American Association of Tissue Banks®

September 12, 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

In Re: CMS-1834-P, Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency

Dear Administrator Oz:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Banks' Tissue Policy Group (TPG) submit these comments related to payment for skin substitutes under the Centers for Medicare and Medicaid Services (CMS or Agency) Calendar Year (CY) 2026 Medicare Hospital Outpatient Prospective Payment Systems (OPPS) Proposed Rule (i.e., OPPS Proposed Rule).

AATB is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 125 accredited tissue banks and nearly 8,000 individual members. These banks recover tissue from more than 70,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the US. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

The AATB TPG includes Chief Executive Officers and senior regulatory personnel from U.S. tissue banks that process donated human tissue. The purpose of the TPG is to drive policy in furtherance of the adoption of laws, regulations, and standards that foster the safety, quality, and availability of donated tissue. The TPG's membership is responsible for the vast majority of tissue available for transplantation within the U.S.

AATB and the TPG appreciate the opportunity to submit comments on the OPPS Proposed Rule, and we are particularly focused on the Agency's proposed changes to payment for skin substitutes. While we acknowledge that the increase in Medicare spending on skin substitutes is unsustainable, we also believe it is critical for any changes in policy to preserve patient access to lifesaving and life-enhancing tissue products and promote the development of innovative products.

Skin substitutes are key medical products that play an important role in the treatment of wounds. Numerous published peer-reviewed prospective multicenter randomized control trials support the use

of skin substitutes in the treatment of wounds like diabetic foot ulcers versus standard of care[1,2,3,4]; the standard of care includes treating wounds with non-skin substitute supplies currently categorized under A codes (e.g. collagen alginates (A6010)).

AATB and the TPG have long argued that skin substitutes should be paid separately from the professional fee and as separately reimbursable products in acknowledgement of their value-add for wound care.[5] In that regard, we appreciate the Agency's proposal to separately pay for the provision of certain groups of skin substitute products under the OPPS, which we believe will significantly improve access to graft procedures in this setting, particularly for large wounds. We similarly have no objection to CMS' plan to implement this policy in both the non-facility and facility outpatient settings. Furthermore, AATB and the TPG believe that this policy should be extended to products that are not in sheet form (but may instead be a gel, powder, ointment, foam, liquid, or injected product).

At the same time, there are several aspects of CMS' proposals that raise concerns or require additional information. While the proposed model may have merit, in order to provide meaningful comment, additional information is necessary. Both AATB and the TPG request CMS to engage with industry to gather information and work towards an appropriate scheme that not only addresses the concerns of CMS, but facilitates innovation in the treatment of wounds and considers the outcomes of that treatment for the patient.

While we recognize CMS' attempt to support reasonable payment rates for skin substitutes, we believe more information should be provided before the proposal is finalized. In particular, we urge CMS to provide additional information on calculated payment rates of each of the three proposed payment categories that reflect incorporation of data from the physician office setting, both on a standalone basis and when paired with hospital outpatient data. Calculated payment rates incorporating office utilization should also be provided for each of the alternatives that CMS is considering, including relying on a full year of data rather than the final quarter and using a pooled payment rate. We would welcome a dialogue with the agency after we have had a chance to review such information.

Despite this need for additional information, one thing is clear: that the proposed payment rate is insufficient to maintain access to not only the current range of skin substitute products, but any innovative enhancements that would enable physicians to choose the products most appropriate for their patients' conditions. In fact, the proposed payment rate may not be sufficient to cover the cost to

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[1] 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.
[2] 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.
[3] 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.
[4] 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.
[5]https://www.aatb.org/sites/default/files/2023/Federal%20Advocacy%20Letters/CMSPhysFeeScheduleFINAL20220906.pdf

manufacture these products, especially those derived from human tissue or prepared in small batches, which could lead to more limited options for physicians and their patients over time.

As we note in our comments in response to the CY 2026 Medicare Physician Fee Schedule proposed rule separately, we believe the Agency's proposed methodology for calculating initial payment rates is particularly problematic. Weighting product-specific utilization using proportions from only hospital outpatient department data will result in underpayment for skin substitutes in the physician's office setting. As CMS is aware, payment for skin substitutes in the hospital outpatient department setting is already capped, which has led to disincentives to treat certain patients with large wounds. Furthermore, hospitals are able to 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 grafts and skin substitutes furnished in physician offices. Thus, finalizing the use of only hospital outpatient data in the OPPS and PFS final rules will result in significant underpayment for skin substitutes in the physician office setting. We believe a different approach that incorporates data from both the facility and non-facility settings would lead to rates that are more representative of the costs that must be borne across both settings. Without sufficient payment in the physician office setting, we do not believe CMS' goal of setting unified policy across both settings can succeed.

We are also concerned with CMS' plan to update the rates for the skin substitute categories annually through rulemaking using the most recently available calendar quarter of ASP data to set the rates. Instead, we believe CMS should update the rates on an annual basis using an inflationary update. This approach would limit the annual increase in skin substitute payments, while also ensuring increases in manufacturer costs are appropriately captured in the payment rate. It would also resolve issues with self-reported ASP data that has contributed to waste, fraud, and abuse. **If an inflationary update cannot be included in the final rule, we would have significant concerns with CMS' overall approach with respect to payments for skin substitutes given the resulting downward pricing pressure on the market and its associated impact on product availability and patient access.**

Finally, we highlight a challenge with CMS' proposal to develop separate APCs for skin substitute products only, given that the labor-related share of the OPPS conversion factor is subject to geographic adjustment. While such adjustment may be appropriate when skin substitute products comprise a small fraction of the weight of the APC, CMS' proposal to create APCs comprised only of skin substitute products would result in the majority of the payment for products being geographically adjusted. Such adjustments are not appropriate for products like skin substitutes whose prices are not tied to local conditions and would only serve to treat patients differently based on where they live. We would expect patients in more affluent areas to have greater access to these products as a result of those geographic adjustments, even though patients in less wealthy areas may have a greater need for the products.

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Thank you for taking these comments into consideration. AATB and the TPG stand ready and willing to assist as CMS as it continues its efforts to establish rational payment policies for skin substitutes that protect access to effective products for the patients who need them.

Respectfully,

Marc Pearce
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Chair
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