ALLIANCE OF

Wound Care Stakeholders

February 2, 2009

Submitted electronically

Mr. Laurence Wilson
Director, Center for Medicare Management
Centers for Medicare and Medicaid Services
7500 Security Boulevard, MS C5-11-24
Baltimore, Maryland 21244-1850

Ms. Elise Berliner
Agency for Healthcare Research and Quality
540 Gaither Road
Rockville, Maryland 20850

Dear Director Wilson and Ms. Berliner:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am writing to request a conference call to address our concerns with the process for the evaluation of the HCPCS codes for negative pressure wound therapy (NPWT) devices. The Alliance is a multidisciplinary consortium of over 15 physician, clinical, provider, patient and manufacturer 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 the following Alliance organizations who possess expert knowledge in complex acute and chronic wounds as well as in wound care research. These include: Society for Vascular Surgery, American College of Foot and Ankle Surgeons, American Physical Therapy Association, American Professional Wound Care Association, American College of Hyperbaric Medicine, American Association for Wound Care Management, National Association for the Support of Long Term Care, American College of Certified Wound Specialists, Coalition of Wound Care Manufacturers and the Undersea and Hyperbaric Medical Society.

Since most of the Alliance physician, clinician or patient organizations either use or benefit clinically from the use of NPWT, we view this initiative by CMS and AHRQ as being very important and having immense implications to our practices. We would like to compliment both CMS and AHRQ in their foresight of requesting a wide range of scientific evidence (i.e. published and unpublished randomized controlled trials, observational studies, other compelling clinical evidence) that uses NPWT devices to impact relevant clinical outcomes. However, due to the significant impact that the results of this initiative would make to our practice and businesses, we would like to ensure that the process and timeline to perform an evaluation of the HCPCS codes is fair, appropriate and transparent.

We are interested in discussing with you the process and timeline that CMS will use for the CMS HCPCS Workgroup in making both the preliminary and final coding decisions for NPWT devices.

We are interested to know whether the CMS HCPCS Workgroup will be using the AHRQ draft or final report to base their preliminary coding decisions. We have concerns that if the Workgroup bases their preliminary coding decisions on the draft instead of the final report, it may contain inaccuracies since it

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has not yet been peer reviewed. This has just recently occurred with the Center for Medical Technology Policy (CMTP), which, thanks to the peer reviewed comments they received after releasing an initial version of their NPWT guidance document, recognized that many of their comments and conclusions required revision. Thus, they are in the midst of a second version. Since this issue is very important to us, we would recommend that the CMS HCPCS Workgroup only use a final version of the AHRQ report to make both their preliminary and final coding decisions.

Moreover, in order to ensure transparency, we would recommend that AHRQ post the stakeholder comments to its preliminary draft on its website just as CMS does.

We have additional concerns if CMS intends to integrate this evaluation of NPWT HCPCS codes into its normal HCPCS coding process timeline which would include the HCPCS Public Meeting. If this is the case, we submit that this issue will take more time to discuss than typically allotted for a primary and secondary speaker. In addition, we question who would select the primary and secondary speaker since these are unique circumstances which differ from a customary manufacturer submitting a HCPCS code application. Again, due to the importance of this initiative, we would recommend that a separate meeting be created (perhaps similar to a MEDCAC format), or the Agency perhaps should allow a three to four hour period of time during the regularly scheduled HCPCS public meeting during which experts in wound care would address their views on the issues. Those that want to speak could contact CMS staff who could then select the speakers. The Alliance would be happy to serve as a resource as we did in 2005 for the MCAC Meeting on "Usual Care of Chronic Wounds."

It is our understanding that AHRQ (through the ECRI Institute) will be "providing CMS with relevant studies and information for use in consideration of coding changes as required by the MIPPA legislation." We are interested in discussing the threshold that the CMS HCPCS Workgroup would be using in determining the studies that would be adequate in making the decisions of whether existing HCPCS codes adequately represent the technology and comparative benefits of NPWT devices.

Finally, many Alliance associations and individual key opinion leaders in wound care who have had years of experience in working with NPWT will be submitting letters to AHRQ with their expert opinion. While expert opinion does not represent a high on level of evidence, we request that the Agency consider it. This is an unusual circumstance as this patient population has very different and challenging wound care problems.

We look forward to discussing these issues with you. I will contact you to set up a convenient time for all involved.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director

c.c. Lori Anderson, CMS