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In the Enforcement Crosshairs: Skin Substitutes

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In general, a skin substitute is a material used to cover and promote healing of skin wounds by acting as a temporary or permanent replacement for damaged skin. These products encompass a diverse array of advanced wound-care materials, including allografts (tissue from another person), xenografts (tissue from animals), and other bioengineered materials. They "are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers." [1] Medicare Part B covers skin substitutes in non-institutional settings when reasonable and medically necessary. [2]

Amid the highly publicized federal crackdown on health care fraud, the use of skin substitutes has become a focal point of those efforts. These products sit at the intersection of clinical practice, reimbursement policy, and enforcement scrutiny. In the span of two years, Medicare Part B spending

on skin substitutes unquestionably has surged, drawing scrutiny from the Centers for Medicare & Medicaid Services (CMS), the Office of Inspector General (OIG) for the Department of Health and Human Services (HHS), and the Department of Justice (DOJ).

OIG Audit Reports

Before January 1, 2026, skin substitutes were classified as a "biologic" for Medicare reimbursement purposes, a classification that is, in part, responsible for the surge in spending on these products. [3] The primary Medicare reimbursement methodology for drugs and biologicals is the use of Average Sales Price (ASP), a volume-weighted average of manufacturers' U.S. sales to all purchasers, plus 6%. [4] Manufacturers are required to submit quarterly sales data, including discounts, through the ASP Data Collection System, enabling CMS to calculate ASP and corresponding payment amounts. [5] When ASP data is unavailable, Medicare may use either total invoice price or Wholesale Acquisition Cost (WAC)-based pricing as an alternative to ASP to calculate reimbursement. [6] In terms of billing, under ASP methodology, "each skin substitute product receives a unique billing code (typically, a Level II HCPCS code) and payment limit." [7] Historically, prices for skin substitutes could be as much as $2,000 per square centimeter. [8]

ASP reporting requirements generally did not apply to manufacturers of certain Medicare Part B biological products, including skin substitutes, until 2022, when changes in federal law required them to report ASP data to CMS beginning in the first quarter of 2022. [9]

In March 2023, OIG reported that many skin substitute manufacturers had not complied with the new ASP reporting requirement. [10] As a consequence, CMS could not calculate ASP-based payment amounts in the first quarter of 2023 for 30 of 68 skin substitute billing codes. [11] Those 30 codes accounted for nearly two-thirds of all Medicare Part B expenditures for skin substitutes. [12] CMS therefore lacked ASP data for the most expensive and most widely used skin substitute products. OIG further found that payments for codes with reported ASP data were 33% below published WACs. [13] The report warned that this disparity could incentivize providers to favor products without ASP-based payment amounts to "capture a much larger spread (i.e., the difference between what they pay for a product and the amount they are reimbursed by Medicare) when payment is set using WACs/invoices." [14]

It appears that OIG's warning was correct. On September 3, 2025, OIG reported substantial growth in Medicare Part B expenditures for skin substitutes furnished in non-institutional settings. [15] Spending increased 640% over two years, reaching more than $10 billion in 2024. [16] Quarterly expenditures rose from approximately $389 million in the third quarter of 2022 to $2.88 billion in the third quarter of 2024. [17] OIG attributed this increase to both higher utilization and rising prices: more beneficiaries received skin substitutes, and beneficiaries who received them underwent more procedures. [18] Over less than two years, spending per Medicare Part B beneficiary tripled. [19]

OIG found that home-based providers billed for more skin substitute procedures and used higher-cost products than office-based providers. [20] In the third quarter of 2024, skin substitutes furnished in the home cost approximately four times more than those furnished in institutional settings. [21] Home-based care accounted for more than half of Medicare Part B spending on skin substitutes. [22]

OIG noted a typical two-quarter lag between manufacturer ASP reporting, CMS verification, and payment-rate calculation. [23] During that roughly six-month period, reimbursements for skin substitutes were based on WAC or invoice prices, which are generally higher than ASP and created a larger "spread." [24] The data suggested this structure incentivized providers to switch, once ASP pricing applied, to newer skin substitute products still reimbursed at WAC or invoice prices to maximize payment. [25]

OIG further warned that skin substitutes remain "particularly vulnerable to questionable billing and fraud" [26] and identified the following patterns in claims data:

- Providers billed for skin substitute procedures at a beneficiary's first visit without trying conservative treatment first;
- New Medicare providers billed only for skin substitutes and not for other wound care services;
- Providers submitted high volumes of same-day claims to bypass Medicare billing controls;
- Providers billed for excessive quantities or for non-approved uses; and
- Non-wound care clinicians (e.g., psychiatrists) billed for skin substitute procedures. [27]

The report cautioned that the current payment framework permits "bad actors" to obtain millions of dollars with minimal patient volume. [28] OIG urged prompt action, including payment reform, to reduce non-institutional Part B spending on skin substitutes. [29]

CMS Policy Changes

On April 11, 2025, CMS announced that it was reviewing its coverage policies for skin substitutes. [30] CMS thereafter proposed new Local Coverage Determinations (LCDs) governing Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers, with an effective date of January 1, 2026. [31] Under the new proposal, 158 skin substitute products would have been non-covered, 154 would have remained subject to a 12-month status quo period under contractor discretion, and only 18 codes for products would have been covered. [32] This proposed LCD would have dramatically reduced the number of skin substitutes covered by Medicare. On December 24, 2025, CMS announced that all Medicare Administrative Contractors (MACs) would withdraw the proposed LCDs before they took effect. [33] Although CMS did not ultimately implement the proposal, the proposed changes nevertheless reflected CMS' broader effort to constrain skin substitute spending.

Effective January 1, 2026, CMS changed its payment methodology and now reimburses most skin substitute products as incident-to supplies under the Medicare Physician Fee Schedule rather than as biological products paid at ASP plus 6%. [34] For calendar year 2026, CMS is applying a single national payment rate of approximately $127.28 per square centimeter for skin substitutes and has indicated that it intends to differentiate rates by Food and Drug Administration regulatory category in subsequent years. [35] CMS projects that the transition from ASP-based reimbursement to incident-to supply payment will reduce Medicare spending on skin substitutes by nearly 90% and decrease gross fee-for-service program expenditures by an estimated $19.6 billion in 2026, without compromising patient access or quality of care. [36]

Also beginning January 1, 2026, CMS implemented the Wasteful and Inappropriate Service Reduction (WISeR) model, which incorporates artificial intelligence, machine learning, and human clinical review for selected services that according to CMS may have little to no clinical benefit and historically have higher rates of fraud, including skin substitutes. [37] The model runs for six years, through December 31, 2031, and operates in six states: New Jersey, Ohio, Oklahoma, Texas, Arizona, and Washington. [38] Providers may either seek prior authorization for selected items and services or elect to undergo post-service/pre-payment review. [39]

Recent Federal Enforcement

Federal enforcement activity directed at skin substitute providers has intensified alongside the rapid increase in expenditures. Since June 2024, DOJ has charged at least 24 individuals in cases involving more than $1.5 billion in alleged intended loss associated with skin substitute claims. These matters share several recurring characteristics:

- Heavy billing over short periods for a small patient population;
- Use of unqualified providers working outside their scope, or medically untrained sales representatives, to decide whether skin substitute applications were medically necessary and how often and how much to apply;
- Billing for skin substitutes for patients without qualifying wounds;
- Services tainted by illegal kickbacks from the distribution chain or by waivers of expensive co-pays;
- Billing for the largest available skin substitute to maximize reimbursement;
- Targeting patients outside the office, especially in hospice, nursing homes, and assisted living facilities; and
- Ignoring prior notices from Medicare contractors about aberrant billing trends.

The largest prosecution charged to date illustrates many of these recurring features: the Arizona case against Alexandra Gehrke and Jeffrey King, which DOJ described as the "first prosecution of its kind." [40] According to prosecutors, Gehrke and King owned and operated multiple wound graft companies in Arizona that employed medically untrained sales representatives to identify Medicare beneficiaries in nursing homes, hospice facilities, and other settings with elderly populations who had a "wound or wounds of any stage." [41] OIG Regional Inspector General David Tawes observed that neither Gehrke nor King was a medical professional: Gehrke had owned an art studio and worked in real estate, and King worked as a DJ and producer. [42]

According to DOJ, Gehrke directed sales representatives to order a single allograft size even when smaller, less expensive options were available and medically appropriate. [43] Licensed nurses then relied on those untrained representatives, failed to exercise independent clinical judgment, and applied allografts without a prior relationship with the patient or consultation with the patient's primary care provider. Many of the wounds did not qualify for treatment because they were infected, had healed, or were not responding to treatment. In return, sales representatives received illegal kickbacks that allegedly reached hundreds of thousands of dollars per month based on the quantity and size of allografts applied. The scheme resulted in the application of large grafts to small wounds, multiple grafts to a single wound, grafts to non-existent wounds, and grafts to terminally ill patients receiving

palliative care, some of whom died within days, or on the same day, of application. In all, prosecutors said the companies owned by Gehrke and King submitted more than $1.2 billion in false allograft claims in only 18 months and received more than $614 million in Medicare payments. [44]

Gehrke and King allegedly received more than $400 million in kickbacks from a wholesale graft distributor, while sales representatives received tens of millions of dollars derived from those payments. The indictment details that distributors paid some kickbacks directly into bank accounts associated with Gehrke and King, and disguised others as rebates issued through a Texas wholesale distributor. [45] To conceal those rebates, the conspirators allegedly used sham invoices listing the full price rather than the rebated price. [46]

Gehrke and King both pleaded guilty to conspiracy to commit health care fraud and wire fraud and received prison sentences of 15.5 and 14 years, respectively, and were each ordered to pay more than $600 million in restitution. [47] Gehrke and one of her companies also agreed to pay more than $279 million, and King agreed to pay $30 million, to resolve False Claims Act allegations that they caused the submission of false claims for medically unnecessary allografts and both received and paid illegal kickbacks. [48]

To date, DOJ has charged at least seven individuals in the scheme, including three nurse practitioners. The billing figures were substantial: DOJ alleges that companies owned by Gehrke and King submitted approximately $205 million in Medicare claims for allografts furnished by one nurse practitioner, Jorge Kinds, to roughly only 120 patients. [49] By way of example, Medicare received one claim for allograft services rendered by Kinds totaling $99,900. [50] In total, Medicare allegedly paid approximately $130 million on those claims associated with Kinds. [51]

DOJ's theory that the failure to disclose rebates may carry criminal liability under the Anti-Kickback Statute (AKS) remains largely untested and arises from the former ASP-based pricing structure for skin substitutes. As a general matter, a seller's rebate may fall within the AKS Discount Safe Harbor if several conditions are satisfied. [52] In some circumstances, those conditions require the buyer to disclose the rebate, including upon request by the HHS Secretary. [53] Furthermore, an arrangement's failure to satisfy a safe harbor under the AKS does not automatically render it illegal. As OIG has noted, "compliance with a safe harbor is voluntary; failure to satisfy a safe harbor does not mean that an arrangement is illegal." [54]

A recent prosecution in the Eastern District of California, although it did not charge a kickback conspiracy, illustrates how the failure to disclose a rebate can arise in the skin substitute context. Felipe Ruiz, a podiatrist and owner of West Coast Podiatry, Inc. (WCP), a podiatric clinic with multiple California locations, purchased skin grafts from sales representative Jose Gabriel Aguirre. [55] According to DOJ, Ruiz permitted Aguirre, who was not a licensed health care provider, to apply skin grafts to patients, and the two then submitted Medicare claims falsely representing that Ruiz had performed the services. [56]

In an effort to curtail reimbursements, several MACs, including Noridian Medicare, which processed the California claims in *Ruiz*, require providers billing common skin substitutes procedure codes to report total invoice price on electronic claims submitted to CMS. [57] Total invoice price is the net

amount the provider pays after discounts, rebates, refunds, or other adjustments and is commonly used by MACs to establish reimbursement rates for skin substitute products in the absence of ASP-based pricing. [58]

According to the complaint in *Ruiz*, WCP participated in several programs that paid rebates based on the volume of skin substitutes it purchased from distributors. [59] For example, if the practice purchased more than $20,000 in a month, it received a 40% rebate. [60] Invoices from one distributor invoked the discount safe harbor and stated that "THE CUSTOMER MUST DISCLOSE THE EXISTENCE OF THE REBATE... TO THE SECRETARY OF HHS OR A STATE AGENCY UPON REQUEST." [61] The investigation determined WCP concealed the total invoice price on certain claims and thereby overbilled Medicare by more than $890,000. For example, WCP billed Medicare $13,680 for one procedure even though records showed that the actual total invoice price for the graft, inclusive of rebates, was $6,840. Although the subsequent indictment did not allege kickback payments or receipts, the complaint in *Ruiz* and charging documents in other skin substitutes cases suggest that DOJ views undisclosed rebates, and the value of that benefit, as kickbacks that can trigger criminal liability.

Given the surge in payments and the corresponding increase in regulatory scrutiny, providers should expect continued federal enforcement emphasis on skin substitutes. In the sentencing memo in *Gehrke*, DOJ stated its awareness of "similar wound allograft schemes operating around the country, including ones across state lines, that have collectively siphoned an extraordinary amount of taxpayer dollars from Medicare and other federal health care programs." [62]

Administrative Enforcement

Audits, investigations, and recoupment actions involving wound care and skin substitutes have increased markedly, driven by DOJ, OIG, CMS, and widespread Unified Program Integrity Contractor (UPIC) overpayment notices targeting wound therapy and skin substitute claims. Multiple CMS contractors are actively engaged in this area. Providers are receiving UPIC Notices of Overpayment alleging aberrant billing patterns and seeking substantial recoupments. Denials based on medical necessity remain common even after providers submit extensive records at redetermination. Common audit focus areas include:

- Medical necessity and documentation focusing on a lack of prior conservative treatment, and failure to meet LCD criteria; [63]
- Billing and utilization aberrations citing excessive frequency and durations beyond the typical ten application limit per 12 weeks; [64]
- Denials related to the use of skin substitute products deemed "experimental" or "investigational;" [65] and
- Records requests for purchasing, invoices, and rebate documentation with a focus on possible kickbacks and the accuracy of claims.

Conclusion

Given the policy shifts and increased enforcement activity in response to skyrocketing costs associated with skin substitutes, stakeholders should take a rigorous, proactive approach to compliance. Now is the time to ensure documentation is accurate and complete, including documenting at least four weeks

of unsuccessful conservative care for chronic wounds, and linking each skin substitute application to the wound's specific characteristics demonstrating clinical decisions guided by medical necessity. It is imperative to stay current on LCD and regulatory changes and maintain the exact LCD and coding guidance in effect at the time of application. Review all discounts and rebates for AKS risks to confirm they meet safe harbor requirements. Apply extra scrutiny to claims for services performed outside the office, including verification of wound size, medical necessity, infection control, and coordination with treating physicians. Also consider how your data may appear to regulators, especially patterns suggesting excessive frequency or volume or a lack of prior conservative treatment.

It seems clear that the boom in skin substitutes enforcement is here to stay, and DOJ, OIG, CMS, and MACs will continue their efforts to curb spending on skin substitutes. A disciplined compliance strategy can help reduce risk and support defensible billing practices.

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