



2017 ANNUAL REPORT OF ACCOMPLISHMENTS AND ACTIVITIES

Value Proposition to Membership	p.2
2017 Accomplishments: Executive Summary	p.3
2017 Activities by Topic	
MACRA, Medicare Payment Reform & Quality Measures	p.5
CMS & CMS Contractors	p.6
HCPCS Coding Reform	p.8
Negative Pressure Wound Therapy	p.10
Surgical Dressings	p.11
Cellular and/or Tissue-based Products for Wounds	p.13
MedCAC & MEDPAC	p.13
FDA	p.13
Emerging Issues	p.14
Alliance Visibility & Coverage in Wound Care Press	p.14
Educational Programs for Members	p.15

VALUE PROPOSITION TO 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.

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 H.R. 2445 "[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.
- Finally, when there was incorrect information on the surgical dressing LCD on a November Noridian webinar, the Alliance acted quickly to request that the DMEMACs **correct** this information in a public forum. (Noridian corrected this information in Feb 2018 by sending two emails to those who participated in the webinar.)

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.

SUMMARY OF KEY 2017 ACTIVITIES BY TOPIC

➤ MACRA, MEDICARE PAYMENT REFORM & QUALITY MEASURES

❖ *Value in Health Study: Economic Impact of Chronic Wounds*

- 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](#)." The study illustrated the full burden of wound care in the U.S. Medicare population. 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 wound care clinicians and manufacturers who want to use this in their research and in lectures. We provided a [fact sheet](#), [news release](#) and the study to Alliance members so as to facilitate sharing of this information with their companies and to their customers.

❖ *Quality Payment Program*

- The Alliance has served as a champion and advocate in terms of educating CMS on how evolving MACRA policies would impact and challenge wound care clinicians and provided recommendations on how value-based care could best be optimized within the wound care space. Our work included [submitting comments](#) to CMS' CY2018 Updates to the Quality Payment Program. Our Comments focused on the lack of relevant quality measures addressing the needs of wound care clinicians. The Alliance suggested that the creation of additional wound care quality measures is necessary to ensure continued quality care. Comments supported the use of QCDRs and the ability of all eligible clinicians to use the QCDR option for reporting.

❖ *Education & Networking with Policy Makers*

- Participated in the April **National Quality Forum** sessions to benefit from the focused discussion on quality and quality measures in today's rapidly evolving and documentation-dependent healthcare environment.
- Shared information and participated remotely in FDA and Duke Margolis Center for Health Policy's September "[A Framework for Regulatory Use of Real-World Evidence](#)." The Alliance encouraged members to participate in person or online.
- Alerted Alliance membership to and participated in the **Health Care Payment Learning and Action Network** spring and fall conferences. Interacted onsite with senior CMS and CMMI staff, as well with as panelists from BCBG, Anthem, Aetna and other payers.
- Shared information with membership about the September Health Affairs meeting, "[Measuring Value In A Diverse Healthcare Marketplace](#)."

➤ CMS AND CMS CONTRACTORS

❖ *Prospective Payment System Regulations*

The Alliance submitted comprehensive comments on relevant issues addressing wound care across the series of CY2018 rate updates issued by CMS for stakeholder comment. While not all Alliance suggestions and recommendations get incorporated (we are but one of many voices that weigh in), the process of submitting “on the record” comments builds credibility, amplifies the voice of the wound care community represented by the Alliance and provides leverage to continue the dialogue on current and emerging issues with regulators moving forward.

- **CY 2018 Physicians Fee Schedule:** The Alliance submitted [comments](#) to the Proposed CY 2018 [Physician Fee Schedule updates](#), addressing a range of issues including evaluation and management services (E/M codes), hyperbaric oxygen therapy, CPT codes for NPWT, and quality measures. In response to CMS’s request for information on flexibility and efficiency opportunities to increase care, reduce costs and reduce burdens for clinicians and patients, the Alliance asked the agency to consider HCPCS coding reform.
- **CY 2018 Hospital Outpatient Prospective Payment System:** The Alliance submitted [comments](#) to the proposed CY 2018 [Hospital Outpatient Prospective Payment System](#) updates. Comments focused on the methodology of packaging policies for cellular and/or tissue-based products for skin wounds (CTPs) - policies that the Alliance believes may be hampering patient access. Similarly, in response to the Agency’s request for comments on how to improve efficiency and flexibly, the Alliance suggested HCPCS coding reform strategies.
- **CY 2018 Hospital Inpatient Prospective Payment System:** The Alliance focused [comments](#) on four specific issues that impact wound care and specifically: (1) The proposal to remove the current pressure ulcer measure (NQF #0678) and replace it with a modified version of the measure entitled “Changes in Skin Integrity Post Acute Care: Pressure Ulcer: Injury”; (2) Clarification of “Pressure Ulcer/Injury” Terminology Used throughout the Proposed regulation; (3) Patient Safety and Adverse Events (Composite) NQF #5031; and (4) Adoption of Malnutrition eCQMs in the Hospital.

❖ *CMS Proposed Decision Memo for Supervised Exercise Therapy (SET)*

- The Alliance submitted April comments to CMS’ Coverage and Analysis Group in response to the agency’s proposed memorandum for Supervised Exercise Therapy (SET) for Symptomatic Peripheral Artery Disease (PAD). The Alliance expressed its disagreement that a SET program be limited to a hospital or outpatient hospital setting, noting that more patients can benefit from SET if the number of settings where it can be delivered is expanded. Comments also noted concern with the direct supervision of a physician requirement.

❖ *CMS New Coverage Decision on Topical Oxygen*

- **Alerted members on CMS new coverage decision regarding topical oxygen** in April. The Agency removed it as being non-covered in a NCD and is now allowing its contractors to determine the coverage.

❖ **Center for Medicare and Medicaid Innovation (CMMI)**

- The Alliance submitted [comments](#) to CMS' request for information on new directions for the CMMI after convening many conference calls with members to determine issues of importance (Nov.). Comments focused on opportunities within specialty physician models, program integrity, and benefit design/price transparency. The Alliance also focused on the growing importance of real world evidence and patient registry data. The Alliance also spoke once again to the importance of developing quality measures that are more relevant to wound care, and pointed again to the relevance of HCPCS coding reform to the CMMI's focus on improved payment models – given the correlation of coding and payment in practice. The Alliance also highlighted other models for CMMI consideration, including patient accountability models and Voluntary Quality Improvement Reporting Model for Hyperbaric Oxygen Therapy and population management models.

❖ **CMS Contractors: A/B MACs, DME MACs, PDAC**

- **A/B MACs:** Submitted 3 oral testimonies and 4 written comments on draft LCDs impacting wound care to the A/B MACs (including but not limited to: disposable and traditional negative pressure wound therapy, cellular and/or tissue based products for wounds, debridement)
 - [Oral testimony](#) to Novitas at its open meeting to collect comments on its draft LCD on wound care. (Jan.)
 - [Written comments](#) to Novitas on draft LCD on wound care (March)
 - [Oral testimony](#) to First Coast Service Option (FCSO) at public meeting convened to collect comments on its draft wound care LCD (Feb.)
 - Written [comments](#) to FCSO draft LCD on wound care (March)
 - [Oral testimony](#) at Wisconsin Physician Services public meeting (March)
 - Written [comments](#) to WPS draft wound care LCD (June)
 - Written [comments](#) to Novitas draft LCD on treatment of varicose veins of the lower extremities (March)

MAC Advocacy Success: The Alliance's work positively influenced the impact of the restrictive Novitas draft LCD. The Alliance actively responded to a concerning Novitas wound care LCD. The final policy, published in Sept. 2017, addressed many of our comments and included more flexibility in performing **debridement** and **NPWT**, coverage for dNPWT and for palliative care and corrections to some of clinically inaccurate information that was in the draft LCD. Additionally, Novitas eliminated the language in which wound volume or surface dimensions needed to decrease by 10% per month or 1 mm/week.

- **Driving greater MAC LCD transparency and accountability:** The Alliance updated members on legislation introduced in the Senate and House focused on a “legislative fix” for some of the issues surrounding LCDs from Medicare Administrative Contractors (MACs). The proposed legislation, S.794 “[Local Coverage Determination Clarification Act of 2017](#),” would improve transparency and accountability when Medicare contractors set LCD policies for physician services provided to Medicare beneficiaries. This legislation addresses many Alliance

concerns by: (a) Requiring open and public MAC meetings that are on the record; (b) Requiring disclosure by MACs of the rationale for an LCD and the evidence for that decision at the beginning of the LCD process; (c) Providing a meaningful reconsideration process for an LCD; (d) Prohibiting MACs from adopting an LCD from another jurisdiction without first conducting its own independent evaluation of the evidence. The Alliance voiced our support to the bill's co-sponsors as well as urged members and aligned stakeholders to add their voice and submit letters of support.

- **DME MACs** - See Surgical Dressings, p.11

➤ HCPCS CODING REFORM

The Alliance of Wound Care Stakeholders co-signed letters with the Alliance for HCPCS II Coding Reform to HHS Secretary and CMS Administrator. These letters sparked a series of meetings with positive, engaged conversations with HHS and CMS senior staff in 2017:

- **Co-signed Letter:** In August, in collaboration with the Alliance for HCPCS II Coding Reform, the Alliance of Wound Care Stakeholders and the 30+ organizations it mobilized - signed on to a letter to request a meeting with (then) HHS Secretary Tom Price and CMS Administrator Seema Verma regarding concerns with the current coding process and asking CMS to:
 - Increase transparency and due process of coding decisions;
 - Separate the criteria used to establish a new HCPCS code from criteria used to establish a coverage policy for the product described by that code;
 - Establish an appeals process to provide independent review/reconsideration of coding decisions, and
 - Improve the PDAC coding verification and code revision processes.
- **First follow-up meeting:** As follow-up, senior CMS staff hosted Alliance for HCPCS II Coding Reform leadership to participate in a November 2017 meeting to further discuss the issues and our recommendations. Senior CMS staff at that meeting included: Demetrios Kouzoukas - Principal Deputy Administrator for Medicare; Liz Richter – Deputy Director, Center for Medicare; Jeanette Kranacs - Deputy Director Division of Chronic Care Management; Joel Kaiser - Director, Division of DMEPOS Policy; Cynthia Hake - Deputy Director, Division of DMEPOS Policy; Kimberly Combs Miller - HCPCS. Staff were engaged, asked questions, were willing to consider reforms, and requested further details. In fact, D. Kouzoukas asked that L. Richter and her staff meet with us and for us to give them examples and more details supporting our concerns and recommendations. This led to a follow-up December meeting.
- **Second follow-up meeting:** In December, we held a follow up meeting with CMS staff in Baltimore and shared examples of how the declining number of new codes, the opaque standards for obtaining a new code, the grouping of more and more dissimilar products all have adverse impacts on patients, providers, innovators, and other stakeholders. This led to CMS requesting another meeting in January 2018.

- **Additional Alliance activities supporting HCPCS coding reform also included:**

- **MedPAC:** Attended November MedPAC meeting where they discussed the notion of adding more DMEPOS to competitive bidding. Marcia Nusgart took advantage of the opportunity to advise the Panel that if the MedPAC staff starts considering the addition of new DMEPOS products to competitive bidding, then it should also recommend that CMS reform the HCPCS coding process – as coding is aligned with payment and the trend for CMS is to take disparate products and, instead of giving them unique HCPCS codes, to place them in a code saying “any type” and with one price. She referenced the GAO study about the codes being so broad that CMS did not know what it is paying for.
 - Comments provided in testimony at this meeting opened the door for a January 2018 meeting on this topic with MedPAC staff in Baltimore.

- **Additional comments & letters:**

- In response to CMS’s request for information on flexibility and efficiency opportunities to increase care, reduce costs and reduce burdens for clinicians and patients, the Alliance - via comments to the **CY2018 Physician Fee Schedule and Hospital Outpatient PPS** – asked CMS to consider reform of the process it uses to assign new HCPCS Level II billing codes to DMEPOS. (See p.6)
- Co-signed letter with the Alliance for HCPCS II Coding Reform to the **House Ways and Means Committee**, addressing opportunities to reform the HCPCS coding process as part of the government’s **“Red Tape Reduction”** initiatives.

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- **Tracking & reporting of HCPCS coding decisions:** Alerted Alliance membership to the dates announced for CMS public meetings to discuss pending applications for new and revised HCPCS codes (May 16–18 for Drugs/Biologicals/Radiopharmaceuticals and Radiologic Imaging Agents; June 7–8 for Durable Medical Equipment and Accessories/Orthotics and Prosthetics/Supplies/Other). Shared agendas and preliminary decisions with members as soon as they were released by CMS. Attended meetings, shared updates and alerted members when new coding decisions were released by CMS.

➤ **NEGATIVE PRESSURE WOUND THERAPY (NPWT)
TRADITIONAL & DISPOSABLE**

❖ ***Written Comments***

- Addressed NPWT payment issues in the **CY2018 Physician Fee Schedule**. Via submitted [written comments](#), requested a national payment rate for CPT Codes 97607 and 97608 - describing negative pressure wound therapy (NPWT) services using a disposable device - similar to the rate proposed in the CY2018 hospital outpatient proposed rule.
- Submitted [comments](#) to **FCSO on wound care draft LCD (DL37166)** and [comments](#) to the strikingly similar wound care LCD (DL35125) from Novitas. Both comments focused on the lack of coverage for dNPWT, stressing inaccuracies with CPT coding descriptors and a lack of sufficient evidence to claim that dNPWT is neither reasonable nor necessary. The Alliance requested in comments that that FCSO should cover dNPWT, providing reasons based on evidence and congressional intent. (March)
- Submitted [written comments](#) to **WPS's wound care draft LCD (DL37228)** focused on the arbitrary utilization parameters for Negative Pressure Wound Therapy (June).
- Alerted membership to the legislation introduced in the House in May, the **“DMEPOS Access and Transparency Act of 2017” (H.R.2445)** by Rep. Marsha Blackburn (R-TN) to amend title XVIII of the Social Security Act to provide for a prior authorization process under the Medicare program for certain high cost DMEPOS.
- Submitted a [letter to Rep. Blackburn](#) (R-TN) in support of the Act and requested an amendment be offered to exclude NPWT from any prior authorization process. (Nov.)

❖ ***Oral Testimony***

- Provided oral testimony to **Novitas** at its January [public meeting](#) on draft wound care LCD (DL35125) and to **FCSO** at its February [public meeting](#) on its draft wound care LCD (DL37166). Both testimonies addressed the NPWT issues stated above.

❖ ***Monitoring, Tracking & Alerting Membership***

- Alerted membership to DMEMACs coverage updates (released in Q1) that included a revised NPWT policy reflecting the new NPUAP staging terminology - [LCD](#) and the [policy article](#).
- Alerted membership to PDAC's Q1-issued a [correct coding bulletin](#) on NPWT, which clarified billing practices for wound dressings and related dressing change items used with negative pressure wound therapy pumps.
- Advised membership on MedLearn Matters article, “[SE17027 – Clarification of Billing and Payment Policies for Negative Pressure Wound Therapy \(NPWT\) Using a Disposable Device](#)” (Sept.)

➤ SURGICAL DRESSINGS

❖ *Final DMEMAC Surgical Dressings LCD*

The Alliance spent tremendous time (June- Dec) and resources to address the problematic final surgical dressing LCD to ensure clarity of the policy to our members. After learning from the DMEMACs at a mid-June HCPCS public meeting that they were releasing the final surgical dressings local coverage determination (L33831) and policy article (A54563), Alliance staff immediately sent it to the membership. The original policy draft, published in 2015, was erroneous and ambiguous. At that time, the Alliance submitted comprehensive comments and held discussion with the MAC medical directors. Yet, the final LCD reflected little of the comments submitted by stakeholders and was nearly identical to the original 2015 draft. Most concerning, the guidance was not consistent with how surgical dressing products are prescribed and utilized by wound care clinicians. The LCD contained significant areas of ambiguity that required further clarity to be workable in a clinical setting. The policy went into effect on July 24. The Alliance sent out a summary of policy issues and concerns, and began mobilizing members to address the problematic DMEMAC surgical dressing LCD by taking the following actions:

- **Worked with Coalition of Wound Care Manufacturers** to coordinate synergistic advocacy strategy.
 - The Coalition hired law firm Latham & Watkins to prepare and send an urgent request letter and appendix to DMEMACs and CMS to delay implementation of future surgical dressing LCD focusing on the legal/procedural issues.
 - The Alliance submitted a **letter** to the DMEMACs and CMS also requesting a delay but focused on clinical issues. (see below)
 - The Alliance reached out to its clinical members to email CMS staff to request the delay - which WOCN and AAWC did.
 - Both the Alliance and Coalition followed up with oral advocacy to obtain a delay with CMS staff; (July)
 - The Alliance then circulated CMS' email response to our emails, which reported that the agency was not allowing for the delay in implementation of the policy. (July)
- **Developed and sent letter to the DMEMACs and CMS reframing questions to seek clarification** on questions related to the Surgical Dressing LCD. In the letter, the Alliance cited the LCD's flaws in coverage criteria, in violation of current Medicare requirements and Congressional intent outlined in the 21st Century Cures Act. Furthermore, the Alliance stated in its comments that proposals in the LCD would eliminate coverage for hydrogel dressings used for stage II ulcers. The LCD includes other coverage restrictions that lack sufficient evidence to support them or that conflict with established standards of care as well. Finally, the Alliance noted that the LCD does not provide any explanation for prohibiting the use of composite dressings to treat lightly exudative wounds, which is also contrary to the standard of care.

- **Prepared and distributed to Alliance members a one pager to send to the Members of Congress involved in the LCD provision of the 21st Century Cures Act.** (July)
- **Contacted CMS and the DMEMACs** to ensure a response to our letters.
- **Convened multiple conference calls** with Latham and Watkins and members to discuss strategy and updates.
 - **Advocacy success:** In September, the Alliance sent another letter to the DMEMACs focusing on clarification issues regarding collagen dressings and wound staging. In October, the DMEMACs responded with a **“clarification letter”** on these. This letter has enabled our members to better understand how to bill for some of the surgical dressing products.
- **Informed Noridian DMEMAC medical director Dr. Peter Gurk regarding misinformation given on Nov. surgical dressing webinars** and **requested that the correct information** be placed in the surgical dressing LCD, DMEMAC advisory article or MedLearn matters article (Dec.).
 - **Advocacy success:** this was ultimately corrected through our advocacy by Noridian emailing those on the webinar with the correct information in Feb 2018.

❖ ***Surgical Dressings – Correct Coding Articles***

- Alerted members to two correct coding articles:
 - One in September the DMEMAC correct coding article “[Correct Coding - HCPCS Coding of Surgical Dressings - Components to Report on the PDAC HCPCS Code.](#)” This article was a direct result of our advocacy with the DMEMACs and PDAC to provide guidance on how to code verify surgical dressings.
 - Second one in October by the PDAC which reiterated the same information as the DMEMAC article.

❖ ***FDA Classification of Antimicrobial Surgical Dressings***

- The Alliance’s advocacy surrounding the FDA classification of surgical dressings continued in background throughout 2017. As you recall, in 2016, the Alliance took a highly proactive role in effectively educating the FDA and its Advisory Panel on the role and real-world value of antimicrobial wound care dressings. The FDA at that time was considering a regulatory classification of these products that could impact access and availability to wound care providers and patients. Our advocacy ultimately helped steer the panel’s recommendation to the FDA that antimicrobial wound dressings should be classified as a Class II with special controls. In 2017, we continued our dialogue with the agency by speaking twice with FDA Branch Chief Plastic and Reconstructive Surgery CDRH Cynthia Chang about the classification of unclassified wound dressings, as well as updating of the 2006 wound care guidance document. (Aug.)

➤ **CELLULAR AND/OR TISSUE-BASED PRODUCTS FOR WOUNDS**

❖ ***Payment & Coverage Issues – CTPs***

- Commented on **issues with the methodology for packaging of CTPs in the CY2018 Hospital Outpatient Prospective Payment System** (see p. 6).

❖ ***ASTM Issues Regarding CTPs***

- Protected the newly established ASTM CTP standard by mobilizing Alliance members who were ASTM members to vote in November to sunset the older, outdated ASTM F2311 Standard: *Guide for Classification of Therapeutic Skin Substitutes*. Alliance staff encouraged member representative to join ASTM, and those who are also in ASTM to participate in the ASTM ballot vote being discussed on its November call: “F2311-08 Should be Sunsetted and not be Reinstated.”

❖ ***FDA Guidance Document on Minimal Manipulation & Homologous Use***

- Notified members regarding the release of the final guidance document issued in December. The Alliance had submitted comments on the draft comment in 2016. Several of our comments were successfully accepted in the final guidance.

❖ ***Monitoring & Updates:*** Alerted members of CMS's January 1, 2017 [OPPS update transmittal](#) includes changes to the high cost/low cost CTP assignments in light of updated data.

➤ **FDA REGULATIONS IMPACTING WOUND CARE**

- Spoke twice with FDA Branch Chief Plastic and Reconstructive Surgery CDRH Cynthia Chang about the classification of unclassified wound dressings as well as updating of the 2006 wound care guidance document. (See Surgical Dressings section on p.11)
- Alerted members regarding FDA release of its guidance on the “Use of real-world evidence to support regulatory decision making for medical devices” and the Sept meeting on “A Framework for Regulatory Use of Real-World Evidence”

➤ **MEDPAC AND MEDCAC**

❖ ***Medicare Payment Advisory Commission (MedPAC)***

- See HCPCS Coding Reform (p.8)

❖ ***Medicare Coverage Advisory Committee (MEDCAC)***

- Sent email to members advising them regarding nominations for MEDCAC Panel.

➤ **EMERGING ISSUES**

While submission of comments is a common end-result “deliverable” of Alliance activity, much work behind the scenes goes in to monitoring emerging issues, relaying inputs and sharing experiences in the field that may be of concern. The Alliance communicates frequently with aligned associations and clinical organizations to exchange information and discuss common strategy. We monitor, analyze and discuss a broad range of issues affecting quality, coverage, coding and reimbursement impacting wound care clinical practice, then regularly update members. Several emerging issues are and have been on our radar screen including:

- Trends in DME pre-authorization/targeted probe and education (TPE)
- Trends in HBOT pre-authorization/TPE
- Claim denial trends; denial concerns and quantification of specific harms that can result from denials
- Trends on Capital Hill regarding site neutral payment legislation, chronic care legislation; competitive bidding legislation
- Eligibility of wound care professionals to receive payment for wound care (e.g., podiatrists, physical therapists)
- Identification of issues & documentation requirements for regulatory burden relief
- Quality measure development for CTP, NPWT and dNPWT
- Medicaid
- Telehealth for wound care

➤ **PROMOTION OF ALLIANCE AND VISIBILITY INITIATIVES**

❖ ***Visibility at Wound Care, Clinical, and Health Economic Meetings***

- Marcia Nusgart gave presentations and led talks on behalf of the Alliance at the following meetings:
 - **European Wound Management Association** – Keynote address on “The Changing U.S. Health Care Climate: What Does it Mean for Wound Care? (May). In addition, the Alliance members Dr. Matthew Garafoulis and Dr. Jeffrey Lehman spoke at the meeting on various wound care topics.
 - **George Washington University Summer Institute in Regulatory Science** “After FDA- What’s Next? A Reimbursement Primer.” (May)
 - **American Association for Wound Care:** Spoke at Fall Board of Directors meeting to provide an advocacy overview and opportunities for ongoing collaboration (Oct)
- Marcia Nusgart attended the following clinical associations annual meetings and other meetings, representing the Alliance:
 - American Venous Forum
 - American Podiatric Medical Association
 - Society for Vascular Surgeons
 - American Professional Wound Care Association
 - Visiting Nurse Association of America Public Policy Meeting
 - European Wound Management Association Meeting

- Wound Ostomy Continence Nurses Association
- Health Care Payment Learning and Action Network's April & October meetings
- The Alliance convened our in-person membership meeting at the Spring and Fall SAWC meeting and covered business/work plan updates, addressed “hot button” and emerging issues and heard from an assortment of expert guest speakers.

❖ ***Promotion of Alliance to Media and to Member Communication Channels***

- Developed and circulated quarterly newsletter to keep targeted trade media, and communications staff at Alliance member organizations, informed of our activities.
- Maintained [Linked-In](#) page for Alliance.
- Enhanced visibility achieved in 2017 as a result of proactive outreach to media included:
 - [Advocacy Update from the Alliance of Wound Care Stakeholders](#) in the March issue of *Ostomy Wound Management*
 - [Legislative Update: a Look at Upcoming Health Policy Through a Wound Care Lens](#) article in April issue of *Today's Wound Clinic*
 - [Demonstrating the Impact and Cost of Chronic Wounds](#) to the October issue of *Ostomy Wound Management*
 - [The changing US healthcare climate: what does it mean for wound care](#) and [Update from the Alliance of Wound Care Stakeholders](#) in the October *EWMA Journal*

➤ **MEMBER EDUCATION**

❖ ***Guest experts educated Alliance members on key issues***

- Lynn Snyder and Kim Tyrell-Knott presented on “Post Election Analysis of Health Care Legislative and Regulatory Trends” at the Alliance’s Spring SAWC meeting.
- Dave McNitt of National Health Advisors provided a “Political Update” to Alliance membership at the Spring SAWC.

❖ ***Ensured Alliance members were aware of relevant published policies, public meetings, workshops, seminars and webinars:***

- Shared updates via quarterly Alliance Advocacy Update e-newsletter
- Sent members emails advising them of public meetings and policy discussions:
 - HCPCS codes when released and public meeting schedule
 - MEDCAC reports and meetings
 - MEDPAC reports and meetings
 - FDA draft and final guidance documents and public meetings
 - Draft and final LCDs
 - ARHQ technology assessments
 - PCORI meetings
 - Health Affairs meeting on “What’s Next for Value-Based Reimbursement in Healthcare” and article Medical Equipment Competitive Bidding Saved Medicare Money”

- Duke-Margolis Center for Health Policy meeting on real-world evidence
- HCPLAN meetings
- GAO report on recommendations regarding coverage of disposable medical devices
- ASTM workshop on antimicrobial combination devices
- CMS webinar- “Cuts to Medicare DMEPOS Payment Based on Competitive Bidding Prices: Comment Opportunity”
- Capitol Hill confirmation hearings and legislation, including: Alerted members of the Senate and House versions of the LCD Clarification Act of 2017 (S.794 and HR.3635)
- News reports, including: alerted members of articles in press regarding wound care (Kaiser Health News articles on hyperbaric oxygen therapy and wound care in August)

❖ ***Welcomed new members in 2017***

- We welcomed the [Amputee Coalition of America](#), BTG, [Medline Industries](#), [Organogenesis](#) and [Prism Medical Products](#), to the Alliance in 2017.

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