Wound Care Advocacy Wins: Separate, Site Neutral Payments for CTPs/Skin Substitutes Remove Access Barriers in Hospital Outpatient Setting; Combat Waste/Fraud/Abuse that has Led to Unsustainable Medicare Spend in Physicians' Office Setting.

Alliance of Wound Care Stakeholders Statement on Final 2026 Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System

November 2025 – The Alliance of Wound Care Stakeholders commends CMS on its initiatives in the final CY 2026 Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System (HOPPS) to reform the payment system for cellular and tissue-based products for wounds (CTPs, or "skin substitutes") in its efforts to combat fraud, waste and abuse of these products and address the excessive spending that has made the current payment methodology unsustainable. Following years of persistent advocacy with CMS policymakers, the Alliance believes the establishment of separate, site neutral payment in 2026 enables clinically appropriate site-of-service decisions – with particular impact in the hospital outpatient department (HOPD) setting, where the current bundled payment methodology has challenged access and driven care to other sites of service. The Alliance has repeatedly addressed this issue to the Centers for Medicare and Medicaid Services in our comments which had already gained the endorsement of the Agency's Advisory Panel on Hospital Outpatient Payment on policy fix recommendations. CMS had not acted on those recommendations until now. In an advocacy "win" for patients and providers alike, HOPDs will now be more able to provide CTPs to patients with larger wounds rather than shifting them to alternate sites of care.

Separate, Site Neutral Payment

The provisions of the CY 2026 Physician Fee Schedule and HOPPS Final Rules bring consistency and stability to CTP payment. Currently, CTPs are packaged into the payment for the application procedure under a bundled payment methodology in the hospital outpatient setting, while in the physicians' office and mobile clinic setting are reimbursed separately based on their cost under the Average Sales Price (ASP) + 6% methodology for biologics and drugs. The final 2026 policies establish a separate "incident-to supplies" payment for CTPs at a standardized rate of $127.14 per cm^2 in 2026 across physician offices/mobile clinics and hospital outpatient department regardless of the specific product used. Moving forward, the Agency has said it will set three differentiated reimbursement categories for CTPs along FDA regulatory status: PMA-approved, 510(k)-cleared, and 361 HCT/Ps. Payment rates for these new categories will be proposed in future CMS rulemaking. (BLA-approved CTPs will remain reimbursed as a biological under CMS' existing ASP +6% methodology.) While the Alliance does not agree with CMS' designation of CTPs as "supplies," we do ultimately support CMS' approach to pay for CTPs separately - *without bundling or packaging*. The move to a consistent, predictable and site neutral separate payment is a positive evolution and improvement to CMS' past payment proposals.

A "Win" for Access in the Hospital Outpatient Setting

The switch to a site neutral separate payment will have a particularly positive impact in the HOPD setting**,** where in 2014 CMS put in place a bundled payment system (to the Alliance's dissent ever since) containing several methodology flaws that have challenged access to CTPs. The Alliance has long advocated for policy fixes, bringing recommendations to – and receiving the endorsement of – CMS' Advisory Panel for Hospital Outpatient Payment multiple times. In the CY 2026 rules, CMS finally addresses many of the issues elevated by the Alliance. With this win, the new payment methodology will:

- **Enable HOPDs to be reimbursed for an adequate payment of CTP products for larger wounds.** Issue: Add-on codes packaged into the bundled rates have not allowed for adequate payment for the HOPDs to purchase the sizes of CTPs necessary to apply to larger wounds. This has forced HOPDs to either absorb the cost of additional CTP product for larger wounds/ulcers (between 25-99 cm^2 or over

100 cm^2) or refer patients out to settings with separate payment. This restricted access to CTPs in HOPDs and ultimately shifted treatment with CTPs to physician's offices and mobile clinics.
Under the CY 2026 OPPS, HOPDs will have more flexibility to be able to treat patients with larger wounds as they will now be separately paid for the service and the product used.

- **Equalize payment for application of CTPs on wounds/ulcers of the same size regardless of anatomic location**
  Issue: Under the bundled payment system, application of CTPs on the feet were assigned to a lower paying Ambulatory Payment Classification group than to the same size wounds/ulcers on the legs. Inconsistent payment made it problematic for HOPDs to manage CTP costs, as the identical amount of product must be purchased for wounds of the same size regardless of anatomic location.
  With the shift to separate payment, CTPs will now be paid equally across all anatomic locations.

Ultimately, with the unbundling and shift to separate site neutral payment Medicare beneficiaries will have improved access to CTPs in outpatient departments regardless of the size or location of their wounds.

Evolution of CTP Payment Proposals, Alliance Advocacy, and Regulatory Priority
The Alliance's perspective on the CY 2026 rules is shaped by our long history of advocacy with CMS surrounding CTPs and the impact of previously-proposed payment approaches on access and practice. CMS has had CTP payment overhaul in its focus for years and solicited stakeholder inputs as proposals evolved:

- In 2023, the HHS Office of Inspector General released a report highlighting "significant gaps" in manufacturer compliance with Average Sales Price (ASP) reporting requirements, leading to potentially tens of millions of dollars in excessive payments for Medicare. The OIG encouraged CMS to address the issue and "work on a more systemic solution."
- In CY 2023 and CY 2024 draft Physician Fee Schedules, CMS proposed packaging payment into the practice expense, which the Alliance vociferously opposed. The Agency ultimately retracting the provisions for further vetting. In CY 2025 rulemaking, CMS did not include substantive CTP payment changes but stated its intention to move forward a future proposal to achieve a consistent payment mechanism for CTPs and previewed further exploration of the "incident-to supplies" approach. The Alliance has been on the record with detailed comments and recommendations - and in dialogue with CMS policymakers – through each of these policy evolutions.
- CTP payment issues elevated in regulatory priority this year with the Justice Department's June 2025 "Health Care Fraud Takedown" finding $1.1 billion in fraudulent CTP/skin substitute claims.
- Most recently, the September 2025 HHS Office of Inspector General report focused on "skyrocketing" spend for the product category that rose from $250 million in 2019 to more than $10 billion in 2024, a "nearly 40-fold increase, while the number of patients receiving these products only doubled." The OIG called on CMS to take "urgently needed action" to rein in the massive spending increase and urged payment reforms "that address fraud, waste, and abuse in skin substitute billing."

The majority of Alliance members believe the separate payment approach in the CY 2026 CMS rules appropriately recognizes these products' distinct value in improving wound care outcomes for patients, protects access to quality care, and promotes clinically appropriate site-of-service decisions – meeting CMS' goals of reducing spend and preventing abuse while also protecting access and supporting innovation. While there are still issues to address and access impacts to monitor, the 2026 rules set an important framework to bring much needed transparency, stability and predictability to CTP/skin substitute reimbursement.

Next Steps: Educating for Implementation, Future Rulemaking
Moving forward, the Alliance will be collecting insights and impacts from members and will remain in active dialogue with CMS about adjustments and improvements – particularly as the Agency begins work setting the differentiated payment rates for CTPs across FDA regulatory categories for CY 2027.

Most immediately, the Alliance will focus on educating clinicians to facilitate implementation of new policies. In addition to the Fee Schedule and OPPs, the Medicare Administrative Contractors' final local coverage determinations on "Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers" are also currently scheduled to go into effect on January 1, 2026 (after two delays) with substantive changes to the number of covered products, allowable applications, and required documentation. Additionally, enhanced prior authorization processes under CMS' Wasteful and Inappropriate Service Reduction (WISeR) Model pilot will go into effect in six states for CTPs and 16 other services considered by CMA as " vulnerable to fraud, waste and abuse." The Alliance will work to be a resource to its members and a sounding board to CMS as these policies are implemented and impact assessed.

About the Alliance of Wound Care Stakeholder: The Alliance has served as a leading voice of wound care advocacy for the past 20+ years. The Alliance unites leading wound care organizations and experts through advocacy and educational outreach in the regulatory, legislative and public arenas to advocate on public policy issues that may create barriers to patient access to treatments or care. With a key focus on coding, coverage and reimbursement, quality measures and wound care research, the Alliance elevates the visibility and united voice of wound care providers to regulators and policymakers. For more information visit www.woundcarestakeholders.org