

Publications

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CMS Finalizes Sweeping Reforms to Skin Substitute Payments Amid Rising Costs and Enforcement Activity

Key Takeaways:

- **Major Financial and Operational Impact:** On Nov. 5, 2025, CMS finalized a rule that fundamentally changes Medicare payment methodology for a broad range of skin substitute products used for wound care. Beginning in January 2026, most skin substitute products will shift from average sales price (ASP)-based payments to a flat, standardized rate. For 2026, that rate is \$127.28/cm² — likely reflecting a major payment cut for most products.
- **Heightened Enforcement:** With significant increases in spending over the past several years, wound care and skin substitutes have been in the spotlight for regulators. Despite the change in payment methodology, enforcement activity is likely to continue, with a focus on medical necessity of treatments and pricing.

Starting Jan. 1, 2026, Medicare will overhaul how it pays for most skin substitute products, moving from ASP-based reimbursement to a standardized flat rate of \$127.28/cm². The change, finalized Nov. 5, 2026, comes as regulators sound the alarm over skyrocketing costs, suspected profiteering and a sharp rise in enforcement. The new model is likely to create financial strain for providers and manufacturers alike, even as federal scrutiny shows no signs of slowing.

Background

In recent years, skin substitutes have become a growing area of government focus. On Nov. 5, 2025, Centers for Medicare and Medicaid Services (CMS) published a final rule implementing sweeping changes to the Medicare Part B payment methodology for skin substitutes— marking the most significant shift in this product category in over a decade. The new rule takes effect on Jan. 1, 2026.

CMS cited “dramatic” increases in spending and launch prices for skin substitutes as a motivation for the change, attributing it in part to industry “profiteering” and other potentially abusive practices. According to the final rule, “Part B spending for these products rose from approximately \$250 million in 2019 to over \$10 billion in 2024, a nearly 40-fold increase, while the number of patients receiving these products only doubled.”

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The HHS Office of Inspector General (OIG) has also flagged this trend, publishing two reports: one in 2023 that identified inconsistent reporting of pricing data by manufacturers and a second in September 2025, warning of the risk of fraud and abuse associated with the Medicare payment methodology for skin substitutes. In particular, OIG warned that the ASP-based methodology could yield a substantial “spread” for physicians — because Medicare often pays providers significantly more than the purchase price for the products.

The Department of Justice (DOJ) has also ramped up enforcement. Recent actions in the wound care space focused on orders of medically unnecessary skin substitutes and kickbacks in violation of the Federal Anti-Kickback Statute (AKS). For example, in 2024, an Arizona couple pleaded guilty to orchestrating more than \$1.2 billion of false and fraudulent claims related to unnecessary wound grafts. According to court filings, the defendants instructed and financially incentivized sales representatives to order wound grafts only in larger sizes to maximize reimbursement, regardless of clinical need. In exchange for these orders, the defendants allegedly received over \$279 million in illegal kickbacks from the product distributor and paid sales representatives tens of millions in unlawful commissions.

More recently, on June 30, 2025, the DOJ announced the 2025 National Health Care Fraud Takedown, a nationwide operation that included criminal charges against seven individuals in connection with \$1.1 billion in allegedly fraudulent Medicare claims for skin substitutes. The cases again center on medically unnecessary skin substitutes and kickback schemes. Notably, some of the individuals charged are health care professionals accused of prescribing skin substitutes in exchange for kickbacks — signaling that physicians and other health care professionals may be targets of continued enforcement in this area.

What’s Changing

Under the existing model, skin substitutes are paid under Medicare Part B as biologics, using the average sales price ASP + 6% methodology, with each product separately coded and priced. When the final rule goes into effect in January, Medicare will pay for skin substitutes based on a product’s regulatory status.

Biological products licensed under Section 351 of the Public Health Service Act (PHS Act) will continue to be paid as biologics under the ASP methodology.

Most other skin substitutes will be reimbursed as “incident to” supplies under the physician fee schedule and subject to a flat payment rate. This change applies to skin substitutes in three regulatory categories: (1) devices subject to premarket approval (PMA); (2) devices subject to 510(k) clearance; and (3) human cells, tissues and cellular and tissue-based products (HCT/Ps) regulated under Section 361 of the PHS Act. For 2026, all three product categories will be paid under Medicare Part B at a rate of \$127.28/cm². In future years, CMS intends to set different payment rates for each bucket based on pricing data it collects from manufacturers and hospitals.

For most products, CMS is retaining the current HCPCS codes for these products and applying the new payment rate. For skin substitute products not in sheet form (e.g., gels, powders, liquids, injectables, 3D-printed constructs, etc.), CMS is retaining the current coding and directing MACs to determine appropriate payment.

This new rule implements a consistent approach across the physician office and hospital outpatient setting, although CMS signaled possible future changes.¹

Implications for Stakeholders

The shift to a flat-rate payment model carries broad implications for physicians, clinics and manufacturers. Most immediately, the new flat rate may not fully cover acquisition and application costs for physicians and other wound care providers — especially for higher priced or complex products — and it may not adequately cover practice overhead expenses. Many providers will need to tighten inventory management to minimize losses from expired or unused products. Rural and lower volume clinics, in particular, may find it difficult to continue offering advanced wound care treatments, potentially limiting patient access.

On the manufacturing side, the new model will require companies to revisit pricing strategies in light of the new payment methodology. At the same time, continued regulatory scrutiny raises the stakes for everyone in the supply chain. With CMS, OIG and DOJ both focused on this space, manufacturers, distributors and health care providers are all potentially targets of enforcement.

For questions about how these CMS changes may affect your organization, please contact your Polsinelli attorney or a member of our Health Care team.

[1] “Depending on the outcomes of this final policy, we may consider packaging skin substitute products with the related application procedures in both the hospital outpatient setting and non-facility setting in future rulemaking.”