Coalition of Wound Care Manufacturers

2016 ACCOMPLISHMENTS

With the ongoing shifts in the U.S. healthcare landscape under a new Presidential administration, coupled with the uncertain 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 industry perspective is of increasing importance. The Coalition's work in 2016 focused on voicing the impacts to wound care and the wound care industry on FDA efforts to reclassify antimicrobial wound dressings and of CMS policies, including its CY2017 prospective payment systems, Medicare Administrative Contractors (MAC) contracting process, Part B Drug Payment Model, Competitive Bidding and others. The Coalition identified and took advantage of multiple opportunities for input, advocacy and comment. Our comments put us "on the record," built credibility across our industry and opened doors for ongoing advocacy and dialogue. Key Coalition accomplishments and activities in 2016 include:

- **Advocated on issues impacting wound care and wound care manufacturers via 14 submitted comments in 2016.**
  - **6 comments to FDA on:** Homologous Use of Human Cells, Tissues, and Cellular and Tissue-Based Products (oral and written comments); Minimal Manipulation of Human Cells, Tissues, and Cellular and Tissue-Based Products; Classification of antimicrobial wound care products (oral and 2 sets of written comments)
  - **7 comments to CMS on:** Hospital Outpatient PPS (2 sets), Home Health PPS, DMEPOS Competitive Bidding, Part B Drug Payment Model, MAC contracting process, Medicare Appeals Procedures
  - **1 comment to A/B MACs:** Cigna LCD for Application of Skin Substitute for Wounds of Lower Extremities

- **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 care 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 effort included:**
  - Submitting comments in advance of the meeting to provide relevant background information on wound care complexities, then submitted post-meeting follow-up comments reinforcing the Advisory Panel recommendation to classify antimicrobial wound dressings as a Class II with special controls.
  - Testifying before the Advisory Panel during the public meeting.
  - Mobilizing a team of manufacturers to testify at the public meeting.
  - Coordinated with the Alliance of Wound Care Stakeholders to ensure a strong clinician voice and perspective at the FDA meeting.

- **Provided a united wound care industry voice to FDA on guidance documents addressing the Agency's regulation of Human Cells, Tissues, and Cellular and Tissue-Based Product (HCTPs) by voicing collective concerns and recommendations**.
  - Established a work group to review the guidance documents on minimal manipulation and homologous use of HCTPs and identify priority issues to address and recommendations to suggest.
  - Submitted written comments to FDA on their minimal manipulation and homologous use guidance documents. Focused comments on key sections of the proposed FDA guidances that are significant departures from or contrary to current regulatory language and that therefore, in our perspective, should have been issued under the proposed rule-making process and not as guidance documents
  - Delivered oral testimony to the FDA during their September 12-13 Public Hearing.

- **Encouraged CMS with a unified industry voice, via submitted written comments, to put mechanisms in its Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program** to better vet vendors, ensure vendor quality and adequately monitor access to products with the current existing program. While CMS did not agree with all of our submitted comments, they did agree with and accept several.

- **Recommended to Pricing, Data Analysis and Coding (PDAC) leadership specific changes** and updates that could address coding verification issues, and mobilized contractor to take action. We will be monitoring PDAC progress and sharing PDAC updates as we see them implemented.

- **Pointed much needed attention to the recurring flaws in the Medicare Administrative Contractor (MAC), Qualified Independent Contractor (QIC) and Recovery Audit Contractor (RAC) medical review processes** that are contributing to the massive Medicare appeals backlog, via submitted comments to CMS on its proposed rule, "Changes to the Medicare Claims and Entitlement, Medicare Advantage Organization Determination, and Medicare Prescription Drug Coverage Determination Appeals Procedures. Encouraged CMS to solve the backlog issue by looking more proactively to improve the claims review and initial determinations process of contractors.

- **Sought great transparency and accountability for MACs and PDAC contractors via submitted comments to CMS' Medicare Administrative Contractor (MAC) contract awards and incentives guidance**. Focused comments on the importance of accountability and transparency, expressed concerns about MACs exceeding statutory authority, and encouraged the establishment of metrics for MACs as well as Pricing, Data Analysis and Coding (PDAC) contractors.

- **Ensured concerns of wound care manufacturers were articulated to CMS by submitting comments to the Agency's proposed rules for its CY 2017 Prospective Payment Systems** (PPS) for Hospital Outpatient Services and Home Health.
    - HOPPS: Reiterated to CMS that its rate setting for CTPs in the draft HOPPs was based flawed data; advocated that CMS issue a MedLearn Matters to describe the proper billing of CTPs. Submitted a follow-on round of comments following issuance of the interim final rule.
    - Home Health: Focused concerns on the implementation of the new statutory benefit to pay home health agencies separately for disposable NPWT. While CMS did not change any specific NPWT language within the final rule following comment review, it did insert examples of billing scenarios for HHAs furnishing NPWT using a disposable device that provided clarity on several of the questions raised in Coalition comments.

- **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. (See listing of experts hosted by Coalition on p.13)

- **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 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.

- **Active supporter and participant 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 detailed 2016 Alliance accomplishments and activities here.)

COALITION OF Wound Care Manufacturers

VALUE PROPOSITION TO MEMBERS:

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 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.**
- **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/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**