

Wound Care Stakeholders

February 1, 2012

Marilyn Tavenner
Acting Administrator, Principal Deputy Administrator and Chief Operating Officer
Centers for Medicare and Medicaid Services
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Acting Administrator Tavenner;

On behalf of the organizations and individuals listed below, I thank you and your staff for meeting with us on January 27, 2012 to discuss our concerns about the need for a validated Negative Pressure Wound Therapy (NPWT) Supplier Competency Checklist in Round 2 of the Durable Medical Equipment, Prosthetics and Supplies (DMEPOS) Competitive Bidding Program (CBP) being implemented by the Centers for Medicare and Medicaid Services (CMS). We appreciated the opportunity to hear and respond to your and your staff's concerns about the NPWT Supplier Competency Checklist proposed by the wound care stakeholder community. Based on our discussion in Friday's meeting, we believe that our goals and those of CMS are aligned around common principles:

- We are not requesting that NPWT be removed from Round 2, and we agree that any NPWT quality standards or validation requirements must allow for robust competition. That is exactly why we vetted our proposed checklist with entire wound care stakeholder community including clinicians, manufacturers and both large and small suppliers. We want to again emphasize as we did in the meeting that no one in the community disagreed about either the need for validated NPWT competency or the reasonableness of the proposed checklist in a competitive marketplace.

The Alliance of Wound Care Stakeholders ("Alliance"), comprised of 19 physician and clinical organizations whose members treat patients with wounds, is the association who sent a copy of the original guidelines to your attention in April and submitted the checklist to Director Jonathan Blum in December 2011 upon his request. The Alliance membership is listed below. Both AAHomecare and AdvaMed have sent you under separate cover their endorsement of the standards and guidelines. As stated in our meeting, there have been no objections to this issue; instead the entire wound care community is solidly in support of it.

- We applaud your commitment to reinforcing the need for safe and effective home use of NPWT. Over the last fifteen years, NPWT has been widely proven to be safe for use in the home, however the training and support provided by NPWT home care suppliers is more complex than that required for simple functional items like bed frames and walkers. We can attest that each and every requirement within our proposed NPWT Supplier Competency Checklist is there because it reflects a responsibility of the suppliers' activities that clinicians, patients and their families need to fulfill in order to ensure safe and effective home use. At the same time, nothing in our proposal goes beyond the scope of responsibility for home medical equipment suppliers. In fact, per the Agency's recommendations, we removed from the checklist any activities which would be the responsibility of the clinicians.
- We believe strongly that Medicare should view competitive bidding of NPWT as more than just a pricing and contracting process. That simple approach to procurement may be appropriate for commodity items, but it is clearly inadequate for therapeutic devices such as NPWT. As you evaluate whether our proposal is necessary and reasonable, we recommend that you compare it to the NPWT procurement procedures used by virtually all health care systems, private payers and group purchasing organizations, each of which requires validation of NPWT competency before awarding contracts. In fact, none of them allow inexperienced suppliers to be considered at all. Implementing our proposal for validated NPWT competency would help to ensure that CMS creates a network of capable and committed NPWT suppliers which is sustainable over the three-year contracting period and will minimize the risk of NPWT access problems like those experienced in Round 1 in 2008.

Additionally, we recommend that CMS inform potential bidders about this new competency validation requirement *immediately* so that they can include this process in their business planning and bid preparation. It would be fundamentally unfair to those bidders if the requirements are changed after the bid window closes.

Finally, the Alliance physicians and clinicians are eager to help CMS develop relevant metrics to monitor the impact of competitive bidding on patient outcomes and safety. Given the different subpopulations of NPWT patients treated in the home, it will be important to compare these patients based not only on the type and severity of wounds treated with the technology, but also the presence and relative severity of complicating conditions, goal of therapy and anticipated course of therapy.

In closing, we urge CMS to adopt an appropriate methodology for validating the NPWT competency of all Medicare Part B suppliers and to implement that process immediately for all potential Round 2 NPWT bidders. As discussed in our meeting, we look forward to a follow-up meeting with you and your staff on February 10, 2012.

Sincerely,

Chris Attinger, MD, *Chief, Division of Wound Healing, Georgetown University
Department of Plastic Surgery*

Renee Cordrey, PT, PhD(c), MSPT, MPH, CWS *representing American Physical
Therapy Association*

Thomas J. Dugan *AdvaMed Wound Section Chair, President, Smith & Nephew, North
America Advanced Wound Management*

Caroline Fife MD, *Memorial Hermann Center for Wound Healing, University of Texas,
Houston*

Viviane Guay *Director, Health Policy & Reimbursement Americas ConvaTec Inc.*

Susan P. Morris *Vice President Global Health Policy & Government Affairs, KCI*

Marcia Nusgart R.Ph. *Executive Director, Alliance of Wound Care Stakeholders*

*The Alliance of Wound Care Stakeholders members include the following physician and clinician organizations:

- American Board of Wound Management
- American College of Certified Wound Specialists
- American College of Hyperbaric Medicine
- American College of Foot & Ankle Surgeons
- American College of Phlebology
- American College of Surgeons
- American Diabetes Association, Foot Council
- Academy of Nutrition and Dietetics
- American Physical Therapy Association
- American Podiatric Medical Association
- American Professional Wound Care Association
- American Venous Forum
- Association for the Advancement of Wound Care
- Dermatology Nurses Association
- National Association for Home Care and Hospice
- Society for Vascular Surgery
- Society for Vascular Medicine
- Undersea & Hyperbaric Medical Society
- Wound Healing Society