ALLIANCE OF

Wound Care Stakeholders

October 3, 2011

Senator Max Baucus
Chairman, Senate Committee on Finance
511 Hart Senate Office Building
Washington DC 20510

Senator Orrin Hatch
Ranking Member, Senate Committee on Finance
104 Hart Senate Office Building
Washington, DC 20510

Congressman Dave Camp
Chairman, House Committee on Ways & Means
341 Cannon House Office Building
Washington, DC 20515

Congressman Sander Levin
Ranking Member, House Committee on Ways & Means
1236 Longworth House Office Building
Washington, DC 20515

Congressman Fred Upton
Chairman, House Energy and Commerce Committee
2183 Rayburn House Office Building
Washington, DC 20515

Congressman Henry Waxman
Ranking Member, House Energy and Commerce Committee
2204 Rayburn House Office Building
Washington, DC 20515

Sent via Facsimile

Dear Honorable Chairmen and Ranking Members,

As executive director of the Alliance of Wound Care Stakeholders ("Alliance"), I am writing to express our deep concern that the Centers for Medicare and Medicaid Services (CMS) may be placing the health and safety of wound care beneficiaries at risk through its Medicare Part B Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS) Competitive Bidding Program. The Alliance is a 501 (c) (6) multidisciplinary trade association consisting of 19 physician, clinical, provider, and patient organizations, whose mission is to promote quality care and patient access to wound care products and services. This letter was written with the advice of Alliance organizations that not only possess expert knowledge in complex acute and chronic wounds, but also in wound care research. A list of participating organizations can be found on our website at www.woundcarestakeholders.org

On August 19, 2011, CMS announced Round 2 of the competitive bidding program, which will be implemented in 91 Competitive Bidding Areas (CBAs) in 2013 and will include a new category for Negative Pressure Wound Therapy (NPWT) devices. NPWT devices are not simple functional products like canes, crutches, walkers or bed frames, rather they are therapeutic systems used to treat complex wounds frequently occurring in highly compromised patients. These devices improve patient outcomes and help lower total treatment costs in hospitals, long term facilities and outpatient settings.

The Food and Drug Administration (FDA) recently focused attention on NPWT devices used in the home, expressing concern that, although these devices can be used safely and effectively in that setting, greater risk mitigation is required to prevent patients using these devices from experiencing serious health problems. As stakeholders in the wound care community, we agree with the FDA. These products are extremely valuable to patients and the health care delivery system. But without adequate training of clinical caregivers, patients and their family caregivers on the device, combined with 24/7 availability of appropriate clinical and technical support, patients with complex wounds could deteriorate rapidly leading to serious health compromise including, but not limited to, systemic infections, loss of limb and even loss of life. The safety risk is real and significant.

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Although physicians, nurses, physical therapists and other health professionals have primary responsibility for managing and overseeing care of NPWT patients, suppliers of these products play a vital role in ensuring the safe and effective use of these devices in the home. The training and 24/7 support that suppliers provide to professional and caregivers is critically important and requires a different set of competencies than those required for simple functional products. For that reason, the competency of all NPWT suppliers, including those participating in the DMEPOS competitive bidding program, should be validated through the external accreditation program already established by CMS, much like the product-specific accreditation required for suppliers of prosthetics, orthotics, rehabilitation products and respiratory products. Validating the competency of suppliers to provide support NPWT patients and caregivers is no less important.

In support of the FDA's recommendations and to assist CMS in the development of NPWT quality and accreditation standards, the Alliance developed and endorsed a set of proposed standards specifically for NPWT suppliers. We submitted these standards to CMS on March 31, 2011 for inclusion in the competitive bidding process (the standards are attached for your review). CMS now simply needs to complete the development process and then forward the final standards to the accrediting bodies for accreditation of individual NPWT suppliers. That accreditation process will ensure that NPWT suppliers have the expertise required for support of the clinicians and patients using these devices.

Unfortunately, the standards development process appears to be stalled and the Round 2 announcement made no reference to accreditation requirements for bidders of NPWT. This is of great concern to all of the clinical organizations represented by the Alliance. If CMS does not incorporate accreditation into the bidding process, we fear a repeat of our experiences in 2008 in the initial Round 1. During the two weeks that Round 1 was in effect prior to its suspension by the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), there were many winning suppliers who backed out of the program after signing contracts because they were unable or unwilling to provide the level of training and support required by clinicians managing advanced wound care. Without access to appropriate products provided by competent suppliers, many of us practicing in those bidding areas were unable to discharge patients from hospitals to home on a timely basis. We fear this problem could happen again without NPWT accreditation.

Our organizations have communicated our concerns to CMS but have received no confirmation that CMS will incorporate NPWT accreditation into Round 2. For that reason, we ask you to ensure that the safety of Medicare beneficiaries is protected by requiring CMS to develop NPWT-specific accreditation for all Medicare Part B suppliers and to incorporate that accreditation into any competitive bidding program for these devices.

If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R. Ph.

Marcia Nusgart, R.Ph.
Executive Director