



2017 ANNUAL REPORT OF ACCOMPLISHMENTS AND ACTIVITIES

EXECUTIVE SUMMARY: KEY 2017 ACCOMPLISHMENTS

2017 demonstrated that having a strong, united voice in today’s hyper-partisan world remains essential. We celebrated our [15th anniversary](#) in 2017. Fittingly, we celebrated with a toast, a [video](#), and a year spent collaboratively and productively providing a unified, balanced and clinically sound 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. A detailed summary of 2017 accomplishments and activities is attached, featuring these key initiatives:

1. **Provided first comprehensive wound care study data demonstrating the clinical and economic expenditure impact of chronic wounds** to the Medicare program and illuminated the need for more wound-relevant quality measures, payment models and Federal research funding. Alliance-sponsored research culminated in an article published in the prestigious economic journal ISPOR’s Value in Health, “[An Economic Evaluation of the Impact, Cost and Medicare Policy Implications of Chronic Nonhealing Wounds](#).” Topline findings showed 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. Upon publication of the study, the Alliance shared a topline [news release](#) and [fact sheet](#) to enable member organizations to share with their own memberships and constituents. We will continue to leverage this study to bolster our advocacy efforts.
2. **The Alliance has been on the record with official comments, oral testimony and letters 17 times this year**, as we pursued accurate, clinically sound local coverage determinations and payment policies via persistent advocacy with A/B MACs, DMEMACs and CMS.

In 2017, this included:

- 6 comments to CMS on the [CY2018 Hospital Outpatient PPS](#), [Hospital Inpatient PPS](#), [Physician Fee Schedule](#), [Physician Quality Payment Program](#), the [Request for Information](#) regarding a new direction of the Center for Medicaid and Medicare Innovation (CMMI), and the Proposed Decision Memo for [Supervised Exercise Therapy for PAD](#).
 - 7 oral and written comments to A/B MACs on [Novitas](#), [First Coast](#) and [WPS](#) wound care LCDs that addressed a range of issues including NPWT, disposable NPWT (dNPWT), debridement, and more.
 - 2 letters to the [DMEMACs](#) raising concerns with the **final surgical dressing LCD**.
 - 1 letter to HHS Secretary and CMS Administrator co-signed with the **Alliance for HCPCS II Coding Reform**.
 - **1 letter to Congress** (Rep. Marsha Blackburn R-TN) requesting [exclusion of NPWT](#) from prior authorization as part of the “[DMEPOS Access and Transparency Act of 2017](#)”
3. **Positively influenced and minimized the impact of a restrictive draft LCD on NPWT.** The Alliance 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. It now includes coverage for dNPWT plus more flexibility in performing debridement and NPWT.
4. **Continued advocacy to address clinical concerns with the DMEMAC final surgical dressing LCD**, ultimately driving a “[clarification letter](#)” addressing several key issues. The final policy (published in June) was not consistent with how surgical dressing products are prescribed and utilized by wound care clinicians. The policy contained significant areas of concern including but not limited to: the removal of clinical judgment in the LCD language; imposing strict frequency limitations on all dressings; and new coverage and utilization criteria which were ambiguous and inconsistent.
- We collaborated with the **Coalition of Wound Care Manufacturers** to coordinate a synergistic advocacy strategy. We submitted a “[request for delay](#)” letter to senior CMS staff focused on clinical issues and ambiguity in the LCD and follow up with oral advocacy to CMS staff and worked with our members to do the same. While CMS did not act on this delay request, our advocacy did achieve action and DMEMAC response:
 - In September, the Alliance [requested clarification](#) on issues regarding 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.
 - In October, the DMEMAC medical directors responded with a [clarification letter](#) that addressed these issues.

5. **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 Alliance of Wound Care Stakeholders 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 twice with Alliance for HCPCS II Coding Reform members (led by Marcia Nusgart) – in Nov. and Dec. – to begin to resolve many of the concerns raised. Additionally, at the November MEDPAC meeting, the Alliance raised the issue in public comments, which led to a January 2018 meeting with MEDPAC staff to address this issue.

As you can see, we worked tirelessly over the past year to ensure that regulatory agencies are aware of impacts to wound care as policies are crafted. The breadth and depth of our comments entrenches the Alliance as a “go-to” resource for government agencies and policy makers. Looking forward, we have much work ahead of us in 2018 and look forward to continued collaboration and success.

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ALLIANCE VALUE PROPOSITION: BENEFITING OUR MEMBERS

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 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 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 on new and draft policies, their anticipated impact and implications and when to take action.

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