ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

September 11, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS- 1676-P
Mail Stop C4-26-05
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:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit the following comments in response to the proposed CY 2018 Physician Fee Schedule. The Alliance is a nonprofit multidisciplinary trade association of health care professional organizations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. Our clinical specialty societies and organizations not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org. There are several provisions included in this proposed rule that impact our members and therefore we have a vested interest. Our specific comments follow.

Proposed CY 2018 Work RVUs

With the passage of the Affordable Care Act, Congress required CMS to identify and review potentially misvalued codes and make appropriate adjustments to the relative values of those services identified as being misvalued. In this proposed rule, CMS has identified two CPT codes that it specifically requested feedback that are related to wound care:

- CPT 29580 (Strapping of Unna Boot), and
- CPT 29581 (Application of multi-layer compression system).

For both of these codes, CMS is underestimating the pre and post service time required for wound care patients. Regarding the pre-service time, clinicians need to perform the following activities: remove old compression, cleanse the wound and skin, apply topical agents and/or potentially debride

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the wound, address the peri-wound skin with topical agents, dress the wound, prepare the skin and then – and only then – perform the application procedure. After the application procedure, clinicians need to counsel the patients on their compression therapy.

In the regulation, CMS has compared CPT code 29580 to CPT 98925. It is not appropriate for CMS to try to compare CPT code 29580 to CPT code 98925 (Osteopathic manipulative treatment (OMT). These CPT codes do not share the same intra-service components or time requirements. As such, the Alliance does not agree that CPT 98925 is a good comparator code. The Alliance also believes that the CMS alternative value is not appropriate. The Alliance recommends that CMS utilize the RUC recommended work RVU for CPT 29580.

Similarly, it is not appropriate for CMS to try to compare CPT code 29581 to CPT code 97597. They also do not share the same intra-service components or time requirements. The work RVU proposed by CMS do not include the added pre-procedure work (removal of old compression, cleansing the wound and skin, applying topical agents and/or potentially debriding the wound, addressing the peri-wound skin with topical agents, dressing the wound, preparing the leg skin and then applying the compression) or post application procedures (i.e. counseling the patients on their compression therapy). As such, the Alliance does not agree that CPT 97597 is a good comparator code to CPT 29581. The Alliance also believes that the CMS alternative value is not appropriate.

The Alliance supports the RUC-recommended work RVUs for CPT code 29580 (a work RVU of 0.55) and CPT code 29581 (a work RVU of 0.60). However, we do not agree that either 29580 or 29581 are good, or accurate comparator codes to 98925 and 97597 respectively.

E/M Codes

The Alliance supports and appreciates the Agency's recognition that the 1995 and 1997 documentation guidelines for evaluation and management services (E/M) are outdated and need to be reviewed and revised as well as the Agency's interest in decreasing the burden on clinicians while increasing meaningful documentation for E/M.

Hyperbaric Oxygen Therapy (HBOT)

The Alliance applauds CMS decision to update the equipment items and the amount of oxygen for HBOT so that the amount of oxygen conforms to the RUC recommended value of 47,000 liters of oxygen which when divided by the Agency conforms to the 30 minute service period for HCPCS code G0277. Many Alliance members provide HBOT to treat their patients and are experts in this treatment modality as well as the research surrounding it. The Alliance is pleased to see that CMS has utilized the RUC recommended amount of oxygen units and agrees with the proposed language. The Alliance recommends that CMS finalize these provisions in the final rule.

Establishing Office-Based PE RVUs for Disposable Negative Pressure Wound Therapy

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 I 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.

In the CY 2018 hospital outpatient proposed rule, CMS proposed a national payment rate of $307.39 for both 97607 and 97608. We believe 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 allow office-based access to this proven wound care therapy for Medicare beneficiaries.

The Alliance believes CMS can and should assign direct cost inputs to this service, 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 practice expense (PE) relative value units (RVUs) for CPT codes 97607 and 97608 and to 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.

Quality Measures

CMS has proposed to revise the previously finalized satisfactory reporting criteria for the CY 2016 reporting period to lower the requirement from 9 measures across 3 NQS domains, where applicable, to only 6 measures with no domain or cross-cutting measure requirement. According to CMS, for individual EPs, this would apply to the following reporting mechanisms: claims, qualified registry (except for measures groups), QCDR, direct EHR product and EHR data submissions vendor product. The Alliance supports the proposed revision and encourages CMS to finalize in the final rule.

Request for Information on CMS Flexibilities and Efficiencies

The Alliance appreciates that CMS would like to start a national conversation about improvements that can be made to the health care delivery system that reduce unnecessary burdens for clinicians, other providers, and patients and their families and we would ask to be part of this conversation. Since CMS aims to increase quality of care, lower costs, improve program integrity, and make the health care system more effective, simple and accessible, we would ask that the Agency consider our recommendations for 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 Alliance 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.

We 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 which included the 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 these 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

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. We appreciate the opportunity to be part of a national conversation about improvements that can be made to the health care delivery system. If you have any questions or would like further information, please do not hesitate to contact me either at 301-530-7846 or marcia@woundcarestakeholders.org

Sincerely,

Marcia Nusgart R.Ph.

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Executive Director