



**Testimony for the Record
Before the House Committee on Appropriations, Labor, Health and Human Services,
Education, and Related Agencies Subcommittee
Public Witness Hearing
Thursday, March 23, 2023**

Chairman Aderholt, Ranking Member DeLauro, and members of the Subcommittee, the American Association of Tissue Banks (AATB) and the American Association of Tissue Banks' Tissue Policy Group (AATB TPG or TPG) are pleased to submit testimony regarding the fiscal year 2024 Labor, Health and Human Services, Education, and Related Agencies (L-HHS) appropriations bill. The AATB and TPG request the inclusion of the following report language addressing proposed CMS policies affecting skin substitute products:

The Committee is aware of stakeholder concerns regarding the Centers for Medicare and Medicaid Services' (CMS) proposal to treat skin substitute products as "incident to supplies" under the Medicare Physician Fee Schedule and to shift from separate reimbursement for skin substitutes administered in physicians' offices to a bundled model that includes the costs of these products in the procedural payment rates. The Committee is concerned that this proposal could limit patient access and potentially lead to detrimental patient outcomes and higher costs. The Committee is aware that the OIG recently released a report on the reporting of average sales price (ASP) by skin substitute manufacturers. The OIG estimated that \$84 million could be saved per quarter from the use of ASP pricing for skin substitutes under Medicare Part B, provided all skin substitute manufacturers consistently comply with the statutorily mandated ASP reporting

requirements. In light of the potential savings that would result, the Committee encourages CMS to give the reporting process enough time for the Medicare program to realize the benefits of ASP pricing.

The Committee is also aware of stakeholder concerns regarding a potential new CMS requirement for manufacturers to obtain written documentation from the Food and Drug Administration (FDA) confirming the regulatory classification of human cells, tissues, and cellular and tissue-based products (HCT/Ps) in order to maintain eligibility for payment. The Committee is concerned about this proposal, given the time required to obtain such documentation, the number of products that FDA would need to evaluate, and the absence of a statutory requirement to obtain such pre-market approval from the FDA for these types of products.

Given the above, the Committee directs CMS to study the potential long-term impact that changes to current skin substitute reimbursement policy will have on beneficiary access and outcomes prior to finalizing payment changes for such products under the Medicare Physician Fee Schedule. The Committee also directs the agency to allow for at least two years before effectuating any new requirement to obtain FDA documentation, such as a Tissue Reference Group letter or Request for Designation (RFD) letter, confirming the appropriate regulatory classification of HCT/Ps, including as part of a HCPCS Level II application process, or to abandon this portion of the proposal.

Pioneered in the late 1800s, skin grafting was one of the first allografts, or tissues grafted from one patient to another. Since then, skin grafts, or “skin substitutes,” have become a common way to treat patients with a variety of conditions, including burns, diabetic foot ulcers, and chronic wounds. Skin substitutes are used in nearly every hospital in the United States; in fact, it is estimated that over 160,000 skin grafts are performed per year across the country on patients with severe burns alone.¹

Access to skin substitutes is particularly important given the disproportionate need across racial and ethnic groups, as Latinos, African Americans, and Native Americans have the highest incidence of foot ulcers in the United States.² Ensuring access to skin substitutes, therefore, would support health equity and improved health outcomes for historically disadvantaged populations.

The AATB and TPG are concerned, however, that CMS’ current consideration and potential future action regarding payment for skin substitutes would significantly restrict patient access to these products, particularly for Medicare beneficiaries seeking care in physician office settings. We are especially concerned that in its Calendar Year 2023 Medicare Physician Fee Schedule (PFS) proposed rule (87 FR 45860), CMS proposed to treat skin substitute products as “incident to supplies” and to bundle the costs of these products into the physician payment rates for the underlying procedures, specifically by including the products as inputs used in establishing the practice expense relative value units (PE RVUs). This is a drastic departure from

¹ Serebrakian, Arman T., et. al. Meta-analysis and Systemic Review of Skin Graft Donor-site Dressings with Future Guidelines. PRS Global Open. 2018 Sept. 24, doi: 10.1097/GOX.0000000000001928

² Oliver, Tony. I; Mutluoglu, Mesut. Diabetic Foot Ulcer. StatPearls [Internet]. 2022 Aug. 8. <https://www.ncbi.nlm.nih.gov/books/NBK537328/>

the current methodology of reimbursement for these products, since skin substitutes administered in physicians' offices are paid separately, generally at the average sales price plus 6 percent (ASP + 6%).

Additionally, CMS proposed to require manufacturers of all products regulated under Section 361 of the Public Health Service Act ("361 HCT/Ps") – a designation under which a large volume of skin substitute products falls – to apply to receive new payment codes (HCPCS Level II A codes) if the products did not already have such codes, and to include as part of that application a letter from the Tissue Reference Group (TRG) within the Food and Drug Administration (FDA) confirming the products' regulatory classification as a 361 HCT/P.

Currently, HCT/Ps requesting new HCPCS coding are required to provide a letter of designation from the TRG, but CMS has not retroactively applied this requirement to already marketed products. Notably, a TRG letter is not a requirement of the FDA's regulatory paradigm for any HCT/Ps, though manufacturers who wish to may request TRG letters to voluntarily seek clarity on product classification from FDA.

While CMS did not finalize these policies in the CY 2023 PFS final rule, CMS stated its intent to revisit skin substitute payment in the next rulemaking cycle. The AATB and TPG are especially concerned that in a January 2023 town hall on this topic, CMS continued to signal interest in treating skin substitute products as "incident to supplies." Should CMS decide to implement these or similar policies, patient access to skin substitutes could be significantly curtailed due to the impact of the policies on payment rates. Ultimately, these barriers to access could result in preventable amputations and death. The greatest impact would be to patients with large

wounds, which are more expensive to treat and for which payments would be least likely to cover expenses. Racial and ethnic minority populations who, as noted above, have the highest incidence of foot ulcers in the United States, would also be disproportionately affected.

We urge the Subcommittee to include language in this year's appropriations bill directing CMS to study the impact of these policy proposals on beneficiary access and outcomes prior to finalizing any payment changes for skin substitute products, and we also encourage the Subcommittee to direct the Agency to allow for at least two years prior to enacting any new requirement to obtain FDA documentation confirming the regulatory classification of skin substitutes.

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 6,500 individual members. These banks recover tissue from more than 58,000 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.