



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



ANNUAL REPORT  
2021

*Providing a Collaborative, Unified Voice to Impact  
Wound Care Regulatory and Legislative Policies*

[woundcarestakeholders.com](http://woundcarestakeholders.com)

## LETTER FROM ALLIANCE LEADERSHIP



**MATTHEW GAROUFALIS, DPM**  
*Co-Chair*



**CAROLINE E. FIFE, MD**  
*Co-Chair*



**MARCIA NUSGART, RPh**  
*Executive Director*

After a year of challenge, change and opportunity, we offer a most important Thank You to our members on the front lines caring for patients while also carving out precious time from their already hectic schedules to participate on our calls, develop comments on regulatory changes, and support the Alliance's advocacy agenda. Your efforts led to the Alliance's astonishing successes in 2021, and for this, we are truly thankful.

The Alliance achieved great successes in many aspects of regulatory policy even amid this year's many challenges, which attests to the Alliance's **strength** and **agility**. This annual report reflects the depth of our membership collaboration, diligent advocacy, educational efforts, and extensive engagement with key government decision makers on behalf of the wound care community and its patients. You will see that in 2021 our unified voice was truly heard and heeded as we set the stage for our continued advocacy in 2022.

Collaboration is a core value of the Alliance, and we continued our mission of working with regulatory agencies, organizations and our member associations. Our executive summary lists our proud collaborations, including but not limited to: FDA staff, CMS contractors, Wound Care Collaborative Community, Clinical Labor Coalition and the Alliance for HCPCS Coding Reform. The creation of our new Government Affairs Work Group has allowed the Alliance to have additional new collaboration leading to a more prominent presence on Capitol Hill with the ability to support legislation of importance to wound care.

2021 brought exciting important changes to Alliance membership structure and addition of key personnel. The Alliance created three new membership categories in response to the need to have these voices heard within our association: (1) independently operated hospital wound care centers; (2) wound care business entity startups (having sales under \$1 million and in business for fewer than two years); and (3) wound care professional service firms. These are all important components of the wound care community. In the new year, we will value their insights, support and participation, in addition to our current members. We hired Kelly Coates and Laura Kearney as Membership Directors and welcomed Gail Mutnik, MPA as our new Chief Operating Officer.

In 2021, we also welcomed many important new members: Acera Surgical, Amniox Medical, Coloplast, Kerecis, Medline Solutions Group, NATROX Wound Care, National Pressure Injury Advisory Panel (NPIAP), Organogenesis and Sanara MedTech.

2022 will be an important year for the Alliance. We will celebrate our 20<sup>th</sup> Anniversary and look forward to seeing you on May 19-20 at our important Wound Care Evidence Summit™ where leaders and payers will answer the question, "How much and what type of clinical evidence do payers need to cover wound care products and services?"

Your participation helps us achieve our mission of advancing wound care and improving coverage, coding and payment issues which benefits the patients we serve. The Alliance would not be where we are today without your continued involvement, and we are honored to share some of our incredible accomplishments this year with you, outlined in our executive summary and in the attached report.

Sincerely,

Caroline E. Fife, MD, and Matthew G. Garoufalis, DPM, Co-Chairs,  
and Marcia Nusgart, RPh, Executive Director

# EXECUTIVE SUMMARY

*Providing a Collaborative, Unified Voice to Impact Wound Care Regulatory and Legislative Policies*

Shaping policy is an on-going, long-term and collaborative effort with repeated public and private meetings and calls with CMS and its contractors, FDA, and other decision makers. Based on input from our front-line clinicians and experts, we present at meetings, submit numerous public comments and other correspondence to educate and influence wound care policy. Alliance staff and members work together to improve coding, coverage and payment to best help clinicians better serve their patients.

## **Our impact in 2021 has been extensive.**

- **As a result of the Alliance’s tenacious advocacy we:**
  - ✓ Obtained a 9.6% increase for disposable negative pressure wound therapy (dNPWT) instead of a 22% reduction in the physician office setting.
  - ✓ Accomplished a National Correct Coding Initiative (NCCI) edit manual change allowing for debridement and compression to be provided on the same day.
  - ✓ Successfully convinced the Centers for Medicare and Medicaid Services (CMS) to retract the proposed 2021 Physicians Fee Schedule provision to bundle cellular and tissue-based products for wounds (CTPs, also known as skin substitutes) in the physician office setting.
  - ✓ Created language, which was accepted and used by CMS, for an MLN Newsletter article explaining why the new synthetic CPT “A” codes should be treated the same as all other CTPs, and how to correctly bill for them.
  - ✓ Obtained a unanimous recommendation from the Advisory Panel on Hospital Outpatient Payment to CMS, which prompted the Agency to begin reviewing recommendations for flawed CTP payment changes.
- **As the ultimate collaborative umbrella organization for wound care, the Alliance** continued to join forces with organizations and its members to impact change through the following efforts:
  - ✓ Collaborated with FDA staff to shape its agenda and speakers for its April 2022 wound healing workshop so it will be synergistic with the Alliance’s Evidence Summit.
  - ✓ Became a charter member and serve on the steering committee of the Wound Care Collaborative Community.
  - ✓ Actively participated with the Clinical Labor Coalition to impact change on the significant physician payment cuts.
  - ✓ Led the Alliance for HCPCS Coding Reform’s efforts to gain clarification from CMS on submitting new electronic HCPCS coding application and won more time for initial submission.
  - ✓ Partnered with a leading group of physicians to advocate to the DMEMACs for coverage of pneumatic compression devices to treat critical limb ischemia.
  - ✓ Spearheaded an ASTM workgroup to update CTP standard used by payers for terminology purposes.
  - ✓ Partnered with Alliance member associations to send letters of support on issues of importance to both organizations:
    - Academy of Nutrition and Dietetics to support Global Malnutrition Global Score.
    - American Podiatric Medical Association to update the Massachusetts Podiatry Act.

- ✓ Created a Government Affairs Work Group to partner with our member organizations that have dedicated government affairs staff on legislative issues impacting the wound care community. The Alliance has lent its name to several sign-on letters as well as directly submitted letters to support (or oppose) legislative wound care initiatives.

- **The Alliance shaped policy development as we:**

- ✓ **Vocally opposed payment cuts** in the proposed CY2022 Physician Fee Schedule by collaborating with the Clinical Labor Coalition and submitting comments to impact change. As a result, the pay cuts were minimized. We will continue to address this in 2022.
- ✓ **Championed CTP payment issues** by submitting hospital outpatient payment methodology recommendations to CMS.
- ✓ **Served as a resource to CMS contractor Noridian medical directors** as they developed their wound care LCD.
- ✓ **Called for transparency in CMS' and its contractors' implementation of the 21<sup>st</sup> Century Cures Act.**

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# 2021 ACTIVITIES AND ACHIEVEMENTS

Detailed activities available to members only.  
Please contact [membership@woundcarestakeholders.org](mailto:membership@woundcarestakeholders.org)