



## **Alliance Advocacy and Comment Development Processes**

### ***Overview & FAQ***

Advocacy is a core component of the Alliance's mission. The staff engages with legislative and regulatory bodies to advocate for policies that promote evidence-based quality care and equitable access to wound care products and services. The Alliance has established processes to elicit member input to establish its policy positions. After the Alliance reaches consensus among its members, Alliance staff formally advocate for this position across all pertinent platforms. Their efforts aim to communicate the Alliance's stance clearly and effectively to legislative and regulatory entities. In striving to achieve this objective, the Alliance Executive Leadership and staff are empowered to exercise their professional judgement in determining the most effective methods for representing the adopted position on behalf of its members. The Executive Leadership includes the Chair of the Board, the Vice Chair of the Board, and the CEO.

These frequently asked questions represent general guidelines. Exceptions may occur based on specific circumstances.

#### **Q1: Which regulatory and legislative issues does the Alliance respond to in order to advocate for its members?**

The Alliance's advocacy efforts involve developing policy positions on wound care issues and communicating these positions with the intention of influencing relevant outcomes. These include but are not limited to: responding to CMS and FDA proposed rules and guidance documents, draft coverage policies, coding initiatives, federal agency issues (e.g., CMS, Office of Management and Budget RFIs and guidance documents, and health care organizations' requests for stakeholder input) and conducting various advocacy initiatives behind the scenes. Our standard methods for communicating these perspectives include: submitting letters, written comments, or oral testimonies to relevant federal regulatory agencies or legislative bodies on behalf of our members, as well as conducting meetings with these officials. Recognizing we cannot respond to all opportunities, the Alliance uses a multi-faceted lens heavily weighted on member consensus to prioritize the issues advocated for its members.

## **Q2: What prompts the Alliance to begin an advocacy effort or respond to an issue?**

The Alliance responds to opportunities and needs brought forward through member suggestions, workgroup requests, regulatory/legislative initiatives, and/or proactive Alliance priorities.

## **Q3: What is the role of the membership in establishing the Alliance's regulatory and legislative positions?**

The Alliance's positions reflect those of its members. To ensure members' voices are heard, their playing an active role through regular participation in monthly membership meetings and workgroups is essential. It is equally essential for members to review and provide feedback on documents circulated for their input, enabling staff to establish the Alliance's official positions on various issues. If a member changes their stance on an issue, staff should be notified so we can accurately represent members and assess if the Alliance's position needs updating.

## **Q4: How does the Alliance decide what issues we take on or respond to?**

The Alliance routinely submits comments on the CMS proposed regulations and/or draft coverage policies that impact the wound care community. Other issues raised by members or within the wound care community are reviewed between the staff and the Board of Directors and examined with the considerations:

- How does this align with our mission and priorities?
- Is this a priority to our membership?
- What is the impact on the wound care community at large?
- How does this fit with our workplan and existing commitments?
- Do we have the necessary expertise, either as a team or in our membership?
- Do we need to pay for expertise or legal counsel to response?
- Does the Alliance have the time and capacity to take on additional topics?
- What is the timeline for response? Can we realistically meet that deadline?

## **Q5: What is the process that the Alliance uses to respond to regulatory and legislative issues to advocate on behalf of its members?**

Our procedures are determined by the timeline associated with each submission. We utilize two primary approaches: (1) Standard Process and (2) Rapid Response.

- Standard Process: Typically applies when submission timelines exceed 45 days, including but not limited to:
  - Local Coverage Determinations (LCD)
  - Proposed Rules
  - Request for Information
  - Guidance Documents
  - Technology Assessments

- **Rapid Response:** Typically applies when submission timelines is less than 45 days, including but not limited to:
  - Legislative Initiatives
  - Request for Information
  - Face-to-face meetings with regulators and legislators, including presentations and informational material
  - Testimonies during open meetings on proposed LCDs and/or CMS Town Hall meetings

### **Q6: What is the standard process?**

Our standard approach to developing and submitting responses is:

- 1. Identify Policy Issue:** Staff systematically monitors regulatory and legislative developments at the national level and communicates with members via email, monthly all-member conference calls, and workgroups to proactively identify potential wound care policy issues. Members are also encouraged to bring relevant topics to the attention of staff at any time.
- 2. Summary of the Policy Issue:** Staff may deliver an initial overview of the proposed regulation or document (such as regulations, LCDs, or guidance documents) to inform members about its contents. When feasible within the allotted timeframe, staff can distribute a more comprehensive summary, highlighting key areas where member feedback may be necessary.
- 3. Member Engagement Opportunity:**
  - The staff engages the members of the Alliance in monthly conference calls and workgroup discussions on issues that warrant comment. These sessions are structured as open forums, allowing members to provide feedback.
  - Based on the discussions and feedback received from the workgroup meetings and the monthly member calls, the staff drafts a comment letter for member review. With 2 to 3 feedback cycles, the Alliance members are engaged to validate the position taken, encouraging input from all members, whether they agree or disagree, including comments which we have not yet discussed with our members. The first cycle goal is to receive substantive feedback and revisions, with subsequent cycles created to strengthen the comments and refine the language.
  - **Comment Revisions:** Relevant feedback is incorporated into revised comments, leading to more detailed policy recommendations based on evidence and stakeholder input.

→ First feedback cycle:

- The staff will send out an initial draft to the members for comment.
- When feedback/edits are provided to the draft comment letter that is consistent with the positions the Alliance has established and does not change the intent of what was written, the staff will make the appropriate edits.
- When feedback/edits are provided that are substantive and do change the intent of what was written or when a new issue is raised for inclusion, the staff includes the edit, highlights the change, and resends the document out for the second round of edits for further vetting.
- Note: The addition of new issues to the comment letter will only be accepted in the first round of comments to ensure that staff has appropriate time to vet it with the members. If new issues are requested to be added to a comment letter after the first round of feedback, the staff may not have the necessary time to vet the issue with the general membership and thus may not include the change. This is why it is important that the Alliance members provide their comments in a timely manner in the first cycle.

→ Second feedback cycle:

- Once staff have received feedback from the initial editing cycle, any language that is contrary or substantive but lacks consensus will not be included in the comment letter. If time permits, staff may arrange a call to discuss these matters further.
- After the first cycle of edits has been made, the second draft is sent out to members. Staff will highlight substantial changes in the second draft and request feedback on them. If consensus is reached to move those edits forward, staff will make the changes and resend the draft to members for final review and edits.

→ Third feedback cycle: final approval of comment letter (if necessary)

- If time allows and if deemed necessary, staff may distribute the third draft to members for the purpose of word-level editing and suggestions focused on clarifying the Alliance's position; this review is not intended for substantive commentary or debate on the merits of the approach. After the deadline for edits has elapsed, staff will regard the document as final.

- 4. Finalize and Submit Response:** In this phase, the staff presents the final version of the comments to the Board Chair and Vice Chair for their consideration and signature. The staff files the comments timely.
- 5. Communicate Final Responses to Membership:** Once comments are submitted, the staff will distribute a copy of the filed comments to the membership for their records and may post the comments on social media, the Alliance newsletter, and on its website.

**Q7: What is the role of the Board in the standard process? Do they play an approval role?**

It is not necessary for the entire Alliance Board to participate in the standard process, as membership is adequately represented through its own involvement. The final version of the comments is reviewed by the Board Chair and Vice Chair for their evaluation and signature.

**Q8: What is the rapid response process?**

The rapid response process is used for issues that require a turnaround time of less than 45 days and/or for responses that are related to pre-established policy positions when the turnaround time is less than 45 days. If the Alliance has not yet determined a position on an inquiry, and time permits, staff may convene an emergency workgroup meeting based on the subject matter and timeframe to discuss and formulate a position. Alternatively, depending on the topic, staff may consult with selected members who possess relevant expertise to assist in developing a position. In both scenarios, staff submits the proposed position to the full Board for approval.

**Q9: When does the Alliance update an established position?**

Unless multiple members bring to the staff's attention a change in their positions, the staff has a right to rely on an existing established policy stance for at least a one-year period.

**Q10: What is the role of the Alliance board in the rapid response process? Do they play an approval role?**

For new Alliance positions, the staff provides the new position to the entire Board for its approval.

**Q11: What options do members have if they disagree with an Alliance policy position?**

The Alliance's comment letters and established positions are based on consensus. We recognize that not all members communicate their acquiescence affirmatively. In the event there is an inability to create consensus, adoption of the policy statement can still occur if the majority still stands. If there is a strong minority who disagree, the policy position will reflect that there was not a full consensus.

Should the Alliance have established a position, and if multiple members subsequently express disagreement with this stance, the Alliance may consider re-evaluating its position on the matter.

**Q12: Does the staff give preference to certain members or member perspectives when developing policy positions or comments?**

No. All members help shape Alliance policies by joining workgroups and monthly calls. We encourage active participation to build consensus on our final outputs.