

Skin Substitute Fraud: The Billion-Dollar Bandage Problem and the Whistleblowers Who Can Stop It

In 2019, Medicare Part B spent about \$256 million on skin substitutes. By 2024, that figure had passed \$10 billion. By 2025, it exceeded \$14 billion. Over that period the number of patients receiving these products roughly doubled. Yet the spending grew more than fortyfold.

That gap between patients and dollars is not a medical story. It is a fraud story, and it is now one of the most active areas of False Claims Act enforcement in the country. The Department of Justice, HHS-OIG, and state Medicaid Fraud Control Units are pursuing skin substitute cases criminally and civilly, and the largest recoveries have come from cases that started with an insider who knew what was happening and decided to speak up.

What are skin substitutes, and why did the system invite fraud?

Skin substitutes, also called cellular and tissue-based products or CTPs, are grafts applied to chronic, non-healing wounds such as diabetic foot ulcers and venous leg ulcers. They are made from human amniotic or placental tissue, animal tissue, or synthetic materials. Many reach the market as Section 361 human tissue products with no premarket FDA review of whether they actually work.

Until the start of 2026, Medicare paid for these products per square centimeter at the manufacturer's reported average sales price plus six percent. New products with no sales history were priced from the manufacturer's own invoices or wholesale acquisition cost. In practice, that meant manufacturers set their own Medicare reimbursement rate. A manufacturer could report a high price to Medicare, then sell the graft to providers at a steep discount. The provider billed Medicare at the high price, paid the manufacturer the low price, and kept the difference. That difference, known as the "spread," is what manufacturers actually sold: not a better graft, but a bigger profit on every square centimeter applied.

CMS finally reclassified most of these products as incident-to supplies and imposed a flat rate of roughly \$127 per square centimeter effective January 1, 2026. But the False Claims Act has a long statute of limitations, and the fraud-filled time period is precisely what the government is now investigating.

The dollars at issue

The numbers in these cases are staggering, even by health care fraud standards.

- **Medicare spending on skin substitutes:** Medicare Part B paid more than \$10 billion for skin substitute products in 2024 and more than \$14 billion in 2025, a roughly 7,100 percent increase over what it paid for the same category in 2019. In 2024, Medicare spent more on skin substitutes than on ambulance rides, anesthesia, or CT scans.
- **Apex Medical (D. Ariz.):** The owners of a wound graft company were sentenced in connection with a scheme the government valued at \$1.2 billion in fraudulent claims and agreed to pay \$309 million to resolve related civil liability. The scheme relied on untrained sales representatives who "found" elderly patients, many in hospice, and applied oversized grafts to wounds that did not need them.
- **United States v. Yukee (S.D. Tex.):** A June 2026 indictment alleges more than \$875 million in Medicare claims for amniotic allografts over roughly two and a half years, of which Medicare paid more than \$293 million, and nearly \$16 million in kickbacks from a single distributor. The indictment describes some of the proceeds: an \$865,000 necklace, a \$594,000 Ferrari, a beach resort in the Philippines. (These are allegations, and the defendant is presumed innocent, but they illustrate the scale.)
- **Vohra Wound Physicians (S.D. Fla.):** The government's 2025 complaint targets one of the largest wound care physician groups in the country over allegedly medically unnecessary surgical debridements driven by production quotas.

For a qui tam relator, these figures matter. Under the False Claims Act, a whistleblower whose case leads to a recovery receives between 15% and 30% of what the government collects. See 31 U.S.C. § 3730(d). In a case measured in millions or hundreds of millions of dollars, that share can be life-changing.

How the schemes work

The fraud in this space tends to follow a handful of recognizable patterns.

- **Marketing the spread.** A manufacturer or distributor pitches a provider not on clinical results but on profit: buy the graft at a discount, bill Medicare at the undiscounted invoice price, and keep the difference. Often the "discount" is a rebate that never appears on the invoice, and the provider does not pay the manufacturer until after Medicare pays the provider. HHS-OIG warned about this practice more than two decades ago. See 68 Fed. Reg. 23731, 23736–37 (May 5, 2003).

- Cash, free product, marketing credits, travel, or payments to sales representatives, brokers, and resellers in exchange for using a particular product. A claim tainted by a kickback is a false claim. See 42 U.S.C. § 1320a-7b(g).
- **Medically unnecessary grafts.** Applying skin substitutes without the conservative care that Medicare coverage rules require first, applying them to wounds that are healing on their own, or applying them to patients in hospice who are not candidates for wound healing at all.
- **Oversized and multiple grafts.** Billing for a graft far larger than the wound, billing full units when a single graft was split among several patients, or billing for a more expensive product than the one actually used.
- **Debridement upcoding.** Billing a surgical excisional debridement when only a selective, non-surgical debridement was performed, often using preprogrammed chart text, and billing for services in settings where Medicare does not pay for them.
- **Patient recruitment.** Using untrained salespeople to canvass nursing homes, assisted living facilities, and hospices for any elderly patient with any wound.

Who sees this fraud

Schemes like these do not run themselves. They depend on people who see the invoices, the rebate agreements, the chart notes, and the sales pitches. The people best positioned to bring a skin substitute case include:

- Sales representatives and distributors who were told to sell the spread rather than the science
- Billing and office staff who noticed that the practice never paid the manufacturer until Medicare paid first, or that private-pay patients never received the product
- Nurses, nurse practitioners, and physicians pressured to apply grafts on a schedule rather than on clinical need, or to hit debridement quotas
- Compliance personnel and coders who flagged oversized grafts, split kits, or boilerplate wound documentation
- Employees of hospices, nursing homes, and assisted living facilities who watched outside wound care vendors canvass their residents

The False Claims Act was written for brave whistleblowers. A *qui tam* complaint is filed under seal, so the defendant does not learn of it while the government investigates. The relator is entitled to a share of any recovery. See 31 U.S.C. § 3730(d). And the statute prohibits an employer from retaliating against an employee for lawful efforts to stop a violation, with remedies that include reinstatement and double back pay. See 31 U.S.C. § 3730(h).

Timing matters. The FCA's first-to-file rule bars later-filed complaints based on the same facts. Because the manufacturers and distributors in this space operate nationally,

multiple potential relators often hold overlapping information, and the one who files first is the one who recovers.

What comes next

This post is the first in a series. In the coming weeks we will take a closer look at specific pieces of this landscape: how "marketing the spread" works in practice and what documents prove it; the Medicare coverage rules for skin substitutes and what a medically unnecessary graft actually looks like in a chart; the major criminal and civil cases to date; and the first-to-file and public disclosure issues that shape whether a relator's case can proceed.

If you have seen conduct like what is described here, we may be able to help you. Pollock Cohen represents whistleblowers in False Claims Act matters nationwide, and consultations are confidential and without charge. You can reach us at [\(212\) 337-5361](tel:2123375361).

This post is for general informational purposes and does not constitute legal advice. Allegations in indictments and complaints are allegations only, and defendants are presumed innocent unless and until proven guilty.