September 8, 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

**In Re: CMS-1848-P, Medicare Program: Medicare and Medicaid Programs; CY 2027 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 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 Physician Fee Schedule (PFS) Proposed Rule (i.e., PFS Proposed Rule).

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.

As noted in previous correspondence, AATB understands that the increase in Medicare spending on skin substitutes between CYs 2019 - 2025 was unsustainable and in need of reform.[1] We also appreciate CMS' goal of implementing a unified payment policy across hospital outpatient and physician office settings, and we support CMS' proposal to likewise provide for consistent payment for products are not in sheet form (but may instead be a gel, powder, ointment, foam, liquid, or injected product). Unfortunately, however, we believe the final payment rates for skin substitutes in CY 2026 – and the proposed payment rates for CY 2027 – are insufficient, particularly in the physician office setting, and will generally not cover the cost to produce such products. AATB also has significant concerns with the geographic adjustment policy for skin substitutes administered in the physician office setting, and 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. Combined, these issues will result in significant product availability and patient access issues in the long run that cannot be ignored.

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

We know CMS is still gathering data to better understand the impact of the CY 2026 Final Rules, but AATB is already hearing from members who are concerned about going out of business or who are investing in other lines of business as a result of the CY 2026 Final Rules. We understand that an oversupply of skin substitutes has generally limited patient access issues thus far, but we also know manufacturers – 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 manufacture 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.

We expect such patient access issues to result in significantly worse patient outcomes. 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.

Similar to last year, we believe the core issue with the current payment policy 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. By using the wrong data to calculate a payment rate, CMS has established a policy that does not allow manufacturers to cover the cost of manufacturing their products, especially those that are derived from human tissue or that are prepared in small batches. As noted above, 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 instead of visiting a hospital outpatient department to obtain needed treatment.

Geographic adjustments to the payment of skin substitutes administered in the physician office setting has also caused patient access issues. Such adjustments are not appropriate for products like skin substitutes whose prices are not tied to local conditions; instead, because of the policy, patients are treated differently based on where they live. Generally, patients in more affluent areas tend to have greater access to these products based on those geographic adjustments, even though patients in less wealthy areas may have a greater need for the products.

Our final 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 manufacturer 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. CMS' final CY 2026 payment policies for skin substitutes may have limited the ability of "bad actors" to take advantage of the system, but they also swept up skin substitute manufacturers who make critical medical products; invest in the personnel and processes to produce safe, high-quality products; and historically have priced those products fairly. To protect patient access and ensure a robust supply of safe and effective skin substitutes, we urge CMS to address our concerns. We stand ready and willing to assist in any way that you deem appropriate.

Respectfully,

Marc Pearce
President & CEO
Association for Advancing Tissue and Biologics