COALITION OF

Wound Care Manufacturers

2014 ANNUAL REPORT SUMMARY

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 (e.g., Office of Inspector General, 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), Medicare Payment Advisory Commission (MedPAC), Patient Centered Outcomes Research Institute (PCORI)

  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 501 c (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.

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2014 ACCOMPLISHMENTS - EXECUTIVE SUMMARY

VALUE PROPOSITION OF THE COALITION

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.

Members enjoy the following benefits:

- ***Has 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 and physician organizations 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. Examples include:***

  - *CMS and CMS contractor meetings*
    - Meetings with Novitas Medical Director Dr. Mitchell Burken with NPWT manufacturer members to educate him on disposable NPWT and then with Coalition staff and antitrust counsel to discuss pricing for G codes.

  - *Submitting Eight Sets of Comments to CMS*
    - 2 sets -Hospital Outpatient PPS (Sept and Dec)
    - 2 sets- Physician Fee Schedule (Sept and Dec)
    - ESRD/DME Competitive Bidding (Aug)
    - Prior Authorization for DMEPOS (Aug)
    - Preliminary coding decision for CTPs for CMS HCPCS public meetings (May)
    - Proposed Methodology for Adjusting Payment Amounts for Certain DMEPOS Using Information from Competitive Bidding Programs (March)

  - *Submitting Four Sets of Comments to CMS contractors*
    - DMEMACs on "Request for Information on Medical Grade Honey as a Surgical Dressing Component"
    - 3 sets of comments to CMS A/B MAC contractors on wound care LCDs:
      - Novitas draft LCD- Application of Bioengineered Skin Substitutes to the Lower Extremity for Chronic Non Healing Wounds (DL27549)
      - Palmetto draft LCD- Debridement of Wounds (DL 35415)
      - First Coast Service Option's draft LCD, "Application of Bioengineered Skin Substitutes for the Treatment of Diabetic and Venous Stasis Ulcers of the Lower Extremities" (DL35384)

- ***Provides members with access to key policy decision makers to address their own and their customers' specific regulatory problems.*** (e.g. CMS senior staff Sean Cavanaugh, Liz Richter, Laurence Wilson, Cindy Hake on HCPCS Coding Reform issues; FDA senior staff Mary Brady on FDA home use issues; USP staff Dr. Fouad Atouf on CTP monograph issues)

- ***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) Examples include:***

  - *CMS Issues- Notified members on:*
    - First Coast's draft LCD is not retired as posted and it will be releasing it in final soon.
    - Sent email to regional CMS offices asking why Novitas policy was pulled which prompted the contractor to issue a provider alert explaining that it had not completed its review and analysis of its policy

  - *AHRQ Issue- Alerted members on:*
    - Issuing AHRQ draft technology assessment on "Negative Pressure Wound Therapy Technologies for Chronic Wound Care in the Home Setting" and advising members that there were only two weeks to submit comments

  - *FDA Issues- Advised members on:*
    - Issuance of FDA Guidance on Home Care
    - Draft guidances on "HCT/P from Adipose" and "Minimal Manipulation of Human Cells, Tissues, and Cellular- and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff."

  - *ASTM and CTPs*
    - Alerted CTP manufacturers to become ASTM members so as to vote positively on the ATM ballot to adopt the CTP document and to have a voice in ASTM guidelines and nomenclature.

- ***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. Examples include:***

  - *Creating Wound Care Quality Measures-Alerted members to*
    - The opportunity to participate in various product specific conference calls to create wound care quality measures that would be submitted through the Qualified Clinical Data Registry; Convened conference call for members to review these measures before submission to CMS.

  - *Congressional Issues- Alerted members on:*
    - 21st Century Cures bill and provision within it regarding disposable negative pressure wound therapy.

  - *HCPCS Coding Issues-Informed members immediately on:*
    - Dates for HCPCS Public meetings, Preliminary Coding Decisions; New HCPCS codes release
    - Success in achieving HCPCS posting coding decisions on its website, demonstration project for web-based notice and comment mechanism for allowing public input on requests to discontinue Level II HCPCD codes that are generated internally based on national program operating needs, are not the subject of other notice and comment mechanisms; and that are replaced by other or new codes and streaming live the HCPCS public meetings

- *CMS/AHRQ Issues-Provided analysis of:*
  - Final rules on Physician Fee Schedule, Hospital OPPS, ESRD/DME
  - AHRQ report on "Negative Pressure Wound Therapy Technologies for Chronic Wound Care in the Home Setting"

- *Legislative and Regulatory Updates*
  - Updates on DMEMAC and A/B MAC Medicare coverage policies; Delay of ICD-10; OIG Reports (LCDs create inconsistencies in Medicare coverage); Clarification of CMS Documentation requirements for home health face-to-face encounters;
  - CMS/DMEMAC personnel changes- Jon Blum leaving CMS; Dr. Paul Hughes to PDAC

- ***Communicates frequently with federal and state policymakers regarding industry positions and needs when the policy is in its formative stage in order to merge proposed or final policies that are adverse to manufacturers with wound care products***. (e.g., working with CMS and DMEMAC medical directors on issues related to coverage of wound care products)

  - Contacted DMEMAC regarding information they were interested in obtaining regarding medical grade honey as a surgical dressing component
  - Speaking with FDA senior staff Dr. Suzanne Schwartz regarding FDA's thinking on revising the 2006 guidance documents on wound care

- ***Attends and informs members about policy conferences and regulatory educational opportunities for them to attend that will impact their products*** (e.g., First Coast and Novitas public meetings on CTPs; USP Meetings on tissue products; ACOs and E Health Seminar; Deloitte Center for Health Solutions discussion on legislative events)

- ***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.***

2014 COALITION 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 2014. These include:

- **Access to Novitas A/B MAC Medical Director resulting in speaking at Coalition strategic planning meeting and meeting with members on disposable NPWT technology.** The Coalition convened meetings with Novitas Medical Director Dr. Burken and the NPWT manufacturers to educate him on their technology and then with Coalition staff and antitrust counsel to discuss pricing for G codes.

- **New CPT codes and carrier pricing issued for disposable NPWT.** The Coalition successfully lobbied the Alliance to go before the RUC to advocate for RUC payment for practice expense for the new CPT codes for the procedure using disposable NPWT (97605, 97606, 976XX11, 976XX12). Together we worked with CMS to ensure that the price of the disposable NPWT was included in the RUC rate since it was not originally included in the practice expense. Ultimately, the new CPT codes were adopted with appropriate coding descriptors, the G codes eliminated, and CMS will use carrier pricing.

- **DMEMACs delays clinically inappropriate LCD on pneumatic compression devices -** The Coalition successfully advocated to the Alliance of Wound Care Stakeholders to take on this issue. Coalition members worked with the Alliance in creating a unified voice in reaching out to CMS senior staff and DMEMAC medical directors and meeting with Congressional staff to discuss the issue. Ultimately, the DMEMACs delayed their implementation of this clinically inappropriate policy.

- **Succeeded in having CMS enact three changes to the HCPCS coding process which were the direct result of advocacy by the Alliance for HCPCS II Coding Reform (placing final decisions on CMS website, public input on requests to discontinue HCPCS codes, live streaming of HCPCS public meetings)**

- **Participated in conference calls to help the Alliance and U.S. Wound Care Registry create 12 new Physician Quality Reporting System (PQRS) wound care measures as submitted through the Qualified Clinical Data Registry (QCDR) process to CMS.** The Coalition convened conference calls with Dr. Caroline Fife as guest speaker to understand the importance and urgency of creating these quality measures since the opportunity presented itself through a new process called QCDR. The Coalition members participated in the various conference calls which created the 12 measures. The establishment of these measures are important since CMS is moving providers to alternative pay models and valued- based payments such as these in the next few years.

- **Submitted Four Sets of Comments on CMS DMEMAC Wound Care Local Coverage Determinations (LCDs)** The Coalition was proactive in submitting 3 sets of comments to Novitas Solutions, First Coast and Palmetto as well as comment to the DMEMACs regarding Honey. In its final LCD, Cigna adopted the new CTP terminology in place of "skin substitutes".

- **Submitted Eight Sets of Comments to CMS-** In the ESRD/Competitive Bidding final rule, the Coalition was successful in preventing CMS from bundling certain DME (i.e. oxygen, standard manual wheelchairs, enteral nutrition, RADs, hospital beds).

- **Active supporter and participant in Alliance of Wound Care Stakeholders activities and achievements: (Have Coalition representative to provide guidance to the Alliance)** In addition to successfully developing new wound care quality the DMEMAC LCD on pneumatic compression, here are the other alliance achievements:
  - Convened successful meeting of wound care researchers and industry representatives to identify concerns with the 2006 Wound Care guidance document and begin to form recommendations that will be further discussed in future meetings.
  - Created Cellular and/or Tissue Based Products for Wounds" (CTPs) guidance document for ASTM F-04 committee which was balloted.
  - Helped to convince the DMEMAC Medical Directors to continue coverage and payment for honey impregnated dressings by submitting comments to their Request for Information on Medical Grade Honey as a Surgical Dressing Component
  - Recognized that the A/B MACs (Novitas Solutions, Cigna) began to use the Alliance terminology "Cellular and/or Tissue Based Products for Wounds" (CTPs) in place of clinically inaccurate term "skin substitutes" in its LCDs and by ASTM in its draft guidance document.
  - Due to Alliance's advocacy in addressing the clinical inaccuracies in the Milliman Care Guidelines (MCG) on Intermittent Pneumatic Compression with its Editor In Chief, the next edition (18th) in 2014 was corrected and more accurate. This will allow the payers who use the MCG for their coverage policies to have ones that are clinically correct and thus allow patient access to these products.
  - Successful in convincing CMS to change QCDR requirements for outcomes measures in final Physician Fee Schedule rule based on our comments submitted to CMS on proposed rule. (Sept).
  - Successful in having the A/B MACs adopt our comments for the following LCDs:
    - Novitas HBOT LCD policy was withdrawn based on Alliance comments. Novitas is willing to work with the Alliance to correct the policy.
    - NGS adopted Alliance's language and revised its LCD language regarding "failed response".
    - Palmetto accepted Alliance's recommendations to add several additional ICD-9 codes to its debridement LCD and eliminated the quantification of the surface area, volume or dimensions of the viable tissue removed in the debridement procedure.
    - Novitas adopted Alliance's CTP terminology and has a less restrictive coverage policy for CTPs (temporarily before the policy was put on hold for further review)

2014 COALITION ACHIEVEMENTS/ACTIVITIES BY TOPIC

➢ NEGATIVE PRESSURE WOUND THERAPY (NPWT) PRODUCTS

Value to Members

The Coalition has been proactive in addressing any issues that could impact coverage, coding and payment implications for NPWT- both traditional and disposable. This includes: taking an active role in submitting comments to CMS and the A/B MACs on coverage policies, educating the A/B MACs such as Novitas medical director on NPWT technology so as to have appropriate pricing for the CPT codes; submitting comments to AHRQ on a NPWT home care technology assessment, competitive bidding and addressing the need for coding, coverage and payment for disposable NPWT technology.

The many activities are described below.

Achievements/Activities

- *Collaborated with the Alliance of Wound Care Stakeholders to obtain appropriate payment for disposable NPWT. Together we worked with CMS to ensure that the price of the disposable NPWT was included in the RUC rate since it was not originally included in the practice expense.*

- *Comments to CMS and A/B MACs LCDs*

  - Advocated for change in Cigna coverage policy with its senior medical director to gain coverage for disposable NPWT. (March- June 2014)
  - Submitted comments to CMS on the Physician Fee Schedule regarding APC reassignment from APC 0016 to APC 0015 (September)
  - Submitted Comments to CMS on their requirements for Prior Authorization and addressed NPWT in this proposed rule by citing it as an example in a study issued on improper payments. (July)

- *Meetings with Novitas Medical Director Dr. Mitchell Burken*

  - Convened meetings with Novitas Medical Director Dr. Mitchell Burken with NPWT manufacturer members to educate him on disposable NPWT and then with Coalition staff and antitrust counsel to discuss pricing for G codes.

- *AHRQ*

  - Submitted comments on AHRQ Draft TA on "Negative Pressure Wound Therapy Technologies for Chronic Wound Care in the Home Setting" (July)

- *Competitive Bidding*

  - Submitted comments to CMS on "The Proposed Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) using Information from Competitive Bidding Programs" (March)

➢ CELLULAR AND/OR TISSUE BASED PRODUCTS FOR WOUNDS (CTPS) (FORMERLY "SKIN SUBSTITUTES")

Value to Members

The Coalition was both proactive and quickly responsive on all aspects of CTP coding, coverage and payment issues. Recognizing that this product sector relies on the expertise of physicians and clinicians to address issues, the Coalition, in addition to submitting comments itself, also supported the Alliance members' initiatives since the A/B MAC Medicare medical directors listen to the Alliance as it is a clinical organization. These efforts create a unified voice for wound care.

In 2014, the Coalition devoted a tremendous amount of resources to address issues facing skin substitutes. It submitted two sets of comments to the A/B MACs (First Coast, Novitas on two different LCDs). In regards to nomenclature, Coalition members took an active role in ASTM to ensure that a guidance document on nomenclature would objectively reflect the industry. While the Coalition continues to oppose the bundling of CTPs, we continue to address appropriate coding coverage and payment for these products as well as to ensure accurate description in the policies.

Achievements/Activities

- *Submitted four sets of comments to CMS that included statements regarding CTPs:*
  - Submitted comments to CMS on CMS-1613-P 2015 HOPPS. (Sept)
  - Submitted comments to CMS on the Final HOPPS regulation with comment period (Dec)
- *Submitted two sets of comments on CTP draft LCDs:*
  - First Coast (July)
  - Novitas (Nov.)
  - The Coalition held numerous conference calls to address comments
- *HCPCS Public Meeting*
  - Karen Ravitz spoke on behalf of the Coalition at May HCPCS Public meeting to support the CMS HCPCS Workgroup preliminary coding decision of not grouping CTPs into surgical dressing HCPCS codes and submitted comments to the HCPCS Workgroup on this issue
- *ASTM*
  - Alerted CTP manufacturers to become ASTM members so as to vote positively on the ATM ballot to adopt the CTP document and to have a voice in ASTM guidelines and nomenclature.
  - Created separate ASTM CTP guidance document and balloted it for the first time with the F-04 committee. Held numerous conference calls to create the document and address negative votes so as to re-ballot successfully in February 2015

➢ WOUND CARE QUALITY MEASURES

VALUE TO MEMBERS

As CMS begins moving providers to alternative pay models and value- based payments, the importance of establishing quality measures is apparent. Since there were very few wound care measures, there was a need to create specific ones. The QCDR will expand the opportunities for quality research since this program will dramatically expand the number of physicians reporting as a result of the imperatives from Medicare to participate. Although the QCDR exists to fulfill Medicare reporting requirements for practitioners, these quality data can be highly valuable for the entire wound care community.

ACHIEVEMENTS/ACTIVITIES

- *Convened conference calls with Dr. Caroline Fife as guest speaker to understand the importance and urgency of creating these quality measures since the opportunity presented itself through a new process called QCDR.*
- *The Coalition members participated in the various conference calls which created the 12 measures one of which was for CTPs.*

➢ DMEMAC AND A/B MAC CONTRACTOR ISSUES

Value to Members

Since these contractors are responsible for coverage policies that pertain to wound care products and procedures, the Coalition members need to be knowledgeable about who the contractors are, any changes to their policies and be ready to respond to coverage changes that impact their products.

Achievements/Activities

- *Novitas A/B MAC Dr. Burken spoke to Coalition members at their strategic planning meeting and then met with Coalition disposable NPWT manufacturers (see NPWT section)*
- *Coalition addressed issues relating to skin substitute/CTP LCDs (see skin substitute/CTPs section).*
- *Coalition addressed issues to wound care LCDs*
- *Informed members of A/B MAC LCD open/public meetings*
- *Informed members on release of DMEMAC request for information on medical grade honey and discussed advocacy on Coalition conference call.*
- *Contacted A/B MAC medical directors multiple times regarding timing of release of CTP LCD policies which were either delayed or put on hold.*

➢ ALLIANCE OF WOUND CARE STAKEHOLDERS

Value to Members

It is critical to have access to a wound care advocacy organization consisting of physician and clinician specialty societies/organizations that can respond to wound care issues that impact the Coalition members and their customers. (Some information is also in the section on CTPs)

Achievements/Activities

❖ *Quality Measures*

- Recognizing the opportunity to develop new Physician Quality Reporting System (PQRS) wound care measures as submitted through the Qualified Clinical Data Registry process to CMS, the Alliance performed the following activities within 3 weeks:
  - Hired a former National Quality Forum senior staff to guide and educate the Alliance members on developing the quality measures
  - Reached out to both Alliance specialty societies and non-wound care associations to understand if and how they were developing quality measures
  - Ensured that the process was transparent by communicating effectively with the members to educate them on the opportunity and fully engaging them in the project. This was done by:
    - Sending 5 emails to the members outlining as series of 8 separate conference calls for member participation on the following subjects: diabetic foot ulcers, venous stasis ulcers, hyperbaric oxygen, pressure ulcers, wound bed preparation, lymphedema, advanced therapies and nutrition. The calls were successful in that they included participation of over 100 clinicians which included both Alliance organizations as well as those who had specific expertise in the subject matter.
    - Sending email to Alliance members after calls concluded to summarize the list of measures created, FAQs and next steps
  - Convened call with CMS QCDR senior staff to outline our plan for creating quality measures and educating them on wound care. CMS staff agreed to allow the Alliance to serve as a de facto specialty society for the wound care field to develop the measures.
  - Collaborated with the U.S Wound Registry (USWR) to develop 12 wound care measures which were submitted and adopted by CMS.
  - Daniel Green, M.D., Medical Officer, CMS, Center for Clinical Standards and Quality (CCSQ), Division of Electronic and Clinician Quality (DECQ) spoke at Alliance's April meeting on the 2014 PQRS QCDR and answered questions.
  - Reached out to Alliance clinical specialty associations to address implementation of the quality measures within their organizations.

➢ *Cellular and Tissue Based Products for Wounds (CTPs)*

❖ *Payment Issues-CTPs*

- Created unified voice of Alliance members to be proactive and quickly responsive to the release of the HOPPs proposed rule as it impacted CTPs by submitting 4 sets of comments to CMS and educated Senator Isakson's staff with constituent Amniox Medical on Alliance's position regarding the HOPPs rule and to discuss the high/low cost thresholds. (Jan)

❖ *Coverage Issues-CTPs*

- Submitted two sets of comments on CTP draft LCD to Novitas and First Coast
- Submitted clarification letter to NGS on L 26003- Biologic Products for Wound Treatment and Surgical Interventions regarding failed response
- Submitted reconsideration LCD requests to change "skin substitute" language to CTP to the WPS, Novitas and Cahaba.

❖ *Coding Issues-CTPs*

- Marcia Nusgart spoke on behalf of the Alliance at May HCPCS Public meeting to support the CMS HCPCS Workgroup preliminary coding decision of not grouping CTPs into surgical dressing HCPCS codes and submitted comments to the HCPCS Workgroup on this issue.

❖ *ASTM-CTPs*

- Created separate ASTM CTP guidance document and balloted it for the first time with the F-04 committee. Held numerous conference calls to create the document and address negative votes so as to re-ballot successfully in February 2015.

➢ ***NPWT***

❖ *Coverage Issues-Disposable NPWT*

- Advocated for change in Cigna coverage policy with its senior medical director to gain coverage for disposable NPWT. Compiled information from companies and wrote letter to Cigna. (March- June 2014)

❖ *Payment Issues-Disposable NPWT*

- Attended RUC meeting to support Alliance clinical associations (APMA, ASPS, ACS, AAOS) who advocated for RUC payment for practice expense new CPT codes for the procedure using disposable NPWT (97605, 97606, 976XX11, 976XX12). The Alliance sent them and to the RUC Committee invoice pricing for the devices to be used in the pricing of the codes. (Feb 2014)
- Worked with CMS to ensure that the price of the disposable NPWT was included in the RUC rate since it was not originally included in the practice expense by performing the following activities:
  - Hired antitrust attorney to collect and submit manufacturer invoice pricing with Alliance staff's help to CMS pricing staff in preparation for July meeting with them.
  - Convened numerous conference calls and meetings to prepare for CMS meeting. (11)
- Met with CMS pricing staff to educate them on disposable NPWT and had antitrust attorney discuss the submitted pricing information with them. (July)
  - At CMS's request for supplemental pricing information, antitrust attorney with Alliance staff's help collected and submitted to CMS complete data of current paid invoices in a designated time frame to ensure that the invoices were not "cherry-picked". (Aug)
  - Antitrust attorney and Alliance staff contacts CMS staff numerous times to ensure the Agency received the information and asks if any questions.
- CMS states in its final rule that the new CPT codes will use carrier pricing. (October)
- Submitted comments to CMS on APC reassignment from APC 0016 to APC 0015

❖ *AHRQ*

- Submitted comments on AHRQ Draft TA on *"Negative Pressure Wound Care Technologies" (*July)

➢ ***Pneumatic Compression Devices***

❖ Organized an Alliance pneumatic compression working group that developed and executed legislative and regulatory strategies to address Sept 2014 DMEMAC release of a clinically inappropriate LCD that severely reduced patient access to necessary home treatment for patients who already have few effective treatment options. This initiative caused the DMEMAC medical directors to delay the LCD.

❖ Due to Alliance's advocacy in addressing the clinical inaccuracies in the Milliman Care Guidelines (MCG) on Intermittent Pneumatic Compression with the Editor In Chief, the next edition (18th) in 2014 was

corrected and more accurate. This will allow the payers who use the MCG for their coverage policies to have ones that are clinically correct and thus allow patient access to these products.

- ***Coverage Issues- Wound Care (Additional)***

Seven Sets of Comments Submitted to CMS (see website)

- Hospital Outpatient Prospective Payment System, Prior Authorization, Home Health Agency PPS- Face to Face Requirement (CMS- 1611-P), Physician Fee Schedule

Additional Comments Submitted to CMS Contractors

- Palmetto draft LCD on Debridement of Wounds;
- Cahaba draft LCD on Ultrasound Therapy for Wounds

Hyperbaric Oxygen Issues

- March: Alliance submitted comments Novitas Solutions for Local Coverage Determination on Hyperbaric Oxygen Therapy
- June: Novitas LCD policy was withdrawn based on Alliance comments.
- July: Dr. Fife sent a letter to Novitas Medical Director Dr. Patterson requesting to help draft the Novitas HBO LCD.

Cochrane Collaboration Issues

- Alliance submits comments to Cochrane Collaboration regarding review of "Honey as a Topic Treatment for Wounds" in that it included a recommendation which had not been part of previous wound care Cochrane Reviews. This deviated from the intent of the Cochrane Review to only inform clinicians of the sufficiency of data for the use of particular product or procedure.

- ***Coding Issues- Wound Care***

Honey as a Component in Surgical Dressings

- Submitted comments to DMEMAC medical directors regarding request for information regarding the use of honey as a component in surgical dressings (July).

- ***Regulatory Wound Care Issues- FDA and USP***

2006 Wound Care Guidance Document on Wound Care

- FDA staff reaches out to Alliance staff to begin a series of conference calls to request Alliance's input on concerns and recommendations regarding the areas that need revision of the guidance document.
- April- Alliance members determined at its meeting that working with FDA on this issue was a priority
- Nov- Alliance convenes meeting of wound care researchers and industry representatives to identify concerns with the 2006 Wound Care guidance document and begin to form recommendations that will be further discussed in future meetings.

United States Pharmacopoeia (USP) Meetings

- Marcia Nusgart and Karen Ravitz attend two USP meetings devoted to cells and tissues. The USP staff has stated that it would like to work more with the Alliance members.

- **MODERNIZATION OF THE HCPCS CODING SYSTEM**

Value to Members

Having a transparent, understandable and predictable process will allow manufacturers to obtain the HCPCS codes their customers need to bill and obtain appropriate reimbursement for their products. If manufacturers are not able to procure distinct HCPCS codes for their products, then this will lead to their products not being prescribed and sold in the marketplace; decreased revenues for the companies and ultimately stifling innovation for new technologies.

Achievements/Activities

- *Convened meeting with CMS senior staff Sean Cavanaugh, Liz Richter, Laurence Wilson, Cindy Hake to address need for HCPCS coding changes (October)*
- *CMS announces at HCPCS public meetings three new changes that the Alliance for HCPCS II Coding Reform had suggested: (placing final decisions on CMS website, public input on requests to discontinue HCPCS codes, live streaming of HCPCS public meetings)*

➢ COMPETITIVE BIDDING

Value to Members

CMS has moved forward with competitive bidding even though the industry has been opposed to it over the years. While surgical dressings are not subject to competitive bidding, NPWT has been included in the second round. The Coalition has kept its members apprised of new issues impacting them on this subject including the CMS proposed and final rules

Achievements/Activities

- *Coalition comments on CMS-1460-ANPRM: The Proposed Methodology for Adjusting Payment Amounts for Certain Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) using Information from Competitive Bidding Programs*
- *Coalition comments on CY 2015 End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) and Durable Medical Equipment Prosthetics, Orthotics, and Supplies (DMEPOS) Proposed Rule*
- *Summarized final regulation and provided information to Coalition members.*

➢ EDUCATING MEMBERS ON IMPORTANT ISSUES THROUGH WEBINARS AND SEMINARS

Value to Members

It is important to educate members on topical issues that will have value to their business and provide an opportunity for inviting company staff and customers to attend.

Achievements/Activities

- *Convened Coalition's strategic planning with the following speakers:*

  - Lynn Shapiro Snyder, Esq., Senior Member of Firm, Epstein, Becker & Green PC
  - S. Lawrence Kocot, Esq., Member of the Firm in the Health Care and Life Sciences practice of Epstein, Becker & Green PC
  - Dr. Fouad Atouf, Director of Biologics and Biotechnology, United States Pharmacopeial Convention (USP)
  - Dr. Mitchell Burken, Medical Director, Novitas Solutions
  - Mary Weick-Brady, MSN, RN, Senior Policy Advisor, Office of the Center Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration
  - Caroline Fife MD, Executive Director, U.S Wound Registry Co-Chair, Alliance of Wound Care Stakeholders
  - Jule Crider, Executive Director, American Association for Wound Care Management

- *Notification of Additional Workshops, Seminars and Webinars:*

  - First Coast public meeting on CTPs; USP Meetings on tissue products; ACOs and E Health Seminar; Deloitte Center for Health Solutions discussion on legislative events

➢ Work with FDA on Wound Care Issues

Value to Members

It is important for the members to be informed and active with the FDA as the Agency addressed issues that impact wound care medical device manufacturers.

Achievements/Activities

- *2006 FDA Guidance for Industry Chronic Cutaneous Ulcer and Burn Wounds – Developing Products for Treatment*

  - Coalition members participated in Alliance's November meeting to identify concerns with the 2006 Wound Care guidance document and begin to form recommendations that will be further discussed in future meetings.

- *FDA's Home Use Guidance Document:*

  - Mary Brady spoke at Coalition's strategic planning meeting in 2014 to discuss the guidance document.

- *Sent members information on following FDA activities:*

  - Draft Guidance Minimal Manipulation of Human Cells, Tissues, and Cellular- and Tissue-Based Products; Draft Guidance for Industry and Food and Drug Administration Staff."
  - Draft Guidance Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) from Adipose Tissue: Regulatory Considerations;