CLIENT ALERTS & INSIGHTS

CMS Proposes Overhaul of Skin Substitute Reimbursement Policy Beginning January 2026 – Implications for Providers, Manufacturers, and Payers in Both Outpatient and Physician Office Settings

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Background On July 16, 2025, the U.S. Department of Health and Human Services' (HHS) Centers for Medicare & Medicaid Services (CMS) published its CY 2026 Medicare Physician Fee Schedule (PFS) Proposed Rule, which includes a sweeping proposal to restructure how skin substitute products are paid in both non-facility (e.g., physician offices) and hospital outpatient settings. The proposal significantly revises prior CMS policy and, if finalized, will have wide-reaching implications for reimbursement, product utilization, innovation pathways, and patient access. Under the proposed rule, set to take effect January 1, 2026, CMS would implement a national, standardized payment methodology for all skin substitutes, with payment rates determined based on regulatory pathway categories outlined by the Food and Drug Administration (FDA) rather than individual product characteristics or clinical differentiation. Clients, including providers, manufacturers, and group purchasing entities, should begin to evaluate the implications of this rule and position themselves for a final rule this fall.

Key Elements of the Proposed Rule

- **Separate Payment for Skin Substitutes in Physician Offices**: Historically, Medicare bundled payment for skin substitute products into the overall procedure cost when used in non-facility (physician office) settings. CMS now proposes to permanently allow separate payments for skin substitute products furnished incident to physician services and supplies, aligning payment policy more closely with hospital outpatient departments.

- **Single Payment Rate Across Settings**: A single payment rate per square centimeter (~$125.38/cm^2) using a volume-weighted average sales price (ASP) methodology will apply to all skin substitute procedures, regardless of product or clinical setting.
- **Rate-Setting Based on ASP or Alternate Pricing Benchmarks**: CMS intends to use ASP reporting to drive rate-setting, with fallback benchmarks to one of the following alternative price points: hospital outpatient mean unit cost (MUC), wholesale acquisition cost (WAC), or 89.6% of the average wholesale price (AWP), when ASP is unavailable. Importantly, CMS proposes to base rates on hospital outpatient department utilization patterns, even for procedures performed in physician offices.

- **Reimbursement Driven by FDA Regulatory Pathway**: CMS proposes to group all skin substitute products into three payment categories based on how the product entered the market (i.e., the product's FDA regulatory status):

1. Premarket-approved (PMA) biologicals[1] and devices

   510(k)-cleared or De Novo pathway devices

   361 HCT/Ps (Human Cell, Tissue, and Cellular/Tissue-Based Products that are regulated solely under Section 361 of the Public Health Service Act)

In future years, CMS intends to propose payment rates that differentiate between the three FDA regulatory categories it proposes.

- **New Product Applications and Innovation Recognition, but CMS Will Not Add Innovation-Based Bonuses (Yet)**: Although CMS acknowledges its payment grouping may not fully reflect clinical value or innovation, it does not propose innovation-based rate add-ons. Instead, CMS seeks comments on how to account for product innovation, including whether pass-through status under the hospital outpatient rules, new technology add-on payment (NTAP) eligibility, or FDA Breakthrough Device designation should trigger special treatment. CMS also proposes to evaluate HCPCS Level II applications for skin substitutes on the biannual cycles that apply to nondrugs/nonbiologicals. CMS further proposes that, should any products come to market under the Biologics License Application, New Drug Application, or Abbreviated New Drug Application pathways that could potentially be considered skin substitutes, CMS would review them on the quarterly HCPCS coding cycles that apply to drugs and biologicals.

Implications for the Industry

This is the first time CMS has aligned payment methodology with FDA regulatory distinctions for skin substitutes, signaling a deliberate shift from traditional product-specific reimbursement toward a more categorical, value-based payment structure. As a result, it introduces both legal and operational challenges for organizations offering, using, or distributing differentiated skin substitute products, especially those that are higher-cost, biologically derived, or cleared through more rigorous regulatory pathways.

While CMS argues that this approach introduces greater predictability and administrative simplicity, stakeholders have voiced serious concerns about its potential consequences. Chief among them is the risk that clinically distinct products that vary widely in cost, effectiveness, durability, or patient suitability will be treated as interchangeable simply because they share a regulatory pathway. CMS has expressly disclaimed clinical differentiation among these categories despite clear distinctions in approval rigor, indications for use, and patient outcomes. By ignoring clinical variability, CMS's proposal could inadvertently reduce access to the most appropriate or advanced products for certain patients, particularly in complex wound care cases.

Furthermore, manufacturers may face new pressures. If products approved through more rigorous FDA processes (like PMA or BLA pathways) receive the same reimbursement as lower-cost alternatives, there may be little incentive to invest in innovation or pursue more demanding regulatory clearances. Over time, this could dampen the development of next-generation therapies. Manufacturers with FDA-intensive products may also face payment compression if grouped with lower-cost substitutes receiving equivalent reimbursement.

Additionally, CMS's plan to base payment on a single, volume-weighted ASP within each group may lead to lower reimbursement levels for higher-cost, clinically advanced products, further discouraging innovation and potentially shifting utilization toward less effective alternatives. Providers and suppliers could experience margin compression, particularly where their product mix includes premium technologies. As such, manufacturers who do not report ASP may find their products reimbursed at lower, less favorable rates. Practices using niche or newer products should monitor whether those products have ASPs because CMS's intent to rely on ASP reporting with fallback to MUC, WAC, or 89.6% AWP can raise compliance concerns. Inaccurate ASP submissions or lapses in reporting could significantly affect reimbursement and create exposure under the False Claims Act (FCA) or increased HHS Office of Inspector General scrutiny.

For providers, the new framework could simplify billing and increase predictability in Medicare reimbursement, but it also raises operational and clinical questions. Practices may need to reevaluate product selection, clinical protocols, and cost-sharing structures in light of uniform payment rates that may not reflect real-world differences in product performance or acquisition cost.

This proposal also introduces new dynamics for other stakeholders. Payers and Medicare Administrative Contractors (MACs) may benefit from a more predictable pricing framework, but they will need to monitor whether it leads to unintended reductions in quality or access. CMS will likely implement additional oversight to mitigate the risk of compromised clinical outcomes driven by price-sensitive utilization.

Patients, too, could feel the impact, mainly if shifts in product use result in reduced availability of certain skin substitutes in settings where margins are already constrained, like physician offices or rural clinics. Access to specific skin substitute products may change depending on how providers and manufacturers respond to the new financial dynamics.

While CMS's justification for this overhaul is partly fiscal, to contain costs and preserve the long-term solvency of the Medicare trust fund, it also reflects concerns about systemic fraud and abuse within the skin substitute market. CMS has signaled increasing frustration with reports of excessive utilization, upcoding, and profit-maximizing schemes involving certain providers and distributors. The proposed rule reflects an effort to curb these practices, dampen the financial incentives that have historically driven questionable billing patterns, and disincentivize opportunistic behavior. While there is no legal right (constitutional or otherwise) to guarantee access to the most advanced treatment available for every medical condition, CMS is attempting to balance resource stewardship of the Medicare Trust Funds with broader beneficiary access. The shift to a uniform, category-based payment model is likely intended to neutralize the economic drivers that have enabled unscrupulous actors to game the system.

In short, CMS's proposed policy marks a major step toward uniform, category-based reimbursement, but one that could reshape market behavior, alter clinical decision-making, and

influence long-term innovation in wound care technologies. Stakeholders are strongly encouraged to review the proposed rule carefully and consider submitting public comments by **September 12, 2025**, including how CMS can balance payment simplicity with clinical nuance and innovation support. Manufacturers and providers with PMA-approved or high-cost products may wish to advocate for product-specific exceptions or innovation-based add-ons.

Timeline and Next Steps

- **Comment Period Ends:** 5 p.m. EST on September 12, 2025
- **Final Rule Expected:** November 2025
- **Effective Date (If Finalized):** January 1, 2026

As the September 12, 2025, comment deadline approaches, stakeholders across the skin substitute landscape should begin preparing now for the operational, financial, and legal implications of CMS's proposed rule. The comment period offers a critical opportunity for manufacturers, providers, and industry groups to submit data-driven feedback, whether challenging assumptions in the proposed rule, advocating for clinical distinctions within reimbursement groups, or requesting safeguards for high-value or innovative products.

In parallel, providers and manufacturers should begin modeling the potential financial impact of the proposed $\$125/cm^2$ unified rate. Even a modest shift in reimbursement methodology can significantly affect supply chain decisions, clinical practice patterns, and long-term pricing strategies. It will be important to consider how these changes may alter margins, particularly in physician office settings or for higher-cost biologics.

Now is also the time to review relevant contracts and commercial agreements, especially those with pricing floors, product-specific reimbursement terms, or change-in-law clauses. If finalized, this rule may trigger the need to renegotiate agreements with payors, suppliers, or distributors to reflect the new payment framework.

Finally, clients should engage legal and compliance teams to ensure readiness for implementation. Manufacturers should verify that product classifications, FDA regulatory pathways, and ASP reporting processes are up to date and fully compliant. Providers, in turn, should assess their documentation practices to ensure that claims continue to meet Medicare's standards for medical necessity, particularly when using advanced or higher-cost products.

The scope and scale of CMS's proposal represent a substantial policy departure with the potential to reshape clinical behavior, reimbursement policy, and innovation incentives. Strategic planning, combined with coordinated public comment, will be essential for stakeholders seeking to protect product value, ensure patient access, and manage regulatory risk under this evolving framework.

As CMS's regulatory priorities continue to evolve around reimbursement structures and fraud and abuse enforcement, Benesch is here to assist your organization in evaluating potential FCA exposure and implementing proactive compliance strategies. If you have questions about how this proposed rule may affect your organization once finalized, or if you would like support drafting formal comments to CMS, the Healthcare+ Practice Group at Benesch is here to help.

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References

1. Centers for Medicare & Medicaid Services, Medicare and Medicaid Programs; CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program, 90 Fed. Reg. 32352, 32512-522 (July 16, 2025), https://public-inspection.federalregister.gov/2025-13271.pdf.

2. Centers for Medicare & Medicaid Services, CMS Proposes Physician Payment Rule to Significantly Cut Spending Waste, Enhance Quality Measures, and Promote Innovation, CMS.gov (July 10, 2025), https://www.cms.gov/newsroom/press-releases/cms-proposes-physician-payment-rule-significantly-cut-

3. Centers for Medicare & Medicaid Services, CY 2026 Medicare Physician Fee Schedule (PFS) Proposed Rule - Skin Substitute Packaging Updates, CMS.gov (July 14, 2025), https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2026-medicare-physician-fee-schedule-p

4. Centers for Medicare & Medicaid Services, Calendar Year (CY) 2026 Hospital Outpatient Prospective Payment System (OPPS) Proposed Rule Fact Sheet, CMS.gov (July 15, 2025), https://www.cms.gov/newsroom/fact-sheets/calendar-year-2026-hospital-outpatient-prospective-payme

[1] CMS also proposes codifying the definition of “biological” under the Public Health Service Act.