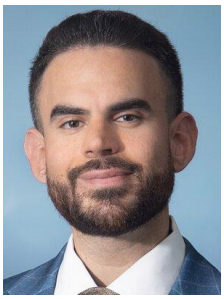
Adapting To Enforcement Focus On Wound Care Fraud

By **David Tarras and Jay McCormack** (October 29, 2025)



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The U.S. Department of Justice's national healthcare fraud takedown this year was the largest in history, charging 324 defendants across 50 federal districts in schemes totaling $14.6 billion in intended loss.[1]

Beneath the headlines, one trend stood out: a striking cluster of cases involving skin substitutes and amniotic wound care grafts, a niche product class that has quietly grown into a multibillion-dollar reimbursement category.

The DOJ, U.S. Department of Health and Human Services' Office of Inspector General, and Centers for Medicare and Medicaid Services have each signaled that this sector will remain a top enforcement priority for the foreseeable future.

Skin substitutes, consisting of cellular or tissue-based products used to cover and heal chronic wounds, are reimbursed under Medicare Part B as if they were biologic drugs. The OIG has cautioned that this framework "creates incentives to bill for more and more units of skin substitutes and to choose products with the greatest spreads."[2]

Between 2022 and 2024, Medicare Part B spending for noninstitutional skin substitute claims increased from $400 million per quarter to nearly $3 billion, a 640% increase. Home care claims now account for more than half of all spending for skin substitutes in the noninstitutional setting, with per-patient costs roughly four times higher than in an office-based setting.

In an Oct. 16 episode of "Off the Chart: A Business of Medicine Podcast," OIG Regional Inspector General David Tawes offered rare public insight into the government's growing alarm over this escalation. Tawes explained that Medicare expenditures for skin substitutes "have risen seven-fold in just two years," surpassing $10 billion in 2024 and projected to exceed $15 billion in 2025.

He noted that billing often occurs per square centimeter, with the average Medicare enrollee billed for approximately 80 square centimeters of graft material each quarter, totaling about $120,000 per patient.[3]

Tawes' remarks followed the Sept. 3 release of the OIG's report, "Medicare Part B Payment Trends for Skin Substitutes Raise Major Concerns About Fraud, Waste, and Abuse," which provided the data foundation for intensified enforcement.

Key Takeaways From the September Report

The September OIG report marked a turning point in federal scrutiny of the wound care sector. Regulators described "explosive growth" in noninstitutional skin substitute billing, particularly in home care settings. This surge was not simply the result of more patients receiving treatment. The average cost per beneficiary had tripled, indicating a pattern of aggressive and potentially inflated utilization.

OIG analysts found that newly enrolled Medicare providers were billing almost exclusively for skin substitutes, that some practitioners submitted excessive quantities of grafts, and that a small number of providers accounted for a disproportionate share of total claims.

The report also emphasized alarming trends in home care billing, where costs were four times higher than comparable office-based procedures. The OIG attributed this to the use of higher-priced products and minimal oversight in home settings, which now represent more than half of all Part B spending in this category despite only accounting for 28% of all Medicare enrollees receiving skin substitutes in the third quarter of 2024.

The agency further noted that many newly marketed products were reimbursed at inflated rates due to delays in average sales price reporting, allowing manufacturers and distributors to profit from temporary pricing gaps.

The OIG identified several other common red flags in skin substitute billing data, such as submitting multiple same-day claims designed to bypass Medicare's $99,999 per-claim cap, and billing by out-of-scope providers with specialties such as psychiatrists or neurologists.

The report warned that the current system "enables bad actors to quickly get paid millions of dollars with minimal patient volume." In one case, a manufacturer reported selling only a few thousand units of a product while providers billed for over 200,000 units, a discrepancy suggesting either severe underreporting or phantom usage.

The OIG also highlighted disparities between traditional Medicare and Medicare Advantage, noting that Medicare Advantage enrollees receive fewer and less expensive grafts due to prior authorization controls and tighter utilization management. This finding reinforced the agency's view that fee-for-service Medicare remains more vulnerable to manipulation and fraud.

The report called for urgent reform, urging CMS and lawmakers to reconsider whether skin substitutes should continue to be treated as drugs or biologics and to explore payment methodologies that better reflect clinical value.

In its conclusion, the OIG warned that the unchecked expansion of skin substitute billing has created fertile ground for abuse and that enforcement, already underway through DOJ-led prosecutions, will intensify absent structural reform. The report's final message was direct: "Action is urgently needed to rein in the massive increases in Medicare Part B spending for skin substitutes."

DOJ's Case Study in Scale

The government's prototype prosecution emerged from Arizona. In January, the DOJ announced that Alexandra Gehrke and Jeffrey King had pleaded guilty to orchestrating "over $1.2 billion of false and fraudulent claims … for expensive, medically unnecessary wound grafts … applied to elderly and terminally ill patients."[4]

The pair operated Apex Medical LLC and Viking Medical Consultants LLC, allegedly hiring untrained sales representatives to locate hospice patients and order amniotic grafts in the largest possible sizes.

They received $279 million in kickbacks from a distributor, directed nurse practitioners to apply grafts "even when medically unreasonable and unnecessary," and submitted more

than $1.2 billion in false claims to Medicare, TRICARE, CHAMPVA and commercial insurers from approximately November 2022 through May 2024.

Federal programs alone paid $960 million, including more than $600 million from Medicare.

U.S. District Judge Roslyn Silver of the U.S. District Court for the District of Arizona sentenced Gehrke and King to 15.5 and 14 years in prison, calling them criminally greedy, and they were each ordered to pay restitution exceeding $600 million.

The 2025 National Takedown

On June 30, as part of the National Healthcare Fraud Takedown, the DOJ announced charges against additional defendants in related skin substitute schemes. The recent indictments illustrate how the DOJ's skin substitute enforcement actions have drawn in an unusually broad range of practitioners, many of whom operated at the outer limits of wound care practice and Medicare billing policy.[5]

Paulino Gonzalez reportedly trained as a physician in Mexico but practiced as a wound care nurse in Las Vegas. He was charged with conspiracy to commit healthcare fraud and with paying and receiving illegal kickbacks in connection with the use of amniotic grafts.

According to the information, Gonzalez received approximately $7.4 million in kickbacks from an allograft distributor in exchange for ordering and applying medically unnecessary amniotic grafts. Between October 2021 and April 2024, the wound care company he worked with billed Medicare for more than $94 million and received more than $54 million in payments.

Mary Huntly, a nurse practitioner, also of Las Vegas, was charged with the same offenses for applying medically unnecessary grafts to Medicare beneficiaries that were procured through kickbacks and bribes. Between September 2022 and April 2024, her company billed approximately $14.3 million, of which more than $9.1 million was paid by Medicare.

Jorge Kinds, a nurse practitioner also connected to the Apex scheme, was charged for applying amniotic grafts without coordination with treating physicians, to superficial wounds that required only conservative care, and in product sizes excessively larger than the actual wound.[6]

Gina Palacios, a nurse practitioner in Phoenix, was charged with conspiracy to commit healthcare fraud for billing $59 million in amniotic allografts that were procured through kickbacks and bribes. Ira Denny, a nurse practitioner out of Arizona, was charged with conspiracy to commit healthcare fraud after allegedly billing for $209 million in medically unnecessary amniotic grafts.

The enforcement effort also extended beyond clinicians. Two nonmedical individuals, Tyler Kontos and Joel Kupetz, were charged with conspiracy to commit healthcare fraud, healthcare fraud and conspiracy to defraud the U.S. in connection with a $1 billion amniotic wound allograft fraud scheme.

Kontos and Kupetz were also charged with transactional money laundering, and Kupetz was charged with receiving healthcare kickbacks. These charges all stemmed from the Apex Medical scheme, which allegedly generated over $1 billion in fraudulent claims.

According to another indictment, Marlen Veliz Rios, the owner of Loves Community Health

Mental Health Inc., was charged with healthcare fraud and conspiracy to commit money laundering. Prosecutors allege that Rios orchestrated a scheme to submit roughly $15.3 million in false and fraudulent Medicare claims for wound care and skin graft products that were either medically unnecessary or never provided.[7]

Collectively, these prosecutions reveal a consistent pattern: marketing and distribution networks identifying lucrative products, recruiting licensed but lightly supervised wound care practitioners, and exploiting Medicare's per-square-centimeter reimbursement structure.

Whether through direct kickbacks, volume-based compensation or disguised referral payments, the schemes converted legitimate regenerative medicine products into vehicles for massive fraud.

Regulators at the DOJ, OIG and CMS have since indicated that this vendor-directed model of wound care will remain a central focus of federal enforcement within the rapidly expanding skin substitute sector.

CMS Responds: Reclassifying Skin Substitutes and Cutting the Spread

The DOJ's Criminal Division has described healthcare fraud involving skin substitutes in both moral and financial terms. In speaking about the skin substitute schemes charged as part of the National Healthcare Fraud Takedown, Assistant Attorney General Matthew Galeotti, who oversees the Criminal Division, stated that many defendants "targeted elderly Americans, performing medically unnecessary skin grafts on dying patients, a callous and disturbing abuse of trust."[8]

Facing mounting data and enforcement pressure, CMS issued a proposed rule in July under the calendar year 2026 physician fee schedule.[9] The rule directly addressed the ballooning costs of skin substitutes and proposed a fundamental change to how they are reimbursed. CMS Administrator Mehmet Oz stated, "We are making it easier for seniors to access preventive services and cracking down on abuse that drives up costs."

CMS noted that Medicare spending on skin substitutes "rose from $256 million in 2019 to over $10 billion in 2024," attributing the increase to "abusive pricing practices, including the use of products with limited evidence of clinical value."

To curb this growth, CMS proposed reclassifying skin substitutes as incident-to supplies instead of biologics, a move projected to reduce Medicare spending on these products by approximately 90% without compromising access to legitimate care.

The DOJ and CMS have also highlighted the growing use of artificial intelligence and predictive analytics to detect and prevent similar schemes. The Centers for Medicare and Medicaid Services announced the Wasteful and Inappropriate Service Reduction model, a six-year initiative designed to combat fraud, waste and abuse in original medicare.[10]

The program will leverage artificial intelligence and clinician review to streamline prior authorization for select high-risk services, including skin and tissue substitutes, that have been repeatedly flagged for questionable billing and excessive utilization.

Oz emphasized that the WISeR model "helps bring Medicare into the 21st century" by protecting beneficiaries from unnecessary, costly care while preserving access for legitimate treatments.

Practical Guidance for Lawyers

Attorneys advising clients in the wound care space should focus on several recurring danger zones that align with OIG findings and DOJ charging theories. Providers, distributors, manufacturers and sales representatives involved in the skin substitute industry should carefully evaluate their business relationships and contracts to ensure that they do not create actual or perceived violations of the federal or state Anti-Kickback Statute.

All parties should maintain robust compliance programs that emphasize appropriate product use and require documentation of conservative treatments before advancing skin substitutes. Organizations are encouraged to promptly investigate any whistleblower or employee complaints, and document all findings.

Providers, particularly those operating in noninstitutional or home care settings, should also use internal data analytics to monitor billing patterns and detect anomalies before they trigger regulatory review.

Several billing practices have been identified by the OIG as red flags for potential fraud, including claims submitted for skin substitute procedures during a patient's first visit without prior conservative treatment, newly enrolled Medicare providers billing almost exclusively for skin substitutes, and high volumes of claims submitted on a single day to circumvent billing system limits.

Other warning signs include billing for excessive quantities of grafts or for nonapproved conditions such as blisters or scrapes, and out-of-scope billing, such as when other specialists, including psychiatrists, submit claims for skin substitute applications.

Another involves the lack of medical necessity or oversized applications, with DOJ repeatedly emphasizing grafts "larger than the wound" and procedures performed on patients "who had already healed."

The use of new or short-lived products to exploit price lags can similarly evidence selling the spread, a pattern the OIG associates with fraud vulnerability.

Tawes explained that, unlike traditional drugs and products, OIG analysis detected that providers were switching from product to product nearly on a quarterly basis, using an example in which one product had $500 million in Medicare expenditures one quarter, and only $1 million the next.

Home care billing now draws perhaps the heaviest scrutiny, making it essential that providers confirm supervising physician relationships and extensively document prior conservative care. The improper use of national provider identifiers or delegated billing has also been flagged by the DOJ as indicative of coordinated fraud schemes, particularly where billing privileges are reassigned without oversight.

Attorneys should further caution clients about vendor relationships lacking fair market value justification, as CMS and OIG expect contemporaneous fair market value analyses and written contracts separating legitimate services from referral or volume-based incentives.

Looking Forward: Regulation Through Data

The current enforcement environment reflects a broader paradigm shift in healthcare oversight. The OIG has acknowledged that enforcement always lags behind data, but new

analytics capabilities now allow anomalies to surface within months rather than years.

Oz echoed this sentiment, stating, "Every dollar we prevent from going to fraudsters is a dollar that stays in the system to serve legitimate beneficiaries."

With CMS moving to reprice skin substitutes as supplies, the DOJ pursuing criminal prosecutions and the OIG publishing increasingly granular fraud indicators, the skin substitute sector has become the new frontier of healthcare fraud enforcement. What began as a niche reimbursement category has evolved into a national test case for the government's data-driven approach to fraud prevention.

For healthcare attorneys, the takeaway is clear. In the current environment, a wound care practice can easily become a compliance hazard if oversight lapses.

To be effective, counsel must consider traditional Anti-Kickback Statute and False Claims Act compliance, along with billing analytics, prior authorization standards and clinical documentation protocols.

As the DOJ, OIG and CMS continue their coordinated campaign, proactive compliance is no longer optional — it is survival.

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[1] DOJ Press Release, District of Nevada Participates in Record-Setting National Health Care Fraud Takedown (June 30, 2025).

[2] HHS-OIG Report, Medicare Part B Payment Trends for Skin Substitutes Raise Major Concerns About Fraud, Waste, and Abuse (Sept. 2025).

[3] Off the Chart: A Business of Medicine Podcast, Interview with HHS-OIG Regional Inspector General David Tawes (Oct. 16, 2025).

[4] DOJ Office of Public Affairs, Arizona Couple Pleads Guilty to $1.2 Billion Health Care Fraud (Jan. 31, 2025); see also Joe Duhownik, "'Criminally greedy' Medicare fraudster ordered to pay $615 million," Courthouse News Service, Oct. 7, 2025.

[5] DOJ Press Release, District of Nevada Participates in Record-Setting National Health Care Fraud Takedown (June 30, 2025).

[6] DOJ Press Release, District of Arizona Charges 7 Defendants as Part of National Health Care Fraud Takedown (June 30, 2025).

[7] DOJ Office of Public Affairs, Arizona Couple Sentenced for $1.2 Billion Health Care Fraud

(District of Arizona Case Summary, Feb. 2025).

[8] DOJ Criminal Division, Remarks by Matthew R. Galeotti, Head of the Criminal Division, National Health Care Fraud Takedown Press Conference (June 30, 2025).

[9] CMS Press Release, CMS Proposes Physician Payment Rule to Significantly Cut Spending Waste, Enhance Quality Measures, and Improve Chronic Disease Management for People with Medicare (July 14, 2025).

[10] Centers for Medicare & Medicaid Services, "CMS Launches New Model to Target Wasteful, Inappropriate Services in Original Medicare," Press Release (June 27, 2025).