

# Wound Care Manufacturers

December 26, 2014

Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1612-FC  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

*Comments Submitted Electronically to [www.regulations.gov](http://www.regulations.gov)*

*RE: CMS-1612-FC: CY 2015 Physician Fee Schedule*

Dear Ms. Tavenner:

On behalf of the Coalition of Wound Care Manufacturers (CWCM) I am pleased to submit the following comments in response to the final CY 2015 Physician Fee Schedule with comment period. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those products that are subject to the competitive bidding program. We appreciate the opportunity to provide you our comments on the final rule.

## **Negative Pressure Wound Therapy as a DHS**

The Coalition was disappointed to learn that CPT codes 97607 and 97608, two new disposable negative wound therapy (NPWT) codes, have been added to the list of “designated health services” (DHS) that cannot be submitted to Medicare when/if the physician has a financial relationship with the entity that provides the item.

It is our understanding that the Stark definition of “referral” does not include services personally performed by the referring/ordering physician. For the typical patient provided with a disposal NPWT device, significant clinical interaction from the physician is necessary to thoroughly clean the wound prior to application of a disposable negative pressure wound therapy device. Specifically, the wound is assessed to ensure no sinus tracts or exposed vessels are present. The skin around the wound is cleansed thoroughly and prepared for dressing application. Gauze or foam dressing material is placed into the depth of the wound with cutting of the foam to size and moistening the gauze with normal saline. At every step of the process, including when tubing and suction apparatuses are attached, the physician is in direct contact with the patient, which, by definition, would appear to exempt these CPT codes from

Stark self-referral rules.

Therefore, the Coalition does not understand the rationale for why CMS has placed these codes as a DHS under the Stark regulations and respectfully request the Agency remove these codes from the DHS list.

We appreciate the opportunity to offer our comments. If you would like any additional information or have any questions please feel free to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "Karen S. Ravitz". The signature is fluid and cursive, with a large, sweeping flourish at the end.

Karen S. Ravitz, JD  
Senior Policy Advisor  
Coalition of Wound Care Manufacturers  
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