CLIENT ALERTS & INSIGHTS

HHS OIG Flags Explosive Part B Spending on Skin Substitutes Signaling Heightened Fraud, Waste, and Abuse Risk and Imminent Payment Reform

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On September 5, 2025, the U.S. Department of Health and Human Services (HHS) Office of Inspector General (OIG) Office of Evaluation and Inspections (OEI) released a Data Snapshot (OEI-BL-24-00420) finding that Medicare Part B spending on skin substitutes in non-institutional settings exceeded $10 billion in 2024, with sharp quarter-over-quarter growth in both utilization and price. The report highlights billing patterns consistent with fraud and abuse risk - such as new Nation Provider Identifiers (NPIs) billing almost exclusively for skin substitutes, "stacking" claims to bypass $99,999.99 payment ceilings and frequent first-visit applications without evidence of conservative care.

Skin substitutes, used in the treatment of chronic wounds such as diabetic foot ulcers and venous leg ulcers, have long been controversial because of high unit costs, their historical classification as "drugs/biologics" under Medicare Part B and allegations of variable evidence of effectiveness.

HHS OIG's analysis highlighted several billing and utilization patterns consistent with fraud, waste and abuse risk, including: (1) large spikes in units per patient and overall enrollee counts, with a disproportionate growth in home-based settings; (2) a wide gap between Medicare Part B and Medicare Advantage (MA) spending, suggesting weaker controls in Part B; and (3) provider switching toward higher-priced products, sometimes tied to payment lags or pricing fluctuations.

OIG's findings follow the Centers for Medicare & Medicaid Services' (CMS) proposal in the Calendar Year (CY) 2026 Physician Fee Schedule (PFS) to reclassify skin substitutes as incident-to supplies rather than drugs/biologics, a policy projected to cut Part B spending by nearly $9.4 billion in 2026. Reclassification, they both argue, would eliminate current "spread" opportunities between acquisition cost and reimbursement, establish group-based rates and align coverage more directly with medical necessity documentation. Together, these developments point to a period of heightened oversight, expanded audit activity and fundamental change in payment policy for providers, suppliers and manufacturers.

Key Findings and Takeaways

- **Heightened scrutiny of utilization and billing practices.** OIG flagged disproportionate growth in home-setting claims, high units-per-patient and product switching to higher-priced substitutes. These patterns are now priority targets for audits, pre-payment review and potential enforcement.

- **Anticipated payment reform.** CMS's CY 2026 proposal would stop treating most skin substitutes as "drugs/biologics," reclassifying them as incident-to supplies and establishing group-based payment rates, projected to cut Part B spending by approximately $9.4 billion in 2026. OIG explicitly referenced this proposal, signaling alignment with CMS's cost-control strategy.
- **Increased fraud and abuse risk tied to systemic incentives.** OIG cited new providers billing skin substitutes almost exclusively, manipulation of claims to bypass dollar ceilings and first-visit applications without documented conservative therapy. It also highlighted wide spreads between Wholesale Acquisition Cost (WAC) and Average Sales Price (ASP), noting that these differentials may encourage overuse, upcoding or selection of higher-cost products.
- **Implications for manufacturers.** OIG noted shifts toward higher-priced products, raising concerns about pricing strategies, ASP reporting and marketing practices that may steer providers. Manufacturers should expect closer scrutiny of rebate programs, distributor channels and product-switching trends.

Why It Matters

This is the clearest signal yet that skin substitutes are moving into a high-scrutiny zone, with both OIG and CMS telegraphing increased claims review, pre- and post-payment audits and structural payment reforms that will compress margins and reduce "spread" opportunities. Providers most exposed include high-volume office-based wound programs, podiatry/dermatology/plastic surgery practices and home/place-of-service suppliers. Manufacturers of newer, higher-priced products with rapid uptake are also under scrutiny, particularly in home-care channels.

While not entirely surprising given prior audit activity, the scale of spending is staggering. The WAC vs. ASP finding is especially important, not because OIG documented actual fraud, but because the report frames the structural incentive itself as a risk factor. That framing suggests regulators and contractors may treat these pricing differentials as red flags warranting audit or enforcement, even absent proof of misconduct. Coupled with CMS's proposal to reclassify skin substitutes as supplies (eliminating spread opportunities), it is clear that financial incentives are the central focus of these upcoming reforms.

Recommended Next Steps

Providers and suppliers should take immediate steps to shore up their compliance infrastructure. A priority action is to conduct a retrospective "hot-spot" audit covering the last six to eight quarters. This review should focus on identifying outliers in units per patient, first-visit application rates, use without documented conservative therapy, product mix skewed toward higher-priced items and any claim "stacking" designed to circumvent claim limits.

Equally important is tightening medical necessity and coverage documentation. Records should clearly reflect diagnoses, wound size and area, conservative care attempted and failed, medical necessity rationales, photographs or wound measurements and lot numbers with units per visit. This level of documentation will be essential to withstand pre-authorization requests and post-payment audits.

Providers should also verify acquisition cost versus payment. Accurate records of purchase prices, rebates and chargebacks should be maintained, and claims should reflect the correct Healthcare Common Procedure Coding System (HCPCS) code, product size and units furnished. Place-of-service and home-based claims should receive special scrutiny, as OIG flagged home-setting utilization as disproportionately high and therefore a likely audit target.

Onboarding and monitoring of new providers should also be strengthened. Organizations should consider additional review for NPIs that are less than twelve months old and demonstrate high concentrations of skin-substitute billing. At the same time, practices should prepare standardized evidence packets including coverage policies, medical necessity checklists and wound progression notes to facilitate pre-authorization submissions and respond efficiently to post-payment reviews.

Manufacturers and distributors should reinforce compliance programs around pricing and ASP reporting. Internal systems should confirm ASP submission accuracy, rebate transparency and adherence to compliance education to mitigate allegations of steering toward higher-spread products. Monitoring of distributor and reseller channels is critical to identify outlier utilization patterns, first-visit applications and use for non-approved indications. Manufacturers should also anticipate the adoption of MA-style tools - such as prior authorization, step therapy and bundled rates into Medicare Part B payment systems - and adjust contracting and product strategies accordingly.

What to Watch Next

The next six to twelve months will be pivotal. CMS is expected to finalize CY 2026 payment policies in the PFS and Outpatient Prospective Payment System (OPPS) final rules by early November 2025, which will determine how skin substitutes are classified and reimbursed beginning January 1, 2026.

In parallel, CMS has announced a six-year Medicare Part B model to pilot prior authorization, including artificial intelligence-enabled review and machine learning, along with human clinical review, for high-risk services such as skin substitutes. Titled the Wasteful and Inappropriate Service Reduction (WISeR) Model, the initial six-state rollout will take place in Arizona, New Jersey, Ohio, Oklahoma, Texas and Washington, with implementation slated for January 2026. Providers in the selected states will need to prepare early for heightened administrative requirements.

On the enforcement side, Medicare Administrative Contractors (MACs) and Unified Program Integrity Contractors (UPICs) have already begun increasing probe-and-educate activities, targeted medical reviews and supplier edits, particularly in geographies with high concentrations of skin substitute spending. Providers and suppliers should expect audit requests and record reviews to continue through late 2025 and intensify ahead of the 2026 payment transition.

Conclusion

OIG's latest report makes clear that skin substitutes are now in the compliance spotlight. With CMS already advancing sweeping 2026 reforms, providers and manufacturers should consider reviewing their documentation, evaluating outlier utilization (especially home-setting and high units per patient) and strengthening compliance programs around ASP reporting and contracting. Early action will mitigate audit risk and position organizations for any expected payment and oversight shifts.