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From Biologics to Bandages, Skin Substitutes Are No Longer the Biologics You Think They Are...

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CMS has a skin substitute problem.

Skin substitutes are wound coverings that are used for burns, trauma, or chronic conditions like wounds associated with diabetes, leg ulcers, etc. According to the National Institutes of Health (NIH), the search for viable skin substitutes dates back to the late 1800s. Here's the problem: modern advances using living cells (biologics) have in recent years yielded material advances in wound care and patient outcomes. Wounds heal faster and better.

These advances come at great cost. Distributors sell skin substitutes in squares of varying size at thousands of dollars per square centimeter. Practitioners recoup this cost by billing payers, frequently Medicare, based on the Average Sales Price (ASP) plus a small percentage. The net effect: in the five-year period from 2019 to 2024, the cost of skin substitutes for the Medicare program has soared from approximately $250 million to more than $10 billion.

DOJ has noticed. In June 2025, DOJ announced a massive national focus on the industry. Lawsuits under the Federal False Claims Act followed, and so have criminal prosecutions. The government has issued civil investigative demands (CIDs) to private practices and, very likely, to skin substitute distributors as well. And in September 2025, the Department of Health and Human Services Office of Inspector General sounded the alarm over potential fraud in the use of skin substitutes.

Finally, last week, CMS brought the government's war on skin substitutes to a whole new front by attacking practitioners' purse strings. Biologics (medications or treatments that come from organic life) are generally reimbursed at a much higher price than mundane practitioner office supplies (e.g., bandages, ointments, exam table paper, etc.). Nevertheless, effective January 1, 2026, the living cell tissue that has materially advanced wound care will now be reimbursed under the same buckets as, for instance, band-aids.

Setting aside the more fraught question of patient care, why does this matter for you?

1. *Enforcement could soon come to your door*. If your organization has treated patients with skin substitutes in the past ten years, then you need to consider the enforcement landscape. Enforcement could mean recoupment proceedings. It could also mean a whistleblower complaint, a direct government inquiry (CID or

subpoena), or something more draconian. Irrespective of the form of an enforcement proceeding, there is a material benefit in having your compliance house in order now, before you face any of these potential enforcement mechanisms.

2. *Potential challenges to CMS's re-classification*. The re-classification of skin substitutes as something other than Biological treatments will likely have a seismic impact on the skin substitute industry. In our post-*Chevron* world, it remains to be seen who will challenge CMS's reclassification of this material from Biologics to Bandages.
3. *Potential Impact on other treatments/industries*. Even if you are not involved in the skin substitute industry, it is worth monitoring the government's penchant for enforcing and now re-defining its way out of an increasing cost center. Consider how the government's actions in this instance could impact the profitability of other healthcare modalities in the future, and what you can do from a legal perspective to prepare.

> CMS currently treats skin substitutes as biologicals for the purposes of Medicare payment. In the CY 2026 PFS final rule, CMS will pay for skin substitutes under the PFS as incident-to supplies, a change expected to reduce Medicare spending on these products by nearly 90% without compromising patient access or quality of care. We estimate this action will reduce gross fee-for-service program spending for skin substitute services by $19.6 billion in 2026, while incentivizing the use of products with the most clinical evidence of success.

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