



ANNUAL REPORT 2020

ALLIANCE OF WOUND CARE STAKEHOLDERS
United Voice of the Wound Care Community

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



Letter from Alliance Leadership



**Caroline E. Fife, MD
Co-Chair**



**Matthew G. Garoufalis,
DPM, Co-Chair**



**Marcia Nusgart, RPh
Executive Director**

As we reflect back on 2020, 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 in our calls, develop comments on regulatory changes, and set and support the Alliance's advocacy agenda. Your efforts led to the Alliance's astonishing successes in 2020, and for this, we are truly thankful.

We are proud of the Alliance's many wins this year, including our nimble COVID-19 leadership. With member support and involvement, our timely advocacy helped wound care clinics continue to care for their patients during the crisis. Beyond COVID-19-related issues, we achieved great successes in other 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 2020 our unified voice was truly heard and heeded.

2021 brings new hope and its own challenges as we welcome a new President, Congress and administrative staff at CMS. Understanding what and how much scientific evidence payers need to cover wound care products and procedures will be top of mind next year as we plan our eagerly anticipated Wound Care Evidence Summit for 2022, when we expect that it will be safe for travel and in-person gatherings.

We are able to continue this important work only through the support of our generous members. We wish you all a safe and vaccinated year and look forward to seeing you face to face.

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

ALLIANCE ACCOMPLISHMENTS 2020

EXECUTIVE SUMMARY

Without precedent, 2020 was the most challenging year for American healthcare. Throughout, the Alliance of Wound Care Stakeholders tenaciously monitored and addressed COVID-19 as well as coverage coding and payment policies that might create barriers to wound patients' access to care. Our impact in 2020 has been extensive. Highlights include:

- The Alliance **led the wound care community's rapid response** to the COVID-19 Public Health Emergency (PHE).
 - ✓ We ensured that wound care was identified as "essential," enabling hospital administrators to keep wound care clinics open and providing care for their patients.
 - ✓ We advocated for and achieved regulatory relief and flexibilities to ensure that policies reflected the on-the-ground realities of wound care clinicians and manufacturers amid the pandemic.
- Our **tenacious advocacy** directly resulted in:
 - ✓ CMS' Durable Medical Equipment Medicare Administrative Contractors (DMEMACs) **issuing a surgical dressing policy article update expanding coverage** for alginate and fiber gelling dressings as both primary and secondary based on language the Alliance supplied for them.
 - ✓ The A/B MAC Palmetto **covering disposable negative pressure therapy (dNPWT)** in nursing facilities and paying at the Medicare physician non-facility rate.
- The Alliance shaped policy development as we:
 - ✓ **Spoke out against physician payment cuts** proposed in CMS' 2021 Physician Fee Schedule.
 - ✓ Submitted recommendations to CMS about **payment methodologies** for cellular and/or tissue-based products for skin wounds (CTPs).
 - ✓ **Spearheaded an effort to establish a distinct wound care subcategory** in the USP Medicare Model Guidelines.
 - ✓ **Identified and elevated HCPCS coding process issues** and procedural barriers to innovative technology in a virtual meeting with the CMS' new Technology Coding and Pricing Group
 - ✓ **Sought process consistency and enhanced transparency** of Medicare Administrative Contactor (CAC) meetings via a virtual meeting with the head of CMS' Coverage and Analysis group.
 - ✓ **Impacted clinical and procedural policies** through the diligent submission of comments about CMS policies (PHE regulatory flexibilities, Hospital Outpatient Payment System, Physician Fee Schedule, Medicare Coverage of Innovative Technology, LCDs (topical oxygen, CTPs, dNPWT), and Capitol Hill legislation (Cures 2.0). Overall, the Alliance submitted 17 sets of comments in 2020.
- **Lee C. Rogers, DPM**, co-founder of the Amputation Prevention Centers of America, joined our board of directors.
- **Created the Wound Care Evidence Summit that was postponed due to COVID-19 precautions.** It is designed to bring together payers, regulators, researchers, clinicians and industry to provide an understanding of what evidence payers require to cover wound care products and procedures. This Summit will be convened once it is safe to travel.

TABLE OF CONTENTS

I. Leadership During the COVID-19 Public Health Emergency	
A. Created Rapid Response & “Wound Care is Essential” Position Statement	p. 5
B. Advocated for Regulatory Flexibilities and Waivers to Protect Wound Care	p. 5
II. CMS & CMS Contractors Focused Advocacy Accomplishments	
A. CMS Policies and Regulations Advocacy	
1. Physician Fee Schedule	p. 7
2. Hospital Outpatient Prospective Payment System	p. 7
3. Additional Proposed Rules	p. 7
a. Medicare Coverage of Innovative Technology	
b. Securing Updated and Necessary Statutory Evaluations Timely	
4. Contractor Advisory Committee Consistency Issues	p. 8
5. HCPCS Coding Reforms	p. 8
6. Texas Medicaid	p. 8
B. CMS Contractors	
1. MAC Local Coverage Determinations and Policy Articles	p. 8
III. Advocacy to Capitol Hill, Government Agencies & Other Organizations	
A. Congressional Advocacy	p. 10
B. Government Accountability Office	p. 10
C. Food and Drug Administration	p. 10
D. United States Pharmacopeia (USP)	p. 10
E. ASTM	p. 11
IV. Alliance Wound Care Evidence Summit	p. 12
V. Product Category Advocacy Initiatives	
A. Cellular and/or Tissue-based Products for Skin Wounds	p. 13
B. Surgical Dressings	p. 15
C. Negative Pressure Wound Therapy: Traditional & Disposable	p. 16
VI. Visibility and Connection Building	
A. New Members in 2020	p. 17
B. Alliance in the Wound Care Trade Media	p. 17
VII. Appendix	p. 18

2020 ACTIVITIES AND ACHIEVEMENTS

Detailed activities available to members only.
Please contact membership@woundcaresakeholders.org.