



2015 ANNUAL REPORT OF ACCOMPLISHMENTS AND ACTIVITIES

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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:

- Has an Executive Director who possesses technical expertise and historical knowledge of wound care issues combined with the healthcare provider perspective to champion positive changes that will benefit the industry. Alliance leadership and staff have strong long-term federal and state regulatory and legislative contacts along with the respect and recognition from clinical organizations, physician specialty societies and regulatory agencies, which translates into important access to them.
- Focuses solely on federal and state regulatory and legislative issues impacting wound care with respect to Medicare and Medicaid coding, coverage and payment issues and using collective power to effect positive change in the wound care arena.
- Initiates and convenes 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. Convenes membership to develop and submit comments to solve coverage, coding and payment issues that adversely impact the Alliance's members and their customers.
- Provides members with access to key policy decision makers to address their own specialty-specific regulatory problems.
- Serves as resource to members in order to answer specific policy questions immediately and provide critical information impacting members' practices (providing updates, attending meetings, alerting members when to take action on issues)
- Monitors and analyzes issues affecting coverage, coding and reimbursement impacting members' products. Sends members updates on timely basis and alerts them on when to take action.
- Communicates frequently with federal and state policymakers regarding industry positions and needs when the policy is in its formative stage in order to address proposed or final policies that are adverse to manufacturers with wound care products (e.g., working with CMS and A/B MAC and DMEMAC medical directors on issues related to coverage of wound care products).
- Attends and informs members about policy conferences and regulatory educational opportunities relevant to their memberships.

EXECUTIVE SUMMARY: KEY 2015 ACCOMPLISHMENTS

- **Increased Alliance’s favorable visibility at CMS and FDA as respected go-to expert resource** and grew relationships via meetings and conversations with senior staff (on pneumatic compression device LCD), DMEMAC and A/B MAC contractors (surgical dressing, pneumatic compression and CTP LCDs) and FDA (2006 guidance update). Our meetings and conversations on targeted issue strategically entrench the Alliance as an effective communicator and key “go-to” resource, for government agencies, which in turn facilitates Alliance access to key Agency staff and ensures that they respond quickly when we contact them with issues (e.g., sent and received clarification to A/B MACs on several CTP LCD policies, meetings requests met).
- **Continued persistent advocacy** with A/B MAC and DMEMAC contractor medical directors to ensure our voice is heard to have accurate and clinically sound coverage LCDs and address fair and equitable processes though speaking at their public meetings and submitting comments.
 - ❖ Spoke at the DMEMAC surgical dressing public meeting and the Palmetto public meetings on “skin substitute” LCDs.
 - ❖ Submitted three sets of comments to the DMEMACs and PDAC on non-covered surgical dressings (i.e. medical honey impregnated dressings)
 - ❖ Organized Alliance clinical associations, suppliers and other clinical associations to work together to submit comments on DMEMAC surgical dressing draft LCD
- **Championed the establishment of the first ASTM standard on CTPs**, which defines and classifies CTPs, and provides a comprehensive set of definitions related to skin wounds. It will be used for terminology purposes by clinicians, manufacturers, and scientists. The guideline was voted positively in the final balloting process by ASTM members at the end of 2015. This took four years and much Alliance/ASTM collaboration to achieve (but by ASTM standards, it is quicker than most other initiatives). The new standard gives further legitimacy to the CTP nomenclature and thus will be helpful both in requesting LCD reconsideration and with the AMA in CPT descriptors to change the terminology from “skin substitute” to CTPs.
- **Convened productive meeting of senior FDA staff** with Alliance wound care researchers and industry representatives to identify concerns and recommendations so as to work with the Agency to modernize its *2006 FDA Guidance for Industry Chronic Cutaneous Ulcer and Burn Wounds – Developing Products for Treatment*.
- **Successfully ensured Alliance wound care concerns were addressed in the final CY2016 Outpatient Prospective Payment System rule**. Key issues advocated by the Alliance and reflected in the final rule, include: increasing reimbursement for NPWT by placing it in different APC category; retaining Q4107 on skin substitutes list; aligning CPT codes for multi-layer compression wraps, Unna boots and total contact casting (TCC) and different APC for TCC leading to increase payment; adopting the Alliance’s supported methodology for determine which tier a CTP would be placed; eliminating status indicator Q1 for low frequency ultrasound.

- **Successfully ensured Alliance’s wound care concerns were addressed in the final CY 2016 Physician Fee schedule.** Key issues advocated by the Alliance and reflected in the final rule include: provisions surrounding the Qualified Clinical Data Registry (QCDR) and specifically, having materials for QCDR nomination available as of December 1 of the prior year followed by 60 days for self-nomination, and submit supplemental information by the January 31 deadline. The Agency also determined not to eliminate the CMS refinement panel that reviews CPT and RVUs at this time.
- **Successful in having First Coast Service Options (FCSO) adopt our comments in their final LCD.** It adopted the following comments: no longer requiring clinicians to document the anticipated amount of repeat applications: smoking cessation is no longer required for coverage (now only documentation of counseling for smoking cessation is required); and there was a clear distinction in coverage after failure to respond to conservative measures between DFU (greater than 4 weeks) and VLU (greater than 6 weeks). Now the language reads “greater than 4 for DFU and greater than 4-6 for VLU.”
- **Successfully advocated Congress to ensure the Alliance-supported disposable medical technology** provision in the 21st Century Cures discussion draft bill was included as part of H.R. 2029, which was signed into law by President Obama in October 2015.
- **Organized stakeholders to present a unified expert clinical voice at the MedCAC** on Peripheral Artery Disease (PAD) after convening stakeholders in advance and building consensus around key issues to raise to panel.
- **Built the Alliance’s reputation as a proactive, professional voice on wound care policy through the submission of 12 sets of comments to CMS and its contractors on diverse topics.** (e.g. Physicians Fee Schedule and Hospital Outpatient Prospective Payment System, LCDs addressing HBOT, strapping, debridement, CTPs, surgical dressings and pneumatic compression). The breadth and depth of these comments builds the Alliance’s reputation as the wound care association that responds quickly and addresses wide range of wound care coverage and guidance issues.
- **Educated members** on important, timely wound care issues by providing outside speakers at Alliance meetings and on its conference calls. (e.g., Dame Nikky Collum of Cochrane Collaboration, Dr. Diane Bild of PCORI, Dave McNitt of Oldaker Group)
- **Increased visibility of Alliance to greater wound care community** by speaking at wound care and clinical association meetings (EWMA, AVF, SAWC, APWCA), gaining coverage in wound care journals, websites and blogs (OWM, APWCA, Wound Source) and in Alliance member newsletters.