COALITION OF

Wound Care Manufacturers

September 24, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1695-P
7500 Security Boulevard
Baltimore, MD 21244-1850

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

Re: CMS-1695-P, Medicare Program: Proposed Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Requests for Information on Promoting Interoperability and Electronic Health Care Information, Price Transparency, and Leveraging Authority for the Competitive Acquisition Program for Part B Drugs and Biologicals for Potential CMS Innovation

Dear Administrator Verma:

Wound care is a national epidemic masked by comorbidities. Nearly 60 million people in the U.S. are living with diabetes or vascular disease, which are the leading causes of chronic wounds. Over 6.7 million patients suffer from non-healing advanced wounds, leading to unnecessary hospitalization and lower extremity amputations. Patients with chronic wounds have longer lengths of stay, unplanned readmissions, and costs to treat. In fact, a recent study shows that *chronic wounds impact nearly 20% of Medicare beneficiaries (over 11 million) and cost as much as 35 billion dollars in Medicare expenditures (including both fee-for-service and Medicare advantage). A large percentage (36%) of care provided to patients with non-healing wounds is provided in hospital-based outpatient clinics (site of service 19 or 22) (*Nussbaum, Carter, Fife et al. "An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds" *Value in Health* 2017. While many patients heal with standard care, there are a significant number that require advanced treatment modalities, such as Cellular and or Tissue Based Products for Skin Wounds or CTPs (formerly referred to as skin substitutes) – which are the subject of a packaging provision within this proposed rule.

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 wounds including but not limited to CTPs and offer the following comments for two issues contained in the proposed rule: payment methodologies for CTPs and pass through status for a specific CTP.

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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.

While the Coalition could not come to consensus on which of the four payment methodologies for CTPs would work best (with members supporting 1 APC, modifications to the current system and the episodes of care), we can offer the following recommendations:

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.

Pass Through Status Issue

Within the proposed regulation, CMS has requested stakeholder feedback on whether PuraPly, a CPT, should be eligible for extended pass through based on a provision contained within the Consolidated Appropriations Act of 2018 which extended pass through for drugs and biologicals which were set to expire on December 2017. The Coalition recommends that CMS does not permit PuraPly to obtain extended pass through.

It is our understanding that while the company who manufactures PuraPly may not have specifically requested pass through status, it now shares in the benefit of another company's (Omidria) lobbying effort for the pass-through extension legislation contained in the Consolidated Appropriations Act of 2018. The push for pass through extension legislation originated from Omidria which was losing pass through status at the end of 2017. Omidria, through lobbying efforts, was able to have Representative Cathy McMorris Rodgers (R-WA) take this issue to the Speaker of the House Paul Ryan (R-Wis) and a provision made it into the legislation. The list of products that were to lose transitional pass-through payment status and then be assigned packaged payment status for 2018 were Omidria, PuraPly (Q4172) by Organogenesis, Amyvid (A9586) by Eli Lilly, and Lumason (Q9950) by Bracco.

By background, the company who manufactures PuraPly applied for pass through status when CTPs were still permitted to apply utilizing the drugs and biologics pass through application. However, CMS deemed that CTPs would be required to apply for pass through status under the medical device pathway -allowing those that already had pass through under the drugs and biologics

pathway to be phased out once their pass through expired. The pass through for PuraPly was to expire December 31, 2017.

It is not the policy of the Coalition to comment on the efficacy of products but to address inconsistencies or our concerns with CMS's processes. The Coalition has concerns that if CMS permits PuraPly to maintain extended pass through status, it would go against the very rationale for the changes CMS is proposing to make in other sections of this proposed rule. As we indicated in earlier parts of this comment letter, CMS has already created "perverse" incentives to utilize certain CTPs over others. However, permitting PuraPly to maintain pass through status– after the three years they have already been granted it – would only perpetuate what CMS is trying to address in this proposed rule. Should PuraPly maintain pass through, facilities would have an incentive to potentially use that product over all others since the reimbursement would be more favorable.

As a reminder, all other CTP products who applied for pass through status before them also had it for 3 years or less. Thus, it would not be fair to continue to allow this one product to have pass through status again. Moreover, by allowing PuraPly to maintain extended pass through status, CMS would not meet the goals of this proposed rule for these products – eliminating the perverse incentives and lowering cost.

Conclusion

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