February 3, 2012

Marilyn Tavenner, Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
200 Independence Ave., S.W.
Mail Stop 314G
Washington, DC 20201

Dear Ms. Tavenner:

Thank you for providing AdvaMed members with an opportunity to continue the dialogue with you and your staff regarding the safe provision of Negative Pressure Wound Therapy (NPWT) to Medicare beneficiaries in the home. When AdvaMed met with you last on March 7, 2011 to discuss the advanced nature of NPWT technology, we recommended that CMS incorporate into existing accreditation standards for suppliers of durable medical equipment, prosthetics, and orthotics (DMEPOS) additional and unique standards that would apply to suppliers of NPWT. The goal of this recommendation was to ensure that only those suppliers qualified to provide the full range of services required for safe and effective provision of NPWT be allowed to provide this service to Medicare beneficiaries. We continue to recommend that the accreditation process recognize the need for unique standards that would apply to NPWT suppliers and believe that this can be accomplished through the use of a checklist, which has been developed as the result of a suggestion of your staff.

AdvaMed members and other patient, clinician, and supplier stakeholders throughout the wound care community agree that NPWT can be safely and effectively used in the home. However, the complex nature of wounds and the multiple health care needs of many NPWT patients demand that these products be administered in a way that ensures patient safety. For these reasons, AdvaMed worked collaboratively with all wound care stakeholder groups to develop NPWT accreditation standards which all parties support and which we discussed with you during our March 2011 meeting.

Since that meeting, and at the request of others within CMS, the standards have been translated into a checklist. AdvaMed recommends that CMS adopt the checklist and that all suppliers participating in Round Two Competitive Bidding be accredited as satisfying the checklist before contracts are awarded to winning bidders. AdvaMed also believes that it is critically important
for CMS to properly inform prospective bidders about the checklist and their need to comply with its requirements while the bid period is open.

Requiring accreditation of NPWT suppliers with the checklist will ensure that those bidding to supply the technology to Medicare beneficiaries are able to provide the devices and supplies associated with NPWT as well as the patient support services necessary to ensure safe and effective provision of the technology in the home. Additionally, informing prospective bidders that they will have to meet the checklist’s requirements will allow them to submit bids that reflect all of the resources and services required to supply Medicare beneficiaries with NPWT services and will help to ensure that contracted suppliers are able to provide appropriate support to Medicare beneficiaries for the duration of their contracts.

AdvaMed welcomes the opportunity to work with CMS to ensure that NPWT products and services provided through the competitive bidding program meet the objectives of the program while promoting the health of wound care patients. Please feel free to contact Richard Price at RPrice@AdvaMed.org or (202) 434-7227 if you would like to discuss any of our recommendations in greater detail or if you have any feedback or questions. Thank you for your consideration of our recommendations.

Sincerely,

Ann-Marie Lynch
Executive Vice President
Payment and Health Care Delivery Policy

cc:
Jonathan Blum
Peter Budetti