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From Biologics to Bandages to Subpoenas: Skin Substitutes Take Center Stage at AHLA

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In November 2025 we published *From Biologics to Bandages, Skin Substitutes Are No Longer the Biologics You Think They Are*, flagging an unmistakable shift at the Centers for Medicare & Medicaid Services (CMS) toward constraining a massive increase in government spending on skin substitutes (the biological-based wound coverings used for burns, trauma, and chronic conditions like diabetic ulcers, and referred to by the government in its enforcement actions as "amniotic wound allografts"). As we explained, the cost of skin substitutes to the Medicare program soared from roughly $250 million in 2019 to more than $10 billion by 2024. CMS's answer was to attack practitioners' purse strings: as of January 1, 2026, living-cell tissue that once commanded biologic-level reimbursement is now paid under the Physician Fee Schedule as an incident-to supply. Practically speaking, skin substitute reimbursement is now in the same bucket as ordinary office supplies like bandages. CMS projected that change would cut gross fee-for-service spending on skin substitutes by an estimated $19.6 billion in 2026. We predicted that CMS's growing scrutiny — paired with a June 2025 DOJ announcement of a national enforcement focus, False Claims Act suits, criminal prosecutions, and civil investigative demands — would soon translate into aggressive enforcement. On July 1, 2026, at the

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American Health Law Association (AHLA) Annual Meeting, senior administration officials made clear that prediction has materialized.

DOJ's "Pay and Chase" Posture

Speaking at the AHLA Annual Meeting, Brenna Jenny, Deputy Assistant Attorney General for the Commercial Litigation Branch of the Civil Division of the U.S. Department of Justice, announced that skin substitutes remain a major focus of the Department of Justice's (DOJ) "pay and chase" enforcement posture. According to Jenny, the government's objective is to identify and then to pursue the (alleged) kickbacks that the government believes fueled the rapid expansion of this industry: following the money from downstream billings back to the arrangements that drove referral and utilization patterns. The message to providers, manufacturers, and marketers alike could not have been more direct. If you are (or were) in the skin substitute business, you should expect government scrutiny.

The 2026 National Health Care Fraud Takedown

Jenny's remarks build on the momentum from the 2026 National Health Care Fraud Takedown the DOJ announced June 23, 2026, which charged 455 defendants in connection with more than $6.5 billion in alleged fraud and expressly called out fraudulent wound care schemes among the conduct targeted. In the wound care cases alone, the government filed charges against 11 defendants — including a company executive and eight medical professionals — across six districts in connection with billions of dollars in allegedly fraudulent claims for "amniotic wound allografts." The centerpiece was a nationwide kickback case in the District of Arizona. The defendant allegedly relabeled tissue-bank allografts at a 2,000% mark-up — charging up to $1,450 per square centimeter — and paid illegal kickbacks of roughly 40% of that amount. Other charged schemes include a $906 million allograft scheme in the Southern District of Texas and a $118 million scheme

in the Middle District of Florida, both detected by the Health Care Fraud Unit's Data Analytics Team. The Health Care Takedown Press Release highlighted that CMS separately realigned Medicare's reimbursement rate to $127 per square centimeter as of January 1, 2026. Read together with the comments made at the AHLA Annual Meeting, the DOJ's efforts on this front signal that skin substitutes are not a one-off enforcement priority but a sustained, coordinated area of focus.

CMS Payment Changes Are Already Bending the Curve

During the AHLA meeting, Kim Brandt, CMS Deputy Administrator and Chief Operating Officer, reinforced that enforcement is only part of the story, and emphasized that payment policy is doing significant work on its own. Brandt reported that following CMS's changes to skin-substitute payment rates, expenditures have dropped by roughly 99%. Perhaps most striking, Brandt noted that even *without* an enforcement action, approximately 60% of billers stopped billing for skin substitutes altogether pre-2026 after receiving nothing more than a notice from CMS identifying an uptick in their related billings. In other words, a single letter prompted a majority of billers to walk away — an implicit acknowledgment, the government will likely argue, of how fragile the underlying billing practices were.

Takeaways

The through-line from our earlier post to the July 1 announcements at AHLA is clear: skin substitutes sit squarely at the intersection of aggressive DOJ enforcement and rapidly tightening CMS reimbursement. For stakeholders across the supply chain, the practical implications are significant:

- ***Expect continued scrutiny.*** DOJ's "pay and chase" framing suggests the government will keep tracing high billings back to the arrangements behind them, with the Anti-

Kickback Statute and False Claims Act as primary tools.

- ***Payment policy is its own risk signal.*** A 99% expenditure decline and a 60% voluntary drop-off in billing after a mere CMS notice will likely be cited by the government as evidence that much of the prior utilization was suspect.
- ***Review arrangements now.*** Manufacturers, distributors, marketers, and providers should revisit consulting, marketing, and referral arrangements tied to skin substitutes and assess billing and medical-necessity documentation before a notice — or a subpoena — arrives.

We will continue to monitor developments in this space. If you have questions about what this means for your organization, Akerman's Healthcare Practice Group can assist in understanding and preparing for the enforcement landscape.
