



KEY 2016 ACCOMPLISHMENTS: EXECUTIVE SUMMARY

With the ongoing shifts in the U.S. healthcare landscape under a new Presidential administration, the unpredictable future of the Affordable Care Act, and the implementation of Medicare payment reform, having a voice in draft policies and regulations to represent a unified wound care perspective is of increasing importance. The Alliance's 2016 work focused not only on the regulatory guidances and local coverage determinations that we've always focused on, but also on the value-based care payment initiatives that are dramatically changing the U.S. healthcare delivery system. We identified and took advantage of multiple opportunities for **input, advocacy and comment**. We worked tirelessly to ensure that regulatory agencies were aware of the issues and impacts to wound care as policies were crafted and considered. Our comments put us "**on the record**," build **credibility** and **open doors** for ongoing advocacy and dialogue. Our visibility at key meetings and proactive conversations on targeted issues strategically continue to entrench the Alliance as an **effective communicator** on wound care issues and **key "go-to" resource** for government agencies and policy makers.

Key accomplishments in 2016 include:

- **Elevated visibility of wound care issues with a united, proactive wound care voice to CMS as it refined regulations guiding implementation of the Medicare Access and CHIP Reauthorization Act (MACRA)**, ensuring that the agency and its policy-makers heard and considered the impacts of the evolving value-based care/payment reform policies to wound care. The Alliance submitted comments to MACRA's "Quality Physician Payment Program," "Quality Measures Development Plan," "Patient Relationships Categories and Codes," and "Episode Groups" draft policies. Our comments put specific wound care issues "on the record" and set the stage for future advocacy activities. We will continue to advocate for inclusion of specific wound care quality measures within MACRA so that wound care clinicians will be able to utilize moving forward.
- **Demonstrated the clinical and economic expenditure impact of chronic wounds to CMS** by commissioning health consultants Dobson DaVanzo & Associates to perform an analysis of Medicare claims and payments. The data illustrated that expenditures for treating Medicare wound care patients are larger than recognized, results in a severe clinical burden and impaired quality of life for Medicare beneficiaries and are most likely underreported. The Alliance submitted findings directly to CMS (as part of MACRA comments) and is now seeking publication of the data in a medical journal.
- **Played an effective, impactful role educating the FDA and its Advisory Panel by providing the relevant information and perspective which allowed the Panel to vote to recommend to the FDA that antimicrobial wound dressings should be classified as "Class II (with special controls)," thus protecting access and availability of antimicrobial wound care dressings for patients and providers.**

Our activities regarding this important issue included:

- Submitted comments in advance of the meeting to provide relevant background information on wound care complexities.
- Mobilized a team of well-known and respected clinicians, scientists, wound care registry data experts, design and endpoints data experts, former FDA official, clinical associations, and manufacturers with FDA expertise to testify at the public meeting, with supportive/complementary messaging.
- Testified before the Advisory Panel during the public meeting.
- Coordinated with the Coalition of Wound Care Manufacturers to ensure a supportive message.
- Educated clinical associations about this issue which encouraged them to also submit comments (e.g., ACFAS, APWCA, WOCN, APTA, AAWC, APMA)
- Submitted post meeting follow-up comments reinforcing the Advisory Panel recommendations to classify antimicrobial wound dressings as a Class II with special controls.

- **Ensured wound care clinical community concerns were articulated to CMS by submitting comments to the Agency’s proposed rules for its CY 2017 Physician Fee Schedule and CY 2017 prospective payment systems (PPS) regulations on Hospital Outpatient Services PPS and Home Health PPS.**
- **Pursued accurate and clinically-sound local coverage determinations via our persistent advocacy with A/B MAC and DMEMAC medical directors** for fair and equitable LCDs and coverage processes. Advocacy in 2016 focused on LCDs addressing hyperbaric oxygen therapy and cellular and tissue-based products (CTPs) for wounds via submitted comments, speaking at public meetings and conversations with medical directors.
- **Built the Alliance’s reputation as a proactive, professional voice on wound care policy through the submission of 21 sets of comments in 2016.**
 - **6 to FDA** on Homologous Use of HCT/Ps, Minimal Manipulation of HCT/Ps, Classification of Antimicrobial Wound Care Products, Use of Real World Evidence.
 - **11 to CMS** on Hospital Outpatient PPS, Home Health PPS, MACRA, Physician Fee Schedule, Patient Relationship Classification, Appeals Process, Drug Payment Model, Quality Measurement Plan, MACRA Episode Groups, Contractor Reform, Quality Physician Payment Programs.
 - **3 to CMS contractors** on HBOT, CTPs, Pneumatic Compression.
 - **1 to ARHQ** on Treatment Strategies for Patients with Lower Extremity Chronic Venous Disease.
- **Expanded and deepened relationships with key CMS and health care reform policy makers**, opening new opportunities for advocacy and dialogue on issues important to wound care:
 - Held in-person meetings with CMS and CMMI senior staff at the Health Care Planning Learning and Action Network (HCPLAN) fall meeting. Accepted as a “committed partner” of HCPLAN.
 - Met with Medicare Payment Advisory Commission (MEDPAC) Executive Director Mark Miller and his staff to discuss issues surrounding proposed quality measuring reporting policies.
- **Educated Alliance members on MACRA, legislative issues and health care fraud investigations and other emerging issues by hosting expert speakers and convening a webinar and to directly address Alliance-specific questions and concerns.** Speakers at Alliance meetings in 2016 included:
 - “Physician Payment Reform, CMS Proposed Rule on Part B Drugs/Biologics and other Regulatory Issues Impacting Wound Care” with Dr. Paul Radensky
 - “Legislative Initiatives Impacting Wound Care & What the Alliance Can Do” with Dave McNitt
 - “MACRA and the Path to Alternative Payment Models” with Dr. Sam Nussbaum
 - “Health Care Fraud Investigations: What to do when the government knocks” – webinar with Lynn Snyder and other experts at Epstein Becker Green.
- **Mobilized Alliance member organizational support and action on key advocacy issues.** By keeping our member-representatives informed of concerns in draft policies, alerting members to relevant public meetings (CMS, FDA, HCPCS, PCORI, etc.), sharing draft policies for comment and more, the Alliance not only ensured a well-educated member base to inform our own comments, but activated organizations to submit their own comments, in their own voice and specific to their own unique issues. This role of the Alliance as an activation-agent enabled member organization to have a greater voice on key issues and enhance their own visibility and advocacy efforts for their memberships.
- **Expanded the strength and reach of the Alliance with 4 new members** welcomed in 2016:
 - American Diabetes Association® Foot Care Interest Group; the Wound, Ostomy and Continence Nurses Society (WOCN); National Lymphedema Network (NLN); and the American Board of Wound Management Foundation.
- **Increased visibility of Alliance to greater wound care community** by speaking at wound care and clinical association meetings (EWMA, APWCA, WUWHS, ISPOR), gaining coverage in wound care journals, websites and blogs (*OWM, Today’s Wound Clinic, Advances in Skin & Wound Care, Wound Source*) and in Alliance member newsletters.



VALUE PROPOSITION TO MEMBERSHIP

The Alliance of Wound Care Stakeholders is an association of physician and clinical organizations focused on promoting quality care and access to products and services for patients with wounds and the providers who treat them. Through advocacy and educational outreach in the regulatory, legislative, and public arenas, the Alliance unites leading wound care experts to advocate on public policy issues that may create barriers to patient access to treatments or care. An umbrella organization that convenes the expertise of the full range of medical specialties involved in wound care, the Alliance of Wound Care Stakeholders is unique in that it:

- **Leverages the collective power** of the Alliance members to ensure that wound care has a strong voice and a seat at the regulatory table when policies are being developed and decisions that impact wound care are made.
- **Represents real-world clinical and technical expertise** on wound care issues, making the Alliance the champion on emerging issues of importance in wound care and positioning the Alliance as a recognized and respected go-to resource for regulatory agencies and other federal entities when addressing these issues.
- **Focuses exclusively on regulatory and legislative issues** impacting wound care coverage, payment, coding, FDA issues and quality measures.
- **Provides important access to regulatory and policy decision makers** via the strong network of federal and state regulatory and legislative contacts of Alliance leadership, staff and members.
- **Has the respect and recognition of regulatory and government agencies** following a proven track record of successful advocacy, led by an experienced and dynamic Executive Director who is passionate about ensuring patient access to and reimbursement of quality wound care.

We achieve this by:

- ❖ Communicating frequently with federal policymakers regarding Alliance positions and needs when the policy is in its formative stage in order to address proposed or final policies.
- ❖ Initiating and convening member meetings with Members of Congress and their staff, Centers for Medicare and Medicaid (CMS) senior level staff, their contractors DMEMAC and A/B MAC Medical Directors, PDAC and FDA.
- ❖ Convening membership to develop and submit comments to solve coverage, coding and payment issues and address quality issues that impact the Alliance's members.
- ❖ Monitoring and analyzing issues affecting quality, coverage, coding and reimbursement impacting wound care clinical practice.
- ❖ Serving as a resource to members in order to answer and clarify specific policy questions immediately.
- ❖ Updating members regularly, alerting about new and draft policies, their anticipated impact and implications and when to take action.