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-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:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the proposed changes to the Hospital Outpatient Prospective Payment and Ambulatory Surgical Payment Systems and Quality Reporting Programs. In addition to submitting these comments, the Alliance would like to request a meeting with CMS to further discuss the packaging of CTP products and the methodology used to determine the high/low threshold as well as the reimbursement for these products.

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 Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. As such, we have a vested interest in this policy. A list of our members can be found at www.woundcarestakeholders.org. 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

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unclear what, if any, adverse effect packaging has on beneficiary access to care. CMS is seeking feedback from stakeholders on common clinical scenarios involving currently packaged HCPCS codes for in which packaged payment is not appropriate under the HOPPS.

Prior to the packaging of skin substitutes – now known as Cellular and/or Tissue-based Products for wounds (CTPs), the Alliance met with CMS and submitted very detailed comments as to why we believed packaging was not appropriate for CTPs. The information we submitted back in 2013 is still appropriate today; thus, we have included those comments along with its corresponding Attachment A and B.

However, now, we have additional data. 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 lose 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 cm^2.

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 Alliance continues to believe that packaging is not appropriate for CTPs.

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. The Alliance presented CMS 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.

In our initial comments, the Alliance recommended to CMS that if they were to move to packaged payment for CTPs, they utilize ASP data and not inaccurate claims data. However, CMS moved

forward with a methodology to establish the high/low cost tier based on claims data.

For the past several years, the Alliance 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 Alliance 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. The Alliance submits that these products are not being coded and billed correctly, thus making the claims data inaccurate and impacting negatively the APC Group assignments. 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; e.g., 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 Alliance'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 Alliance 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 which 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 Alliance 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.

While we have consistently made these recommendations – CMS has stated in the response to comments that it is not the Agency's responsibility to monitor whether hospitals are accurately billing for these products. With all due respect, **the Agency's ability to calculate an appropriate threshold for distinguishing high versus low cost products depends on the accuracy and completeness of the data used to make this calculation**. Although the Alliance opposes any packaging of CTPs – and has since the inception, we request that 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 comprises 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. Alliance 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. The Alliance along with the United States Wound Registry is happy to work with CMS in identifying what the upper limit should be.

Additionally, while submission of quarterly ASP data is made to the CMS ambulatory services department that processes ASP data for drugs and CTPs, this is not the group that oversees that outpatient payment policy. It is our understanding that an agreement made with the outpatient group on ASPs for CTP sizes used on wounds treated in outpatient settings is not binding on the group responsible for ASP reporting, as stated above. Thus, in order to maintain accurate data, the Alliance maintains that only ASP reporting for CTPs used to treat wounds in the hospital outpatient setting should be used to accurately establish the high/low cost threshold. Finally, CMS should publish all the of the reported ASP prices for CTPs.

As such, the Alliance urges CMS to revert to its practice of using ASP data to set the high/low cost threshold for packaging. 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 Alliance would like to point out that the MUC has risen 188% since 2015. As such, the Alliance 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.

Grandfathering 8 CPT Products

The Alliance strongly supports the decision by CMS to grandfather 8 CPT products that, based on the

proposed threshold, would have been moved from the high cost tier to the low cost tier. Until CMS can create a system in which the rates are established using correct data and the annual threshold has minimal increases, the Alliance recommends that those products continue to stay in the high cost bucket. This allows for the least possible disruption in care and a more stable, less volatile marketplace.

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 Alliance 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 Alliance 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 Alliance 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 time and staff time and not be reimbursed for them. We believe that it is unreasonable for the Agency to not pay for the add-on procedure codes that include the CTP product.

The Alliance 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 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.

The Alliance recently signed on to an August 15, 2017 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 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs comments that included its 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 Alliance appreciates the opportunity to provide our comments. In summary, the Alliance recommends 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.

- 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.

- Provide edits for facilities that do not purchase CTPs to adequately cover the base of the entire wound and the wound margins which 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.

- 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.

- Eliminate packaging for CTPs

- Revert back to utilizing ASP data that is only appropriate to the intent of the proposed rule (i.e. CPT codes 15271-15278 and C5271, C5273, C5275, C5277 (APC 5052 and 5054) if the Agency is to continue packaging CTPs

- Publish all of the reported ASP prices for CTPs

- Examine ways to ensure transparency of the data being used for these high/low cost threshold calculations, as well as developing a process to ensure greater predictability of payment amounts. The Alliance would like to point out that the MUC has risen 188% since 2015. As such, the Alliance 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.

- Work with stakeholders to obtain the data necessary to create appropriate APCs for the application of CTP products

- Read the comments submitted by the Alliance for HCPCS II Coding Reform and adopt their recommendations of:
    - Increasing 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;
    - Clearly separating 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;
    - Establishing a transparent appeals process to provide an independent review or reconsideration of coding decisions; and
    - Improving 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).

The Alliance would like to request a meeting with CMS to further discuss the packaging of CTP products and the methodology used to determine the high/low threshold as well as the reimbursement for these products.

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.
Executive Director