ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

August 31, 2015

Mr. Andrew Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1633-P
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Re: CMS-1633-P Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare-Dependent, Small Rural Hospitals under the Hospital Inpatient Prospective Payment System

Dear Acting Administrator Slavitt:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit the following comments in response to the proposed CY 2015 Hospital Outpatient Prospective Payment System (HOPPS). The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations 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. These comments were written with the advice of the Alliance member clinical specialty societies and organizations who 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 wound care and therefore we have a vested interest in ensuring that our comments are taken into account by your staff as they write the final rule. Our specific comments follow.

RESTRUCTURING OF SKIN-RELATED PROCEDURE APCS

For CY 2016, CMS has proposed to restructure many APCs, leading to significant changes in payment for many services. We are concerned about these dramatic changes in payment and recommend that CMS review these changes to verify that they correctly reflect hospitals' costs. Some of the restructuring proposals resulted in wide variations in payment and produced groupings that are too broad, which in turn

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creates APCs that do not appropriately reflect resource distinctions. One area in particular that we are concerned with is in the restructuring of all the skin-related procedure APC assignments by combining the debridement and skin procedure APCs. While CMS believes this will more appropriately reflect the costs and clinical characteristics of the procedures within each APC there are some areas in which the Alliance disagrees including, but not limited to, Total Contact Casting and Disposable Negative Pressure Wound Therapy.

Total Contact Casting

First, with respect to total contact casting, CMS has inappropriately proposed to assign CPT 29445 – application of a rigid leg contact cast (total contact casting) in the same APC as the application of an Unna Boot (CPT 29580) and the application of a multi-layer compression systems (CPT 29581). Total contact casting is not clinically similar nor is it similar in terms of resource use to those procedures codes included in APC 5102. In reviewing the RVUs and procedure codes in either proposed APC 5102 and 5101, the procedure code for the application of an Unna Boot and the application of multi layer compression wrap are more clinically similar to those procedures in APC 5101. Having them bundled together in this proposal is inconsistent with the resources required and the clinical benefit derived by a total contact cast.

The result of this inappropriate assignment will be a reduction in the hospital fee from $225.90 (2015) to $130.96 (2016). That is over a 40% reduction in payment for this procedure. As a result, clinicians will no longer be able to continue providing this option to treat their patients. Total contact casting is the clinical standard of care for diabetic foot ulcers (DFUs). Due to a non-coverage decision by the DME MACs in August 2014 for walker boots, application of a total contact cast is now the most viable option for off-loading a diabetic foot ulcer. The impact on diabetic patients with these severe wounds will be dramatic and likely result in an overall cost increase to the hospital system with re-admissions, surgeries and amputations.

As such, the Alliance recommends that:

1) Total contact casting - CPT 29445 - should be placed into APC 5102,
2) The applications of an Unna Boot (CPT 29580) and a multilayer compression system (CPT 29581) should not be placed in APC 5102 but rather APC 5101 and
3) The APCs should be adjusted accordingly to reflect the appropriate payment which is closer to $225.

Disposable NPWT

Last year, CMS reassigned HCPCS codes G0456 and G0457 for the application of disposable Negative Pressure Wound Therapy (NPWT) from APC 0016 (Level III Debridement and Destruction) to APC 0015 (Level II Debridement and Destruction). This year, CMS has proposed to reassign these services (now reported with new CPT codes – 97607 and 97608) into the consolidated APC for skin and debridement services APC 5052 (Level 2 skin procedures). The Alliance does not believe that the payment rates cover the cost of the disposable device used in these services and therefore the rates are not adequate within this APC.

The rates for NPWT are determined based on a geometric mean cost. A significant difference in the geometric mean costs of traditional versus disposable NPWT services should be expected. However, the

2014 geometric mean costs for all NPWT services are remarkably aligned, showing that only a very small portion of device costs (often $200 to $800 per procedure) are getting captured in the claims data for single-use NPWT.

The Alliance questions this rate. Hospitals do not incur ANY device and supply costs when furnishing traditional NPWT in the outpatient setting, as the equipment (reusable pump, wound exudate canisters and supply kits) used in these services is separately purchased, delivered and billed by durable medical equipment (DME) suppliers to Medicare DME contractors. The only costs incurred by hospitals providing traditional NPWT are service costs, not device/supply expenses. Yet, disposable NPWT is different from traditional NPWT since it requires the use of a separately packaged, distinctly labeled, hospital-purchased device.

Due to the newness of the CPT codes (97607 and 97608), outpatient claims may not be capturing the cost differences between traditional NPWT and disposable NPWT. New codes can present challenges in terms of updating charge masters, and this dynamic can often be all the more challenging when new HCPCS codes are not only G codes but G codes with remarkably similar descriptors to CPT codes for traditional NPWT. Hospitals appear to have been confused about proper billing and coding for disposable NPWT in both 2013 and 2014. We believe that this has resulted in flawed data used to establish the APC assignments.

Therefore, the Alliance recommends that CMS consider third-party data sources on device prices and invoices to help guide their decision on APC assignment. In the meantime, the Alliance recommends that CMS assign disposable NPWT - a clinically proven, cost-saving service - to APC 5053 in order to match the resources of this treatment with comparable skin procedure services. We further recommend that CMS work with stakeholders to obtain better cost data in order to ensure the appropriate APC assignment.

STATUS INDICATOR FOR LOW-FREQUENCY ULTRASOUND THERAPY

The newly-proposed APC for low-frequency ultrasound therapy ("LFU Therapy"), APC 5051, was assigned the Q1 status indicator, which would inappropriately characterize this independent service as an "ancillary service" and bundle payment for LFU Therapy with S, T, and V services. The status indicator for this APC and the CPT code that describes LFU Therapy, 94610, must revert to the "T" status indicator previously assigned to it. CMS guidance has made clear that Status Indicator Q1 is assigned only to ancillary services, which include "minor diagnostic tests and procedures that are often performed with a primary service."

We submit that the CPT Code 97610 is a primary service, not an ancillary service, per the definitive guidance on this code from the American Medical Association ("AMA"). First of all, the CPT descriptor of the service includes not only the LFU Therapy itself, but also wound assessment and instructions for ongoing care, encompassing the full scope of required practitioner services related to providing LFU Therapy. In addition, guidance from the AMA in the June 2014 CPT Assistant clearly describes this service as a standalone procedure. The clinical vignette included therein notes that the service described by 97610 includes "careful wound assessment, measurement, and photography" before cleansing the wound and surrounding tissue. A qualified health care professional must be in "continuous attendance" during the provision of LFU Therapy, and at its conclusion, performs an additional assessment of the wound bed and surrounding tissue and applies an appropriate dressing. Even more compelling, the AMA states that debridement services and LFU Therapy "represent different interventions using different medical equipment

with distinctly different clinical outcomes," suggesting that one service is not ancillary to another. Attributing Status Indicator Q1 to 97610 would directly contradict the guidance from the AMA and the limits on CMS's authority to package services as "ancillary" by associating LFU Therapy with a "primary" debridement procedure.

In addition to the clear clinical guidance demonstrating that LFU Therapy is not an ancillary service, the cost data provided by CMS in the Proposed Rule confirms that LFU Therapy is an independent service. First, as a matter of practice, the CMS data show that providers frequently perform LFU Therapy as a standalone, independent procedure, with greater than half of the 12,091 procedures coded with CPT 97610 being billed as single claims with no associated service. Second, neither APC 5051 nor CPT code 97610 meets the Geometric Mean Cost ("GMC") criteria CMS established to define "ancillary services." On the theory that low-cost procedures are more likely to be ancillary than higher-cost procedures, CMS limited the initial set of APCs containing conditionally packaged services to those APCs with a proposed GMC of less than or equal to $100. GMC cost data for CY 2015 indicated that the GMC of APC 0012 (the APC into which LFU Therapy was placed) exceeded this $100 threshold, and cost data included in the Proposed Rule indicates that the GMC of APC 5051 (the APC into which LFU Therapy has been placed for 2016) significantly exceeds the $100 threshold. By assigning the Q1 status indicator to this APC, CMS would arbitrarily package services like LFU Therapy that are not ancillary services and do not meet the cost thresholds established by CMS. To avoid the inconsistent and arbitrary application of its definition of "ancillary services," CMS must ensure that CPT code 97610—an independent clinical procedure that exceeds the cost thresholds for ancillary services—does not receive a Q1 status indicator.

STATUS INDICATOR FOR TRADITIONAL NEGATIVE PRESSURE WOUND THERAPY

CPT codes for traditional negative pressure wound therapy, 97605 and 97606, also have been placed in the newly created APC 5051 and received a status indicator Q1. Again, it is contrary to CMS's guidance that the status indictor of Q1 is assigned only to ancillary services – which includes minor diagnostic tests and procedures that are often performed with a primary service. NPWT is not an ancillary service.

Furthermore, CMS limited the initial set of APCs containing conditionally packaged services to those APCs with a proposed GMC of less than or equal to $100. NPWT exceeds the $100 GMC criteria.

Therefore, the Alliance recommends that CMS must ensure that CPT codes 97605 and 97606 –which are independent clinical procedures that exceed the cost threshold for ancillary services – do not receive a Q1 status indicator.

NEED FOR TRANSPARENCY BY CMS REGARDING DATA USED TO SET APC PAYMENT RATES

Furthermore, the Alliance urges CMS to remain transparent about the data it uses to set APC payment rates. For example, while the cost of the device should be included in the APC payment rate for device intensive procedures, - and represented in the offset file – it is unclear if the costs of all the services in a given APC are truly representative of the cost of particular procedures. The Alliance also knows that not all device HCPCS codes are brand name specific. We request that the data CMS uses in setting payment rates is returned with

more transparency so we can confirm that CMS is truly capturing which devices are being used and reported under the APC and the code(s) CMS wants hospitals to report.

PACKAGING OF SKIN SUBSTITUTES

New Methodology for Establishing High/Low Threshold

CMS has provided a new methodology for determining the high or low threshold. The Alliance appreciates CMS's approach and agrees with the either Mean Unit Cost (MUC) or Per Day Cost (PDC) approach in determining the high or low threshold. As such, we recommend that CMS finalize the proposal to use the new methodology using either the MUC or PDC in determining the high or low cost threshold.

Low Cost Cellular and/or Tissue based Products for Wounds (CTPs)

For CY 2016, the changes included in the proposed rule will place low cost products in APC groupings that will result in payment reductions of 29%. The Alliance is concerned that this change will create barriers for the use of these low cost products. The Alliance has reviewed how the high cost products (CPT 15271-15278) were cross walked to APC 5054 and 5055 and recommend that CMS crosswalk low cost products (CPT C5271-C5278) in the same manner from APC 0327 and 0328 to APC 5053 and 5054. Low cost products were never assigned to APC 0329 and therefore should not be assigned to the new APC 5055 in 2016. This would more appropriately reflect the cost of applying and using these products and would encourage clinicians to continue to use these lower cost products. Finally, the Alliance recommends that CMS work with stakeholders to obtain the data necessary to create appropriate APCs for the application of CTP products.

CTPs (Skin Substitutes) that Lack Claims Data

The Alliance supports the CMS proposal to place CTPs that lack claims data into a high or low cost grouping based on available data for average sales price (ASP) plus 6%, wholesale acquisition cost (WAC) plus 6%, or 95% of average wholesale price (AWP). The Alliance recommends that CMS finalize this proposal to set rates for skin substitute products when claims data are not available

Edits

CMS's ability to calculate appropriate payment rates depends on the accuracy and completeness of the claims data. To ensure that the agency has the data it needs, the Alliance continues to urge CMS to require complete and correct coding for packaged services including CTP. This will ensure that appropriate thresholds are being established. CMS should never see the number "one" unit being billed for these products. CMS and its contractors do reviews for these services all the time. If the contractor sees "one" unit being billed, it should kick the claim out of the system in the same way that it would for an overpayment. The contractor, in this case, should then request that the billing facility correctly bill for the products.

Furthermore, the Alliance requests that CMS issue a MedLearn Matters (MLM) to describe the proper billing of these products. This will ensure that accurate, appropriate billing is being submitted – which in turn will ensure accurate, appropriate thresholds being established for CTP products.

Finally, the Alliance recommends that CMS continue to monitor the impact of the high and low cost threshold pricing on the use and availability of CTP products and to continue to consider other approaches for covering these products – if necessary.

CONCLUSION

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director