COALITION OF

Wound Care Manufacturers

June 8, 2011

Cynthia Hake
Director, HCPCS Workgroup
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8013.

Submitted Electronically

Re: June 8, 2011 DME CMS HCPCS Public Meeting Attachment #11.040

Dear Ms. Hake:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am submitting the following comments in response to today's HCPCS public meeting. The Coalition represents leading medical device companies who manufacture a wide range of wound care technologies including surgical dressings, skin substitute products, and negative pressure wound therapy devices used by Medicare beneficiaries for the treatment of wounds.

While I did not deliver any oral comments at today's HCPCS public meeting, I am submitting these written comments related to agenda item #1, attachment 11.040 regarding the HCPCS codes for the Kalypto Medical NPD 100. Over the years, the CMS HCPCS Workgroup has heard recommendations from the Coalition and its members to support accuracy in HCPCS coding. We would like to go on the record supporting the new descriptors that Kalypto has requested today for its device:

- **EXXX-Negative pressure wound therapy pump, home model, portable for use on wounds, and with integrated wound dressing /exudate collection capacity**
- **AXX1-Integrated wound dressing/exudate collection capacity for use with negative pressure wound therapy pump, home model, portable; 25-50 cc**
- **AXX2-Integrated wound dressing/exudate collection capacity for use with negative pressure wound therapy pump, home model, portable; 51-100 cc**
- **AXX3-Integrated wound dressing/exudate collection capacity for use with negative pressure wound therapy pump, home model, portable; 101-150 cc**

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We were pleased that CMS had issued new codes in its preliminary coding decision for the Kalypto Medical NPD 100; however we did have concerns with the descriptors since they were not accurate in describing the device. We submit that the Kalypto system is negative pressure wound therapy (NPWT) and not a suction pump and should be described as such. The Kalypto system functions as NPWT and is used for the same patient population as other NPWT devices. As stated in the presentation this morning, the FDA has also determined that the Kalypto system is substantially equivalent to other NPWT systems.

In addition, the current absorptive wound dressing coding descriptors used in the preliminary coding descriptors should be changed to the recommendations above to conform to the dressings and kit that Kalypto uses. This kit not only includes the dressings but also the tubing and other supplies associated with the NPWT kit.

Finally, there was discussion this morning regarding Kalypto's outcome studies. Dr. Serena had mentioned various studies that he has performed which he will be submitting for publication. In issuing new codes for this preliminary decision, we believe that the HCPCS Workgroup was satisfied with the documentation that Kalypto has provided recently. We believe that this level of evidence for coding has been historically consistent for this product category.

We applaud the CMS HCPCS Workgroup for issuing new codes but urge them to adopt the new code descriptor recommendations stated in this letter and today in the HCPCS public meeting in order to maintain the accuracy and integrity of the HCPCS coding system.

Thank you for your consideration of our comments.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director