COALITION OF Wound Care Manufacturers

EXECUTIVE SUMMARY: KEY 2017 ACCOMPLISHMENTS

Having a strong, united voice as policies and regulations are drafted in today's hyper-partisan world remains essential. Throughout 2017, the Coalition provided a unified wound care perspective to CMS and its contractors, FDA, Capitol Hill and other key policy stakeholders in the wound care space. 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," built credibility and opened doors for ongoing advocacy and dialogue. Several of our key activities and top accomplishments in 2017 include:

- **Advocated for fair, rational and clinically/procedurally-sound policies** to Congress, HHS, CMS and its contractors by submitting 11 sets of comments, oral testimonies and letters.
    - **2 comments to CMS** on CY2018 Hospital Outpatient PPS and Physician Fee Schedule.
    - **5 comments to A/B MACs** addressing Novitas, WPS and FirstCoast LCDs.
    - **1 letter to DMEMACs** continuing to raise concerns with the final surgical dressing LCD.
    - **1 letter to HHS and CMS**, co-signed with the Alliance for HCPCS II Coding Reform.
    - **2 letters to Congress members** addressing competitive bidding/HCPCS coding (then-Rep. Tom Price) and voicing support for support the "DMEPOS Access and Transparency Act of 2017" (Rep. Marsha Blackburn).

- **Positively influenced and minimized the impact of a restrictive draft LCD on NPWT.** The Coalition actively responded to a concerning Novitas wound care local coverage determination issued in January. We testified at Novitas' public meeting and submitted comments recording our concern about the overall lack of evidence to support the proposed changes, the elimination of coverage of disposable Negative Pressure Wound Therapy (dNPWT), and the arbitrary utilization parameters set for NPWT and debridement services. The final policy, published in Sept., resolved many of our comments. The now includes coverage for dNPWT plus more flexibility in performing debridement and NPWT.

- **Continued to proactively raise procedural and clinical concerns with the DMEMAC final surgical dressing LCD.** Published in June, the final local coverage determination was not consistent with how surgical dressing products are prescribed and utilized by wound care clinicians, and contained significant areas of ambiguity – particularly related to collagen dressings, hydrogels and the staging systems. The Coalition convened a dedicated **surgical dressings work group** and coordinated with the Alliance of Wound Care Stakeholders to coordinate a synergistic advocacy strategy. We retained the assistance of a law firm to develop a **"request for delay" letter** focused on legal/procedural issues in the LCD, while the Alliance submitted a letter focused on clinical issues. While the DMEMACs did not act on this delay request, our advocacy did achieve action and DMEMAC response:
    - In October, the DMEMAC medical directors responded with a "**clarification letter"** that addressed collagen dressings, staging systems and hydrogels - areas of the LCD that were causing confusion in clinical practice and impacting patient care/patient access to products and services.
    - This "clarification letter" has assisted our members and their customers **to better understand how to bill** for some of the surgical dressing products.
    - In addition, we requested clarification on misinformation provided at a November 2017 surgical dressing Noridian seminar by calling and emailing the DMEMAC medical director. *(Note: In 2018, due to our advocacy, Noridian emailed each webinar participant the correct information)*

- **Pursued accurate and clinically sound local coverage determinations (LCDs)** via our persistent advocacy with A/B MAC and DMEMAC medical directors for fair and equitable LCD and coverage processes. The Coalition testified at two public meetings and submitted three written comments on draft wound care LCDs in 2017.

- **Served as the impetus for the PDAC to modernize its Coding Verification Application and** website. Medicare's Pricing, Data Analysis and Coding Contractor (PDAC) took action following Coalition advocacy efforts. The Coalition played a significant role in prompting the update, following our previous submission of questions and requests for clarity surrounding the current application process. The Coalition members served as a resource on updating the Coding Verification Application. In addition, as an outcome of our inquiry and identification of concerns, the PDAC is in the process of updating content and instructions on its website.

- **Elevated the need for HCPCS coding reform** to ultimately help improve patient access to medically necessary products and simplify the process for manufacturers to bring products to the wound marketplace. In collaboration with the Alliance for HCPCS II Coding Reform, the Coalition co-signed a **letter** to (then) HHS Secretary Tom Price and CMS Administrator Seema Verma expressing concerns with the current coding process and asking CMS to (1) Increase transparency of coding decisions; (2) Separate criteria used to establish a new HCPCS code from criteria used to establish a coverage policy for the product; (3) Establish an appeals process to provide independent review/reconsideration of coding decisions and (4) Improve the PDAC coding verification and code revision processes.
    - Senior HHS/CMS staff followed-up the letter by meeting with Alliance for HCPCS II Coding Reform members (led by Marcia Nusgart) twice – in Nov. and Dec. – to begin to resolve many of the concerns raised. Additionally, at

the November MEDPAC meeting, the Coalition raised the issue in public comments, opening the door for a January 2018 meeting with MEDPAC staff addressing how HCPCS coding impacts competitive bidding.

- **Ensured concerns of wound care manufacturers were articulated to CMS by submitting comments to the Agency's proposed CY 2017 Prospective Payment Systems (PPS)**.
    - HOPPS: Focused on methodology of packaging policies for cellular and tissue-based products for wounds (CTPs) – policies that the Coalition believes may be hampering patient access or resulting in other undesirable consequences.
    - Physician Fee Schedule: Focused comments on (1) practice expense relative value units for disposable negative pressure wound therapy and (2) HCPCS coding reform opportunities.

- **Provided first comprehensive wound care study data to Coalition on the clinical and economic expenditure impact of chronic wounds** with the support of the Alliance-sponsored study analyzing Medicare claims and payments. Topline findings show that chronic wounds impact nearly 15% of Medicare beneficiaries (8.2 million) at an annual cost to Medicare conservatively estimated at $28.1 to $31.7 billion. Data was reported in aggregate, by wound type, and by setting – all helpful insights for manufacturers in the wound space. We provided a fact sheet, news release and the study to Coalition members so as to facilitate sharing of this information with their companies and to customers.

- **Informed and educated Coalition members on Medicare payment reform, MACRA and key issues and policies impacting wound care** by convening and hosting expert speakers to directly address Coalition-specific questions and concerns.

- **Mobilized Coalition's members to take company-specific 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 Coalition not only ensured a well-informed member base to inform our own Coalition comments, but activated companies and organizations to submit their own comments, in their own voice and specific to their own unique issues. This role of the Coalition as an activation-agent for collaborative industry advocacy enabled member organization to have a greater voice on key issues and enhance their own visibility and advocacy efforts.

- **Actively supported and participated in Alliance of Wound Care Stakeholders activities** to ensure that the wound care provider clinical expert voice is proactively speaking to the impact of policies on patients and providers. (See Alliance activities on www.WoundCareStakeholders.org)

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:

- **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 staffs** 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/webinars** and regulatory educational opportunities for them to participate in 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.
- **Has leadership and staff 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; Has leadership and staff with 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.

OUR 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, legislative, 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.

OUR OBJECTIVES

- Continue to position the Coalition of Wound Care Manufacturers as a highly visible, respected and
  credible resource of industry information for:
  - Congress
  - Centers for Medicare and Medicaid Services (CMS) and its contractors, including: Durable Medical Equipment Medicare Administrative Contractor [DMEMAC] and A/B MAC Medical Directors; Pricing Data Analysis Contractor (PDAC) and Center for Medicare and Medicaid Innovations (CMMI)
  - 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.