COALITION OF

Wound Care Manufacturers

September 11, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments Submitted Electronically to **http://www.regulations.gov**

Re: CMS 1676-P: Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2018

Dear Administrator Verma:

The Coalition of Wound Care Manufacturers ("Coalition") is submitting the following comments in response to the CY 2018 Physician Fee Schedule. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including but not limited to Negative Pressure Wound Therapy (NPWT).

PE RUVs for Disposable Negative Pressure Wound Therapy

The Coalition would like to request that CMS consider establishing office based PE RUVs for disposable negative pressure wound therapy when the Agency finalizes the CY 2018 physician fee schedule.

NPWT refers to the application of negative pressure across a wound and can come in the form of traditional as well as disposable systems. The aim of NPWT is to facilitate wound healing, promote granulation of the wound bed, and provide a bridge to surgical closure. NPWT is ideal for chronic wounds that are "stuck" and unable to progress. NPWT is cost effective by helping certain wounds progress through the healing process which in turn reduces the hospital readmission rates and overall healthcare expenditures.

According to the World Health Organization negative pressure wound therapy is more effective at healing wounds than wet to dry dressings when used on acute and chronic wounds, as well as burn victims.

Several NPWT manufacturers offer disposable NPWT products for use in patient homes

5225 Pooks Hill Rd | Suite 627S
Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410
marcia@nusgartconsulting.com

and other non-hospital settings – such as physician offices. These disposable NPWT products offer the same benefits and functionality as the traditional NPWT offered to patients in a hospital setting and aid in patient compliance through portability, discreetness and simplicity of use

The FDA indication for use is the same for both disposable and non-disposable NPWT technologies and both types of devices use similar mechanisms of action to apply a sustained level of negative pressure to the wound bed and surrounding tissue to remove exudate and to promote wound healing.

In January 2015, the American Medical Association (AMA) revised the Category 1 CPT codes (97605 and 97606) for negative pressure wound therapy (NPWT) and created two new, permanent Category 1 CPT codes for disposable NPWT, shown below:

> 97607 *Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment, including provision of exudate management collection system, topical application(s), wound assessment, and instruction(s) for ongoing care, per session, total wound(s) surface area less than or equal to 50 square centimeters*
>
> 97608 *Negative pressure wound therapy (e.g., vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment, including provision of exudate management collection system, topical application(s), wound assessment, and instruction(s) for ongoing care, per session, total wound(s) surface area greater than 50 square centimeters*

These CPT codes describe NPWT services using a disposable device. Since the implementation of these new CPT codes, there has been confusion among physicians regarding the payment rates for these new CPT codes when performed in the office setting, as CMS opted not to assign national fee schedule amounts for these codes in 2015, and instead allowed the carriers to price these services. This decision was based partly on the heterogeneity of products that were described by the available CPT codes at that time.

CMS proposed a national payment rate of $307.39 for both 97607 and 97608 in the CY 2018 hospital out patient proposed rule (OPPS). However, there are currently no office based practice expense relative value units (PE RVUs) for disposable negative pressure wound therapy. The Coalition believes that a similar payment rate under the PFS final rule, accounting for differences in costs across these disparate settings of care, will create much needed transparency and predictability for physicians, and would allow office-based access to this proven wound care therapy for Medicare beneficiaries.

The Coalition would like to recommend that CMS assign direct cost inputs to disposable negative pressure wound therapy, which would allow the establishment of national

payment rates for CPT codes 97607 and 97608 in the final PFS rule for CY 2018. Specifically, we recommend that CMS adopt PE RVUs for CPT codes 97607 and 97608 and establish national payment rates for these CPT codes in a manner that is consistent with the payment rates in the hospital outpatient department and home health settings.

Request for Information on CMS Flexibilities and Efficiencies

The Coalition is pleased and appreciates the Agency's request for information on areas in which CMS can improve regulatory flexibilities and efficiencies in order to reduce unnecessary burdens on clinicians, patients and their families. While CMS wishes to reduce unnecessary burdens, the Agency wants to ensure that quality of care and lower costs are achieved. In doing so, the Coalition would like to request that CMS consider moving forward with reform of the process used by it to assign new Healthcare Common Procedure Coding System (HCPCS) Level II billing codes to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

We submit that the HCPCS Level II Coding Process needs reform since it currently is not transparent, understandable or predictable. Over many years, this has created strong barriers to appropriate coverage and reimbursement for new technologies and products. The current process has a chilling effect on innovation that drives researchers and R&D investments away from DMEPOS, ultimately compromising access to quality care for millions of Medicare beneficiaries and other individuals. Although this process is administered by the Centers for Medicare and Medicaid Services, this badly flawed process impacts Medicare and all payers using the uniform code set. Reform is needed to ensure the goals of a meaningful code set are met, namely, uniformity in billing, appropriate coverage and reimbursement policies, and patient access to quality care.

The Coalition has worked with CMS officials responsible for the HCPCS code set over the past decade to improve this process. Unfortunately, to date only incremental changes have been made that do not address the more significant deficiencies with the process. The need to make these improvements stems from a longstanding history of concerns with the HCPCS Level II coding process. Despite repeated discussions with CMS staff over the years, our concerns with the HCPCS Level II coding process persist—leaving clinicians, manufacturers, payers and most importantly, patients, with a coding system that inadequately describes the products that are being provided and billed.

The Coalition recently signed on to a letter from the Alliance for HCPCS Coding Reform that was sent to both HHS Secretary Tom Price and CMS Administrator Seema Verma requesting a meeting to address this issue and discuss our recommendations. We understand that the Alliance for HCPCS Coding Reform has also submitted comments to the Physician Fee Schedule that included their August 15, 2017 letter to CMS and its corresponding attachments. While the letter contained a prioritized list of recommendations that we would like CMS to consider in making improvements, I have listed below the general principles:

1. Increase transparency of coding decisions and adopt procedural protections to enable stakeholders to participate in the coding decision process, including a mechanism for stakeholders to respond to coding decisions. We further recommend the creation of a HCPCS Level II Coding Advisory Committee to assist the HCPCS Coding Workgroup;

2. Clearly separate the criteria used to establish a new HCPCS code (or verify use of an existing code) from criteria used to establish a coverage policy for the product(s) described by that code. Coverage criteria should never be considered when making coding decisions;

3. Establish a transparent appeals process to provide an independent review or reconsideration of coding decisions; and

4. Improve the coding verification process used by the Medicare Pricing, Data Analysis and Coding contractor (the "PDAC"), as well as the CMS-initiated code revision process (e.g., for internal or modifying code descriptor).

We believe the recommendations contained in the August 2017 Alliance for HCPCS II Coding Reform letter will ultimately help improve patient access to medically necessary products and should therefore be embraced by CMS and adopted as expeditiously as possible. If you would like a copy of this letter, please contact me.

Conclusion

The Coalition appreciates the ability to comment on this proposal and hopes that the Agency will consider our requests as it finalizes the CY 2018 physician fee schedule.

Sincerely,

Karen S. Ravitz, JD
Senior Policy Advisor
Coalition of Wound Care Manufacturers
301 807 5296