

Insights

SKIN IN THE GAME - DOJ'S FALSE CLAIMS ACT FOCUS ON WOUND CARE AND SKIN SUBSTITUTES

What providers should know and where to focus compliance efforts

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What providers should know about DOJ's enforcement focus on wound care and skin substitutes

The Department of Justice (DOJ) and the Centers for Medicare and Medicaid Services (CMS) have made wound care services and skin substitute product manufacturers some of their primary healthcare fraud enforcement targets. The recent string of False Claims Act (FCA) settlements makes clear that scrutiny of these providers shows no signs of slowing.

In December 2025, DOJ [announced](#) resolution of the largest wound graft enforcement matter to date, resolved through criminal pleas and an FCA settlement, based on theories of medical necessity and inappropriate billing. The owners of several Arizona wound graft companies, who [pleaded guilty](#) to conspiracy to commit healthcare fraud and wire fraud, were each sentenced to over 14 years in prison for orchestrating a scheme that generated over \$1.2 billion in false claims for medically unnecessary wound grafts submitted to Medicare, TRICARE, and CHAMPVA between 2022 and 2024. The owners and their marketing company separately agreed to pay \$309 million to resolve FCA liability. Sales representatives with no medical training allegedly identified elderly and hospice patients with wounds of any kind, then directed nurse practitioners to apply the largest, most expensive skin substitutes—regardless of medical necessity. One of the wound graft company owners allegedly received over \$279 million in kickbacks from the graft distributor in exchange for steering business its way.

Smaller wound care providers are also not flying under the radar. In [July 2025](#), a Florida dermatology practice and affiliated surgery center [agreed](#) to pay \$847,394 to resolve allegations of upcoding wound repair claims following skin cancer surgery. DOJ alleged that over a seven-year period from 2017 to 2024, the practices billed simple linear repairs as if they were more complex flap repairs, and smaller flap repairs as if they were larger—with both practices triggering higher Medicare reimbursement. Brought under the FCA, the relator took home over \$150,000 of the recovery—a reminder that former employees remain one of DOJ's most effective sources for

uncovering coding-level fraud that might otherwise go undetected even in the era of DOJ's increased data-driven enforcement.

Not every FCA wound care enforcement theory turns on medical necessity or provider coding accuracy alone. In November 2025, DOJ [announced](#) a \$45 million settlement with one of the nation's largest providers of specialty wound care to nursing home and skilled nursing facility residents. In addition to allegations of medically unnecessary debridement procedures and improper coding, DOJ focused heavily on the company's billing system itself. The government alleged the company had manipulated its electronic health record (EHR) and billing software to default to the higher-reimbursed billing code, regardless of the procedure actually performed. Under the five-year Corporate Integrity Agreement signed with the Department of Health and Human Services – Office of Inspector General (HHS-OIG), the company must implement a compliance program, conduct risk assessments, and hire an Independent Review Organization to review its claims and health information technology systems.

Most [recently](#), on September 2, 2026, a Kentucky-based provider of at-home wound care services agreed to pay \$2,646,186.72 to resolve allegations that it violated the FCA by overbilling Medicare and TRICARE for costly skin substitute products. The settlement is part of a broader investigative initiative known as "Operation Skin Scam," built specifically to uncover fraud schemes involving expensive skin substitute materials. The allegations here turned not on medical necessity or upcoding, but on the invoice itself: DOJ claimed the provider billed Medicare and TRICARE using inflated purchase prices for the products, thus inflating the reimbursement. This Operation's name leaves little doubt: DOJ will continue to aggressively pursue fraudulent skin substitute billing across the industry.

Where providers should focus risk assessment and enforcement efforts

These four matters make clear that wound care is now a top-tier enforcement priority for DOJ, HHS-OIG, and CMS alike. Wound care providers and companies that manufacture, distribute, or bill for skin substitutes should expect continued, coordinated scrutiny. Providers should treat this as a priority compliance area. Proactive auditing and compliance monitoring in the following areas, in particular, remain essential to mitigate risk in this era of heightened scrutiny: (1) medical necessity, (2) debridement coding, (3) skin substitute billing and acquisition cost, (4) documentation, which should accurately reflect the patient's condition and the care provided, (5) EHR default settings and billing controls, and (6) financial incentives and vendor and distributor relationships.

As always, the BCLP team will be closely monitoring developments in this space and is available to provide guidance to clients assessing their wound care and skin substitute FCA exposure in light of this new enforcement trend.

Related capabilities

- False Claims Act

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