COALITION OF

Wound
Care
Manufacturers

2015 ANNUAL REPORT
OF ACHIEVEMENTS AND ACTIVITIES

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MISSION

- Serve as an advocacy organization for a regulatory, economic and legal climate that promotes patient access to wound care products and their corresponding services.

- Impact regulatory, government, and public affairs issues that affect wound care manufacturers.

- Provide members with targeted advocacy, information, education and guidance to optimize success in the complex world of health care legislation and regulations.

OBJECTIVES

- Continue to position the Coalition of Wound Care Manufacturers as a highly visible, respected and credible resource of industry information for:

    - Congress
    - Regulatory agencies (Centers for Medicare and Medicaid Services [CMS], its contractors: Durable Medical Equipment Medicare Administrative Contractor [DMEMAC] and A/B MAC Medical Directors; and Pricing Data Analysis Contractor [PDAC]
    - Food and Drug Administration (FDA), State Medicaid Agencies, Agency for Healthcare Research and Quality (AHRQ), Office of Inspector General, Medicare Payment Advisory Commission (MedPAC), Patient Centered Outcomes Research Institute (PCORI), U.S. Pharmacopeia (USP)

  These federal agencies control the coding, coverage and payment rules under Medicare and Medicaid for wound care products or are organizations influential on these processes.

- Continue to position the Coalition of Wound Care Manufacturers and its members as leaders in the wound care industry.

- Continue to support the Alliance of Wound Care Stakeholders as an entity to unify the wound care industry. The Alliance is a 501c(6) multidisciplinary trade association of physician and clinical specialty societies/organizations whose mission is to promote quality care and patient access to wound care products and services. The Alliance serves as a credible independent but complimentary resource to federal and state policy decision makers for the wound care industry.

VALUE PROPOSITION:
COALITION OF WOUND CARE MANUFACTURERS

Membership provides the ability to identify, strategize, and take action on regulatory and legislative issues using the collective power of the Coalition. Legislators and regulators prefer working with coalitions, rather than individual companies, especially when the issues are similar. The Coalition of Wound Care Manufacturers is unique in that it:

- ***Has an Executive Director who possesses technical expertise and historical knowledge of wound care issues combined with the manufacturer's perspective to champion positive changes that will benefit the industry. She has 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 manufacturers with respect to Medicare and Medicaid coding, coverage and payment issues and using collective power to effect positive change in the wound care industry.***

- ***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 and also submits comments to solve coverage, coding and payment issues that adversely impact the Coalition's members and their customers.***

- ***Provides members with access to key policy decision makers to address their own and their customers' specific regulatory problems.***

- ***Serves as resource to members in order to answer specific policy questions immediately and provide critical information impacting members' products (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 for them to attend that will impact their products.***

- ***Provides members with access to key wound care opinion leaders to advance members' role as a leader in wound care****.*

- ***Obtains information from federal and state policymakers on behalf of certain members without providing any risk to company in identifying themselves to the agencies.***

EXECUTIVE SUMMARY: 2015 SUCCESSES

While successes in Washington have been hard to come by, we are pleased to state that we have had achievements in very distinct areas in 2015. These include:

- **Successful in obtaining a positive final ASTM ballot so as to create a unique standard on CTPs that defines and classifies CTPs, and provides a comprehensive set of definitions related to skin wounds.** It will also be used for terminology purposes by clinicians, manufacturers, and scientists. This took four years to achieve but by ASTM standards, it happened quicker than most other initiatives. This gives further legitimacy to the CTP nomenclature; thus, will be helpful both in requesting A/B MAC LCD reconsiderations and with the AMA regarding CPT descriptors to change the terminology from "skin substitute" to CTPs .

- **Succeeded in having CMS adopt the Coalitions' recommendations in our Outpatient Prospective Payment System comments. (OPPS)** These included:

  - Successfully had CMS keep Q4107 on the skin substitutes list after the Agency proposed to remove it as they believed it was an implantable biologic product.
  - Changes were made in the final rule to more appropriately align CPT codes for multi-layer compression wraps, Unna boots and total contact casting (TCC). CMS, at our request, assigned the application of multi-layer compression wraps and the application of an Unna's boot in a different APC than that of the application of a total contact cast. Payment increased for the APC to which TCC was assigned.
  - CMS adopted the methodology for determining what tier a CTP would be placed. We supported the MUC or PDC threshold being utilized.
  - CMS eliminated status indictor Q1 for low frequency ultrasound at our request.
  - Succeeded in gaining an increase in reimbursement for disposable NPWT from $146.65 to $225.55 after CMS moved it from APC 0015 to 0016.

- **Met with PDAC staff and developed lists of questions on coding verification issues that will be placed on the PDAC website in 2016 that will lead to consistent, fair and transparent processes in the future.**

- **Advocated for appropriate wound care dressing processes and to educate CMS HCPCS coding staff, the DMEMACs and PDACs on multicomponent dressing issues by:**

  - Submitted 3 letters to the DMEMAC and the PDAC regarding their inappropriate process for changing coverage policy for medical honey impregnated surgical dressings.
  - Speaking at HCPCS public meeting regarding a surgical dressing agenda item that needed clarification of coverage and payment for silver used in a multicomponent dressing which resulted in the HCPCS Workgroup revising its preliminary decision.

- **Submitted three sets of comments on CMS A/B MAC draft wound care local coverage determinations (LCDs) for CTPs and one to the DMEMAC for their draft LCD on surgical dressings. These included:**

  - Submission of 3 sets of comments to First Coast and Palmetto as well as attending and speaking at two of the Palmetto public meetings regarding its CTP draft LCD.
  - Submission of comments to the DMEMACs on their surgical dressing draft LCD and presented oral testimony during an open public meeting to address the draft policy.

- **Convened successful meeting of senior FDA staff with Coalition and Alliance industry regulatory representatives and Alliance clinical associations to identify concerns and recommendations regarding the *2006 FDA Guidance for Industry Chronic Cutaneous Ulcer and Burn Wounds – Developing Products for Treatment.***

- **Proactively advocated on HCPCS coding reform issues**:

  - Worked with Dave McNitt of the Oldaker Group to address strategy and engaged the personal offices of every Member of the Energy & Commerce Health Subcommittee on HCPCS coding reform, met with Committee leadership on 21st Century Cures Bill, secured the inclusion of the Alliance's policy positions in the Congressional Record for the April 30th Legislative Hearing on the "Cures" bill, drafted legislative language for inclusion in an appropriate legislative vehicle, began educational and advocacy with professional staff of Senate HELP and Finance Committees.
  - Submitted comments to CMS on "Healthcare Common Procedure Coding System (HCPCS) Codes Used for Processing Medicare Claims for Miscellaneous Durable Medical Equipment (DME)."

- **Active supporter and participant in Alliance of Wound Care Stakeholders activities and achievements. Alliance 2015 achievements include:**

  - **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.
  - **Continued persistent Alliance 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 as shown below:
    - Speaking at the DMEMAC surgical dressing public meeting and the Palmetto public meetings on "skin substitute" LCDs.
    - Submitting three sets of comments to the DMEMACs and PDAC on non-covered surgical dressings (i.e. medical honey impregnated dressings)
    - Organizing Alliance clinical associations, billers 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.
  - **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**.
  - **Successfully ensured Alliance's wound care concerns were addressed in the final CY 2016 Physician Fee schedule**.
  - **Successful in having First Coast Service Options (FCSO) adopt our comments in their final LCD on Application of Skin Substitute Grafts for Treatment of DFU and VLU of Lower Extremities**

- **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 to CMS sets of comments on diverse topics**. (e.g. Physicians Fee Schedule and Hospital Outpatient Prospective Payment System), its contractors (e.g., LCDs addressing HBOT, strapping, debridement, CTPs, surgical dressings, 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.