COALITION OF

Wound Care Manufacturers

September 27, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services Department of Health and Human Services
Attention: CMS-1717-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Re: Medicare Program: Proposed Changes to CY 2020 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs

Dear Administrator Verma:

On behalf of the Coalition of Wound Care Manufacturers (CWCM), I am submitting the following comments in response to the proposed changes to the Hospital Outpatient Prospective Payment System. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of chronic non healing wounds including but not limited to Cellular and/or Tissue Based Products for Skin Wounds (CTPs).[1] Our comments will solely focus on the proposed payment methodologies for these products.

Payment Methodologies for CTPs

Since 2014, CMS has issued regulations to package CTPs. From the inception of the packaging of CTPs, the Coalition believed that the system would not work, would create perverse incentives and was flawed. The Coalition appreciates that after a few years utilizing this pricing methodology, CMS has come to the same conclusion and applauds its decision to rework the payment methodology for CTPs.

However, CMS has over the past few years floated a number of different payment methodologies through proposed rule-making. The Coalition has concerns that each time CMS has put out proposals, the information provided for the proposed methodologies is vague. In addition, CMS continues to avoid requiring accurate data reporting nor has CMS demonstrated that they will be utilizing it in the development of any of the payment methodology adopted. The Coalition has repeatedly stated it could not support any of the payment methodologies CMS has proposed unless accurate data is utilized.

[1] In 2013, the Alliance of Wound Care Stakeholders led a multi-year effort to update the clinically inaccurate term of "skin substitutes" with a consensus agreement to name this class of products Cellular and/or Tissue-based Products for skin wounds (CTPs). This terminology was adopted by the standard setting organization ASTM. ASTM developed its unique standard guide for CTPs - F3163-16. We urge CMS to adopt and use this term as well.

In order to accurately set payment rates for CTPs in any payment methodology, 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 since these products are not being coded and billed correctly thus resulting in the claims data being inaccurate, the APC Group assignments will be 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 ASP or invoice 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.

Furthermore, 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 ASP or invoice data be utilized rather than claims data for establishing the payment methodology for 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.

If CMS does not wish to use ASP data an alternative it to utilize invoice pricing to establish the rates moving forward.

While the Coalition could not come to consensus on which of the payment methodologies for CTPs would work best we would like to reiterate our key recommendations from the CY 2019 Proposed OPPS rule, which, unfortunately, are just as relevant to this current proposed rule. We offer the following recommendations for CMS to take into consideration in the development process:

1. CMS should move quickly in establishing the CTP payment reforms
2. CMS must work with wound care stakeholders in creating whatever methodology is ultimately chosen
3. CMS must be transparent in providing the data utilized.
4. CMS's revised payment methodology should support reduced copays for Medicare beneficiaries.
5. CMS needs to utilize the correct CTP cost information
6. CMS must ensure that facilities are billing correctly for CTPs
7. CMS must ensure that patients come first and they continue to have access to this valuable adjunctive therapy.
8. When CMS proposed packaging, the Agency did not perform an impact analysis on payment rates or patient access. Therefore, CMS must conduct an impact analysis and provide its results in a transparent manner.
9. CMS should take into consideration that there are a wide variety of patients with chronic wounds, that wounds heal differently and that treatment is individualized.

Finally, the Coalition is a member of the Alliance of Wound Care Stakeholders and we agree with their more detailed comments on this proposed rule. We urge CMS to adopt their recommendations.

The Coalition appreciates the Agency's consideration of these comments as a new payment methodology is developed. We would be pleased to work with the Agency also as stated in our recommendations as part of a stakeholder work group to collaborate with and provide a forum for more detailed discussion on alternatives within this very complex topic.

Sincerely,

Karen Ravitz, JD
Health Care Policy Advisor