



ALLIANCE OF
**WOUND CARE
STAKEHOLDERS**
POWER THROUGH COLLECTIVE ADVOCACY

2025

**ADVOCACY
IMPACT
REPORT**

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LEADERSHIP MESSAGE

Wound care organizations and providers thrive when government regulations support fair reimbursement, appropriate coverage and equitable patient access.

That is our focus.

A Message from Alliance Executive Leadership

Substantial Medicare payment reforms, new deregulation efforts and increasing federal scrutiny of select wound care products created a fast-moving policy landscape in 2025, making our unified and respected voice more essential than ever. Throughout the year, the Alliance served as an expert credible voice that policymakers relied on for clinical insight and real-world impact, reinforcing our important role at the intersection of government, policy, and clinical care.



Dr. Matthew Garoufalidis
Board Chair



Kara Couch
Board Vice Chair



Marcia Nusgart
Founder & CEO

Together, We Drove Meaningful Policy Evolution.

The Alliance supported and influenced CMS' major payment reforms for cellular and tissue-based products for wounds (CTPs or skin substitutes) - some of the most consequential payment updates to this product sector in years. The changes, which went into effect in January 2026, reflect the Alliance's long-term engagement on this issue. Of note is the "win" for hospital outpatient departments, which - with unbundling and separate payment - will now be able to provide CTPs to patients with larger wounds. We've alerted CMS to barriers to CTP access in the hospital outpatient setting for years due to flaws in the bundled payment methodology. As we know from experience, advocacy is often a long game of being on the record again and again. CMS' return to separate payment shows us that persistence pays and our recommendations are considered. We will maintain a close focus on this issue as the payment policy evolves.

Together, We Focused on Solutions Across the Wound Care Ecosystem.

From working to strengthen payment for blood-derived products and solving surgical dressing claims processing issues to building support for point-of-care imaging reimbursement, Alliance advocacy spanned multiple product categories. Our member-driven workgroups continued to identify challenges early and shape actionable recommendations that inform and influence regulatory policy.

Together, We Spoke Up When We Saw Policy Flaws and Inaccuracies.

Importantly, we prevented the advancement of flawed methodologies in policies that impact wound care, most notably stopping the inaccurate non-pressure ulcer cost measure and securing a pause of the FDA's antimicrobial dressing reclassification by proactively and tenaciously raising concerns and providing alternative solutions.

Together, We Advocated for a Better Policy Environment.

On Capitol Hill and across federal agencies, we urged improvements to Medicare physician payment, expanded PAD screening, aligned Medicare Advantage with fee-for-service, and highlighted risks associated with medical device tariffs. In response to the new Administration's deregulation initiatives, we submitted recommendations to the White House Office of Management and Budget, the Department of Health & Human Services and CMS identifying specific policies for elimination or revision to remove burdens and inefficiencies in wound care.

Your Membership Fuels This Work.

Your membership in the Alliance allows us to respond rapidly to regulatory proposals, develop comments, mobilize experts, and sustain the day-to-day advocacy needed to influence CMS rulemaking, FDA policies, and Congressional legislation. Most importantly, it ensures that wound care – so often underrecognized – has a strong and respected presence and seat at the table in policy discussion. Your ongoing involvement and support ensure that the Alliance will remain at the intersection of government, policy, and wound care to ensure that the wound care community's perspectives are heard and provider and patients' needs are represented.

Experienced Leadership, Enduring Impact.

We extend gratitude to the Alliance's staff and Board of Directors for their commitment, expertise, and leadership. Their collective efforts, together with yours, have been essential in advancing the Alliance's mission and strengthening its impact. The end of 2025 brings leadership transition, as Board Chair Dr. Matthew Garoufalis concludes a decade of exceptional service and guidance. The Alliance is thankful for his principled leadership, friendship and sense of humor. We are in strong, capable hands with our newly appointed 2026 Board chair Kara Couch and vice-chair Julie Rhodovi. We welcomed three new Board members this year, bringing fresh perspectives and expertise to the organization: Emory Healthcare's limb preservation coordinator Karen Bauer, DNP; Regenerative & Hyperbaric Medicine president Dr. Helen Gelly, and Veros Healthcare Consulting managing partner Amanda Trask, MBA. Across our Board, staff, and members, we are well positioned to remain an advocacy powerhouse!

The following report summarizes the Alliance's 2025 accomplishments, focused on the issues we faced, the actions we took, and the impacts we achieved. We look forward to continuing this work with you in 2026!

With appreciation,

The Alliance of Wound Care Stakeholders

Matthew Garoufalis, DPM, FASPS, FACFAOM, CWS - Board Chair

Kara Couch, MS, CRNP, CWCN-AP, FAWWC - Board Vice Chair

Marcia Nusgart, RPh – Founder & CEO

Reflections on 10 Years of Alliance Leadership

After a decade of service on the Alliance of Wound Care Stakeholders Board of Directors, it is time for me to step aside and allow space for fresh perspectives and continued evolution. Reflecting on these years, I am inspired by the dedication, collaboration, and shared purpose that define our unique association of diverse organizations and businesses. The Alliance stands as a powerful example of what can be accomplished when voices and interests across wound care unite around a common mission.



My involvement with the Alliance began in its earliest days, when I attended its first business meetings in the early 2000s as a member of the APMA Board of Trustees. I quickly recognized that the Alliance's unique collective reach enabled advocacy and influence that no single organization could achieve alone. The Alliance has consistently elevated wound care before the Centers for Medicare and Medicaid Services, the Food and Drug Administration, Congress, and other key stakeholders to ensure the field is visible, understood, considered, and respected within the broader healthcare ecosystem and federal health policy decisions.

The 10+ years of annual reports on the Alliance website reflect the breadth of our impact. In my mind, they also invite reflection on what might have occurred had the Alliance not been there to advocate on behalf of wound care. We would all be far more vulnerable to shortsighted policies and ill-informed regulations!

I'm honored to have served as Alliance Co-Chair and then Chair during this period of significant growth and transition. Over the past several years we've increased in members and member categories, strategically shifted to a larger and more formalized Board structure, and built a governing body marked by thoughtful leadership, diverse expertise, and a shared commitment to patients and providers. We've influenced policy, educated stakeholders, and advanced meaningful change by being on the record and at the table. None of this would have been possible without our exceptional staff and our member representatives who – above and beyond their "regular" jobs with the organizations they represent – work tirelessly on Alliance advocacy initiatives to protect and defend wound care in an increasingly complex policy environment.

The 10+ years of annual reports on the Alliance website reflect the breadth of our impact. In my mind, they also invite reflection on what might have occurred had the Alliance not been there to advocate on behalf of wound care. We would all be far more vulnerable to shortsighted policies and ill-informed regulations!

I leave my time with the Alliance immensely proud, profoundly grateful, and confident that the Alliance is well positioned for continued impact and success in the years ahead. It has truly been a privilege to serve and to work alongside so many dedicated leaders in a field we all care deeply about. I am honored and humbled to have contributed.

Dr. Matthew Garoufalis
Board Chair, Alliance of Wound Care Stakeholders



Year In Review: EXECUTIVE SUMMARY

2025 Advocacy Highlights

2025 Executive Summary

Amid significant changes to Medicare payment and coverage plus heightened federal scrutiny of wound care products, the Alliance advanced member priorities to shape policy, protect patient access, support clinical practice, and promote high-quality wound care.

-  **Supported separate payment for CTPs that removes access barriers in HOPDs.** Building on years of advocacy on past payment proposals, the Alliance submitted detailed recommendations that supported and informed CMS' new site-neutral, separate payment structure for CTPs included in both the CY 2026 Physician Fee Schedule and the Hospital Outpatient Prospective Payment System. Changes will reduce fraud/misuse, and decrease Medicare spend on this product category. With the unbundling and separate payment of CTPs driven by Alliance advocacy, hospital outpatient departments win since they will now be able to provide these products to patients with larger wounds.
-  **Supported implementation of clinically flexible, evidence-based CTP LCDs.** Throughout 2025, the Alliance reiterated support of the CTP local coverage determinations finalized in 2024 that our advocacy helped to shape -- policies that after prior release, withdrawal and reissuance now reflect a substantial amount of stakeholder feedback to preserve clinical flexibility, protect evidence-based use of CTPs, and provide a process for evidence submission to expand covered products. The Alliance alerted members to 2025 implementation delays and led programs to educate clinicians about implementation. While the LCDs were ultimately withdrawn in late-December just days prior to their implementation date, the Alliance still believes that LCD implementation is important for appropriate coverage of CTPs that have clinical evidence and to ensure that they are used appropriately.
-  **Sought improved national payment for blood-derived products.** Building on last year's success securing a national payment rate, the Alliance continued urging CMS to more appropriately capture complexity, clinician time and supply costs in upcoming rate updates. The Alliance conducted a clinician survey to quantify actual pre-, intra-, and post-procedure times, establishing realistic clinical work estimates and positioning the Alliance with data to seek updated rates in the CY 2027 rulemaking cycle.
-  **Launched advocacy to establish reimbursement for Point-of-Care Imaging (POCI).** The Alliance created a new POCI workgroup in 2025 in response to member interest in establishing better reimbursement and coverage pathways. We conducted clinician surveys to capture POCI technologies currently being used, codes billed and collected new evidence to challenge a non-coverage decision by Palmetto.
-  **Worked to resolve ongoing surgical dressing claims processing problems.** Alerted DMEPOS medical directors to persistent denials and coding inconsistencies, submitted real-world examples, and recommended solutions.

- 
Stopped flawed non-pressure ulcer cost measure from moving forward. The Alliance identified methodology flaws in CMS' proposed non-pressure ulcer cost measure and escalated concerns about its inability to fairly assess clinician spend and cost allocation. Due to the combination of the Alliance's feedback and the Alliance clinician workgroup members not supporting the measure the way it was written, CMS' advisory committee did not advance the measure. At this time, the measure is being rewritten with Alliance clinical member input.
- 
Paused FDA's proposed reclassification of antimicrobial dressings. Escalated concerns to the new FDA and OMB leadership, emphasizing patient access risks. Although scheduled to issue in October 2025, FDA has not issued the final rule — a meaningful regulatory pause that reflects the impact of advocacy.
- 
Responded to new federal priorities on deregulation and tariffs. Identified numerous opportunities to reduce regulatory burdens in wound care in comments to CMS, HHS and OMB on deregulation. Voiced public health risks associated tariffs on medical equipment and devices.
- 
Submitted 19 comments to regulators and legislators in 2025, elevating perspectives and recommendations from the wound care community in policy development.

2025 by the Numbers

19

Comments/letters submitted to policymakers

6

Webinars & online educational sessions for members

8

Presentations at conferences

3

Bills/legislation supported to improve wound care

44

Workgroup calls

13

New members

73

Total members





Advocacy Focus: PRODUCT ACCESS, PAYMENT & COVERAGE

Antimicrobial Wound Dressings
Autologous Blood-Derived Products
Lymphedema Compression Garments
Non-Pressure Ulcer: Cost Measure
Point of Care Imaging
Pressure Injury
Surgical Dressings
Therapeutic Shoes for Diabetics
Topical Oxygen Therapy
Total Contact Casting
A Closer Look: CTP Payment & Coverage

1 *Antimicrobial Wound Dressings*

The Alliance continued to pursue withdrawal of FDA's proposed reclassification of these products. In late-2023, the FDA Administration proposed rules that would categorize certain unclassified antimicrobial-containing wound dressings and liquid wound washes with "a high level of antimicrobial resistance (AMR) concern" as class III medical devices (requiring Premarket Approvals/PMAs), and those with a "medium or low level of AMR concern" as class II (with special controls/510(k) notices). These unclassified devices currently require premarket notification with 510(k) requirements. The new classification would, the Alliance believes, result in the unnecessary withdrawal of products from the market – and a likely secondary effect would be that clinicians turn to antibiotic pharmaceuticals in their place, exacerbating the very resistance problems that FDA is trying to address through the proposed regulation. The Alliance submitted detailed comments in 2024 and, with the early-2025 changes in Federal agency leadership, we elevated concerns directly to the new FDA Commissioner and OMB Director following their early 2025 confirmations. We also reiterated our rationale for withdrawal in comments to OMB as part of broader deregulation recommendations. Our FDA Regulatory Workgroup maintains active focus on this issue.

Key Takeaway

Although FDA had reported October 2025 as its target date for final rule publication, FDA did not finalize or publish the restrictive reclassification in 2025 - protecting access to these valuable products for patients with wounds and validating the impact of our advocacy.

2 *Autologous Blood-Derived Products*

Building on last year's success securing a national payment rate, the Alliance urged CMS to recognize and more appropriately capture complexity, clinician time and supply costs by updating the payment rate in future rulemaking cycles. The Alliance submitted detailed comments to the CY 2026 Physician Fee Schedule. We conducted an independent survey (created by JD Lymon Group) to quantify actual pre-, intra-, and post-procedure times, establishing realistic clinical work estimates to incorporate in our advocacy.

Key Takeaway

Our concerns and recommendations are formally on the record with CMS. Survey results will provide robust quantitative evidence of clinical work values. The Alliance is strategically positioned to advocate for increased rates in the upcoming CY 2027 rulemaking cycle.

3 *Lymphedema Compression Garments*

The Alliance maintained focus on the need for clinician reimbursement for measurement and fitting, illustrating to CMS the care delays that are resulting from current policies. We incorporated this issue in our deregulation recommendations submitted to the Department of Health and Human Services (HHS). We opposed CMS' CY 2026 Home Health Prospective Payment System proposal to revive the Competitive Bidding Program (CBP), requesting in submitted comments that lymphedema compression garments not be added should CMS in fact move ahead the CBP in 2026 or consider future expansions moving forward.

Key Takeaway

There were no changes made in CY 2026 rulemaking regarding clinician payment for measurement and fitting, but advocacy on this issue continues. Regarding the CBP, CMS did finalize expansion in 2026, but lymphedema compression garments were not included. Moving forward, the Alliance will continue advocacy to prevent these products from being added in future CBP updates.

4 *Non-Pressure Ulcers: Episode-Based Cost Measures*

The Alliance escalated methodology concerns that threatened the accuracy of the new episode-based cost measure that CMS is developing to inform clinicians of the cost of their beneficiary's care for which they are responsible and to allow for CMS to identify doctors whose spending on wound care patients is far outside the "norm" when compared to other wound care practitioners.

As the measure will be considered for use in the cost performance category of the Merit-based Incentive Payment System (MIPS), it is important for it to be based on fair, meaningful and correct criteria – as flaws and inaccuracies will result in negative consequences for wound care providers participating in MIPS. The Alliance raised substantive concerns to CMS about inaccuracies in the proposed episode-based cost measure for non-pressure ulcers, including flawed attribution methodologies and insufficient clinical data capture. Throughout 2025, we elevated concerns about the measure's inability to fairly and reliably assess clinician spending on wound care patients to CMS, its contractor Acumen and its panel of advisors on this topic.

Key Takeaway

SUCCESS! CMS' Pre-Rulemaking Measure Review Clinician Recommendation Group did not advance the non-pressure ulcer cost measure following the January 2025 meeting, citing many Alliance-raised issues. The measure will undergo additional testing and refinement before reconsideration. We secured enhanced participation by Alliance-aligned, wound care-informed clinicians in the measure-development workgroup to ensure that future iterations better reflect clinical reality.

5 *Point of Care Imaging (POCI)*

The Alliance launched a new POCI workgroup in 2025 to address member priorities surrounding enhanced coverage and reimbursement for this category of products. We conducted clinician surveys to document the POCI technologies being used, codes billed, and reimbursements received in real world practice, which will serve as important data for future advocacy conversations on reimbursement. We also collected new evidence to challenge a non-coverage decision by Palmetto. The Alliance urged CMS to include point-of-care wound imaging solutions in any future Software as a Service (SaaS) reimbursement framework, emphasizing that imaging tools assessing wound size, depth, physiology, and healing trajectory are currently underutilized due to lack of explicit reimbursement. We encouraged CMS to develop billing codes for image capture, interpretation, and care planning for approved wound care imaging tools.

Key Takeaway

The Alliance established a strong foundation for future coverage and reimbursement, strengthened by newly consolidated evidence and increased member engagement. This groundwork positions the Alliance to lead advocacy as CMS evaluates new payment pathways and coverage options moving forward.

6 *Pressure Injury*

The Alliance submitted comments to the National Quality Forum (NQF)'s proposed updates to its Serious Reportable Events (SRE) List that expanded its list of 27 areas of serious reportable events to all healthcare settings, including SRE 15: "Patient Harm Associated with a Stage 3 Pressure Injury, Stage 4 Pressure Injury, or Deep Tissue Injury Acquired After Admission." In submitted comments, the Alliance recommended not only that SRE 15 not be expanded to other healthcare settings "since it is totally different and unique from others that are currently on the list" but also that it be removed from the list entirely, as pressure injuries can be a normal physiologic response to underlying comorbidities and should not be categorized alongside never events like wrong-site surgery. If the NQF is not willing to delete SRE 15 from the 2025 list, the Alliance recommended that NQF limit SRE 15 to only hospital/acute care settings and eliminate ambulatory/outpatient, post-hospital/subacute and home care.

Key Takeaway

The NQF's update to the SRE list remains pending at annual report publication. The Alliance continues active monitoring and engagement to prevent pressure injury from being considered a "serious reportable event" across all healthcare settings.

7 *Surgical Dressings*

Despite claims processing improvements achieved last year, technical claims processing challenges persisted into 2025. The Alliance informed DMEMAC medical directors and sought fixes to resolve issues such as denial of full orders when only one component is non-covered; modifier A1-A9 processing errors; frequency of change discrepancies between clinical need and LCD allowables; misinterpretation of collagen clinical usage; and more. The Alliance elevated the need for action by requesting meeting with DMEMAC medical directors, now scheduled for 2026.

Key Takeaway

Ongoing advocacy and meetings scheduled with the DMEMAC medical directors will provide the opportunity for implementation of our recommendations to fix the ongoing claims processing issues.

8 *Therapeutic Shoes for Patients with Diabetes*

The Alliance advocated that CMS eliminate the dated and burdensome co-signing requirements in Medicare's Therapeutic Shoe Program for Patients with Diabetes that delay timely access. We supported AANP and APMA initiatives by including recommendation in Alliance comments on deregulation, Physician Fee Schedule, and OPDS to permit podiatrists, nurse practitioners, and other qualified providers to prescribe medically necessary therapeutic shoes without physician co-signature requirements. Additionally, we emphasized that this change would eliminate care delays, improve patient outcomes, and support amputation prevention.

Key Takeaway

While CMS did not make policy updates, the Promoting Access to Diabetic Shoes Act (H.R. 1616/S. 1805) on Capitol Hill maintains political attention on this issue. The Alliance signed on to a letter in support of this legislation. The Alliance continues monitoring and advocacy efforts.

9 *Topical Oxygen Therapy (TOT)*

As part of our advocacy to secure a positive coverage decision for TOT in diabetic foot ulcers, the Alliance convened two strategic meetings in early 2025 - one with DMEMAC medical directors and one with CMS coverage staff. We requested a positive decision for TOT to be added to the Oxygen and Oxygen Equipment Local Coverage Determination based on new clinical evidence, raised concerns with conclusions from the 2024 Contractor Advisory Committee (CAC) meeting, and discussed pathways for coverage.

Key Takeaway

Dialogue with CMS and the DMEMAC medical directors remains ongoing as the Alliance continues pressing for publication of a positive coverage decision for TOT.

10 *Total Contact Casting (TCC)*

The Alliance urged CMS to correct National Correct Coding Initiative (NCCI) policies that prevent hospital outpatient departments from receiving separate payment for total contact casting when performed on the same day as debridement or application of a CTP – an issue the Alliance has been raising to CMS since 2021. We flagged the issue again in our 2025 OPPS comments as well as in our deregulation recommendations submitted to CMS, the Department of Health and Human Services and the White House Office of Management and Budget.

Key Takeaway

Changes were not made in CY 2026 rulemaking, despite years of advocacy. The Alliance remains persistent in advancing this issue and encouraging policymakers to implement policy fixes.

A Closer Look: CTPs

2025 brought some of the most significant payment and coverage policy shifts in the history of CTPs.

CTP Payment: Background

Evolution of “New” CTP Payment Approach: Background & Context

The seismic changes in the “new” payment provisions for cellular and tissue-based products for wounds (CTPs, also known as skin substitutes) in the CY 2026 Medicare Physician Fee Schedule and Hospital Outpatient Prospective Payment System are in fact an outcome of many years of CMS attention on payment reform and recognition of the massive and unsustainable spend for CTPs. Many of the changes in the hospital outpatient rule were a direct result of sustained Alliance advocacy as payment proposals evolved, were withdrawn, resurfaced, and intensified under growing regulatory scrutiny. Viewed in context, the seismic policy changes finalized in 2025 are the outgrowth of a range of factors:

2025 CTP Payment Reform: How We Got Here

1 A decade of access challenges in the outpatient setting stemming from bundled payment put in place.

- **CY 2014:** CMS implemented bundled payment in OPPTS.

2 CMS repeated attempts to solve inconsistent CTP payment across sites of care.

- **CY 2023:** CMS proposed packaging payment into the practice expense (this provision was withdrawn from the final rule due to vocal opposition and advocacy led by the Alliance).
- **CY 2024 & 2025:** CMS stated its intention to propose a future payment overhaul and solicited feedback on the “incident-to supplies” model.
- **CY 2026:** CMS proposed and finalized site neutral single payment for the hospital outpatient and physician office and finalized the “incident to supplies” model in the physician office.

3 Increasing federal scrutiny of Medicare expenditures and fraud focused on CTPs/skin substitutes.

- **2023** HHS Office of Inspector General report highlighted “significant gaps” in manufacturer compliance with ASP reporting requirements, leading to millions of dollars in excessive payments. The OIG encouraged a “systemic solution.”
- **2025** Justice Department “Health Care Fraud Takedown” included \$1.1B in fraudulent CTP claims.
- **2025** OIG report on skyrocketing CTP spending that rose from \$250M (2019) to \$10B (2024). The OIG called for “urgently needed action” and payment reforms “that address fraud, waste, and abuse in skin substitute billing.”

2025 Alliance Advocacy on CTP Payment

Throughout 2025, Alliance advocacy helped ensure reforms balanced CMS' goals of curbing fraud and reducing inappropriate spending, while still protecting appropriate patient care and innovation of evidence-based products. Theoretically, the revised payment rates together with the single, separate, site neutral payment methodology would have brought consistency and predictability to reimbursement across physicians' offices, mobile clinics and hospital outpatient settings. Treatment decisions would have been made based on patient need rather than site of service payment policies. However, CMS included a geographic adjustment for CTPs in the Physician Fee Schedule final rule. The Alliance has concerns about this since it will create discrepancies in payment for rural versus urban physician practices: reimbursement will be higher for CTPs when provided in physician offices in urban areas and lower in rural areas. This will negatively impact patient access in rural areas and is inconsistent with the single, site neutral payment that CMS claims it achieved.

The Alliance advocated on these issues in our comments to the CY 2026 OPSS and Physician Fee Schedule:

- Supported CMS initiatives to combat fraud, waste and abuse; address the excessive spend.
- Submitted detailed recommendations to the proposed CY 2026 OPSS and PFS supporting site-neutral separate payment, seeking appropriate payment rates, while at the same time disagreeing with "incident-to supplies" categorization.
- Conducted extensive analysis of proposed payment rate, sought clarity/transparency, and forwarded alternative rate recommendation.
- Emphasized CMS' Advisory Panel on Hospital Outpatient Payment endorsement of Alliance-proposed reforms.

Advocacy Win: CTP Payment in HOPD Setting

Over the years, the Alliance has been the leading voice and expert resource to CMS as the Agency considered multiple reforms to its approach and methodology for CTP payment in the hospital outpatient department (HOPD) setting. Our persistent advocacy included presenting multiple times over the past few years to CMS' Advisory Panel on Hospital Outpatient Payment, which endorsed and elevated the Alliance's recommendations to CMS. Our concerns about access barriers to CTPs in the HOPD and our policy fix recommendations have also been a key focus of the Alliance's submitted comments to CMS' proposed HOPPS rules. It finally took until 2025 when success occurred: CMS finally addressed many of these concerns and adopted many of our recommendations after years of tenacious advocacy. (See details on the CY 2026 HOPPS final rule on p.18.)

CTP Payment Reforms: Outcomes, Impacts and Next Steps

■ Payment Provisions in Final CY 2026 Fee Schedule and OPPS Rules

- Separate "incident-to supplies" payment across sites of care.
- 2026 single payment rate of \$127.14 per cm² (increase from \$125.38/cm² in draft rule); Future 3-tiered payment categories tied to FDA regulatory status.
- Retention of ASP + 6% for evidence-supported BLA products.

Alliance Perspective

The Alliance believes that these reforms balance CMS' goals of curbing fraud and reducing inappropriate spending, while still protecting legitimate patient care and innovation of evidence-based products.

■ Separate Payment - Enhanced Access to CTPs in HOPD Setting

The return to separate payment in hospital outpatient departments is expected to enhance Medicare beneficiaries' access to CTP treatment there, reversing the current trend of referrals to other settings due to reimbursement challenges under the bundled payment system.

- HOPDs will once again be able to use CTPs to treat wounds larger than 25 cm² as they will be separately paid for the service and the product used, rather than needing to absorb cost under the bundled payment system or refer patients out.
- HOPDs will now be paid consistently for use of CTPs on wounds of the same size across all anatomic locations, rather than reimbursed differently for foot wounds vs. leg wounds.

Alliance Perspective

These are policy fixes that have been persistently advocated by the Alliance to remove barriers to equitable CTP access in HOPDs. With the unbundling and shift to separate payment, Medicare beneficiaries will have improved access to CTPs in HOPDs regardless of the size or location of their wound.

A Look Ahead

This area remains a priority area of Alliance advocacy focus. 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. We will also address the geographic adjustment (which we do not support) as it will impact CTP access in rural areas when provided in a physician's office. The Alliance will remain a go-to resource and vocal advocate for the wound care community on these issues.

Seismic changes to coverage of CTPs for diabetic foot ulcer and venous leg ulcer were made in "future effective" Local Coverage Determinations from each Medicare Administrative Contractor (MAC) that were finalized and published in November 2024 and scheduled for implementation in February 2025. That February implementation date was then delayed to April 2025 under the new Administration's pause order, then to January 1, 2026, to enable submission of additional evidence for coverage consideration, then withdrawn."

Advocacy and Education

While awaiting the evolving implementation date, the Alliance placed focus in 2025 on supporting the policies amid well-endowed lobbying efforts to have them withdrawn, and on education to prepare Alliance members – and the clinician community at large – for implementation and the documentation and product selection changes to be required. The Alliance offered multiple educational programs, webinars, and Q&A with policymakers and MAC medical directors to help clinicians prepare for the complexities of implementation (see "Education" section).

Current Status

Although CMS specifically referenced in the final CY 2026 Medicare Physician Fee Schedule and Hospital Outpatient PPS rules released in November 2025, and then confirmed the January 2026 implementation in a December 15th guidance that summarized several product status and evidence submission process updates to the LCDs, the LCDs were surprisingly withdrawn by CMS on December 24th, just days before their scheduled implementation date. As a result, coverage for skin substitutes continues under prior existing policies, which vary by MAC jurisdiction.

A Look Ahead

The Alliance will remain in dialogue with the MACs and CMS as coverage policies for CTPs are reconsidered amid the new payment reforms to be put in place. The Alliance will continue working as a resource to our members and a sounding board to the MACs and CMS as policies are reconsidered. We will actively monitor how policy reforms affect real-world access, so that together we can identify challenges and recommend solutions. Our priority is and remains ensuring that Medicare beneficiaries with chronic wounds maintain access to high-quality, evidence-based care.



Advocacy Focus:
**MEDICARE
EFFICIENCY,
TRANSPARENCY
& DEREGULATION**

The Alliance works to ensure Medicare policies and programs are efficient, transparent, and grounded in clinical evidence.

Advancing Wound Care Priorities in Medicare Policies

In 2025, we advanced numerous policy initiatives to protect patient access, reduce administrative burden, and promote evidence-based decision-making across federal programs.

Competitive Bidding Program (CBP)

The Alliance opposed CMS' proposal to revive the CBP in our comments to the CY 2026 Home Health PPS rule. We supported the Wound, Ostomy, and Continence Nurses Society's (WOCN) opposition to inclusion of ostomy supplies in any CBP expansion that may be put in place. Despite broad stakeholder objections, CMS finalized the CBP expansion in the CY 2026 Home Health rule and added ostomy supplies. Alliance advocacy on this issue continues.

Real-World Evidence

In comments to CMS' proposed guidance "Study Protocols That Use Real-World Data (RWD)," the Alliance supported CMS' effort to expand the use of RWD and real-world evidence (RWE) in Medicare coverage. We recommended that use of RWD for RWE be extended to all coverage determinations, such as LCDs, and not just to the national coverage determination coverage with evidence development process as proposed.

Data Availability & Health Technology Ecosystem

The Alliance urged expanded reimbursement for tools that improve efficiency, such as remote patient monitoring, point-of-care imaging, automated coding, and voice-enabled documentation in comments to CMS' Request for Information (RFI) on digital health and the broader technology ecosystem. We emphasized that while these technologies reduce administrative burden and enhance care, many lack payment pathways – which limits adoption.

Peripheral Artery Disease (PAD) Screening

The Alliance joined national cardiovascular and diabetes organizations on a co-signed letter urging CMS to establish a National Coverage Determination for PAD screening and follow-up testing for high-risk Medicare beneficiaries to mitigate health disparities and prevent avoidable amputations.

Medicare Managed Care

The Alliance supported prior authorization reforms but emphasized in submitted comments that only when Medicare Advantage organizations are held accountable will the changes in the Medicare Managed Care proposed rule be a success.

Deregulation

(See next page)

Leveraging Deregulation Opportunities to Improve Wound Care

As part of the President's priority to reduce private expenditures required to comply with Federal regulations, the Department of Health and Human Services (HHS), the White House Office of Management and Budget (OMB), and CMS each issued requests for information (RFIs) seeking deregulation recommendations and regulatory relief opportunities. These RFIs prompted the Alliance to submit recommendations to a range of government agencies as part of our effort to leverage the Administration's deregulation priorities to reduce burdens in wound care:

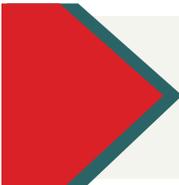
The Alliance submitted wound care focused responses to a range of federal agency RFIs:

CMS	HHS	OMB	Commerce	FDA
"Unleashing Prosperity Through Deregulation of the Medicare Program" "Health Technology Ecosystem"	"Ensuring Lawful Regulation and Unleashing Innovation to Make American Healthy Again"	"Deregulation"	"Section 232 National Security Investigation of Imports of PPE, Medical Consumables, & Medical Equipment, Including Devices"	"Measuring & Evaluating Artificial Intelligence-enabled Medical Device Performance in the Real-World"

Alliance Deregulation Recommendations:

The Alliance's specific deregulation recommendations included but not limited to the following:

- Withdraw FDA's proposed reclassification of antimicrobial wound dressings
- Fix problematic payment provisions for CTPs in the Hospital Outpatient PPS
- Revise Coverage With Evidence Development processes and Transitional Coverage for Emerging Technologies pathways
- Correct problematic NCCI edits impacting Total Contact Casting
- Adjust lymphedema compression garment coverage policies to enable payment for clinicians to measure and fit patients
- Update the 2006 "Chronic Cutaneous Ulcers and Burn Wounds - Developing Products for Treatment"
- Issue enforceable guidance to Medicare Advantage Programs requiring that their coverage and documentation requirements align with, and are no more restrictive than, those established under Medicare Fee-for-Service.



Tariffs: The Alliance also flagged public health impact concerns in its response to the Department of Commerce's request for public comment on its "Section 232 National Security Investigation of Imports of Personal Protective Equipment, Medical Consumables, and Medical Equipment, Including Devices," which opened the door to tariffs on medical devices.



Advocacy Focus:
**LEGISLATION &
CONGRESSIONAL
ACTION**

The Alliance connects policy and practice with educational advocacy to ensure that members of Congress and their staff understand how legislative proposals translate into real-world consequences for wound care delivery and patient access.

Supporting Legislation That Protects Wound Care

Alliance advocacy on Capitol Hill urged legislators to:

Safeguard Physician Payment & Stabilize the Wound Care Workforce

The Alliance joined with 100+ healthcare provider organizations in a co-signed letter urging Congress to take immediate action to reverse the current 2.8% Medicare Physician Fee Schedule Conversion Factor reduction, provide clinicians with a positive payment update in 2025 appropriations bills, and support the bipartisan Medicare Patient Access and Practice Stabilization Act.

Reduce Preventable Amputations & Advance Early Detection Policies

We met with Members of Congress in support of the Amputation Reduction and Compassion Act to expand Medicare and Medicaid coverage of peripheral artery disease screening, thus reducing preventable amputations.

Support the CTP LCD

The Alliance submitted a letter to select Members of Congress in support of the CTP LCD being implemented.

Protect Patient Access During Federal Funding Disruptions

The Alliance co-signed a multi-organization letter urging Congress to restore funding for essential programs during the government shutdown to protect vulnerable populations and stabilize community health supports.

Modernize Podiatric Scope of Practice (Massachusetts)

Submitted a letter of support for Massachusetts State House bill "An Act Relative to the Definition of Podiatry," that would modernize the state's podiatric scope of practice law to allow podiatrists to treat the foot, ankle, and lower leg.



Snapshot: COMMENTS SUBMITTED

The Alliance's consistent submission of formal comments is a core advocacy tool that ensures our perspectives inform policy development today while also establishing an enduring, on-the-record foundation for sustained advocacy influence moving forward.

Snapshot: 2025 Comments Submitted

Shaping Policy with Wound Care Insights, Impacts & Recommendations

CMS

- Comments to Medicare Managed Care proposed rule on changes for contract year 2026 (Jan)
- Cosigned letter to CMS requesting a NCD for peripheral artery disease (March)
- Comments to CMS Proposed Guidance on Study Protocols That Use Real-World Data (March)
- Response to CMS Request for Information; Health Technology Ecosystem (June)
- Comments to Proposed 2026 Home Health Prospective Payment System Update (Aug.)
- Comments to Proposed 2026 Hospital Outpatient Prospective Payment System Update (Sept.)
- Comments to Proposed 2026 Medicare Physician Fee Schedule Update (Sept.)

CMS Contractors

- Letter to DMEMACs on Ongoing Surgical Dressings Claims Processing Challenges (Oct.)

Food & Drug Administration

- Letter to FDA Urging Withdrawal of Proposed Reclassification of Antimicrobial Wound Dressings (April)
- Comments to FDA on Evaluating Performance of AI-Enabled Medical Devices (Nov.)

White House Office of Management and Budget (OMB)

- Letter to OMB Urging Withdrawal of Proposed Reclassification of Antimicrobial Wound Dressings (April)
- Recommendations to OMB in Response to RFI Seeking Opportunities for Deregulation (May)

Department of Health & Human Services (HHS)

- Recommendations on Deregulation Opportunities Submitted to HHS (July)

Department of Commerce

- Comments to Section 232 National Security Investigation on Medical Imports (Oct.)

National Quality Forum

- Comments to National Quality Forum's 2025 Serious Reportable Events List Update (July)

Congress & Legislatures

- Cosigned Letter to Congress Urging Action to Avert Cuts to Medicare Physician Payment (Feb.)
- Letter to Congress on Future Effective CTP LCDs (March)
- Letter to Massachusetts State House Supporting Legislation to Modernize Podiatric Scope of Practice Law & Expand Access to Care (July)
- Letter to Congress to Resolve Funding Impasse & Restore Access to Vital Health Programs (Nov.)

AT A GLANCE

Delivering Wound Care Expertise to Regulators and Policymakers

19

Comments submitted in 2025

8

to CMS & CMS Contractors

2

to FDA

2

to OMB

1

to HHS

1

to Commerce Department

1

to NQF

4

to Congress

Alliance in Action Photo Gallery

Our Members Power Our Mission





EDUCATION & RESEARCH

The Alliance's educational programs aim to equip members with a clear understanding of policy issues and implementation pathways, supporting effective adoption and compliance across clinical and business settings.

Translating Policy into Practice

At the Alliance, we don't just work to change policy; we help members implement it. The Alliance provided unique engagement with regulators and created educational opportunities in 2025.

Q&A with Regulators: Cigna Government Services

We created the opportunity for our members to speak with CGS's medical director Dr. Meredith Loveless in January as part of a Zoom Q&A focused on the final CTP LCDs.

Q&A with Regulators: First Coast Service Options

FCSO's medical director Dr. Anitra Graves provided insights to members on MAC policy development processes and evolving opportunities for enhanced inclusion of real-world evidence at the Alliance business meeting at the Spring SAWC.

Q&A with Regulators: Audits & Appeals

We hosted two former HHS Office of Inspector General senior counsels - David Traskey (Garfunkel Wild) and Shannon DeBra (Epstein Becker Green) - who presented "What to Do When the Government Calls: Preparing for and Responding to Audits and Appeals" at the Alliance business meeting at the Fall SAWC.

Webinar: Implement 2025 Medicare Final Rules

We collaborated with HMP Global on a webinar series to aid providers' understanding of relevant 2025 Medicare policy updates and share real-world implementation experiences, challenges and tips

Webinar: Tips for Implementing the CTP LCD

With HMP Global, we educated clinicians about the seismic changes to CTP utilization, documentation, coding, and billing under the final, future effective local coverage decisions.

**Webinar:
Comply with LCDs and
Be Audit Ready**

With HMP Global, we shared some typical challenges and solutions to implement and comply with payer documentation requirements; discussed importance of conducting internal audits to prepare for external audits.

**Publication:
Payer Insights
from Wound Care
Evidence Summit™**

We published “Payers’ Perspectives on Wound Care Coverage Policy Determination: What We Know and Ways to Move Forward” in **Wounds** (February), highlighting payer insights that emerged from the Alliance’s 2022 Wound Care Evidence Summit™.

IN PARTNERSHIP WITH **WOUNDS** **WOUNDSOURCE** **ALLIANCE OF WOUND CARE STAKEHOLDERS**

**Ready! Set! Go!
Implement 2025 Medicare
Final Payment Rules**

**Physician Fee Schedule, Hospital
Outpatient & Home Health**

– Webinar –
February 12, 2025

Karen Ravitz, JD
Health Policy Advisor
Alliance of Wound Care Stakeholders

Kathleen D. Schaum, MS
President
Kathleen D. Schaum and Associates

**Wound Care Centers and Teams:
How to Address the Growing Need with
Shrinking Support**

Moderator and Speaker: Dr. Kumar Madassery
Speakers: Kara Couch, Dr. Matthew Garoufalos, Dr. Nicolas Mo

Developed in collaboration with the Alliance for Wound Care Stakeholders

#SAWCSpringWHS

WOUNDS

PROCEEDINGS

Payers’ Perspectives on Wound Care Coverage Policy Determination: What We Know and Ways to Move Forward

Marissa J. Carter, PhD; Marcia Nugent, MPH; and Winifred Hayes, PhD

ABSTRACT
Many coverage challenges in wound care stem from a lack of shared clarity among researchers, manufacturers, payers, and regulators about the clinical evidence payers need to make positive coverage determinations. The Alliance of Wound Care Stakeholders, a multidisciplinary trade association, convened its Wound Care Evidence Summit in May 2022 to explore this issue and identify shared challenges and solutions with a diverse range of policymakers, payers, and researchers. This article focuses on payers’ clinical evidence requirements and the processes used when making coverage determinations, as discussed at the Summit. The authors explore the role of alternative sources of evidence beyond randomized clinical trials that were raised in the discussions: clinical practice guidelines, health technology assessments, and clinical consensus. The article reviews discussions around the use of these in coverage decisions and explores potential solutions to achieve evidence-based practice and coverage policies that meet the needs of all patients with chronic wounds.

The path to gain regulatory approval from the US FDA is separate and distinct from the process for gaining coverage and reimbursement by Medicare and private payers. Evidence of efficacy and safety—which for the most part is the bar that must be cleared to satisfy the FDA for market access—does not necessarily translate into coverage and reimbursement by payers, including Medicare. Payers look to the quality of the evidence and the bar of “reasonable and necessary,” as well as whether a product is better than the existing standard of care and should be covered.



MEMBERSHIP, WORKGROUPS & BOARD

At the intersection of government, health policy & wound care, Alliance members have a seat at the table.

2025 Membership

In 2025, the Alliance added 13 new members (in red) and closed the year with 73 members total.

Clinical Association Members

Academy of Nutrition and Dietetics
American Association of Nurse Practitioners
American Board of Wound Medicine & Surgery
American College of Clinical Wound Specialists
American College of Foot & Ankle Surgeons
American Diabetes Association® Amputation Prevention Alliance
American Limb Preservation Society
American Physical Therapy Association
American Podiatric Medical Association
American Society of Plastic Surgeons

American Venous Forum
Amputee Coalition
Association for the Advancement of Wound Care
National Pressure Injury Advisory Panel
Post Acute Wound & Skin Integrity Council
Society for Vascular Medicine
Society for Vascular Nursing
Society for Vascular Surgery
Undersea & Hyperbaric Medical Society
Wound, Ostomy and Continence Nurses Society
Wound Healing Society

Non-Clinical Association Members

ABWM Foundation
Coalition of Wound Care Stakeholders

Business Entity Members

Acera Surgical
Advanced Oxygen Therapy
Asclepii
Bio Compression Systems
BioXtek
BioTissue
Clara Care
Curitec
ETS Wound Care
Flen Health

Gentell
Healogics
Integra LifeSciences
Kerecis
LifeNet Health
MIMEDX
MIMOSA Diagnostics
Modulim
NATROX Wound Care
Open Wound Research

Organogenesis
Prism Medical Products
Reapplix
RedDress Medical
RegenLab USA
Smith & Nephew
Solventum
Tissue Health Plus
Urgo Medical North America

Provider Entity Members (Provider Groups and Wound Clinics)

Advanced Wound Therapy
Bayhealth Wound Care
Indiana Foot & Ankle
Old Mission Wound Care
Omni Wound Physicians
Parkview Physicians Group

Personic Health
Practitioners in Motion
Renovo Wound and Hyperbarics
TenMed Wound and Hyperbarics
United Wound Healing
United Woundcare Institute

The Wound Pros
Wound Care & Hyperbaric Center -
Piedmont Atlanta
WoundFit
Wyoming Wound Care

Professional Services Firms (Associate Members)

The Frank and Lizzie Show
Kathleen D. Schaum & Assoc.
MedTech Solutions Group

Shoreline Medical Administration
SmartTRAK



Workgroups

As problematic coding, coverage and payment policy issues have continued to impact access, and as our role as a united and respected voice for wound care has become increasingly critical, our areas of focus, membership, Board of Directors and Alliance Workgroups have all grown too.

To proactively respond to the evolving needs of members and the growing range of emerging issues impacting wound care coding, coverage and payment, the Alliance has a range of workgroups enabling solution building around shared areas of concern. Participants play a critical role in identifying shared concerns and shaping action plans, policy recommendations and Alliance comments to policies.



Cellular and Tissue-based Products (CTPs)



Surgical Dressings



Topical Oxygen



Blood-Derived Products



Lymphedema



Point of Care Imaging



Government Affairs



FDA Regulatory

Collaborations:

The Alliance participated in a number of collaborations to expand our network of aligned stakeholders and create new opportunities to develop solutions together to address problematic health policies:

AdvaMed

AA Homecare Medical Supplies Council

CAC Engagement/MAC Workgroup

Clinical Labor Coalition

Lymphedema Advocacy Group

Medical Device Manufacturers Association

National Alliance for Care at Home

National Association of Accountable Care Organizations

PAD Working Group

US Medical Compression Alliance

Wound Care Collaborative Community

Wound Healing Foundation

Board of Directors *(as of November 2025)*



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Alliance Board of Directors



Alliance Staff



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ABOUT THE ALLIANCE

Together, we collaborate, educate and advocate to influence policy and ensure an appropriate and fair regulatory and legislative environment that supports quality wound care, evidence-based clinical practice and innovation in wound care.

The Value of Membership

At the Intersection of Government, Health Policy & Wound Care, We Have a Seat at the Table.

Since its founding in 2002, the Alliance of Wound Care Stakeholders has served as the unified advocacy voice for the wound care community on regulatory and legislative policy issues. We elevate the visibility and influence of wound care by uniquely enabling the multi-disciplinary wound care community to collectively and collaboratively engage on issues of commonality, elevating the visibility and united voice of wound care to regulators and policy makers.

Our Mission

Be the unified and respected voice for the wound care community to ensure access to quality care for all patients with chronic wounds.

Our Focus

Advocate on policy issues that create barriers to patient access to necessary treatments or care, with a focus on coding, coverage and payment policies, quality measures and wound care research.

Our Members

The Alliance is a 501(c)(6) multidisciplinary association of physician specialty societies, clinical and patient associations, wound care provider groups, wound clinics, and business entities working collaboratively with CMS, FDA, and other federal agencies to inform policy, educate policymakers, ensure quality care, and protect access to products and services for patients with chronic wounds. As a united voice, we are stronger together to influence and shape policy change to create a regulatory and legislative environment that supports evidence-based clinical practice and innovation in wound care.



We know our voice is louder when we share it with our inter-professional colleagues—physicians, surgeons, nurses, podiatrists, manufacturers, clinics—when we are all saying the same thing, fighting together to get our patients the care that they need.

We know we are stronger when working together with the Alliance than apart.

— American Physical Therapy Association



ALLIANCE OF
**WOUND CARE
 STAKEHOLDERS**
 POWER THROUGH COLLECTIVE ADVOCACY



Together, We Advance Wound Care



woundcarestakeholders.org
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