COALITION OF

Wound
Care
Manufacturers

Coalition of Wound Care Manufacturers
Oral Remarks:
Physician Fee Schedule – Skin Substitutes
Town Hall Meeting
January 18, 2023

Good Afternoon my name is Karen Ravitz and I am the Health Care Policy Advisor for the Coalition of Wound Care Manufacturers.

The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including skin substitutes. Our members have a vested interested in ensuring that whatever policy objectives CMS has and whatever policy it moves forward with are created in a sound manner and do not negatively impact patient access to these products which are known to reduce infection and amputations in patients with diabetic foot ulcers. Loss of limb or even life is not something to be taken lightly. CMS needs to get this right – the implications are too significant not to.

The Coalition thanks the Agency for holding this Town Hall meeting But with all due respect, the Agency still has not put out substantive information on the proposal to package skin substitutes in the physician office yet, has put forth 4 questions in which stakeholders are left to provide hypothetical remarks in less than an ideal timeframe to address them. Anyone of these questions warrants more than 5 minutes to provide substantive feedback – let alone 4 questions in which we are provided a total of 5 minutes to address all without substantive and necessary information provided by the Agency. This does not seem to be a constructive use of time.

The Coalition believes that the Agency needs to be more transparent and provide more information to stakeholders before any rulemaking can take place. The Coalition agrees with the previous speaker and also recommends that CMS issue a framework document prior to any rulemaking and afterwards hold another longer townhall meeting. We also agree with all

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the comments stated and the issues for CMS to consider that were presented by both Dr. Rudolf and Ms. Nusgart.

In response to the questions posed - for the first question CMS indicated that the reason for the proposal to package skin substitutes in the physician office setting was its desire to have a consistent payment approach between the physician office and hospital outpatient setting. However, these payment systems are different and packaging in the physician office for this product sector will be very challenging. Furthermore, packaging of Skin substitutes has not worked well in the hospital outpatient setting and has been revised multiple times over the years. In fact CMS has recognized there are issues and has tried to address them over the years by making multiple revisions to their methodology and in putting forth at least 4 proposals for alternative payment methodologies over the past 5 years in order to have a more effective system. So why would CMS try to emulate and be consistent with a system that hasn't worked and is still evolving? It doesn't make any sense nor is it something that we support.

If CMS is interested in a consistent payment approach that will not impact patient access but will provide cost savings to the Medicare Trust Fund, the Coalition recommends that the Agency use ASP +6, and publish ALL products and their pricing on the Medicare Part B Pricing Data File over the next two to three years - before any substantive changes are made. The framework is already in place so implementation would be very easy.

ASP would allow for pricing consistency and achieve CMS's goal of reducing out of pocket co-payments since CMS would not be paying based on list or invoice pricing but rather on vetted sales price, inclusive of discounts. Using ASP can achieve cost savings– which other speakers have already addressed. The Coalition believes that publishing any reported ASP (1) creates a level field for all manufacturers; (2) prevents overbilling of the Medicare Trust Fund; (3) decreases Medicare beneficiary financial responsibility; (4) ensures clinicians select products based on clinical efficacy and (5) assures transparency in the program.

In response to the second question – by setting cost thresholds in the Hospital outpatient setting CMS drove artificial cost inflation. This is not an appropriate criteria. But what is? What supply code would CMS create

here? What are the characteristics? More information is needed from the Agency as we do not believe that there is consistent equitable criteria that is appropriate for a unified payment rate for these products as the uses of these products vary, and are chosen based on multiple factors including but not limited to the type and size of the wound, the intended use, and the product type. Therefore, there would be significant variability in resource costs within the PE methodology and CMS would need to have too many levels of reimbursement to accommodate this variation and for packaging to work.

In response to the fourth question – the Coalition supports the term cellular and or tissue based products for skin wounds or CTPs and believes that this nomenclature along with the standards set by the ASTM incorporates all products currently or that will enter the marketplace.

Finally, from a procedural perspective I am wondering if the Agency is going to make public any comments that are submitted in writing by those that were not able to speak today and what the mechanism is for the general public to submit comments as nothing has been published.

I appreciate the opportunity to provide our feedback to the Agency.

Thank you.