COALITION OF

Wound Care Manufacturers

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:

The Coalition of Wound Care Manufacturers ("Coalition") is pleased to be submitting our comments to CMS on its proposed regulation regarding the Hospital Outpatient Prospective Payment System CMS-1633-P). 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 provisions contained in this proposed rule. As such we have a particular interest in this regulation. For your reference, throughout our comments, we refer to "Skin Substitutes" as Cellular and/or Tissue Based Products for Wounds (CTPs) as it is a more clinically appropriate term and has widely been accepted in the clinical community when referring to these types of products. Our specific comments follow.

Specific Comments

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 (5102) as the application of an Unna Boot (paste boot CPT 29580) and the Application of a multi-layer compression systems CPT 29581). Total contact casting is not clinically similar to the application of Unna Boots or the Application of a multilayer compression system. Similarly total contact casting is not similar in terms of resource use to the application of an Unna Boot or the

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

application of a multilayer compression system procedures codes included in APC 5102. The procedure codes 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. While Total contact casting is the clinical standard of care for diabetic foot ulcers (DFUs), clinicians will no longer be able to continue providing this option to treat their patients if the procedures remain in the same APC due to the reduction in payment.

In order to provide the clinical homogeneity that CMS is striving for, the Coalition recommends that 1) CPT 29445 - Total contact casting be placed into APC 5102. Furthermore, we recommend that CPT 29580- The application of Unna Boots and CPT 29581 - multilayer compression wraps be placed in APC 5101. Finally, the Coalition recommends that the APCs be adjusted accordingly to reflect the appropriate payment.

Disposable NPWT

Last year, CMS reassigned HCPCS codes G0456 and G0457 for 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 Coalition 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 Coalition questions how CMS arrived at 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 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 Coalition 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 Coalition 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 Q1

CMS has proposed to assign the Q1 status indicator to many procedures within the newly proposed APC 5051. There are a couple of procedures that we believe were assigned this status indicator in error including Low-frequency Ultrasound Therapy and Traditional Negative Pressure Wound Therapy.

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." 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, 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 confirm 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," the Coalition recommends that CMS does not issue a Q1 status indicator to CPT code 97610 as it is an independent clinical procedure that exceeds the cost thresholds for an ancillary service.

Traditional Negative Pressure Wound Therapy

Similarly, traditional negative pressure wound therapy (NPWT), 97605 and 97606 also have been placed in the newly created APC 5051 and received a status indicator Q1. As with low frequency ultrasound, traditional NPWT does not meet the definition of a status indicator Q1. NPWT is not an ancillary service and exceeds the $100 geometric mean cost (GMC).

To avoid the inconsistent and arbitrary application of its definition of "ancillary services," the Coalition recommends that CMS does not issue a Q1 status indicator to CPT code 97605 or 97606 as they are independent clinical procedures that exceed the cost thresholds for an ancillary service. We further recommend that these codes maintain their "T" status indicator.

Transparency

Furthermore, the Coalition 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 Coalition also knows that not all device HCPCS codes are device 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 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/low threshold. As such, we recommend that CMS finalize the proposal to use new methodology either MUC OR PDC to determine the high low cost threshold. However, we would also like to better understand, in depth, how these MUC and PDC claims data numbers were calculated, particularly when CTPs have always been driven by ASP.

While we support the concept of this new methodology, we are not clear how this claims data is used and we do not have access to the inputs CMS used to derive the claims or weighted claims data. The Coalition requests that CMS be willing to make the MUC and PDC data utilized fully transparent and available.

Low Cost 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 Coalition is very concerned that this change will create barriers for the use of these low cost products. The Coalition has reviewed how the high cost products were crosswalked to APC 5054 and 5055 and recommend that CMS crosswalks low cost products 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.

Skin Substitutes that Lack Claims Data

The Coalition supports the CMS proposal to place skin substitute products 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 Coalition 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 Coalition continues to urge CMS to require complete and correct coding for packaged services including skin substitutes. This will ensure that appropriate thresholds are being established. CMS should never see one unit being billed for these products. CMS and its contractors do reviews for these services all the time. If one unit being billed the claim should kick it out of the system the same way that would for an overpayment and the contractor, in this case, should request that the billing facility correctly bill for the products. Furthermore, the Coalition 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 skin substitute products.

Erroneous Removal of Skin Substitute (CTP) Product

CMS has asserted that some CTP products are implantable and not *typically used to promote healing of wounds on the skin.* This assertion is incorrect. While a product may have multiple indications for use, when CTP products are used to treat wound care patients they are NOT implantable. Graftjacket® RTM is an example of one product that was removed from the "Skin Substitute Cost Group"– and there are others. While Strattice TM is marketed for use other than in wound care and therefore would be considered an implantable device, Graftjacket® RTM is a CTP that is used to treat patients for wounds. Removal of Graftjacket® RTM from the "Skin Substitute Cost Group" List would be inaccurate when this product is used as a CTP. This removal by CMS will restrict an approved skin substitute for use by practicing providers. The Coalition recommends that products, when used to treat wound care patients (since they are not implantable when used in this manner) remain on the "Skin Substitute Cost Group" List.

Conclusion

We appreciate the opportunity to provide you with our comments on this important draft policy. Should you have any questions or require any additional information, please do not hesitate to contact me.

Thank you for your consideration.

Sincerely,

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