December 4, 2025

The Honorable Mehmet Oz, MD, MBA
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

RE: CMS-1832-F, Medicare and Medicaid Programs; CY 2026 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program

Dear Administrator Oz:

The Association for Advancing Tissue and Biologics (AATB) writes regarding payment for skin substitutes under the Centers for Medicare & Medicaid Services' (CMS or Agency) Calendar Year (CY) 2026 Medicare Physician Fee Schedule (PFS) Final Rule (i.e., PFS Final Rule). AATB submitted comments on September 10, 2025, which raised concerns regarding several aspects of CMS' skin substitute proposals in the CY 2026 PFS Proposed Rule, but today we write regarding only one: namely, the final payment rate for skin substitutes of $127.14/cm^2, a number we think was calculated using the wrong data and thus has resulted in an unsustainably low payment rate. This is an issue of such importance that, despite other areas of significant disagreement, we have decided not to highlight any of our other concerns with the PFS Final Rule at this time, enabling your attention to be focused on the payment rate.

AATB is a non-profit organization dedicated to promoting, innovating, and advancing the safety, quality, availability and benefits of donated human tissue for transplantation worldwide. AATB achieves this through standards development, accreditation and certification programs, education, research, and collaboration with regulatory and legislative partners, helping ensure donated tissue has the greatest impact on patient care.

AATB recognizes the need for skin substitute payment reform; as numerous reports have highlighted this year, the growth in spending on these products is unsustainable and requires the Agency to act decisively.[1] However, we fear that the Agency's effort to curb inappropriate spending on skin substitutes under the PFS goes too far. If manufacturers can no longer afford to produce skin substitutes because of the drastic cuts imposed in the PFS Final Rule, patients will inevitably suffer.

The significant impact of the payment rate under the PFS Final Rule will be compounded by implementation of the nationwide final Local Coverage Determinations (LCDs) on Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg

[1] https://oig.hhs.gov/reports/all/2025/medicare-part-b-payment-trends-for-skin-substitutes-raise-major-concerns-about-fraud-waste-and-abuse/

Ulcers, which are scheduled to take effect on January 1, 2026; combined, the PFS Final Rule and final LCDs will reduce the availability of this life changing solution for practitioners and the patients they care for. AATB has already heard from members who, due to the combined impact of the LCDs and PFS Final Rule, are laying off employees and implementing other cost-saving measures, such as reducing output, suspending clinical studies, and pulling back on research and development that could result in new and innovative products. The impact of the low payment rate will be felt most by patients living in rural or low cost of living areas due to the geographic adjustments to payments for skin substitutes in the PFS Final Rule. Patients living in rural areas already suffer from a lack of healthcare providers and advanced technologies; geographic adjustments will only compound those challenges.

Products most likely to be affected are those derived from human tissue, which are mandated to be prepared in small batches, as these products cost more to manufacture and are subject to strict FDA requirements – including for storage, processing, and distribution. That is unfortunate, as numerous published peer-reviewed prospective multicenter randomized control trials support the use of skin substitutes derived from human tissue in the treatment of wounds like diabetic foot ulcers and venous leg ulcers.[2,3,4,5,6] At best, providers will have fewer options for treating patients with complex wounds, and at worst, patients will suffer amputations or death because they are unable to access the human tissue-derived products best suited for their care.

At the heart of the matter is the agency's decision to move forward with setting a flat payment rate using utilization data from only hospital outpatient department settings. As noted in our comment letter on September 10, 2025, on the proposed rule, payment for skin substitutes in that setting is not representative of the true costs that physicians bear in the private office site of service. Payments in hospital outpatient departments have been bundled and capped, which has led to disincentives to treat patients with large wounds. Furthermore, AATB reiterates that hospitals can negotiate lower payment rates that are not available to individual physician offices, which will leave physicians at a disadvantage, ultimately reducing patient access to skin substitutes furnished in physician offices. Incorporating data from both the facility and non-facility settings would be a more appropriate way to determine skin substitute payment rates based on the costs that physician offices may bear.

Adding to our concern is CMS' plan to update rates annually through rulemaking using one or more recently available calendar quarter(s) of ASP data to set the rates. We expect this plan will result in

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[2] Guo X, Mu D, Gao F. Efficacy and safety of acellular dermal matrix in diabetic foot ulcer treatment: A systematic review and meta-analysis. Int J Surg. 2017 Apr;40:1-7. doi: 10.1016/j.ijsu.2017.02.008. Epub 2017 Feb 14.

[3] Cazzell S, Vayser D, Pham H, Walters J, Reyzelman A, Samsell B, Dorsch K, Moore M. A randomized clinical trial of a human acellular dermal matrix demonstrated superior healing rates for chronic diabetic foot ulcers over conventional care and an active acellular dermal matrix comparator. Wound Repair Regen. 2017 May;25(3):483-497. doi: 10.1111/wrr.12551. Epub 2017 Jun 12.

[4] Reyzelman AM, Bazarov I. Human acellular dermal wound matrix for treatment of DFU: literature review and analysis. J Wound Care. 2015 Mar;24(3):128; 129-34. doi: 10.12968/jowc.2015.24.3.128.

[5] Zelen CM., et al. An Aseptically Processed, Acellular, Reticular, Allogenic Human Dermis Improves Healing in Diabetic Foot Ulcers: A Prospective, Randomised, Controlled, Multi-Centre Follow-Up Trial. Int Wound J. 2018 Apr 22. doi: 10.1111/iwj.12920.

[6] Serena, Thomas E. M.D.; Orgill, Dennis P. M.D., Ph.D.; Armstrong, David G. D.P.M., M.D., Ph.D.; Galiano, Robert D. M.D.; Glat, Paul M. M.D.; Carter, Marissa J. Ph.D.; Kaufman, Jarrod P. M.D.; Li, William W. M.D.; Zelen, Charles M. D.P.M.. A Multicenter, Randomized, Controlled, Clinical Trial Evaluating Dehydrated Human Amniotic Membrane in the Treatment of Venous Leg Ulcers. Plastic and Reconstructive Surgery 150(5):p 1128-1136, November 2022. | DOI: 10.1097/PRS.0000000000009650

downward pricing pressure on the market, which will further limit product availability and patient access. An annual inflationary update would instead adequately control annual increases in skin substitute payments, while also enabling manufacturers to recoup their costs and continue to offer these critical products.

As noted above, AATB fully supports efforts to eliminate unethical practices, but paying for skin substitutes at a rate of $127.14/cm^2 is economically unsustainable for far too many AATB members. Additionally, CMS' effort to limit spending will jeopardize the ability of manufacturers to make these products available to patients who need them. It is not too late for CMS to reverse course, and AATB implores the Agency to do so by revising the final payment rate and modifying skin substitute policies so that they are sustainable – and allow for ongoing access to critical wound care products – over the long term.

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Thank you for taking these comments into consideration. AATB is willing to assist the Agency in any way you deem appropriate.

Respectfully,

Marc Pearce
President & CEO
Association for Advancing Tissue and Biologics