COALITION OF

Wound Care Manufacturers

2013 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 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 decision makers for the wound care industry.

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2013 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 Members of Congress and their staff, 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:***

  - *Members of Congress*
    - Representative Renee Elmers (R-NC) to discuss wound care reimbursement issues (Feb)
    - Representative Robert Casey (D-PA) staff to discuss concerns with amendment to delay the HOPPS rule for only two CTPs (Dec)
  - *CMS and CMS contractor meetings*
    - HOPPS-Hospital Outpatient Payment Group to discuss the proposed rule on HOPPS and specifically the packaging of skin substitutes
    - HCPCS II Coding Reform-Meeting with CMS Deputy Director Liz Richter, CMS senior staff and representatives from the Alliance for HCPCS II Coding Reform to discuss recommendations for change in the HCPCS coding process.
    - PDAC and Collagen dressings-Communicated both verbally and through multiple emails with the PDAC staff, PDAC medical director and Medicare Contractor Management Group Director Karen Jackson regarding problems with changes in coding verification for collagen products.

  - *FDA Meeting*
    - FDA's Mary Brady regarding Home Use and Medical Device Tools

  - *Comments to CMS and its contractors*
    - Hospital Outpatient PPS (Sept)

- 4 sets of comments to CMS A/B MAC contractors on wound care LCDs
  - Novitas (July, Nov)
  - Cigna (April)
  - First Coast (March)
- Draft Guidance on Coverage with Evidence Development

❖ ***Provides members with access to key policy decision makers to address their own and their customers' specific regulatory problems.*** (e.g. Representative Renee Elmers (R-NC); CMS Staff Dr. John McInnes and Karen Jackson; FDA staff Mary Weick-Brady [Chair, FDA Homecare Committee] and Jay Crowley; DME MAC Medical Directors; and CBIC representative Amelia Booth,)

❖ ***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:***

- *FDA Issues- Advised members on:*
  - Draft guidance on Medical Device Development Tools and the comment period deadline
  - Final Guidance on qualifying Medical Device Development Tools
  - Issuance of the FDA Final Rule for UDI
  - FDA published notice that is transferring oversight responsibilities for certain wound care products containing live cells from the Center for Devices and Radiological Health (CDRH) to the Center for Biologics Evaluation and Research (CBER)
- *CMS Issues-Advised members on:*
  - Significant change in reimbursement in outpatient hospital settings for CTPs
  - New guidelines issued by CMS for NCDs.
  - Draft Guidance Document on Coverage with Evidence Development.
- *Milliman Guidelines on Intermittent Pneumatic Compression Pumps*
  - Worked with members to address inaccuracies contained in the guidelines. Spearheaded drafting a letter to Milliman on behalf of the Alliance to address the inaccuracies in the guidelines.
- *ASTM and CTPs*
  - Alerted skin substitute manufacturers to become ASTM members so as to have a voice in ASTM guidelines and nomenclature and informing them of the ASTM activities

❖ ***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:***

- *Congressional Issues- Alerted members on:*
  - Senator Casey's amendment offered in the Senate impacting packaging and informed them to contact their member of Congress to include all CTPs in the delay
  - American Taxpayer Relief Act when it passed Congress with summary of provisions of interest for Coalition members.
- *HCPCS Coding Issues*
  - Informed members immediately on HCPCS coding issues: Dates for HCPCS Public meetings, Preliminary Coding Decisions; New HCPCS codes release

- *Legislative and Regulatory Updates*
  - Updates on DMEMAC and A/B MAC Medicare coverage policies [skin substitutes]; GAO report on Medicare Contractors; FDA UDI Guidance; Clearance of Medical Devices through the 510K process; Issuance of final Guidance on Wireless Medical Devices; Notification of Noridian Clarification regarding the procedure for compression therapy

❖ ***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)
- Contacted CMS with questions of clarification prior to submitting comments on the HOPPS proposed rule.

❖ ***Attends and informs members about policy conferences and regulatory educational opportunities for them to attend that will impact their products*** (e.g., HOPPS APC Advisory Panel meeting First Coast Public meeting on draft LCD for Skin substitutes; CMS Advisory Panel on Hospital Payment meeting and how to submit comments if interested. FDA workshop synergizing development and medical device labeling; Special Open Door Forum on the New Hospital Admission Criteria; ECRI Institute conference "Use of Evidence in Policy and Practice"; National Journal webinar "Building a Higher Performing Medicare System")

❖ ***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.***

2013 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 2013. These include:

➢ **PDAC reverses position on coding of collagen surgical dressings-** The Coalition led the charge to rescind the coding requirements to only allow collagen dressings that include 90% or more collagen into the codes. We contacted the PDAC by phone and email many times to obtain clarification of this issue which included the definition of "clinically predominant component." We contacted the PDAC medical director and elevated the issue to CMS Medicare Contractor Management Group Director Karen Jackson. We convinced the PDAC to return to its original criteria and to give giving reasons on its website for the previous changes in coding verification.

➢ **Reform of HCPCS Coding System-** As members of the Alliance for HCPCS II Coding Reform, the Coalition was proactive in meeting with CMS Deputy Director Liz Richter and senior staff to address recommendations sent to Deputy Administrator Jon Blum. There has been follow-up to request that CMS

adopt some of the "easy lift recommendations". The Coalition helped to draft these recommendations and participate on conference calls to develop them.

- **Clarification of DME Face to Face Meetings Requirements -**After attempts by other associations failed to obtain clarification on rule, the Coalition brought the group together on a conference call with key CMS staff Melanie Combs-Dyer and Kevin Young to address the issues and provide guidance for providers who prescribe DME and manufacturers. This provision was delayed since there were so many concerns raised regarding the procedures.

- **Submitted Four Sets of Comments on CMS A/B MAC Contractors Wound Care Local Coverage Determinations (LCDs -** The Coalition was proactive in submitting 2 sets of comments to Novitas Solutions, and to Cigna and First Coast. In its final LCD, Cigna adopted the new CTP terminology in place of "skin substitutes".

- **Active supporter and participant in Alliance of Wound Care Stakeholders activities and achievements: (Have Coalition representative to provide guidance to the Alliance) (See Alliance section for more details)**

    - *Creation of new terminology to replace "skin substitutes"* with the more clinically accurate "cellular and/or tissue based products for wounds" (CTPs). The Coalition agreed to adopt this term and has used it in our comments to CMS and its A/B MAC contractors.
    - *Hospital Outpatient PPS rule*- met with Director John McInnes and senior staff to address concerns with the proposed rule on packaging of CTPs. Coalition member helped in meeting strategy and procuring Paul Radensky to provide legal arguments and follow up information to staff. Coalition submitted HOPPs comments.
    - *Follow up with CMS and AHRQ staff on CTPs*-Provided information to Alliance for completion of CTP classification charts and bibliographies so as to send to AHRQ and CMS staffs as a follow up from meetings
    - *Milliman Care Guidelines (MCG) on Intermittent Pneumatic Compression*-Participated in drafting letters to MCG on concerns with inaccurate guidelines which impacted patients' access to these devices since payers were adopting the guidelines. The advocacy resulted in MCG convening a conference call with the American Venous Forum to correct this situation so that the 2014 version would be clinically correct.
    - *Wound Care Quality Measures*- Educate Coalition members on the importance of the Alliance working to establish wound care quality measures and to support the effort financially.

- **Alerted Coalition members to contact their Senators to stop Senator Casey's amendment to delay the HOPPS rule for only two CTP manufacturers.** The Coalition members' advocacy helped to provide the impetus that allowed for Senator Casey to withdraw the amendment and allowed for education with both Senator Casey and Senator Isakson's staff on this issue.

- **AHRQ-**Adopted many of Coalition's comments in its final version of its technology assessment on CTPs

- **Face time with Key CMS and FDA Policymakers**-The Coalition provided its members with opportunities to speak with CMS and FDA key policymakers with responsibility for regulatory policies impacting wound care. (Speakers at Coalition strategic planning meeting, SAWC senior executive meeting, Coalition meetings at CMS)

- **Convened 19 Coalition conference calls and two meetings in 2013 to ensure communication of valuable information to and from the Coalition members. There were 3 additional conference calls for the Alliance for HCPCS II Coding Reform during which Coalition members participated.**

2013 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, providing information on competitive bidding and addressing the need for coding and coverage for disposable NPWT technology.

The many activities are described below.

Achievements/Activities

- *Comments to CMS and A/B MACs LCDs*
  - Submitted comments to Novitas regarding NPWT provisions in its LCD.
  - Submitted comments to CMS on the Hospital Outpatient PPS proposed rule re: APC for NPWT
  - Worked with manufacturers to submit reconsideration of NPWT coverage policy
  - Sent to members release of suction pump policy

- *Disposable NPWT*
  - Followed up with manufacturers to continue working on CPT coding for disposable NPWT from Coalition's 2012 physician's fee schedule comments
  - Submitted information to Alliance to forward to medical specialty societies to send to RUC for establishing reimbursement for disposable NPWT codes.
  - Sent summaries of CMS proposed and final rule on DME minimum lifetime requirement and changing items from routinely purchased to capped rental. This issue impacts disposable NPWT.
  - Submitted comments to Novitas Solutions on draft LCD that impacted disposable NPWT

- *Competitive* Bidding
  - Amelia Booth of the CBIC provided competitive bidding update at Senior Executive Coalition meeting at SAWC.

- Addressed issues relating to NPWT being included in the second round of competitive bidding.
- Provided Members rates for NPWT when the second round of competitive bidding was release

❖ *Clarification of DME Face to Face Meetings Requirements*

- After attempts by other associations failed to obtain clarification on rule, the Coalition brought the group together on a conference call with key CMS staff Melanie Combs-Dyer and Kevin Young to address the issues and provide guidance for providers who prescribe DME and manufacturers. This provision was delayed since there were so many concerns raised regarding the procedures.

➢ **Cellular and/or Tissue Based Products for Wounds (CTPs) (formerly "skin substitutes")**

Value to Members

In 2012, skin substitutes/CTPs 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. Both in 2012 and in 2013, The Coalition was both proactive and quickly responsive on all aspects of skin substitute/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 representatives.

In 2013, the Coalition devoted a tremendous amount of resources to address issues facing skin substitutes. It submitted four sets of comments to the A/B MACs (First Coast, Novitas on two different LCDs and Cigna). In regards to nomenclature, the Coalition members worked with the Alliance to address more appropriate terminology for skin substitutes and supported the new term-- Cellular and/or Tissue Based Products for Wounds (CTPs). The Coalition has also adopted this term and continues to promote it though our comments. We also took an active role in ASTM to ensure that a guidance document on nomenclature would objectively reflect the industry. Finally, the Coalition worked feverishly with the Alliance of Wound Care Stakeholders to halt the adoption of packaging of skin substitutes in hospital outpatient departments. By working with the Alliance, it held an in-person meeting with high level CMS staff. The Coalition members helped to address the meeting strategy and one helped to procure attorney Paul Radensky to provide legal arguments and follow up information to staff. The Coalition also submitted HOPPS comments to CMS. (See Alliance section for more details)

Achievements/Activities

❖ *CMS*

- With the Coalition's support, the Alliance along with Coalition representatives met with Dr John McInnes and other key senior staff from the Hospital and Ambulatory Policy Group to discuss the hospital outpatient PPS packaging proposal and its detrimental impact on manufacturers, hospitals and clinicians.
- Submitted comments on the HOPPS proposed rule regarding the packaging of skin substitutes

- Commented on two different versions of Novitas draft LCD on skin substitutes (July and November)
- Commented on the Cigna draft LCD on skin substitutes (April)
  - Cigna released its final LCD and included the Coalition and Alliance recommendation to use the CTP nomenclature
- Commented on the First Coast draft LCD on skin substitutes (March)
  - The Coalition held numerous conference calls to address comments

❖ *Nomenclature to replace the term "skin substitutes"*
- Coalition discussed in multiple conference calls terms that Alliance skin substitute working group recommends
- Coalition agreed to adopt nomenclature adopted by the Alliance

❖ *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 meetings/conference calls
- Successfully advocated with ASTM F-4 committee to allow the creation of a separate guidance document 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

❖ Coalition sent emails to members informing them of contract and jurisdiction changes and other pertinent information from A/B MACs. (e.g., CMS awards Noridian A/B MAC Jurisdiction 1 contract. Palmetto protested)
❖ Coalition addressed issues relating to skin substitute/CTP LCDs (see skin substitute/CTPs section).
❖ Informed members of A/B MAC LCD open/public meetings
❖ 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)

Achievements/Activities (convened 63 conference calls/meetings in 2013, up from 43 in 2012, 30 in 2011 and 9 in 2010).

- *Quality Measures*
  - Recognizing the need for developing wound care quality measures, the Alliance performed the following activities:
    - Convene Alliance meeting on quality measures at SAWC spring
    - Attended National Quality Forum annual meeting and MAP Clinician workgroup meeting
    - Submitted two sets of quality measures to CMS on venous stasis (compression) and diabetic foot ulcers (offloading). Addressed on Alliance calls the need for testing of these measures and funding and prepared budgets with timelines of activities.
    - Decided to work with the US Wound Care Registry as they self-nominated being a Qualified Clinical Data Registry to CMS and developed wound care quality measures in 2014 (Dec)

- *Hospital Outpatient Prospective Payment System (HOPPs) and 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 doing the following:
    - Sending the proposed rule out to members and asking them for questions that they would like Alliance staff to submit to CMS for answers (July)
    - Hired attorney Larry Oday to review HOPPs rule and address implications and possible strategies on Alliance call (Aug)
    - Attended CMS APC meeting when packaging issues were discussed and advised members that the meeting was webcast for their own viewing (Aug)
    - Represented the wound care industry in meeting with Director John McInnes and his senior staff to address concerns; worked with attorney Paul Radensky to address legal argument; AAWCM to state financial issues and clinical associations to have representatives state the clinical arguments. Held multiple conference calls to determine strategy. CMS requested further information on legal arguments and financial issues. (Aug)
    - Reached out to other associations to determine their positions on issues (Aug)
    - Submitted comments to CMS (Sept)
    - Hired attorney Paul Radensky to review final rule on HOPPS and give guidance on Alliance call for advocacy strategy and next steps
  - Educated Senator Casey's staff on Alliance position regarding his amendment to delay the HOPPs rule but include all CTPs instead of those who are PMA or BLA cleared by FDA (Dec)

- Alerted members about amendment and asked them to call their Members of Congress to include all CTPs in the delay
- Met with Senator Casey's staff to educate them on Alliance's position

❖ *CTPs*
- Submitted four sets of comments on CTP draft LCDs:
  - First Coast (March)
  - Cigna Government Services (April)
  - Novitas Solutions (July, Nov.)
- Alliance votes positively to adopt new term "Cellular and/or Tissue Based Products for Wounds (CTP) in place of skin substitutes (March)
  - Due to our advocacy, Cigna Government Services adopts the updated term "Cellular and/or Tissue Based Products for Wounds (CTP) in place of "skin substitutes" in its final policy (May)
  - Term being adopted and used in clinical journals (i.e. Kestrel wound care, Advances in Wound Care)
- Alliance follows up on its meeting with AHRQ and CMS staff (Hospital and Ambulatory Policy group, Chronic Care Policy Group and Coverage and Analysis Group) staffs by sending them the following information on CTPs:
  - Classification of CTPs in pictoral diagrams
  - Chart of classification of CTPs with Q codes
  - Bibliography of both RCTs and non-RCTs for CTPs
- AHRQ adopts many of Alliance comments in final version of its technology assessment (June—should we include this- it was released earlier than that and we just found out about it)

❖ *Comments Submitted to CMS*
- Coverage with Evidence Development (January)
- Inpatient Prospective Payment System (June)
- Hospital Outpatient Prospective Payment (Sept)

❖ *Milliman Care Guidelines (MCG) on Intermittent Pneumatic Compression*
- Submitted two letters to MCG's Editor in Chief and CEO to address inaccuracies in its guidelines which impacted patient's access to these devices since payers were adopting them in their coverage policies. (July, Dec) The Alliance followed up with multiple phone calls and emails.
- Organized Alliance clinical associations to also send letters of concern to MCG (American Physical Therapy Association, Society of Vascular Medicine, American Venous Forum)
- Advocacy resulted in MCG convening a conference call with the American Venous Forum to correct this situation so that the 2014 set of published guidelines would be clinically accurate.

❖ *NPWT*
- Worked with manufacturers to submit reconsideration of NPWT coverage policy
- Submitted information to RUC on behalf of business entities for disposable NPWT reimbursement

- *Face to Face Meetings for Physicians Who Prescribe Durable Medical Equipment (DME)*
  - Alliance convened call with CMS staff Melanie Comb-Dyers to obtain clarification on the requirements for the new face-to-face exam requirements going into effect July 2013. This impacts any physician who prescribes DME for their patients. (May)
  - Alliance sent out summary of call to members on this issue (June)

- *ASTM*
  - Successfully advocated with ASTM F-4 committee to allow the creation of a separate guidance document for CTPs

- **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

- Provided CMS Deputy Administrator Jon Blum, CMS senior staff and representatives from the Alliance for HCPCS II Coding Reform with our recommendations regarding HCPCS coding reform. (August)
- Followed up on our recommendations by meeting with CMS Deputy Administrator Liz Richter, 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. (October)
- Consulted with former CMS Acting Administrator Leslie Norwalk to review actions CMS could possibly take to implement the recommendations proposed for our thank you letter.
- Sent thank you note to CMS Deputy Administrator Liz Richter and staff for meeting and recommended easy actions the Agency could take currently since the codes were being released (Nov)

- **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 and had Amelia Booth from the Competitive Bidding Implementation Contractor (CBIC) update them.

Achievements/Activities

- ❖ Provided competitive bidding second round rates to members
- ❖ Secured Amelia Booth from to speak to Coalition members re: Competitive bidding and NPWT.
- ❖ Asked for clarification of bid winners not being vetted and thus problems with patient access

➢ **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:*
  - Mary Weick-Brady-(Senior Policy Advisor, Office of the Center Director, Center for Devices and Radiological Health, US Food and Drug Administration)
  - Dr. John McInnes, MD JD (Director, Division of Outpatient Care, Hospital and Ambulatory Policy Group, Centers for Medicare and Medicaid Services)
  - Karen Jackson (Director, Medicare Contractor Management Group, Center for Medicare and Medicaid Services)
  - Jay Crowley- Senior Advisor for Patient Safety, Center for Devices and Radiological Health, US Food and Drug Administration)
  - Caroline Fife MD (Chief Medical Officer, Intellicure, Co-Chair, Alliance of Wound Care Stakeholders
  - Lynn Shapiro Snyder (Epstein Becker and Green)
  - Jule Crider (Executive Director, American Association for Wound Care Management)

- ❖ *Coalition Senior Executive Meeting at SAWC*
  - Amelia Booth from Competitive Bidding Implementation Contractor (CBIC) addressed Coalition members

- ❖ *Notification of Additional Workshops, Seminars and Webinars:*
  - CMS conference call regarding ACO implementation update
  - Marilyn Tavenner confirmation hearing
  - FDA workshop on "Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products"
  - Members invited to participate in April 29, 2013 *FDA Public Workshop:* Accessible Medical Device Labeling in a Standard Content and Format during which Marcia Nusgart served as moderator
  - Special Open Door Forum on the New Hospital Admission Criteria

- ECRI Institute conference "Use of Evidence in Policy and Practice"
- National Journal webinar "Building a Higher Performing Medicare System"

➢ **Work with FDA on Home Use Initiative, Unique Device Identifier and Product Labeling 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

❖ *FDA's Home Use Guidance Document:*
- Coalition has worked with FDA's Mary Brady over the years to give input on its home use document.
- Marcia Nusgart sent Coalition members guidance document for review and comment
- Mary Brady spoke at Coalition's strategic planning meeting in 2013 to discuss the guidance document so the Coalition can submit comments.

❖ *Device Labeling*
- Members invited to participate in April 29, 2013 *FDA Public Workshop: Accessible Medical Device Labeling in a Standard Content and Format* during which Marcia Nusgart served as moderator

❖ *Unique Device Identifiers (UDI)*
- Jay Crowley of FDA spoke at Coalition's strategic planning meeting and asked for comments on UDI
- Sent to members information of FDA final rule on UDI (Sept)

❖ *Sent members information on following FDA activities:*
- FDA published notice that is transferring oversight responsibilities for certain wound care products containing live cells from the Center for Devices and Radiological Health (CDRH) to the Center for Biologics Evaluation and Research (CBER).(Aug)
- October 7, 2013 FDA Public Workshop on "Synergizing Efforts in Standards Development for Cellular Therapies and Regenerative Medicine Products." (Sept)