August 27, 2026

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-1850-P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Standardization and Comparability of Hospital Price Transparency (HPT) Data; Prior Authorization; Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA); and Notices of Closure of Teaching Hospitals and Opportunities To Apply for Available Slots

Dear Administrator Oz:

The Association for Advancing Tissue and Biologics (AATB or Association) submits these comments related to payment for skin substitutes under the Centers for Medicare and Medicaid Services (CMS or Agency) Calendar Year (CY) 2027 Medicare Hospital Outpatient Prospective Payment Systems (OPPS) Proposed Rule (i.e., OPPS Proposed Rule). We request to meet with you or an appropriate member on your staff to discuss our concerns in greater detail.

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

We wrote last year in response to the CY 2026 OPPS Proposed Rule and CY 2026 Medicare Physician Fee Schedule (PFS) Proposed Rule (and both Final Rules) primarily to highlight that (1) skin substitutes are an important medical product for the treatment of wounds; (2) the payment rate of $127.14/cm^2 for skin substitutes in CY 2026 when used in the office and hospital outpatient department setting is insufficient and will generally not cover the cost to produce such products; and (3) we have significant concerns with CMS' plan to update the rates for skin substitutes annually through rulemaking using the most recently available calendar quarter of ASP data, which will result in downward pricing pressure on the market and, combined with the other issues noted previously, result in significant product availability and patient access issues.[1] AATB continues to urge CMS to recognize these three points and adjust the Agency's payment policies for skin substitutes in CY 2027.

[1] https://www.aatb.org/sites/default/files/Government%20Advocacy%20Correspondence/AATB%20TPG%20CY%2026%20OPPS%20proposed%20rule%20comment%20letter%20FINAL.pdf

AATB understands that the increase in Medicare spending on skin substitutes between CYs 2019 - 2025 was unsustainable and in need of reform. We also believe the Agency's decision to pay separately for the provision of certain groups of skin substitutes under the OPPS has improved access to graft procedures in that setting, especially large wounds. However, we raised concerns last year that the payment rate would be insufficient to maintain long-term access to the previously available range of skin substitute products, in part because the payment rate was insufficient to cover the cost of producing skin substitute products, especially those derived from human tissue or prepared in small batches. We continue to believe this is an urgent issue that CMS must address. While we understand that an oversupply of skin substitutes has generally limited patient access issues thus far, we know skin substitute processors – some of whom are our members – have laid off employees, eliminated research and development plans, and in some cases, decided to sell their products for less than it costs to produce them. In the long run, we expect these companies may cease operations or pivot and invest in other lines of business, which will result in the patient access issues we have warned about.

If processors go out of business or stop producing skin substitutes, there will be real harm to patients. Our letter last year described how numerous 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. If these important products are no longer available, we expect to see an increased rate of hospitalizations, amputations, and death.

As we described last year, we believe the core issue is the Agency's decision to weight product-specific utilization using proportions from only hospital outpatient department data when determining a payment rate for both the CY 2026 PFS and OPPS, which has resulted in underpayment for skin substitutes in the physician office setting in particular. Payment for skin substitutes was already capped in the hospital outpatient department setting, so using OPPS data to calculate a payment rate was not indicative of the true costs that are borne across both settings. AATB understands CMS' goal of implementing a unified policy across both settings, but without sufficient payment in the physician office setting, we do not believe that the current payment policy can succeed. This is especially true in rural areas where patients may be able to more readily access a physician's office than a hospital outpatient department to obtain needed treatment.

Our second major concern is that CMS plans to update the payment rates for skin substitute categories annually through rulemaking using the most recently available calendar quarter(s) of ASP data to set the rates. In our comment letter last year, AATB argued that this policy would result in downward pricing pressure on the market; instead, we recommended that CMS update the rates annually using an inflationary update, which would limit the annual increase in skin substitute payments while also ensuring increases in processor costs are appropriately captured in the payment rate. We appreciate that CMS has recognized it does not have sufficient data to revise the CY 2027 payment rates, but we remain concerned that the continuation of CMS' existing policies for 2027 will further limit the availability of skin substitutes for patients who need them. We urge the Agency to implement an inflationary update for the skin substitute payment rate in CY 2027 and beyond to help stabilize the market.

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

Sincerely,

Marc Pearce
President & CEO
Association for Advancing Tissue and Biologics