successive annual reports. The agency convened a town hall, promised further analysis, and continued to examine options while the market adapted to a payment structure that rewarded price inflation. Structural factors like data lag, fragmented regulatory authority, administrative rulemaking calendars, and the political cost of cutting payments all contributed to the delay.

By 2026, fiscal and political pressure made a reckoning unavoidable. CMS implemented a sweeping reset: skin substitutes were reclassified from biological-like separately payable products to supplies, and a single national average payment rate of $127.14 per square centimeter was applied across all product categories — whether approved through the FDA's most rigorous Premarket Approval (PMA) pathway, cleared through the 510(k) process, or entering the market under the lower-burden 361 HCT/P framework. CMS projected the change would reduce spending by nearly 90 percent or approximately $19.6 billion in gross savings for CY 2026.

Reform was absolutely necessary, but the possibility of an overcorrection risks creating new negative unintended consequences. By applying one flat rate across products that CMS itself acknowledged differ by regulatory pathway, clinical evidence, and resource consumption, the agency replaced one pricing distortion with another. Evidence from Q1 2026 already documents site-of-care migration toward hospital outpatient departments, margin compression in community-based wound practices, and intensifying calls for pathway-differentiated rates. The window to correct the correction is the CY 2027 rulemaking cycle.

**Core Finding**

*Medicare's payment architecture for skin substitutes created structural incentives for price inflation and manipulation, and tolerated those incentives despite repeated warnings, and then corrected them through a blunt administrative reset that solves one distortion while risking several new ones. Neither the spiral nor the shock was inevitable. Both were products of policy choices, and policy inaction, that can and must be made more deliberately going forward.*

## I. The Policy Problem: When Payment Formulas Become Market Signals

Medicare is the dominant payor in wound care. For a large segment of the wound care market, particularly mobile and community-based practices serving mostly elderly and vulnerable populations with diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) patients, Medicare's coverage decisions, coding assignments, and payment rates do not merely describe what the market produces. They define it. When Medicare pays generously for a product category, that category expands. When it pays based on manufacturer-reported prices, those prices rise. When it allows fallback reimbursement methods that are difficult to audit, the fallback becomes the norm.

This dynamic is not unique to skin substitutes, and it is not primarily a story about corrupt actors. It is a structural feature of government-administered healthcare pricing. Rational firms operating in a market defined by a single dominant payor will adapt their strategies to match the signals that payor sends. When those signals are distorted — when the payment formula rewards price escalation over clinical differentiation — the market adapts accordingly. Understanding this distinction matters: it shifts the policy diagnosis from enforcement to design, and it reframes the question from who broke the rules to what the rules incentivized.

What makes the skin substitute episode unusually instructive is the speed and scale of the distortion, the clarity of the warning signals, and the bluntness of the eventual response. Between 2019 and 2024, a relatively narrow product category generated a nearly forty-fold spending increase. Federal oversight bodies documented the mechanism. CMS proposed a structural fix in 2022, which reclassified skin substitutes as supplies. Stakeholder opposition to the proposal was intense, and not without merit. Skin substitutes represent a heterogeneous category of products with meaningful differences in clinical evidence, manufacturing complexity, and cost structure. Treating all products as undifferentiated supplies risked underpayment for clinically differentiated products and distortion of innovation incentives.

However, the rejection of the supply-based model did not resolve the underlying structural flaw — the linkage between manufacturer-reported prices and Medicare reimbursement. In the absence of an alternative reform, the existing incentive structure remained in place during the period of most rapid spending growth. By the time the agency acted, the numbers had become politically intolerable and the corrective action unavoidably coarse.

The episode sits at the intersection of three policy domains that rarely speak to each other in the same document: FDA regulatory classification, Medicare reimbursement architecture, and administrative enforcement. Understanding what went wrong requires holding all three simultaneously. The causal chain below maps how structural features in each domain compounded to produce the crisis — and how the 2026 reset addressed only part of it.

***Figure 1: Causal Chain — From Payment Design to Policy Crisis***

| | | | | |
|---|---|---|---|---|
| **1. Market Entry** | FDA 361 HCT/P pathway: minimal manipulation standard, no premarket approval required | Low barrier to market entry for placental and tissue-derived products | Proliferation of 70+ products; rapid expansion of the CTP market | Large, heterogeneous market with variable evidence quality |
| **2. Payment Architecture** | ASP+6% in physician office; WAC/invoice fallback when ASP unreported; OPPS high/low grouping | Maximize stated prices; avoid ASP reporting; seek high-cost OPPS classification | Systematic price escalation; widespread ASP noncompliance; Q-code proliferation | Medicare payment increasingly disconnected from any real market transaction price |
| **3. Oversight Lag** | OIG warnings (2023); MedPAC annual reports; CMS proposes reform, defers implementation (2022–2024) | No corrective signal reaches the market; reform risk remains low | Continued price optimization; additional market entrants; spending compounds annually | Annual spending reaches $10.2B (2024); political and fiscal crisis becomes unavoidable |
| **4. Administrative Reset** | Single flat rate of $127.14/cm² across all FDA pathways effective January 1, 2026 | Uniform payment regardless of evidence quality, cost basis, or clinical differentiation | Site-of-care migration to HOPD; product exits; compressed margins in community-based practices | ~90% projected spending reduction; access uncertainty and innovation risk unresolved |
| **5. Unresolved State** | No stable national coverage criteria; no differentiated pathway-specific rates; no access monitoring | Audit inconsistency persists; compliant providers bear back-end enforcement burden | Appeals backlogs; investigational-use denials applied to Q-coded products with no clinical basis | New unintended consequences emerging in Q1 2026 |

*Sources: CMS CY 2026 PFS Final Rule; OIG Report OEI-12-22-00200 (2023); MedPAC Data Books 2024–2025.*

This framework, regulatory entry, payment design, oversight lag, administrative reset, and unresolved secondary effects, structures the analysis throughout this white paper. Each section

examines one phase of the chain, tracing how structural features created the conditions that the next phase could not contain.

## II. Regulatory Architecture: How FDA's HCT/P Framework Shaped the Market

To understand the Medicare payment story, it is necessary to understand the regulatory landscape that shaped which products entered the market and under what evidentiary burden.

### The 361 HCT/P Framework

FDA's Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/P) regulatory framework, codified in 21 CFR Part 1271, uses a risk-based tiered structure. Products that meet the criteria set out in 21 CFR § 1271.10, including minimal manipulation and homologous use, can be regulated solely under section 361 of the Public Health Service Act (PHS Act). For such products, FDA's regulatory focus is on communicable disease risk, donor screening, and good tissue practices. These products are not subject to the premarket approval or clearance requirements that apply to devices, biologics, or drugs.

Products that do not meet all section 1271.10 criteria — for example, because they involve more than minimal manipulation or are intended for non-homologous use — are regulated as drugs, biologics, or devices and face correspondingly higher premarket evidence burdens. The most demanding pathway, Premarket Approval (PMA), requires robust clinical evidence of safety and effectiveness. The 510(k) clearance pathway requires demonstration of substantial equivalence to a legally marketed predicate device. The 361 HCT/P pathway, by contrast, requires no premarket submission if the product satisfies the criteria.

This tiered structure is scientifically defensible as a risk-management framework. It was not designed as a wound-care market-entry program. But in practice, it created a regulatory environment in which many placental membrane and other tissue-derived wound products could reach the market without PMA-level evidence. MAC LCD materials filed in connection with the 2024 proposed coverage determination described 76 recognized skin substitute graft and CTP products, of which 68 were categorized as acellular dermal substitutes, with large numbers derived from placental membranes and only a small minority classed as cellular products. AHRQ's 2020 technology assessment described the product landscape as a broad collection of heterogeneous skin substitute products with variable evidence quality across the category.

### How FDA Classification Became a Medicare Payment Category

The connection between FDA regulatory pathway and Medicare reimbursement crystallized in 2026, when CMS explicitly aligned its new payment categories (APCs 6000, 6001, and 6002) to FDA pathway: PMA, 510(k), and 361 HCT/P respectively. That alignment tells a story: FDA classification had become commercially central not just at market entry, but at payment. The regulatory tier a product occupied was now determinative of its Medicare payment bucket.

This has significant downstream implications. A product that entered under the 361 HCT/P framework, with a lower evidence burden, is now placed in the same payment category as products that underwent extensive clinical trials and manufacturing scrutiny required by PMA.

Conversely, a PMA product is placed in the same 2026 transitional rate bin as a far less clinically documented competitor. That is the overcorrection risk in concrete form: the payment structure that failed to differentiate on price now fails to differentiate on evidence.

## III. Medicare Payment Design and the Arbitrage Pathways

The spending spiral did not emerge from a single flaw. It emerged from the interaction of multiple payment mechanisms across different care settings, each of which had its own vulnerability to price manipulation.

### The Physician-Office Setting: ASP+6% and the WAC Fallback

In the non-facility (physician office) setting, CMS historically paid most skin substitutes as Part B biologicals under the ASP-plus-6-percent methodology. Under this framework, Medicare reimbursement for a product is set at the manufacturer's reported average sales price plus a 6 percent add-on. The intent of ASP-based payment is to anchor reimbursement to actual transaction prices in the market, not to inflated list prices.

The mechanism broke down in two ways in the skin substitute market. First, when manufacturers failed to report ASP data, as OIG found 30 of 68 reviewed billing codes had failed to do, CMS's fallback payment basis was the Wholesale Acquisition Cost (WAC) or invoice-reported amounts. These are inherently less reliable price anchors than ASP data derived from actual sales across the market. OIG calculated that every quarter in which WAC or invoice rates governed could cost Medicare tens of millions of dollars in excess payments above what proper ASP reporting would have produced.

Second, even when ASP was reported, the structure created an upward price incentive. In a market dominated by a single payor (Medicare) that reimburses at a markup above the manufacturer's own reported price, with no countervailing direct-consumer price sensitivity, the rational commercial strategy is to report the highest defensible sales price. Some manufacturers concluded that ceiling was far above what CMS initially anticipated. By 2025, CMS described prices exceeding $4,000 per square centimeter for certain products and characterized the pricing environment as exhibiting abusive practices.

### The Hospital Outpatient and ASC Setting: High/Low Grouping

In hospital outpatient departments (HOPD) and ambulatory surgical centers (ASC), CMS packaged most skin substitute costs into the associated application procedure beginning with the CY 2014 OPPS final rule, treating these products as supplies integral to the procedure rather than separately payable items. To maintain resource homogeneity within procedure payment groups, CMS divided products into high-cost and low-cost groupings, with annual thresholds based on cost data. A product's placement in the high-cost versus low-cost group depended on cost data, and in a market where manufacturer-stated or manufacturer-reported costs influenced that determination, there was commercial value in being categorized as high-cost.

### The Coding Proliferation Problem

Layered over both settings was a third mechanism: HCPCS coding proliferation. Skin substitutes were assigned Q-codes — temporary billing codes issued by CMS outside the standard CPT process — as a rapid market-entry coding mechanism. These codes enabled

billing before a product had an established permanent coding designation. As the product field expanded and manufacturers sought distinct billing identities, the number of active Q-codes multiplied. By the time the 2026 reform was finalized, the landscape included scores of active Q-codes for skin substitute products, each with its own payment rate, prior authorization status, and coverage rules across different MAC jurisdictions.

The proliferation of Q-codes had a secondary consequence beyond reimbursement: it created interpretive ambiguity in the audit and appeals process. As discussed in Section VII, at least one Medicare review contractor treated a product's Q-code designation as evidence of investigational status, a fundamental misreading of what Q-codes are and how they function, with material consequences for compliant providers.

## IV. A Decade of Drift: Warning Signals and Policy Lag (2019–2024)

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The spending trajectory described in Table 1 below was not invisible to federal oversight bodies. The warnings arrived clearly and repeatedly. What is striking in retrospect is not the absence of information, but the gap between the receipt of that information and decisive policy action — and the structural reasons that gap persisted long enough to cost Medicare billions of dollars.

***Table 1: Medicare Part B Skin Substitute Spending, 2019–2026***

| Year | Part B Spending | Year-Over-Year Change | Notable Development |
|---|---|---|---|
| 2019 | $252 million | Baseline | ASP+6% framework in place |
| 2021 | ~$1.0 billion | +297% vs. 2019 | Coding proliferation accelerates |
| 2022 | ~$1.6 billion | +60% vs. 2021 | OIG begins monitoring ASP compliance |
| 2023 | ~$4.4 billion | +175% vs. 2022 | OIG report published; CMS defers physician-office reform for second cycle |
| 2024 | $10.2 billion | +132% vs. 2023 | MedPAC documents spiral; one product exceeds $1.5B; CMS characterizes market as exhibiting "abusive pricing" |
| **2026 (Projected)*** | **~$1.0 billion (est.)** | **~90% reduction — est. $19.6B gross savings (CMS projection)** | **Flat $127.14/cm² transitional rate; incident-to supply** |

| Year | Part B Spending | Year-Over-Year Change | Notable Development |
|---|---|---|---|
| | | | **classification in physician office** |

** CMS projected gross savings of approximately $19.6 billion for CY 2026. Source: CMS, CY 2026 PFS Final Rule Fact Sheet and October 31, 2025 Press Release.*

## The Warning Timeline

In the 2022 PFS proposed rule, CMS signaled awareness of the problem explicitly enough to propose a structural solution: reclassifying skin substitutes in the physician-office setting from biological-like separately payable products to practice-expense supplies. That proposal, if adopted, would have fundamentally altered the price-inflation incentive. CMS withdrew it in the final rule, citing the need for additional stakeholder engagement and further analysis. A town hall was convened in January 2023.

In March 2023, the HHS Office of Inspector General published a report finding that 30 of 68 reviewed billing codes lacked ASP-based payment amounts because manufacturers had not complied with reporting requirements. OIG projected that invoice- and WAC-based fallback payments could cost Medicare tens of millions of dollars per quarter and explicitly urged CMS to act quickly, including with interim mechanisms while a systemic solution was developed. The agency did not implement interim mechanisms.

MedPAC's July 2024 Data Book documented a stunning spending ramp: $1.0 billion in 2021, $1.6 billion in 2022, and preliminary 2023 data already above $4 billion. The Commission's September 2024 comment letter to CMS specifically flagged one product, Dual Layer Impax Membrane, exceeding $1.4 billion in 2023 spending alone, with annual expenditure per beneficiary of $279,000. MedPAC urged continued reform while preserving patient access.

In 2024, the Medicare Administrative Contractors (MACs) proposed Local Coverage Determinations (LCDs) for DFU and VLU skin substitute use, aimed at tightening front-end coverage criteria. Those proposed LCDs were finalized for a January 1, 2026 effective date, and then withdrawn on December 24, 2025, the day CMS announced its enforcement posture under the new payment regime. That sequence is itself evidence of regulatory instability: coverage policy moved from proposed, to final, to withdrawn within the span of one rulemaking cycle.

> **The Cost of Delay**
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> *From OIG's March 2023 warning that ASP noncompliance was costing Medicare tens of millions per quarter, to CMS's implementation of the 2026 reset, approximately 36 months elapsed. During that period, annual spending grew from approximately $1.6 billion (2022) to $10.2 billion (2024), an increase of $8.6 billion over three years. The cost of waiting for a perfect reform was a near-perfect storm of fiscal and political pressure that ultimately forced a blunt one.*

## Why CMS Did Not Act Sooner

The delay is not fully explained by political interference or agency indifference. Several structural factors created genuine friction between identifying the problem and fixing it — factors that are relevant to any future design of corrective mechanisms.

Data lag was the first constraint. ASP data arrives to CMS on a quarterly basis, with additional processing time before it can inform policy. MedPAC's annual data books document prior-year

spending, meaning that by the time data confirmed a crisis pattern, the market had already adapted to the distorted signal for another twelve months. The feedback loop between administrative price signals and regulatory response was measured in years, not quarters.

Fragmented regulatory authority compounded the lag. FDA regulates product entry under the HCT/P framework. CMS governs payment methodology under the PFS and OPPS rules. MACs administer coverage at the local level. OIG enforces compliance through post-payment review. No single agency owned the entire feedback loop, from product entry to payment to utilization to correction. Each regulatory actor could see part of the picture; none had both the authority and the data to act comprehensively.

The annual rulemaking calendar imposed its own rhythm. A structural change proposed in the CY 2023 PFS cycle, if deferred in the final rule, cannot be finalized until the CY 2024 cycle at the earliest, with implementation the following January. A reform proposed in 2022 and deferred twice does not reach patients and providers until 2026. The mismatch between the market's ability to adapt in real time and the rulemaking process's annual cadence is not a failure of will. It is a design gap.

Finally, the political risk of payment reduction is real and asymmetric. Cutting reimbursement for products used in wound care invites stakeholder opposition framed as patient-access threats. That framing, regardless of the clinical evidence, raises the political cost of acting before a crisis becomes undeniable. CMS faced a genuine dilemma: act early and absorb the stakeholder backlash before the data fully justified it or wait for the data to be unambiguous and absorb the fiscal cost of waiting. The agency waited.

### The Role of Special Interests

Organized stakeholder advocacy was present throughout. The Alliance of Wound Care Stakeholders, the American Podiatric Medical Association (APMA), individual manufacturers, and provider coalitions all submitted formal comments and public statements on payment and coverage proposals. Some urged faster reform; others argued proposed rates were too low or methodologically unsound. There is public reporting that a political donation of $5 million from a skin substitute manufacturer to a PAC in 2025 preceded a delay in a coverage restriction, an episode that appropriately drew scrutiny.

That evidence matters, but it does not explain the full arc of the 2019–2024 spiral. Lobbying affected the pace and shape of reform debates. It did not create the underlying structural incentive — the ASP-plus-markup framework that rewarded price escalation — which was in place long before any particular advocacy campaign. The more durable policy argument is that the payment design created a fertile environment for gaming regardless of whether any particular actor crossed a legal line.

## V. The 2026 Reset: Anti-Abuse in Purpose, Blunt in Form

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By late 2025, CMS faced a policy choice with no comfortable options. The evidence of systematic distortion was unambiguous and the political moment demanded action. Three paths were available: continue under the existing architecture and absorb further spending growth; pursue a gradual, differentiated transition that would take multiple rulemaking cycles to implement; or execute an immediate, system-wide reset. CMS chose the third.

### What CMS Changed

The CY 2026 reform had three structural elements, finalized in the November 2025 PFS and OPPS final rules with an effective date of January 1, 2026. In the non-facility (physician office) setting, CMS discontinued separate biological-style payment for most skin substitutes. Instead, products are now paid as incident-to supplies when furnished as part of covered application procedures, with reimbursement embedded in the practice expense component of the procedure's relative value unit (RVU) structure. The separately-payable reimbursement channel, the one that had permitted ASP-plus-markup escalation, was eliminated.

In the hospital outpatient and ASC setting, CMS unbundled skin substitute product payment from the application procedure and created three new Ambulatory Payment Classification (APC) codes aligned to FDA regulatory pathways: APC 6000 for PMA products, APC 6001 for 510(k) products, and APC 6002 for 361 HCT/P products. Corresponding unlisted codes ( Q4431, Q4432, and Q4433) were also established.

Despite creating three pathway-aligned APCs, CMS set a single transitional national payment rate of $127.14 per square centimeter across all three categories for CY 2026. The agency stated it chose the single rate at the level of the highest average across the three FDA categories so that it would not underestimate the resources involved, and indicated it intends to propose differentiated rates between categories in future rulemaking years. CMS projected the combined changes would reduce Part B skin substitute spending by approximately 90 percent, an estimated $19.6 billion in gross savings.

> **Implementation Rate Note**
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> *CMS's final 2026 PFS fact sheet cited an approximate average payment rate of $127.28 per cm². The January 2026 transmittal and APC payment tables (Transmittal 13573) set the operative payment at $127.14 per cm² for APCs 6000, 6001, and 6002. This white paper uses $127.14 as the average implemented rate.*

### What Justified It

The anti-abuse rationale for a reset was well-founded. OIG, MedPAC, the MACs, and CMS itself had all documented that the prior system was fiscally broken. The gap between manufacturer-stated prices and any defensible clinical or resource-cost basis had become, by CMS's own description, a product of abusive pricing. The enforcement record, including $185 million in improper payment stops in 2025 and a documented case of more than $4.3 million in purported wound-care claims for a single beneficiary with no prior wound treatment history, confirmed that the signal distortion had generated downstream fraud and misuse at scale.The conclusion that these products should not be reimbursed through a mechanism anchored to manufacturer-reported price was supported by OIG, MedPAC, and the academic health policy literature on supply-chain pricing incentives.

## VI. The Risk of a New Unintended Consequence

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The case for the 2026 reset is stronger than the case against it. But a defensible reform is not necessarily a calibrated one. The choice to execute an immediate flat-rate reset, rather than a

phased, differentiated transition, left several specific gaps in the new framework, and those gaps are already producing predictable adverse consequences.

The 2026 reset was implemented without:

- Product-level differentiation within FDA pathway categories, despite CMS's own acknowledgment that PMA, 510(k), and 361 HCT/P products differ in evidence quality and resource consumption;
- A phase-in period or transitional payment bridge to allow provider business models, especially mobile wound care, to adjust;
- Outcome linkage: no mechanism ties the new payment rates to healing outcomes, amputation avoidance, or other patient-centered measures;

Each of these gaps creates a specific and foreseeable risk.

## Risk 1: Underpayment of Clinically Differentiated Products

CMS explicitly acknowledged that PMA, 510(k), and 361 HCT/P products differ in their regulatory burdens, clinical evidence requirements, and resource profiles. It then applied a single payment rate to all three. CMS's stated rationale, setting the rate at the highest average so as not to underestimate resources, is an anti-underpayment measure at the category aggregate level. It is not a guarantee of payment adequacy at the individual product level, particularly for PMA products that underwent costly clinical trials to demonstrate efficacy and that carry higher manufacturing and quality-assurance costs than lower-pathway competitors.

If a PMA product and a 361 HCT/P product receive identical Medicare reimbursement, and the PMA product carries a substantially higher cost basis, physician-office practices face an economic choice between the two that is not driven by clinical differentiation. The single-rate structure may inadvertently advantage lower-evidence products over higher-evidence ones — the opposite of the innovation incentive CMS described as a goal of the new framework.

## Risk 2: Site-of-Care Migration

The elimination of separate payment for skin substitutes in the non-facility setting does not eliminate the clinical need for those products. It shifts the economic math. Wound care providers operating in physician-office or mobile settings, who now receive reimbursement embedded in practice expense RVUs, may find the economics of advanced CTP use unworkable for higher-cost products. Hospital outpatient departments, which receive separate APC-based product payment and have structurally larger cost-absorption capacity, may become the economically preferred setting for CTP application.

That shift would have ironic consequences. Hospital outpatient care is consistently more expensive to Medicare on a per-encounter basis than physician-office or mobile wound care. Evidence from Q1 2026 already documents increased HOPD utilization and significant margin compression in physician-office and mobile wound-care practices, validating what was predicted in the rule's stakeholder comment period. If community-based providers exit the advanced CTP market — serving patients in their homes or long-term care facilities who have limited access to hospital outpatient departments — the access impact will fall **disproportionately on the most vulnerable** segment of the wound care population: elderly, mobility-limited Medicare beneficiaries with diabetic foot ulcers and venous leg ulcers who depend on in-home care.

## Risk 3: Coverage Instability Compounding Payment Shock

The withdrawal of the MAC LCDs on December 24, 2025, announced the same day as the 2026 payment implementation, removed the front-end coverage standard that had been under development since 2024. Providers entering 2026 face a simultaneously restructured payment system and an absent stable coverage determination. The pre-2024 LCD landscape, a patchwork of MAC-specific policies across Novitas, CGS, Palmetto, WPS, and other contractors, has been partially displaced but not uniformly replaced.

Coverage instability combined with payment shock is precisely the condition that historically produces overcorrection on the back end: heightened audit activity, expanded investigational-use denials, and the kind of review-level inconsistency that shifts compliance burdens from bad actors to compliant providers. The evidence from audit and appeals records, as discussed in Section VII, shows that dynamic was already operating under the old regime. Without deliberate policy intervention to establish stable national coverage criteria, there is no structural reason to expect it to self-correct under the new one.

### Risk 4: Chilling Innovation Investment

CMS stated that a goal of the new framework is to incentivize competition and reward more innovative products. The transitional single rate is in some tension with that goal. A manufacturer that has invested in PMA-level clinical evidence to differentiate its product, and that faces the same Medicare payment rate as a lower-evidence competitor, has a weakened commercial case for that investment. Until pathway-differentiated rates are finalized for CY 2027, the innovation incentive signal remains distorted. Research and development investment decisions operate on longer time horizons than a single rulemaking cycle; the twelve-month gap between the 2026 single-rate implementation and a potential 2027 differentiation is long enough to affect pipeline decisions that will shape the wound-care market for years.

## VII. The Provider in the Middle: A Case Study in Audit Burden and Review Inconsistency

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Abstract arguments about payment design and systemic risk can obscure what the audit and appeals environment looks like from the ground. The following case study, drawn from the administrative record of a wound care provider that operated under both the pre-2026 payment framework and the UPIC audit environment, illustrates concretely how the regulatory turbulence of this period fell on compliant providers.

> *Patient and provider identifiers are anonymized. The case involves real administrative decisions at the QIC and OMHA/ALJ levels during 2024–2025.*

### The QIC Denial: A Q-Code as Proof of Investigational Status

In a 2024 claim for wound care furnished to Patient A, a Medicare beneficiary with a documented chronic wound, the treating provider applied a cellular and tissue-based product billed under a Q-code designation (a temporary HCPCS billing code assigned by CMS pending permanent coding). The claim was denied at the redetermination level and, on reconsideration, upheld as unfavorable by the Qualified Independent Contractor (QIC).

The QIC's rationale was striking: the product was deemed experimental and investigational because it was assigned a Q-code. In the QIC's reasoning, Q-code designation was treated as

a proxy for investigational status, an indicator that the product had not achieved the market acceptance or clinical recognition associated with permanent coding.

That reasoning was analytically incorrect, and consequentially so. Q-codes are temporary billing codes issued by CMS as an administrative mechanism to enable billing while permanent coding is under development. A product's assignment to a Q-code reflects coding process timing, not a clinical determination that it is experimental or outside standard medical practice. Many well-established, widely used wound care products have held Q-code designations for years. Treating Q-code status as investigational evidence conflates a billing classification with a coverage standard that has no regulatory basis.

The clinical record underlying Patient A's claim was not a marginal case. The wound had followed a trajectory of failed conservative treatment before advanced CTP therapy was initiated — a clinical pattern consistent with standard escalation criteria. The denial did not engage the clinical documentation. It engaged the product's coding designation.

## The ALJ Reversal: Restoring Regulatory Clarity

On appeal to the Office of Medicare Hearings and Appeals (OMHA), the Administrative Law Judge reviewed the same claim and issued a fully favorable decision for the provider. The ALJ found that Q-codes are temporary billing codes, not evidence of investigational status; that the product was used as a wound covering in a manner consistent with homologous use under section 361 of the PHS Act; and that the QIC's reasoning conflated coding classification with coverage status in a manner unsupported by the governing regulatory framework.

The ALJ's decision was legally sound. It was also the product of a multi-level appeals process that required the provider to sustain the administrative burden of a redetermination, a QIC reconsideration, and an OMHA hearing — a process spanning more than twelve months from the date of service. During that period, the contested claim was subject to recoupment pressure, the patient's care record required preservation across review levels, and clinical staff time was diverted from care to appeals documentation.

## What This Case Reveals

Three policy conclusions emerge from this record.

First, at least some review contractors used broad investigational-use reasoning as an expedient spending-control tool during the period of payment-policy uncertainty between 2023 and 2025. That is not a sustainable quality-control mechanism, it is an untargeted burden that falls on compliant and non-compliant providers alike, penalizing correct billing decisions and distorting the audit signal.

Second, the inconsistency between the QIC denial and the ALJ reversal illustrates a broader pattern documented in Medicare audit research: different review levels applying different legal theories to the same underlying facts, without the provider being afforded notice of the changed rationale or an opportunity to respond specifically to it. When the QIC applied an investigational theory not raised at the redetermination level, the provider's response was structurally disadvantaged. The appeal succeeded not because the system functioned as designed, but despite the barriers the system created.

Third, the administrative burden of defending a correct billing decision through multiple appeals levels, over a product whose Q-code CMS itself assigned, is not a byproduct of a well-designed

enforcement system. It is evidence that back-end enforcement is doing work that front-end payment and coverage policy should have done earlier. The 2026 payment reset does not resolve this. Without stable coverage criteria and consistent audit guidance, the same dynamic will recur under the new payment framework, directed now at a narrower but still ambiguous field of covered products.

## VIII. Policy Recommendations

The following recommendations are organized by urgency and by the actor best positioned to implement them. They address the specific design gaps identified in this analysis — and are intended to be actionable within the current legislative and regulatory calendar, not aspirational reforms for a future Congress.

***Table 2: Policy Recommendations Summary***

| # | Recommendation | Action Required | Priority |
|---|---|---|---|
| 1 | Mandate validated ASP reporting with automatic payment ceiling upon noncompliance | CMS rulemaking / Congressional directive | **Immediate** |
| 2 | Differentiate CY 2027 payment rates by FDA pathway and clinical evidence tier | CMS rulemaking (PFS/OPPS CY 2027) | **Urgent** |
| 3 | Establish automatic spending-velocity guardrails triggering expedited review | Congressional authorization / CMS regulation | **High** |
| 4 | Restore stable national coverage criteria; halt case-by-case investigational-use review | CMS/MAC guidance; OIG enforcement guidance | **Immediate** |
| 5 | Conduct formal access and outcomes assessment in Q3/Q4 2026 with mandatory public reporting | CMS / OIG / GAO study directive | **High** |
| 6 | Authorize AI-enabled real-time pricing-anomaly detection for high-risk Part B product categories | CMS pilot authorization / Congressional directive | **Medium** |

### Recommendation 1: Mandate Validated ASP Reporting with Automatic Payment Ceilings

Congress should direct CMS to require all manufacturers of separately billable Medicare Part B products in the skin substitute category to submit validated, auditable ASP data on a quarterly basis. CMS should be authorized and directed to impose an automatic payment ceiling, reverting to the lower of WAC or a benchmark rate, for any quarter in which a manufacturer fails to submit compliant ASP data. The OIG recommended this approach in 2023. The cost of

inaction has now been quantified: tens of millions per quarter for at least twelve quarters. Retroactive application to the 2023–2025 period should be considered.

### Recommendation 2: Differentiate CY 2027 Payment Rates by FDA Pathway and Evidence Tier

CMS should finalize differentiated payment rates across its three APC categories (PMA, 510(k), and 361 HCT/P) in the CY 2027 OPPS and PFS rulemaking cycle, consistent with its stated intention. Those rates should reflect not only FDA pathway but, to the extent data are available, relative cost basis and clinical evidence quality. CMS should issue interim guidance by Q3 2026 describing its methodology for deriving pathway-specific rates, to provide manufacturers and providers with planning certainty ahead of the proposed rule.

### Recommendation 3: Establish Automatic Spending-Velocity Guardrails

Congress should authorize and direct CMS to implement automatic spending-velocity triggers for separately billable product categories: specifically, a mandatory expedited review and rulemaking process when any single product category's annual Part B expenditure exceeds a defined threshold, such as a 50 percent year-over-year increase sustained across two quarters, or when a single product accounts for more than a specified percentage of total category spending. This mechanism would have triggered review for skin substitutes as early as 2022. It should be statutory, not merely administrative, so that it cannot be deferred unilaterally by the agency.

### Recommendation 4: Restore Stable National Coverage Criteria

CMS and the MACs should develop and publish stable national coverage criteria for skin substitutes under the new payment framework, providing clear clinical indications, product eligibility standards, and documentation requirements. These criteria should be prospective and consistent across MAC jurisdictions, eliminating the patchwork of pre-2024 local policies that created interpretive inconsistency in the audit environment. Simultaneously, OIG should issue formal guidance to UPICs and review contractors clarifying that Q-code designation does not constitute grounds for an investigational-use denial absent affirmative clinical evidence that the product was used for an experimental indication.

### Recommendation 5: Commission a Formal Access and Outcomes Assessment

Congress should direct CMS, OIG, or GAO to conduct a formal assessment of patient access and clinical outcomes under the 2026 payment framework, with a reporting deadline of Q4 2026. The assessment should examine whether site-of-care shifts are occurring, whether any patient populations have experienced reduced access to advanced wound care, whether the rate of wound complication or hospitalization has changed, and whether the innovation pipeline for advanced CTPs has been affected. The results should inform the CY 2027 rulemaking cycle and, if warranted, emergency corrective action.

### Recommendation 6: Authorize AI-Enabled Real-Time Pricing-Anomaly Detection

The central failure in the skin substitute episode was not informational scarcity — it was the absence of real-time surveillance mechanisms capable of acting on data that was already available. Price escalation, ASP noncompliance, and utilization velocity were all visible in the claims record years before CMS acted. The oversight infrastructure simply was not designed to respond to them at the speed the market moved.

Congress should authorize CMS to pilot an AI-enabled pricing-anomaly detection system for high-risk Part B product categories. Such a system would monitor claims data continuously and flag specific, operationally defined triggers for expedited review or automatic payment ceilings — for example: price-per-cm² readings exceeding two standard deviations above the category median; sudden clustering of ASP non-reporting paired with WAC or invoice-based fallback payments; quarter-over-quarter spending velocity spikes above a defined threshold for any single product code; and single-product dominance when one item accounts for a disproportionate share of total category expenditure. Cross-referenced against FDA pathway classification and available outcome proxies, these signals would generate a tiered alert, not a unilateral payment decision, that routes to expedited human review.

The data infrastructure to support this largely exists within CMS's existing claims systems; the governance logic does not. Such a system would require careful design to avoid false positives and to ensure that anomaly detection informs, rather than replaces, clinical and coverage judgment — but that is an engineering problem, not an argument against building it. The alternative is another decade-long spiral in the next high-growth product category, corrected only when the numbers become politically intolerable.

## IX. Conclusion: The Lessons Beyond Wound Care

The skin substitute episode is, at its core, a story about the distance between policy intent and policy effect when administered prices become the primary market signal. FDA's 361 HCT/P framework was designed to protect public health through proportionate regulation. Medicare's ASP-plus-markup framework was designed to tie reimbursement to real market prices. Both had defensible rationales. Their interaction, in a market where Medicare is the dominant payor and manufacturer-reported prices can directly influence reimbursement, produced outcomes neither was designed to generate.

The warning signals were not subtle. OIG documented them. MedPAC quantified them. CMS proposed the structural fix — and then deferred it, three years in a row, while spending compounded. The 2026 reset was driven by fiscal and political urgency rather than calibrated design. That is why it arrived as a flat rate rather than a differentiated one, why it withdrew coverage criteria the same day it implemented payment changes, and why Q1 2026 data already document the site-of-care migration and access concerns that were entirely predictable from the structure of the rule.

The actionable lesson is narrow and specific: payment formulas that anchor reimbursement to manufacturer-reported prices, without validated reporting requirements and automatic correction triggers, will be exploited — not necessarily through corruption, but through rational commercial adaptation to a distorted signal. The solution is a payment architecture with feedback controls that respond faster than the market exploits them. For the Medicare beneficiaries at the center of this story, elderly patients with diabetic foot ulcers and venous leg ulcers who depend on advanced wound care to avoid amputation, both the spiral and the shock carry real consequences. They deserve a payment system designed to learn, correct, and differentiate.

The CY 2027 rulemaking cycle is the next decision point. The recommendations in this paper are designed to be actionable within that window. The architecture for real-time pricing oversight does not yet exist. Building it is the work the 2026 rules left unfinished.

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