

# ADVOCACY AND REGULATORY AFFAIRS IN LIMB SALVAGE AND WOUND HEALING

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*Diabetic Limb Salvage (DLS) Conference*  
*April 8, 2026*

# Objectives

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- What is advocacy?
- Who are the different groups that provide advocacy and to whom do they advocate?
- Why is advocacy important?
- What are the legislative and regulatory issues impacting limb salvage and wound healing?
- How to be an advocate.

# What Is Advocacy – Why Does It Matter?

*Advocacy is the organized effort to influence the policies, regulations, and systems that determine how care is delivered, covered, and reimbursed. In limb salvage and wound healing, the gap between what clinicians know works and what patients can access is almost entirely a policy gap. Advocacy utilizing evidence is what closes it.*

## Legislative

Working with Congress & state legislatures to introduce, support, or oppose bills. Hill visits, committee testimony, constituent outreach.

## Regulatory

Engaging CMS, FDA and OIG during formal rulemaking — public comments on OPPS rates, MPFS proposed rules, NCDs. FDA guidance documents and proposals that impact products and devices coming into the marketplace.

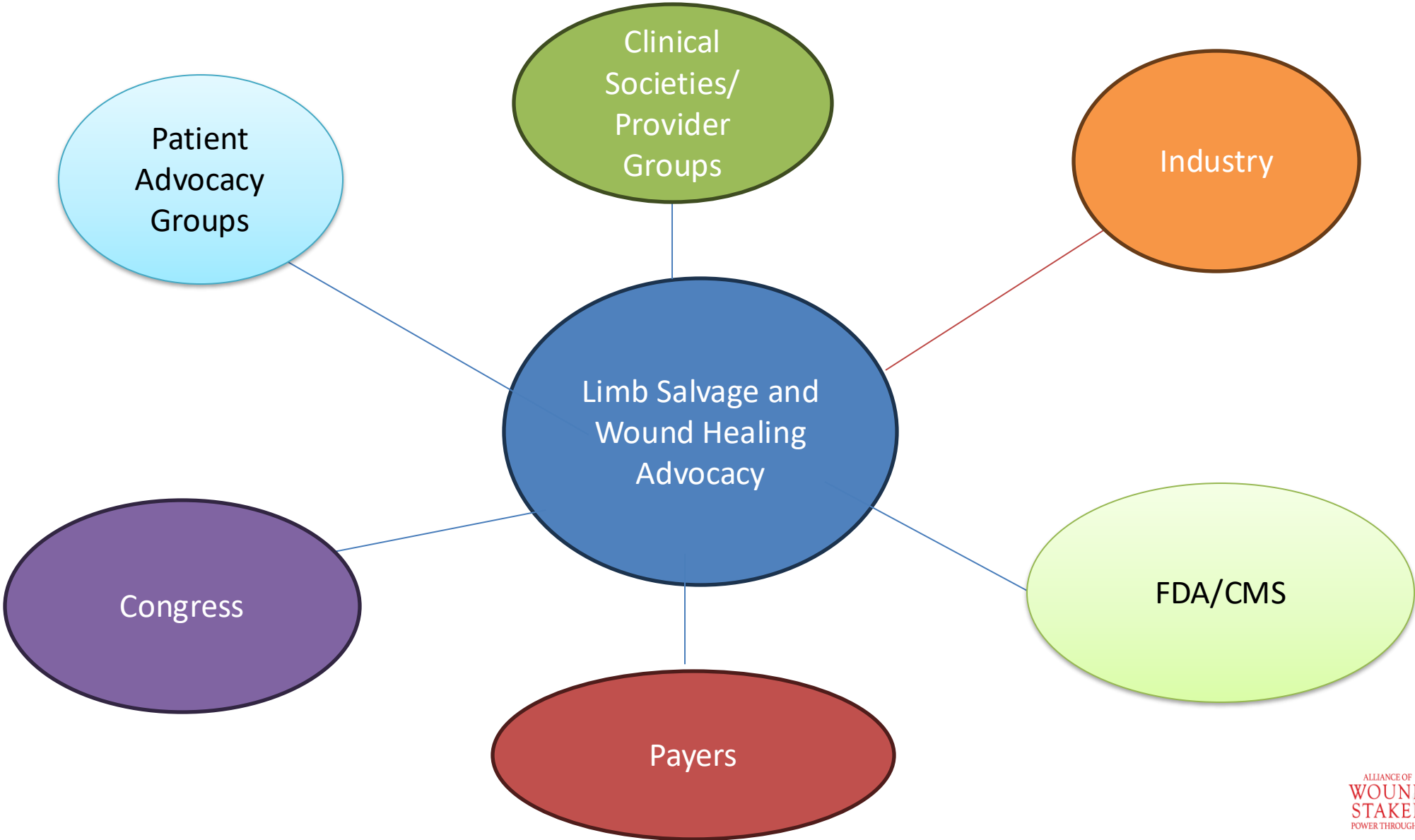
## Payers

Engaging CMS, Medicare Administrative Contractors, commercial insurers and Medicare Advantage plans through comments on local coverage determinations (LCDs), medical policy meetings, appeals, evidence submissions.

## Coalitions

Building unified networks across patients, clinicians, specialty societies and industry. Multi-org coalitions carry far greater credibility than any single voice.

# Key Stakeholders



# ABOUT THE ALLIANCE OF WOUND CARE STAKEHOLDERS

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

That is our focus.

**Our Mission** Be the **unified voice for the wound care community** to ensure access to quality care for **all patients with chronic wounds**.

**Our Approach** Unite wound care stakeholders on regulatory and legislative policy issues focused on **coding, coverage, payment, quality measures, and wound care research**.

- Collaborate, educate policymakers, and advocate policy positions.
- Bring clinical voice and evidence-based information to policy makers.
- Ensure our members have early, accurate information about emerging policy and regulatory changes so they know what to expect and the impact of those policies on their organization.

**Our Model** A **membership-based association** representing physician specialty societies, clinical and patient associations, non-clinical associations, wound care provider groups, wound care clinics, business/support business entities,& professional services firms.

# THE NEED FOR A UNIFIED AND RESPECTED WOUND CARE VOICE

## *WHY WAS THE CREATION OF THE ALLIANCE NECESSARY?*

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**Wound care is not a recognized medical specialty by the American Board of Medical Specialties.**

- Interdisciplinary practice: DPMs, MDs, DOs, PTs, OTs, RNs, NPs, PAs, and others. Each has their own clinician specialty associations, but wound care is but one of the numerous issues they focus on, and it is often a low priority.
- Multiple voices, but no united voice.

**Disparate messaging in advocacy leads to inaction or undesirable outcomes.**

- Need existed to create central organization to represent all voices across wound care.
- Created the **Alliance of Wound Care Stakeholders** in 2002 as a unique “association of associations” elevating a unified wound care voice in policy discussions.

# OUR ADVOCACY REACH IS EXTENSIVE

## UNIFIED WOUND CARE VOICE ON POLICIES, REGULATIONS, AND LEGISLATION:

- Capitol Hill health care legislation
- Coding issues, including HCPCS coding and CPT issue
- Coverage issues CMS/CMS contractor policies, local coverage determinations, and billing & coding articles
- FDA guidances
- Payment issues, including the annual Physician Fee Schedule and Prospective Payment Systems
- Quality measures
- Technology assessments

## PROTECTING A RANGE OF PRODUCT CATEGORIES:

- Surgical dressings including antimicrobial
- Blood-derived products (PRP)
- Cellular and/or Tissue-Based Products for Wounds (CTPs)
- Debridement services
- Topical oxygen and Hyperbaric oxygen therapy
- Negative pressure wound therapy
- Pneumatic compression devices & lymphedema compression treatment items
- Imaging and Diagnostic technologies

## ADDRESSING A RANGE OF THREATS TO WOUND CARE PRACTICE:

- Competitive bidding
- Lack of adequate reimbursement
- Medicare advantage plans
- HCPCS coding process
- Lack of transparency
- Prior authorization
- Perceived lack of wound care evidence
- Restrictive LCDs & Problematic Coverage Policies

## SUPPORT WOUND CARE RESEARCH:

- [“Better Wound Care Begins With Better Evidence: Outcomes of the Wound Care Evidence Summit”](#) (2024)
- [“An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds”](#) (2017)
- [“Harnessing Big Data for Wound Healing Research”](#) (2016 ISPOR)
- [“Consensus Principles for Wound Care Research Obtained Using a Delphi Process”](#) (2012)
- [“Payers’ Perspectives on Wound Care Coverage Policy Determinations”](#) (2025)

## SUPPORT QUALITY MEASURES

- Continued development of wound care-relevant QCDR measures

# Issues Impacting Limb Salvage and Wound Healing

## Legislative

- **ARC Act (H.R. 307):** mandate Medicare PAD screening + arterial testing before amputation
- **Seniors Deserve SMARTER Care Act (HR 5960):** block AI-driven WISeR prior authorization expansion
- **Improving Seniors' Timely Access to Care Act:** MA prior auth reform (enacted 2022)
- **Consolidated Appropriations Act, 2026 (HR7148),** includes critical directives to the Centers for Medicare & Medicaid Services (CMS), the Centers for Disease Control and Prevention (CDC), and the Health Resources and Services Administration (HRSA) to advance key Peripheral Artery Disease (PAD) programs

# Issues Impacting Limb Salvage and Wound Healing

## Legislative (cont.)

- **Medicare Advantage Prompt Pay Act (H.R. 5454 / S. 2879)** is bipartisan legislation introduced in 2025 to mandate faster payments from Medicare Advantage (MA) plans to healthcare providers, aiming to ensure 95% of clean claims are paid within 14 days (in-network) or 30 days (out-of-network).
- **Promoting Access to Diabetic Shoes Act (HR 1616 and S 1805)**, which would authorize nurse practitioners (NPs) to certify their Medicare patients' need for therapeutic shoes Diabetic Shoes
- **CTPs** – several bills introduced to increase the payment for CTPs
- **[H.R. 2005](#), DMEPOS Relief Act of 2025** - Competitive Bidding Legislation

# Issues Impacting Limb Salvage and Wound Healing

## Regulatory

- **2024 HBOT Outpatient Prospective Payment System Final Rule Rate Error:** Alliance of Wound Care Stakeholders forced retroactive correction of 40%+ cut (Feb 2024).
- **HBOT:** Possible Misvalued Code issue in 2026 rulemaking cycle for CY 2027.
- **Autologous Blood Derived Products (ABDP):** Alliance of Wound Care Stakeholders submits misvalued code application to CMS in order to increase the payment rate for ABDP.
- **CTPs** – Payment policy changes. OIG investigations.

# Issues Impacting Limb Salvage and Wound Healing

## Regulatory (cont.)

- **Wasteful and Inappropriate Service Reduction (WISeR)** – Prior Authorization for CTPs in 6 states (WA, AZ, TX, OK, OH, NJ).
- **OIG Investigation**– Peripheral Vascular Procedures in Office settings (W002435914).
- **Competitive Bidding**
- **Lymphedema**-Issues relating to Implementation of the Lymphedema Treatment Act
- **Point of Care Imaging (POCI)**

# Issues Impacting Limb Salvage and Wound Healing

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## Payers

- **Diabetic Shoes**
- **Topical Oxygen**
- **POCI**
- **CTPs** – possible coverage policy - Local Coverage Determination (LCD) vs. National Coverage Determination (NCD)

# Issues Impacting Limb Salvage and Wound Healing

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## Coalitions

- **Alliance of Wound Care Stakeholders:** leading multi-org coalition (APMA, AAWC, ACFAS, industry).
- **Congressional PAD Caucus:** bipartisan 35-member caucus co-founded by Reps. Payne & Bilirakis to raise awareness.
- **SCAI** leads advocacy efforts on the Hill with stakeholder groups and the PAD caucus.
- **DLS / DFCon conferences:** annual multidisciplinary forums bridging clinical evidence and policy audiences.
- **APMA** leads effort for increasing beneficiary access to medically necessary therapeutic shoes for persons with diabetes.

# EXAMPLE: IMPACT OF SUCCESSFUL ADVOCACY

## ISSUE:



In the final 2024 Hospital Outpatient Payment System (HOPPS) update, CMS - unexpectedly, and without explanation - implemented a significant reduction to the payment rate for HBOT with a 40% cut in the APC rate that could have ultimately resulted in site closures and limited patient access.



ALLIANCE  
ADVOCACY



## IMPACT:



Successfully mobilized CMS to make technical correction. The Agency re-issued a corrected HBOT payment rate in an update to the 2024 HOPPS.

*CMS expressed appreciation to the Alliance for quickly bringing the issue to their attention, which allowed for CMS to investigate and make corrections to their calculation error prior to the policy going into effect.*

# HOW CAN CLINICIANS ADVOCATE FOR CHANGE?

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## **Make Your Voice Heard:**

- Engage in formal rulemaking
- Join your physician specialty societies and clinical associations and become involved in advocacy committees
- Congressional and legislative engagement at the federal and state level
- Payer engagement

## **Additional Actions:**

- Generate and publish clinical evidence on limb salvage and wound healing
- Enlist your patients as advocates
- Be aware of laws, regulations and policies that impact your practice

# SHAPE POLICIES WITH A POWERFUL, TRUSTED, AND UNIFIED VOICE

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*What if there was no united voice for wound care to drive these policy changes and improvements?  
**Let's keep collaborating!***

Thank you for allowing us to introduce the Alliance and share the importance of wound care advocacy.

**Contact  
the  
Alliance**

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