COALITION OF

Wound Care Manufacturers

2012 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 [DME MAC] 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), and Medicare Payment Advisory Commission (MedPAC)
- These federal agencies control the coding, coverage and payment rules under Medicare and Medicaid for wound care products.
- 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 now is a 501 c (6) multidisciplinary trade association of physician, clinical and patient 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 decisionmakers for the wound care industry.

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2012 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, physician and patient 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 Centers for Medicare and Medicaid (CMS) senior level staff, their contractors DME MAC 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:***

    - Meeting with CMS Acting Administrator Marilyn Tavenner, Jon Blum and senior staff to discuss the Agency's adoption of the Negative Pressure Wound Therapy (NPWT) supplier accreditation checklist (January)
    - Meeting with CMS Director Jon Blum and senior staff along with Alliance of Wound Care Stakeholders to discuss CMS's decision that competitive bidding contracts will ONLY be awarded to suppliers who meet the Medicare quality standards and that are accredited specifically for furnishing covered NPWT items and services. (March)
    - Meeting with CMS Deputy Administrator Jon Blum, CMS senior staff and representatives from the Alliance for HCPCS II Coding Reform to discuss changes in the HCPCS coding process. (September)
    - Meeting with FDA's Mary Brady regarding PDAC labeling requirement (January)
    - Contacting the PDAC (phone and by email) to inquire about delay in coding verification for collagen products (spring and fall)
    - Submitting comments to AHRQ on technology assessment for skin substitutes. (January)
    - Submitting comments to A/B MAC contractor Noridian on its draft skin substitute LCD policy (July)
    - Submitting two sets of comments to CMS on Medicare Physician Fee Schedule – face to face requirement (September) and G-codes (December)

- ***Provides members with access to key policy decisionmakers to address their own and their customers' specific regulatory problems.*** (e.g. Mary Weick-Brady [Chair, FDA Homecare Committee], Elise Berliner [AHRQ], DME MAC Medical Directors, CMS Staff Jonathan Blum, Carol Blackford, and Amy Bassano)

- ***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:***

    - Informing members of the disastrous effect the Noridian draft skin substitute LCD would have and notified and rallied members to testify and submit comments during the Noridian open door meeting and open comment period.
    - Advising members on AHRQ technology assessment on skin substitutes and working with them to submit comments.
    - Alerting skin substitute manufacturers to become ASTM members so as to have a voice in ASTM guidelines and nomenclature
    - Alerting members to PDAC's change in coding for collagen dressings
    - Advising members on AHRQ notice requesting manufacturer's studies for venous ulcer treatment to include in the Agency's report on "Chronic Venous Ulcers: A Comparative Effectiveness Review of Treatment Modalities."
    - Advising members on FDA draft guidance document on Devices Intended for Home Use and stating that comments will be due in 2013.

- ***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:***

    - Sending members legislative and regulatory updates (e.g., updates on DMEMAC and A/B MAC Medicare coverage policies [suction pump policies, skin substitutes]; IRS final regulations on the ACA excise tax imposed on the sale of certain medical devices, new PDAC updates- product information on sample requirements for surgical dressings, new information on FDA post surveillance for medical devices)
    - Educating members on impact of the 2012 elections (Debra McCurdy speaking on Coalition call), articles on fiscal cliff, impact of Supreme Court decision on Affordable Care Act (webinar)
    - Informing members immediately on HCPCS coding issues: dates for HCPCS Public meetings, Preliminary Coding Decisions; New HCPCS codes release
    - Sending members information about attending CMS' MedCAC meeting on Evidentiary Characteristics for Coverage with Evidence Development

- ***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 DME MAC medical directors on issues related to coverage of wound care products)

- ***Attends and informs members about policy conferences and regulatory educational opportunities for them to attend that will impact their products*** (e.g., CMS' Care Innovations Summit, , PCORI Draft National Priorities for Research and Research Agenda, AHRQ Annual Meeting, Hearings on Capitol Hill on competitive bidding, CMS Open Door Meetings for DME, Long Term Care)

- ***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.***

2012 COALITION SUCCESSES

While successes in Washington have been hard to come by, we are pleased to state that we have had a few successes in very distinct areas in 2012. These include:

- **CMS adopts NPWT supplier accreditation checklist** that the Coalition, Alliance of Wound Care Stakeholders and other associations developed. This occurred only after these organizations met with Acting Administrator Tavenner in January 2012. In March, CMS stated that competitive bidding contracts will ONLY be awarded to suppliers who meet the Medicare quality standards and that are accredited specifically for furnishing covered NPWT items and services.

- **Alliance of Wound Care Stakeholders' "Consensus Principles for Wound Care Research Obtained Using a Delphi Process" Published in May/June *Wound Repair and Regeneration*** – The Alliance created a multidisciplinary expert panel (**P**anel **O**n **W**ound Care **E**vidence-based **R**esearch - **POWER™)** in wound care research from its participating organizations to define a set of principles to provide direction to all stakeholders involved in clinical or comparative effectiveness research in wound healing. A modified Delphi approach was used to help reach consensus on the principles. A manuscript was generated that has been published in the peer reviewed publication *Wound Repair and Regeneration.*

- **PDAC Rescinds the Requirements for Product Labeling-** We had visited the PDAC in December and addressed the problems associated with the labeling especially on respiratory products. We had also raised it with Mary Brady of the FDA at the Coalition of Wound Care Manufacturer's strategic planning meeting. It is our understanding that the orthotic association was very vigilant in making their concerns known to the PDAC also.

2012 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 and suction pumps. This includes: taking an active role in ensuring that quality standards are developed and implemented within CMS, alerting the members of the release of the suction pump LCD, and addressing the need for coding and coverage for disposable NPWT technology in the form of G codes.

Since NPWT was chosen for the second round of competitive bidding, it was important to ensure that only accredited suppliers who were knowledgeable about providing NPWT would win bids. This would support the FDA recommendations regarding the use of NPWT. Therefore, the Coalition worked with the Alliance of Wound Care Stakeholders to be vigilant in advocating for CMS to adopt the NPWT supplier accreditation checklist. The many activities are described below.

Achievements/Activities

- Met with CMS Acting Administrator Marilyn Tavenner, Jon Blum and senior staff to discuss the Agency's adoption of the Negative Pressure Wound Therapy (NPWT) supplier accreditation checklist (January 27)
- Met with CMS Director Jon Blum and senior staff along with Alliance of Wound Care Stakeholders to discuss CMS's decision that competitive bidding contracts will ONLY be awarded to suppliers who meet the Medicare quality standards and that are accredited specifically for furnishing covered NPWT items and services. (March 9)
- Addressed issues relating to NPWT being included in the second round of competitive bidding. In addition to working on the supplier accreditation checklist, the Coalition providing the information to its members on two Congressional hearings on the topic- May 9 House Ways and Means Subcommittee on Health; September 11 Healthcare and Technology Subcommittee Hearing on "Medicare's DME Competitive Bidding Program: How are small suppliers faring?"
- Informed members on release of DMEMAC LCD on suction pumps (March 1) and discussed advocacy on Coalition conference call.
- Submitted comments on the physician fee schedule (Dec) to advocate for G codes to gain payment for disposable NPWT technology and meeting with CMS to discuss NPWT coding.

➢ Skin Substitutes

Value to Members

In 2012, skin substitutes drew the attention of CMS and its contractors who tried to limit coverage by writing draconian draft local coverage (LCD) determinations and issuing draft technology assessments. The Coalition was both proactive and quickly responsive on all aspects of skin substitute 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 representatives.

AHRQ was first to issue a complex and problematic technology assessment, which if left unchallenged, would have given the A/B MAC contractors an opportunity to use to validate non-coverage of skin substitutes. Noridian then released its draft LCD which contained many problematic provisions- one of which allowed the contractor to change the LCD depending on the outcome of the final version of the AHRQ technology assessment.

By the Coalition submitting comments and supporting the Alliance in proactively meeting with AHRQ to discuss the comments and methodology flaws, it put the Agency on notice and delayed the final from being released. The Coalition also submitted comments to Noridian regarding its problematic LCD on skin substitutes. In regards to nomenclature, the Coalition members worked with the Alliance to address more appropriate terminology for skin substitutes and took an active role in ASTM to ensure that a guidance document on nomenclature would objectively reflect the industry. Finally, the Coalition supported the efforts of the Alliance in proactively educating CMS coding, coverage and payment senior staff in a seminar on these topics. If the Coalition had not responded in a timely and united fashion to address all of these issues, there could have been severe restrictions on coverage of skin substitutes.

Achievements/Activities

- AHRQ
  - Jan-Submitted comments regarding the draft technology assessment on skin substitutes
  - July-Met with AHRQ staff in July to address our concerns with the problematic methodology and comments.

- CMS
  - Aug- With the Coalition's support, the Alliance scheduled two meetings with CMS staff to discuss the following:
    - Alliance wound care specialists team met with 25 senior staff from three key CMS divisions (Coverage & Analysis Group-coverage; Hospital and Ambulatory Policy Group- payment; Chronic Care Policy Group- coding) to discuss framework and terminology, clinical evidence, and regulatory status under FDA and its relationship to benefit categorization under Medicare law.)
    - Alliance POWER authors met with CMS Coverage staff to position Alliance's "Principles of Wound Care Research" as a paper to provide CMS with guidance as the Agency develops policies on these issues. It was discussed how the Principles compared with CMS's views on Coverage with Evidence Development. CMS Response: Complimentary, "A Kumbaya Meeting" and showed the results of 10 years of Alliance relationship-building
- Noridian draft LCD on skin substitutes
  - The Coalition supported the Alliance in its following efforts:
    - Noridian has held conference calls/meetings on its Part A and B side in April and May—Dr. David Armstrong spoke on the Part B call; Dr. Barbara Aung spoke on the Part A call (APMA requested her to speak) The Alliance sent a draft of its concerns to both parties for their consideration.

        - The Alliance requested involvement of its members in Noridian jurisdiction related to CAC meetings, state associations and mobilization of members to submit comments. Alliance sent one pager for societies to use with its members; posted call for action on Alliance home page website
        - Formed skin substitute workgroup; held multiple calls; submitted comments
    - The Coalition held numerous conference calls to address comments and to contact providers in the Noridian area to submit comments.

- Nomenclature to replace the term "skin substitutes"
    - Coalition discusses in multiple conference calls terms that Alliance skin substitute working group recommends
    - ASTM
        - Coalition members become ASTM members to participate in discussion on nomenclature and guidance document so as to align with Alliance nomenclature
        - Participated in ASTM Nov 2012 meeting/conference call
        - Currently organizing Alliance members to participate in reviewing guidance document, participating in conference calls and voting in March 2013 on name/document

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

- Coalition sent emails to members informing them of changes and other information from A/B MACs. (e.g., CMS awards Noridian A/B MAC Jurisdiction E contract. Bid was protested by Trailblazers)
- Coalition addresses issues relating to skin substitute LCDs (see skin substitute section).
- Informed members on release of DMEMAC LCD on suction pumps (March 1) and discussed advocacy on Coalition conference call.
- Contacted DMEMAC medical directors multiple times regarding timing of release of pneumatic compression LCD

Alliance of Wound Care Stakeholders

Value to Members

It is critical to have access to a wound care advocacy organization consisting of physician, clinician and patient groups that can respond to wound care issues that impact the Coalition members and their customers. (Some information is also in the section on skin substitutes)

<u>Achievements/Activities</u> (convened 43 conference calls/meetings in 2012, up from 30 in 2011 and 9 in 2010).

In addition to the activities on skin substitutes (please refer to that section, the Alliance also accomplished the following:

- "Consensus Principles for Wound Care Research Obtained Using a Delphi Process" Published in May/June *Wound Repair and Regeneration*
- NPWT Accreditation Checklist
  - Met with CMS Acting Administrator Marilyn Tavenner, Jon Blum and senior staff to discuss the Agency's adoption of the Negative Pressure Wound Therapy (NPWT) supplier accreditation checklist (January 27)
  - Met with CMS Director Jon Blum and senior staff along with Alliance of Wound Care Stakeholders to discuss CMS's decision that competitive bidding contracts will ONLY be awarded to suppliers who meet the Medicare quality standards and that are accredited specifically for furnishing covered NPWT items and services. (March 9)
  - Noted in Feb 6 Wall Street Journal article "*Medicare Auctions are Working Well, Lowering Costs*." Sent Letter to Editor to address inaccuracies.
- AHRQ Venous Stasis Ulcer Technology Assessment- Requested to be on Technical Expert Panel and submitted two sets of comments on "Prioritization of Future Research Needs for Chronic Venous Ulcers" (September)
- PCORI- educated members on Patient Center Outcomes Research Institute by having Dr. Robert Zwolak speak on Alliance conference call (Feb)
- CMS Comments- Submitted three sets of comments to CMS:
  - CMS-1588-P Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and FY 2013 Rates and to the Long Term Care Hospital PPS and FY 2013 Rates (May)
  - Physicians fee schedule (Sept)
  - Physicians fee schedule final rule re: G codes for NPWT (Dec)
- National Correct Coding Initiative- Alliance prepares summary brief for education of SVS and APMA
- Equity and Access for Podiatric Physicians under Medicaid Act (S1309/HR3364)- Sent letter of support to Members of Congress to support (Aug)
- Organized, Moderated and Spoke on "Health Care Reform- What Does the Future Hold- A Panel Discussion" at SAWC spring with CMS Medical Officer Richard Wilde, APMA Representative Dr. Mark Block and SVS Representative Dr Michael Dalsing

➢ <u>Modernization of the HCPCS Coding System</u>

<u>Value to Members</u>

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.

<u>Achievements/Activities</u>

- ❖ Met with CMS Deputy Administrator Jon Blum, CMS senior staff and representatives from the Alliance for HCPCS II Coding Reform which included Coalition representation to discuss changes in the HCPCS coding process. (September)

➢ 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 now been included in the second round. The Coalition has been proactive by working with the Alliance of Wound Care Stakeholders to create a final version of the supplier quality standards and meeting with CMS staff to urge its adoption by the Agency. This will ensure that only suppliers who are knowledgeable about NPWT will win the competitive bidding, thus allowing a level playing field. This is in line with the FDA recommendations. The Coalition has been at the forefront to send information to members on the second round of competitive bidding so that they are aware of when to take action on this issue. (This information is also in the section on NPWT)

Achievements/Activities

- ❖ Met with CMS Acting Administrator Marilyn Tavenner, Jon Blum and senior staff to discuss the Agency's adoption of the Negative Pressure Wound Therapy (NPWT) supplier accreditation checklist (January 27)
- ❖ Met with CMS Director Jon Blum and senior staff along with Alliance of Wound Care Stakeholders to discuss CMS's decision that competitive bidding contracts will ONLY be awarded to suppliers who meet the Medicare quality standards and that are accredited specifically for furnishing covered NPWT items and services. (March 9)
- ❖ In addition to working on the supplier accreditation checklist, the Coalition providing the information to its members on two Congressional hearings on the topic- May 9 House Ways and Means Subcommittee on Health; September 11 Healthcare and Technology Subcommittee Hearing on "Medicare's DME Competitive Bidding Program: How are small suppliers faring?"

➢ 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

- ❖ **Jan 2012-Convened Coalition's strategic planning and invited speakers:**
  - Mary Weick-Brady-(Food and Drug Administration, Senior Policy Analyst) *"Update on the FDA Home Health Initiative"*

- Mary St Pierre – National Association for Home Health and Hospice *" Issues Impacting Home Health Agencies*"
- Carol Blackford (CMS Deputy Director, Chronic Care Policy Group, Center for Medicare Management) *"CMS Issues and Medical Device Manufacturers" – answered specific issues re PDAC*
- Ben Martin (Epstein Becker and Green)- "*FDA Issue Impacting Medical Device Manufacturers"*
- Lynn Shapiro Snyder (Epstein Becker and Green)- "*Key Federal Health Law Issues and Their Impact on* Medical Device *Manufacturers in 2012"*
- Jule Crider (Executive Director American Association for Wound Care Management) *"Issues Impacting Wound Care Clinics"*

❖ November 19, 2012 Coalition Conference call speaker-Debra McCurdy (Reed Smith) gave an update on how the re-election of President Obama and the Members of Congress would impact medical device manufacturers

❖ Advised members of Epstein Becker and Green webinar on impact of Supreme Court decision on Affordable Care Act

❖ **Advised Coalition members on CMS, A/B MAC and DMEMAC webinars relating to regulatory issues in their business**:
- Trailblazers- Understanding the LCD Process
- Trailblazers - Quality Reporting
- Center for Medicare and Medicaid Innovation Care Innovations Summit with Administrator Marilyn Tavenner, CMS' Director of Medicare Management Jonathan Blum and Medicaid Director Cindy Mann
- Patient Centered Outcomes Research Institute (PCORI) unveiled a Draft National Priorities for Research and Research Agenda and held a National Patient and Stakeholder Dialogue
- CMS Webinar for suppliers on billing claims correctly

➢ Work with FDA on Home Use Initiative Issues

Value to Members

It is important for the members to be informed and active with the FDA as the Agency prepares its guidance document on Home Use since their products will be impacted by the document.

Achievements/Activities

❖ Coalition has worked with FDA's Mary Brady over the years to give input on its home use document.

❖ Marcia Nusgart sends Coalition members recently released guidance document and invites Mary Brady to speak at Coalition's strategic planning meeting in 2013 to discuss it so Coalition can submit comments.