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-1678-P,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850.

Submitted electronically to regulations.gov

Re: [CMS-1678-P] Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Verma:

The Coalition of Wound Care Manufacturers ("Coalition") is submitting the following comments in response to the CY 2018 Hospital Outpatient Prospective Payment System. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including but not limited to Cellular and/or Tissue Based Products for Wounds. Within proposed rule there are several sections that address CPTs. As such, we have a vested interest in the language contained in this proposal. The Coalition is a member of the Alliance of Wound Care Stakeholders (Alliance) and our comments are in alignment with the comments submitted by the Alliance. Our specific comments follow.

Comment Solicitation on Packaging of Items and Services Under the HOPPS

In the OPPS proposed rule, CMS states that as the HOPPS continues to move towards a prospectively determined encounter-based payment and away from separate fee schedule-like payment, CMS continues to hear concerns from stakeholders that the packaging policies may be hampering patient access or resulting in other undesirable consequences. CMS notes that given that aggregate spending and utilization continue to increase for covered outpatient services, it is unclear what, if any, adverse effect packaging has on beneficiary access to care.

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Prior to the packaging of skin substitutes – now known as Cellular and/or Tissue-based Products for wounds (CTPs), the Coalition submitted comments to CMS stating our

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

concerns for a bundled program for these products. We believed at the time – as we do now, that unless CMS was able to utilize accurate claims report data, there would be problems in establishing the rates for the application as well as the products used. In fact, packaging has caused many low cost products to be forced out of the marketplace. The ones that remain in the low cost tier are struggling to be utilized as facilities are choosing high-tiered products in order not to loose money on the low-tiered products. The volatility of the yearly adjusting thresholds can virtually eliminate product usage if the product falls from the higher cost threshold to the lower cost tier. The threshold calculations continue to rise in the high cost tier due to the methods that CMS has employed in creating the tiers and in its methodology in supporting products entering the market with high cost per cm2.

Our comments specific to the issues and recommendations we have regarding the methodology are provided below. However, in response to CMS request for stakeholder comments regarding packaging, the Coalition continues to believe that packaging is not appropriate for CTPs.

Grandfathering 8 CPT Products

The Coalition appreciates and fully supports the decision by CMS to grandfather 8 CPT products. Those grandfathered products would have been moved from the high cost tier to the low cost tier for CY2018 without this language being contained in this proposal. The Coalition recommends that CMS finalize the grandfather provisions for the 8 CTP products identified so that they will remain in the high cost tier for CY 2018.

Methodology for Packaging of Skin Substitutes (Cellular and/or Tissue Based Products for Skin Wounds –"CTPs")

Since 2014, CMS has issued regulations to package cellular and/or tissue based products for skin wounds (CTPs). From the inception of the packaging of CTPs, CMS did not utilize the correct cost information because the number of square centimeters applied were not coded and charged correctly. CMS was presented with actual invoices to prove that the product costs built into the packaged payment were not accurate. CMS has the cost for these products as submitted by the manufacturers. However, CMS moved forward with the packaging of CTPs with flawed data. As a result, the way CMS established the packaged payment for CTPs created the predicament we are facing today – hospitals are losing money in the application of a CTP using a packaged payment methodology, low cost tiered products are slowly disappearing from the marketplace, and there is volatility in the establishment of the high low cost threshold.

The packaging of CTPs has resulted in unintended consequences. Instead of controlling costs, packaging has forced hospital outpatient departments (HOPD) to significantly

reduce or cease using CTPs for the sickest of patients that require product in excess of the calculated amount within the application codes. If CMS is determined to continue with packaging, the Agency needs to look to the true cost of the products, establish multiple levels of packaging and ensure that no package provides a larger payment incentive than the other.

For the past several years, the Coalition has consistently recommended to CMS that in order to accurately set the packaged payment rates for CTPs, correct coding and billing of these products is essential. The Coalition continues to maintain that it is the responsibility of CMS to ensure that these products are coded and billed appropriately so that the APC Group assignments are assigned correctly. We submit that these products are not being coded and billed correctly: the claims data are inaccurate and the APC Group assignments are negatively impacted.

It is the responsibility of CMS to ensure that hospitals are not only reporting the correct CPT application code, but also that the number of units applied align with the number of units reported with the CPT code. For example, claims should never show a unit of 1 (per centimeter) attached to the product code when the physician applies a CTP to a 20 sq. cm wound. Moreover, if the procedure code is reported for 100 sq. cm, a minimum of 100 units of sq. cm should be reported on the claim for the product. In addition CMS should verify that the correct revenue code for the products is reported on the claims: revenue code 636, not 278, should be reported on the claim. Finally, the charges reported should be a multiple of the ASP prices.

Unless CMS establishes edits to accurately reflect the number of square centimeters (units) that have been applied, the APC Group assignment will continue to be inaccurate. APCs are evaluated every year. It is the Coalition's recommendation - and has been for the past three years - that CMS educate facilities on the correct coding and billing of CTPs. This will ensure that appropriate APC Group assignments are made which reflect the true costs of the CTPs. In addition, the Coalition recommends that CMS mandates its Medicare Administrative Contractors to establish edits that reject claims whose CTP codes reflect one wound size and whose products codes do not reflect a similar size reflected in the units reported. If only one unit is coded and billed for wounds that are 20 sq.cm in size, or if less than 100 units of sq. cm of product is reported when the procedure is reported for a 100 or more sq. cm size wound, then the claim should be kicked out of the system. Moreover, CMS should also edit for facilities that do not purchase CTPs to adequately cover the base of the entire wound and the wound margins that are not large enough to allow for the surgeon's choice of the fixation. The contractor should request that the facility purchase the right size product to cover the entire wound and correctly code the correct number (units) of sq. cm applied.

The Coalition urges CMS to issue a Medicare Learning Network Matters® (MLN Matters®) article and initiate edits to describe the proper coding and reporting of units. This will ensure that accurate, appropriate claims are submitted – which in turn

will ensure accurate, appropriate APC Group assignments for CTP products. Accurate claims reporting is absolutely necessary and it is up to CMS to ensure this occurs. In the meantime, CMS needs to use other data to establish accurate APC groups for packaged CTPs.

To help in the establishment of accurate APC groups, cost thresholds and ultimately reimbursement for CTPs, we request that if CMS continues with packages payment for CPTs, CMS go back to utilizing ASP data rather than claims data for establishing the high/low cost threshold if CMS continues to package CTPs.

ASP data comprise manufacturer-certified actual sales prices for these therapies, which provide a more accurate reflection of true market cost than the hospital claims data, which estimate costs from product-specific charges reduced by departmental ratios of cost-to-charges overall. It is well established that claims-based cost data are subject to charge compression and do not reflect accurate costs for individual treatments. Coalition members previously submitted evidence to CMS that ASP data for these products are quite consistent with hospital acquisition cost data. However, CMS could also check the ASP against the ECRI report information in which hospitals have to report. This would allow for a check and balance in the rates to ensure that manufacturers are not inflating their ASP data.

To further delineate our recommendation to utilize ASP pricing and to validate those CTPs being utilized in the hospital outpatient or ambulatory surgical center settings for wound closure, CMS should request manufacturers segregate out those products' Stock Keeping Units (SKUs), or other product identifiers, that are specific to CTPs 15271-15278 and C5271, C5273, C5275, C5277 (APC 5053 and 5054) during their quarterly ASP reporting and only use those codes to determine the ASP. Many CTPs have applications that are outside of the jurisdiction of the proposed rule (e.g. those used in association with CPT 15777) and those price considerations should not be utilized to determine the cost of the product in the settings under this proposal. This request is consistent with using the claims data on the 2018 proposed rule. To ensure manufacturers comply with the reporting, CMS should establish a reporting threshold commensurate with the upper limit of a wound treated in a hospital outpatient department.

As such, the Coalition urges CMS to revert to its practice of using ASP data to set the high/low cost threshold for packaging and to publish all of the reported ASP prices for CTPs. This will help to establish more stability in the marketplace and to ensure a level playing field.

Finally, we also urge CMS to examine ways to ensure transparency of the data being used for these calculations, as well as developing a process to ensure greater predictability of payment amounts. The Coalition would like to point out that the MUC has risen 188%

since 2015. As such, the Coalition recommends that the amount by which the threshold can increase be limited to the consumer price index. This will help mitigate the huge swings in the high/low cost tier threshold – which has led to CMS grandfathering 8 products this year.

Add On Codes

Add-on codes are distinct clinical procedures that have been valued by the AMA independently from the primary procedure and that the AMA specifies should be listed separately, in addition to the primary procedure. CMS packaged the CTP application add-on codes which inappropriately voids the AMA's separate valuation of these codes. CMS's policy also essentially results in hospitals not being reimbursed for the additional clinical care and supplies required, including the additional amount of CTPs, that may be required when performing an add-on service, which ultimately has adversely impacted patient access to some CTP products.

CMS has not demonstrated how it accounts for the full range of supplies and devices that may be used and/or the typical number of levels furnished to a patient in an outpatient encounter in setting the packaged APC rate.

The Coalition believes that packaging all add-on codes has been an overly broad, indiscriminate proposal that has not promoted payment accuracy or advanced patient care. For a variety of reasons, the Coalition has not agreed with the APC placement or rates for packaged CTPs. We believe that the APCs that were created –along with the rates associated with them – have been very low and arbitrary for the majority of the products that currently have coverage and payment. CMS has eliminated extra payment for add-on procedure codes that include CTPs, yet the additional product still needs to be provided. While the we can understand why CMS would eliminate extra payment for procedure codes that do not include CTPs, it is difficult to understand how CMS believes an outpatient facility can afford to utilize additional CTP products OR staff time and not be reimbursed for them. Currently the Agency is not paying for the add-on procedure codes that include the CTP product. This is completely unreasonable.

The Coalition recommends that CMS work with stakeholders to obtain the data necessary to create appropriate APCs for the application of CTP products.

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 reforming the process used 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