American Association of Tissue Banks®

September 6, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

In Re: CMS-1807-P, Medicare and Medicaid Programs; CY 2025 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Prescription Drug Inflation Rebate Program; and Medicare Overpayments

To Whom It May Concern:

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 under the Centers for Medicare and Medicaid Services (CMS or Agency) CY2025 Physician Fee Schedule (PFS) Proposed Rule (i.e., PFS Proposed Rule).

The American Association of Tissue Banks (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 120 accredited tissue banks and over 7,000 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.

Concerns with and Response to CMS CY2025 PFS Proposed Rule: The AATB and TPG appreciate that CMS has not proposed any changes related to payment of skin substitutes under the PFS, but we continue to object to the premise that skin substitutes (or "cellular and tissue-based products (CTPs) for skin wounds") should be considered incident to supplies captured within the Practice Expense Relative Value Unit (PE RVU) methodology – as we discussed in our letters responding to both the CY2023 and CY2024 PFS Proposed Rules. These products are not supplies, but key medical products that are critical in supporting the treatment of certain chronic wounds. Unlike standard wound dressings and bandages, these products contain key extracellular matrix components such as collagens, fibronectins, and laminins that contribute to improved wound outcomes. Numerous published prospective multicentered

randomized control trials have proven that CTPs for skin wounds provide a unique clinical benefit and are significantly more effective in supporting the healing of wounds such as diabetic foot ulcers versus standard of care;[1,2,3,4] the standard of care includes treating wounds with actual supplies currently categorized under A codes [e.g. collagen alginates (A6010)].

Incorporating skin substitutes into the PE RVU methodology would have significant ramifications for the payment that physician offices could receive for the application of these products due to the constraints on payment that apply under the PFS. First, the pool of PE RVUs is subject to budget neutrality, which limits the ability of payments to keep pace with cost increases. Furthermore, the PFS is subject to an additional overall budget neutrality requirement, which may lead to reductions in the PFS conversion factor. Indeed, budget neutrality adjustments have led to negative payment updates under the PFS for the last four years, since 2021, and the conversion factor is again facing a decline for 2025 as well.

Furthermore, annual PFS payment updates are not meaningfully tied to inflation. While payments under the Medicare Hospital Outpatient Prospective Payment System (OPPS) increase annually based on increases in the hospital market basket, the PFS receives zero or little inflationary updates based on current law, even before application of budget neutrality adjustments. Thus, if payments for skin substitutes are incorporated into PE RVUs, payment for these products would be significantly constrained over time. This constraint on payment growth under the PFS would lead to divergence in payments across different care settings, with payments increasing more quickly under the OPPS than under the PFS. Rather than achieving consistent payment across settings, incorporation of skin substitutes into PE RVUs could instead exacerbate payment differentials, encourage greater use in more expensive outpatient hospital settings, and limit access for patients in office settings.

Given the above, we continue to urge CMS to abandon consideration of incorporating skin substitutes or CTPs for skin wounds into the PE RVU methodology.

Other Comments: We note that CMS again proposes that "billing and payment codes that described products currently referred to as skin substitutes would not be counted for purposes of identifying refundable drugs for calendar quarters in 2025." The AATB and TPG support this approach, which continues to provide stability and reduces burden for tissue processors during this uncertain period. We understand CMS plans to revisit this policy in future rulemaking, and we encourage the Agency to engage with stakeholders during such rulemaking process.

We also reiterate our concern that – for products regulated under Section 361 of the Public Health Service Act ("361 HCT/Ps") – CMS and its Medicare Administrative Contractors are increasingly moving towards requiring tissue processors to obtain and furnish letters from the FDA's Tissue Reference Group

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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.

(TRG) to confirm a product's regulatory status. Currently, FDA offers TRG letters on a voluntary basis to manufacturers who wish to seek certainty regarding the appropriate regulatory paradigm for their products. Making a TRG letter a condition of Medicare coverage or payment, as CMS has previously proposed, has already and could continue to overwhelm the TRG, resulting in significant delays in obtaining such letters. Our understanding from the FDA is that since 2020, the number of annual TRG requests has increased from 11 to 145 in 2023, with no additional resources provided to the TRG to accommodate such requests. Our experience in 2024 is that tissue banks continue to experience delays in receiving responses and letters from TRG. Furthermore, applying such a requirement retroactively to existing products without an appropriate "on-ramp" may result in an abrupt loss of access to these products.

In 2022, the AATB and TPG reviewed a large number of recent tissue bank submissions to the TRG and found that TRG response times averaged 140.7 days, with a range of 26 to 344 days. We are currently conducting a similar analysis and preliminary data shows that average response times over the past two years have increased to 194.75 days on average, with a range of 73 to 268 days. As a result of these delays, we believe it is important for CMS to provide manufacturers with ample time to adhere to any new requirements related to TRG letters and suggest allowing at least eighteen months to apply for and obtain a TRG letter. The AATB and TPG believe CMS' proposal in the CY2023 PFS Proposed Rule to require receipt of a TRG letter and apply for a new HCPCS Level II code within 12 months would have been infeasible and resulted in severe disruptions in beneficiary access to many well-established products. An eighteen-month timeline would have been necessary to achieve compliance with minimal disruption.

Finally, the AATB and TPG note that we continue to engage with the MACs regarding the recently issued draft local coverage determinations and their association local coverage articles. We have recommended changes to such draft policies[5] and urge you to consider how the proposed LCDs/LCAs, combined with any future changes in the PFS, could reduce patient access to important skin substitute products; disincentivize innovation in wound care; and lead to greater health disparities and worse outcomes for patients.

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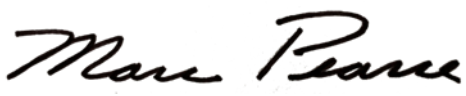
Thank you for taking these comments into consideration. The AATB and TPG stand ready and willing to assist in any way that you deem appropriate.

Respectfully,



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[5] https://www.aatb.org/sites/default/files/2023/Federal%20Advocacy%20Letters/AATB%20TPG%20letter%20re%20skin%20subs%20LCDs%205.31.24%20FINAL.pdf