COALITION OF

Wound Care Manufacturers

September 17, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1753-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically to regulations.gov

Re: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

Dear Ms. Brooks-LaSure,

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit comments in response to the CY 2022 proposed hospital Outpatient Prospective payment and Ambulatory Surgical center Payment Systems. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including skin substitutes. As a result of provisions contained in this proposal related to wound care and specifically synthetic skin substitutes, we have a vested interest in this proposed rule and offer the comments below.

The Coalition is extremely concerned with the synthetic skin substitute section of the proposed rule. We raised significant issues in the FY 2021 rule which were unfortunately not addressed by the Agency. These concerns continue with the release of this proposed rule. Our comments focus on these issues:

- Requirement to consult with the FDA Tissue Reference Group (TRG) or obtain a Request for Designation (RFD) regarding being appropriately regulated solely under section 361 of the PHS Act and the regulation in 21 CFR part 1271.

- Definition and coding of synthetic resorbable skin substitutes.

- Payment Inequities in Provider Based Departments impacting Medicare beneficiary access to CTPs.

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FDA ISSUES REGARDING HCT/PS

The Coalition has concerns regarding the language in this proposed rule in which the Agency is requiring a determination from the Tissue Reference Group or a Request for Designation by the FDA. Specifically, the language in the proposed rule states,

> "We also want to clarify that the availability of an HCPCS code for a particular human cell, tissue, or cellular or tissue-based product (HCT/P) does not mean that that product is appropriately regulated solely under section 361 of the PHS Act and the FDA regulations in 21 CFR part 1271. Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271."

Our concerns are as follows:

- CMS seemingly has already implemented this provision before this proposed rule has become final by requesting this information in the new electronic HCPCS application whose deadline for submission for drugs and biologics is now October 1, 2021. We have requested that CMS staff with responsibility for creating the HCPCS code application consider removing the question asking for this information from skin substitute manufacturers until this proposed rule becomes final. It seems that from a procedural matter, that the Agency should not be requiring information that has not yet been finalized in rulemaking.
- The placement of this requirement is located in a section of the proposed rule in which synthetic skin substitutes are being discussed. While it appears that the Agency is making this a requirement for HCT/Ps, we want to ensure that CMS understands that not all skin substitutes are HCT/Ps. In fact, synthetic skin substitutes have undergone clearance through the FDA 510(k) process. We would expect that these products along with other skin substitutes that have 510k clearance or PMA or BLA approval should not be required to obtain another determination from the FDA Tissue Reference Group or a Request for Designation from the FDA.
- Finally, we request clarification that in fact, the Agency is requiring a determination from the Tissue Reference Group or a Request for Designation from the FDA only for HCT/P products. The language contained in the discussion of this requirement is not clear and we would like to ensure that the only products in which this requirement is applicable are those HCT/Ps governed under 361 of the Public Health Service Act.

As a general matter, the Coalition agrees with the Agency's proposed requirement for 361 HCT/P products to obtain a determination from the FDA Tissue Reference Group or a Request for Designation from the FDA. However, as stated above, we have issues with the Agency requesting this information on a new HCPCS coding application before this proposal is finalized as well as the uncertainty of whether CMS is requiring ALL skin substitutes to go to the TRG or obtain an RFD is not appropriate. The Coalition would like to emphasize: manufacturers whose products have gone through the 510K, PMA or BLA process should NOT be required to get a decision from the TRG or an RFD. The distinct clearance process that these products have gone through should be sufficient for the Agency to move forward and either issue a HCPCS code or accept the HCPCS code already issued.

As such, the Coalition recommends the following:

- CMS should remove this requirement from the HCPCS code application requesting "

"verification of HCT/P subject to section 361 of the Public Health Service Act (PHS Act) and 21 CFR 1271, if applicable" until this proposed rule is final.

- CMS should provide clarification as to whether a manufacturer who has 510K, PMA, or BLA approval/clearance for its skin substitute and has submitted an application for a Q code but has not been issued it yet by CMS needs to go through the TRG or obtain an RFD in order to receive it?
- If a manufacturer has received a Q code for their product, regardless of its FDA pathway, does the manufacturer need to go back to the TRG or obtain an RFD in order to maintain their Q code designation?
- Is the requirement to obtain an RFD or a letter from the TRG only applicable to HCT/Ps?

The Coalition supports the Agency requirement for HCT/Ps under the 361 of the PHS to go to the TRG or receive an RFD prior to applying for a HCPCS code. However, as stated above, we seek clarification on this issue since the Coalition is adamantly opposed to any requirement by the Agency for companies who have already gone through the 510K, PMA or BLA process to be required to go to the TRG or obtain an RFD.

SYNTHETIC RESORBABLE SKIN SUBSTITUTES

Inclusion of Synthetic Resorbable Skin Substitute Products in the Skin Substitute Definition

In the CY 2021 OPPS final rule, CMS modified its description of skin substitutes to include synthetic resorbable skin substitutes in addition to biological products. We were in agreement with the modified description. In the current OPPS proposed rule, CMS reiterated the language from last year's regulatory proposal, which states, "We also propose that our definition of the skin substitutes includes synthetic skin substitute products in addition to biological skin substitute products." While the Coalition agrees that synthetic skin substitutes be part of the definition of what constitutes a skin substitute, we are categorically opposed to the different treatment of these products for coding and payment purposes. CMS should treat synthetic resorbable skin substitute products consistent with the treatment of all other skin substitute products.

Are concerns are as follows:

- Despite including synthetic resorbable skin substitutes in the definition of a skin substitute, CMS has created new "C" codes solely for synthetic resorbable skin substitute products. **The Coalition continues to disagree that these products should be issued a general C code. This is not consistent with any other skin substitute in the marketplace who are required to obtain** unique product HCPCS Q codes which are brand specific based on a "per sq.cm" size (unless the product is an injectable or micronized). We believe that CMS should be consistent and follow the same process of assigning "Q" codes to a synthetic resorbable skin substitute that it has used for coding all other established skin substitutes. The pathway to obtain a Q code through the HCPCS coding process is well established and should be required for ALL skin substitutes. In fact, there is precedent for this action. Hyalomatrix is considered a synthetic skin substitute as categorized in the Agency for Healthcare Research and Quality (AHRQ) 2020 Technology Assessment, *Skin Substitutes for Treating Chronic Wounds*. CMS assigned HCPCS code Q4117 in 2011 to Hyalomatrix, **which demonstrates that fully synthetic skin substitutes can function within the current coding and OPPS framework. Creating new HCPCS codes for a just a few products increases administrative burden on providers and payers and is unnecessary.**

- The code descriptor for the C1849 code established by the Agency is too broad and encompasses all synthetic products that are or will be coming into the marketplace. Currently, there are several synthetic resorbable skin substitutes which are being utilized in the hospital inpatient setting that did not have a pathway to obtain a Q code previously. By creating such a general code, CMS will not be able to identify what product is being utilized since the code is not product specific. Thus, the **assignment of one HCPCS code, C1849, to all synthetic resorbable skin substitutes does not provide the information needed to appropriately assign each unique brand of synthetic resorbable skin substitutes to the correct APC package.**
- As stated above, CMS lumped all synthetic products into this one HCPCS code. In doing so CMS automatically assigned the C1849 code to the high cost APC package. The rationale was that there is only one product with ASP pricing which places them in this APC. However, there are multiple synthetic resorbable skin substitutes in the marketplace which are being utilized currently and not all synthetic resorbable skin substitutes have provided ASP pricing data to the Agency. Therefore, not only is the lumping of all of these products into the C code not consistent with the handling of all other skin substitutes, the established pricing will not be accurate and as such the placement of this category into the high cost bucket may be unwarranted for all the products that may be utilized. However, **CMS will not have the ability to know this information since the products within this category do not have a unique HCPCS code and as state above, the Agency will not know what product is in fact being utilized.**

The Coalition recommends that CMS be consistent in treating synthetic resorbable skin substitutes like ALL other skin substitutes and not try create differences. **True pricing and resource data will emerge that can better guide reimbursement if all skin substitutes are required to obtain a Q code.** To ensure consistency, the Coalition once again provides the Agency the following recommendations: (and did so last year as well):

- Since CMS has continued to maintain that synthetic products should be included in the definition of "skin substitutes", then CMS should issue Q codes by brand names for all synthetic resorbable skin substitutes. This should include all synthetic products that are entering the marketplace as well as CMS revisiting the products that are currently in the A6460 and A6461 codes (Synthetic, resorbable wound dressing...) and reassign them Q codes or request that the companies reapply through the HCPCS coding process to be reassigned Q codes when appropriate. This will allow for a more consistent and transparent process as well as the ability of the Agency to gain true pricing and resource data.
- CMS should eliminate the new code C1849 skin substitute, synthetic resorbable per sq. cm., as it is not an appropriate code for this product sector especially since these products should be treated the same as all other skin substitutes and be issued Q codes by CMS. This non-brand specific coding convention for synthetic resorbable skin substitutes does not follow precedence and is not an appropriate code. Individual skin substitute products are each issued *unique brand specific* Q codes by CMS which adequately allows for *individual* product identification, high or low-cost placement into appropriate pricing categories, and product coverage considerations.
- Creation of the new C1849 code defines a number of unknown "synthetic" skin substitute product brands and has an unintended consequence for product coverage. By grouping all synthetic products into the C1849 code, CMS will force to blanket coverage (or non-coverage) policy positions among all products within that grouping, not only for CMS and MACs, but private payers as well.
- As is required for all other new skin substitutes entering the marketplace, any new synthetic resorbable skin substitute entering the marketplace should be assigned to the low-cost

package until the manufacturer has submitted its average sales price (ASP) or Wholesale Acquisition Price Cost (WAC) information to the CMS. If the manufacturer's quarterly ASP/WAC information shows that the product should be in the high cost package, the CMS should make that reassignment. From that point on, the synthetic products should follow the current OPPS payment methodology based on claims **and** pricing data. By lumping in all synthetic resorbable skin substitutes into one code it also appears that CMS will need to take an average of the ASP being submitted to it by the different product manufacturers to establish as a group whether to place this group of products into the high or low cost tier. Again, this differentiation should not take place. All products should have the ability to submit individual ASP pricing and be placed in the high or low cost bucket independent of any other product ASP.

The Coalition has and continues to agree that synthetic resorbable skin substitutes be part of the definition of a skin substitute, however, we continue to oppose the use of the C1849 code, the different treatment that synthetic resorbable skin substitutes have been given over ALL other skin substitutes and the blanket placement of all synthetic resorbable skin substitutes into the high cost bucket regardless of whether each individual product merits being in this category.

Inequities in the Current Payment System Creating Barriers to Access

Payment for Add on Codes

The primary cost of the application procedure is the skin substitute product itself. The specific cost for a procedure for an individual patient will vary depending on the size of the wound being treated. Under the OPPS, CMS packages payment for all add-on codes, including the skin substitute procedure add-on codes, into the payment for the base procedure. Rather than appropriately recognizing the variation in cost between small and large wounds, CMS pays the same amount for both. Add-on codes that are packaged into the OPPS bundled rates are not adequate to allow the provider-based departments (PBDs) to purchase the additional sq. cm. of skin substitutes necessary to apply to all wound/ulcer sizes. In fact, none of the add-on codes have been available for additional payment. This policy creates substantial barriers to treating larger wounds in the hospital outpatient department. We believe that, in practice, larger wounds are not typically treated in the hospital outpatient department because of the effect of the add-on code packaging policy and therefore, the estimated cost from the OPPS claims data reflects the cost of treating smaller wounds that would be reported with the base code. To be blunt, because the add-on codes represent wounds/ulcers that require the purchase of additional product, patients with wounds/ulcers larger than 25 sq. cm up to 99 sq. cm and also those greater than 100 sq. cm, are not being offered medically necessary skin substitutes in the PBDs because the financial burden is being placed on PBD who cannot, and should not have to, absorb this cost.

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's packaging policy 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 skin substitutes, that may be required when performing an add-on service, which ultimately has adversely impacted patient access to these services in a PBD.

To remedy this issue, on August 23, 2021, the Alliance of Wound Care Stakeholders (Alliance) recommended to the Advisory Panel on Hospital Outpatient Payment (the "Panel") to urge CMS to issue an exception for the payment of CTP application add-on codes and assign the existing CPT

add-on codes (15272 and 15276; 15274 and 15278) to an appropriate APC group allowing for payment. This recommendation provides an easy remedy for CMS to implement and there has been precedent set in CMS providing these types of exceptions, (i.e. chemotherapy).

The Panel unanimously approved the Alliance recommendation that CMS assign the existing CPT add-on codes (15272 and 15276; 15274 and 15278) to an appropriate APC group allowing for payment and issue an exception for the payment of CTP add-on codes. During the discussion, it was evident that the Panel agreed that these CPT codes should be assigned to appropriate APCs allowing for payment and should not be treated any differently than blood products that also were approved to have add on code payment.

The Coalition urges CMS to adopt the Panel's recommendation.

Assignment of APC for the Same Size Wound/Ulcer Regardless of Anatomical Location

The APC for the same size wound/ulcer should be the same whether the wound/ulcer is located on the leg or foot, since the same resources and amount of product are being utilized. CMS has assigned APC 5054 when a 125 sq. cm wound/ulcer is located on the foot and APC 5055 when that same size wound/ulcer is located on the leg. This inequity does not make sense as the treatment of the wounds/ulcers require the same amount of product to be purchased regardless of where the wound/ulcer is located.

During the August 23, 2021 Advisory Panel on Hospital Outpatient Payment (HOP) meeting, the Alliance of Wound Care Stakeholders provided another recommendation to the Panel: to assign the same APC groups for the same size wound regardless of anatomical location on the body. The Panel also unanimously approved this recommendation.

Facilities should not have inequities in payment when the same resources are being utilized for the same size wound. Anatomic location or a wound/ulcer should not be a barrier to access nor should there be a cost differentiation in treating the same size wound that happens to be located on a different body part.

The Coalition urges CMS to adopt the Panel's recommendation to assign the same APC groups for the same size wound regardless of anatomical location on the body.

Conclusion

The Coalition appreciates the opportunity to provide our comments on this proposed rule. To summarize, our recommendations are as follows:

- CMS should remove the requirement to obtain a determination from the TRG or an RFD from the FDA from the HCPCS code application until this proposed rule is finalized.
- CMS should provide clarification regarding the following issues:
    - Whether a manufacturer who has 510K, PMA, or BLA approval/clearance for its skin substitute and has submitted an application for a Q code but has not been issued it yet by CMS needs to go through the TRG or obtain an RFD in order to receive it?
    - If a manufacturer has received a Q code for their product, regardless of its FDA pathway, does the manufacturer need to go back to the TRG or obtain an RFD in order to maintain their Q code designation?

    - Is the requirement to obtain an RFD or a letter from the TRG only applicable to HCT/Ps?
- Adopt the inclusion of synthetic resorbable skin substitute products in the definition of "skin substitutes" .
- Eliminate the assignment of a C code for synthetic resorbable skin substitutes and apply Q codes in order for consistency and transparency.
- Adopt the Advisory Panel on Hospital Outpatient Payment (HOP) recommendations at its August 23, 2021 meeting:
    - Assign the existing CPT add-on codes (15272 and 15276; 15274 and 15278) to an appropriate APC group (the Alliance believes that this would allow for adequate work and product acquisition payment) and issue an exception for the payment of CTP application add-on codes.
    - Assign the same APC groups for the same size wound/ulcer regardless of anatomical location on the body.

The Coalition requests that CMS consider and adopt our recommendations: If you have any additional questions or would like further information, please do not hesitate to contact me.

Sincerely,

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