COALITION OF

# Wound Care Manufacturers

September 8, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1786-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

*Submitted Electronically to www.regulations.gov*

Re: Medicare Program; Calendar Year (CY) 2024 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (P-1786)

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 2024 proposed Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs (CMS-1786-P). The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including skin substitutes. Skin substitutes are an effective advanced treatment for patients with chronic wounds and therefore, an important treatment modality for clinicians. As such, we have a vested interest in any proposals related to these products. We offer the comments below.

The Coalition is extremely concerned with the skin substitute section of the proposed rule. We raised significant issues in the CY 2022 and CY 2023 rules which were unfortunately not addressed adequately, accurately, or simply ignored by the Agency. These concerns continue with the release of this proposed rule.

## General Comments

Beginning in CY 2014, almost 10 years ago, CMS began to package skin substitute products with their associated surgical application procedure. According to CMS, packaging was seen as a way to have a "total prospective payment more reflective of the average resource costs of the procedures" and "to promote more efficient resource use by hospitals."[i] After initially proposing to package skin substitute products into their associated procedures without accounting for differing resources among the products, CMS created two groups of skin substitute products for packaging – a low-cost and a high-cost group. CMS believed that the packaged payments for the procedure, including

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payment for the skin substitute, were "adequate and would not discourage the use of the skin substitute products used in these procedures." This statement has been incorrect since the inception of this payment methodology. The consequences have been that the payment is not adequate, access has been impacted, artificial inflation took and continues to take place, and now there are few to no low-cost options which were plentiful prior to packaging.

In the CY 2019 proposed rule, six years after packaging took place, CMS solicited comments on four alternative payment methodologies to promote long term payment stability. CMS did not make substantive changes to the skin substitute payment policies for CY 2019, and continued the same payment policies for skin substitutes, including allowing any skin substitute product that was assigned to the high-cost group in CY 2018 to be assigned to the high-cost group for CY 2019, regardless of whether the product exceeded or fell below the CY 2019 MUC or PDC threshold. In subsequent rulemakings, CMS continued to discuss the skin substitute payment methodology, but has not altered the policy, and for CY 2024, it again proposes to continue the current payment mechanism.

The Agency has published alternative proposals for over 7 years to address the issues being raised. Time and again stakeholders have consistently stated that the Agency needs to correct the flaws in the skin substitutes payment methodology and do what is right. Yet, the Agency continues to just leave things as status quo even the current system is not working. Case in point:

- There are patient access issues – which have been identified in several studies.
- There is inconsistency in the way products are being treated – in payment and coverage - depending on the HCPCS code being issued despite the products all being categorized as skin substitutes.

Over the years, stakeholders have repeatedly told the Agency how to fix this. How to level the playing field. How to save valuable money in the trust fund. How to ensure that they are not paying out more than necessary. How to ensure patient access to care. We submit that after ten years, CMS should be taking action and changing these policies to help Medicare beneficiaries.

The Coalition is again providing our recommendations to the Agency to address leveling the playing field and address the significant access to care issues. We urge the Agency to give careful review of these recommendations and to implement them.

## ASP Pricing

CMS has stated repeatedly that it is interested in a consistent payment approach that will not impact patient access but will provide cost savings to the Medicare Trust Fund. Stakeholders have repeatedly and consistently stated that the way to achieve this goal is to continue to use ASP+6 methodology, publish ALL products and their pricing on the Medicare Part B Pricing Data File and utilize CMS's enforcement authority to ensure that manufacturers are reporting and providing the correct information for their products.

Prior to 2014 when CMS bundled payment in the hospital outpatient setting, CMS did have a consistent payment approach to skin substitutes. CMS paid separately for the application of the skin substitute and for the skin substitute itself using the same payment methodology as biologicals—ASP + 6%. In creating the packaged payment system, CMS broke from the consistent payment methodology and beginning in 2014, was packaging skin substitutes under the hospital outpatient PPS while separately paying for them in the physician's office. The change in 2014 resulted in an increased number of patients receiving care in the physician office setting as the payment

methodology in the outpatient hospital setting was flawed and hospital outpatient departments began losing too much money on treating patients with larger wounds.

Furthermore, as CMS is aware, Congress passed the Consolidated Appropriations Act which states that effective January 1, 2022, ASP reporting is mandatory for "products that are payable under this part as a drug or biological" – which would include skin substitutes[ii]. The Agency should simply revert back to separate payment for skin substitutes utilizing ASP pricing since there is already a framework in place, implementation would be very easy and again would be complimentary to section 1847A(f)(2) of the Social Security Act. Manufacturers agree with the ASP reporting requirement and want/need to comply with this Congressionally mandated requirement. Given the mandatory submission of ASP for all skin substitutes, CMS should use the data that is already being provided to it to form the payment for any given skin substitute.

In addition to the Congressional mandate of ASP reporting for all skin substitutes, the OIG and MEDPAC validated the Coalition statements that there are cost savings that are attached to utilizing ASP. In 2023, the OIG issued a report on ASP which stated, "with clearer ASP reporting and publishing guidelines, the Agency would recognize cost savings."[iii] [iv] The OIG further stated when ASP was reported for skin substitutes there were cost savings. [v] Additionally, MEDPAC has also recognized the importance of ASP pricing on cost savings by stating "using ASP will help protect the Medicare Trust Fund by not overpaying for products that are not listed on the national ASP file."[vi] These are important and salient points for the Agency to consider as it not only strives for consistency and fixes the skin substitute payment methodology but also tries to protect the Medicare Trust Fund.

CMS using ASP pricing could establish uniform pricing based on all the skin substitutes ASP not only being reported but also published on the quarterly ASP pricing files. This would allow for pricing consistency and would achieve CMS's goal of reducing out of pocket co-payments since the Agency would not be paying for skin substitutes based on list or invoice pricing but rather on vetted sales price, inclusive of discounts. Using ASP is a more transparent means of pricing these products and at the same time, CMS can also achieve cost savings in the process. The Coalition believes that publishing any reported ASP for drugs and biologicals. The Coalition believes that publishing any reported ASP for drugs and biologicals (1) creates a level field for all manufacturers; (2) decreases Medicare beneficiary financial responsibility; (3) ensures clinicians select products based on clinical efficacy (4) assures transparency in the program.

ASP will also broaden access to medically necessary treatment to some patients receiving care through state Medicaid programs. Many Medicaid programs often require ASP to pay for products. As such, the reporting and use of ASP will help achieve CMS' health equity goal while supporting patient care outside the Medicare program.

Stakeholders have consistently recommended and are still recommending that the Agency use ASP pricing. ASP pricing is the direction that the Agency should be going in order to achieve all the goals they claim to want to achieve – health equity, consistent payment approach across settings, protect patient financial responsibilities, protect access, and protect the trust fund by achieving significant cost savings.

Packaging was a failure for this product sector and the band aid approach CMS has been putting forward to try and fix the failed packaging payment methodology is not working. It is time for CMS to act and adopt recommendations that stakeholders have consistently been submitting to the Agency for years.

**The Coalition recommends that CMS should withdraw its policy to package payment and utilize ASP +6 for all skin substitutes and publish all data in the pricing data file.**

## Access to Care

The inequities in the current payment system continue to create barriers to access. During the August 21, 2023, Advisory Panel on Hospital Outpatient Payment the Alliance of Wound Care Stakeholders presented 5 recommendations in which the Panel overwhelmingly voted to support and recommend that CMS adopt.[vii] The Coalition supports all of these recommendations as they will help correct the flaws that exist in the payment methodology as well as inappropriate APC assignments for skin substitutes (which the Panel refers to as cellular and or tissue-based products for skin wounds or CTPs) which have impacted access to care in HOPDs. Specifically, the recommendations include:

1. CMS should
   - assign the existing CPT® add-on codes (15272, 15276, 15274, and 15278) and HCPCS codes (C5272, C5276, C5274, and C5278) to appropriate APC groups allowing for separate payment and
   - issue an exception to separately pay for these add-on codes.
2. CMS should assign the CPT and HCPCS codes for the same size wound, regardless of anatomical location on the body, to the same APC groups.
3. CMS should assign all new CTPs with both Q and A HCPCS codes to the low-cost APC groups until a manufacturer provides cost information to CMS.
4. CMS should realign both the high-cost and low-cost application procedure codes to higher paying APC groups that reflect the current average sales prices of all CTPs.
5. CMS should not assign CTPs that are not in sheet form (e.g., gel, powder, ointment, foam, liquid, or injected) to any APC group.

The Coalition is a proud member of the Alliance of Wound Care Stakeholders who put forward these recommendations as the clinical associations who participate in the Alliance have struggled with the payment and their ability to treat their patients as the methodology in the OPPS is severely flawed. The Alliance has provided rationale for the recommendations which goes into great detail regarding the issues faced by clinicians. The Coalition urges the Agency to implement all of the Panel recommendations related to CTPs (skin substitutes).

## Automatic Assignment to the High-Cost Bucket for Skin Substitutes Being Issued "A" Codes

The Coalition is categorically opposed to the CMS proposal stating that "any skin substitute product that is assigned a code in the HCPCS A2XXX series be assigned to the high-cost skin substitute group including new products without pricing information." Yet, "new skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX series would be assigned to the low-cost category until pricing information is available to compare to the CY 2024 MUC and PDC thresholds." The inconsistency in the way different classes of skin substitutes are being treated is unacceptable.

In fact, all skin substitutes in the marketplace currently are required to submit ASP pricing data to CMS as a result of the Consolidated Appropriations Act – which includes all the skin substitutes being issued HCPCS "A" and "Q" codes. Yet, CMS has not only determined that the skin substitutes assigned HCPCS "A" codes do not need to follow the reporting requirement of the law,

it has given a free pass to products being assigned into the high-cost bucket without providing ANY pricing information to justify their placement there. CMS indicated that the reason for the automatic assignment of HCPCS A2XXX codes into the high-cost bucket is a result of this class of skin substitute products being assigned the HCPCS C1849 code previously and any new product that would have fit into the description of that code also be placed into the high-cost group even without providing pricing information. However, there are significant flaws to this logic.

First, not all products that are being assigned to the A2XXX code would fit within the definition of the C1849 code, which is for synthetic skin substitute products, but are still automatically being assigned to the high-cost group. Second, the C1849 code was discontinued and is no longer an active code. Products that were contained within that code set when it was initially established were placed in the high-cost bucket as a result of only one manufacturer in that product class submitting pricing information. The other manufacturers in that product class rode the coat tails of that one company and benefitted immensely but the Medicare program failed in its responsibility by not requiring the other products to provide pricing information. Once the C code was discontinued, any product that was already in the marketplace at that time (which fit the definition of the C code) had been assigned to the high-cost bucket.

Since CMS cannot seem to decide how to revise the terribly flawed payment methodology currently in place, the Agency has kept a product in the high-cost bucket if it was placed in there in the previous year - even if the MUC and PDC for that product fell below the high-cost threshold. However, since the discontinuation of the C code, many other products have come into the marketplace that have been assigned an A2XXX code. Since the C code was discontinued and those products received a unique HCPCS code, they should have been required to provide pricing information as ALL skin substitutes who obtain a unique code are required to do in order to be placed in the high or low-cost bucket. By having ALL A2XXX products automatically assigned into the high-cost bucket without providing pricing data –CMS has failed in its fiduciary duty They have failed in their responsibility to ensure that Medicare beneficiaries are not paying more than necessary for the access to these products. They have failed in following their own requirements for placing products into the high and low-cost group and they have ignored enforcing the law that has been passed by Congress and specifically that ASP reporting for skin substitutes is mandatory.

As such, the Coalition opposes the following CMS proposal and urges the Agency to remove this language before this policy becomes final:

*Any skin substitute product that is assigned a code in the HCPCS A2XXX series be assigned to the high-cost skin substitute group including new products without pricing information.*

Instead, the Coalition recommends that skin substitutes previously coded using C1849 should be assigned based on their product specific per day or mean unit cost to the high or low-cost group and ASP is required to be submitted to make that determination. Further the Coalition recommends that any product coming in the marketplace be required to submit ASP pricing data to be considered for the high or low-cost bucket. Finally, the Coalition recommends that ALL skin substitute ASPs be published on the pricing data file.

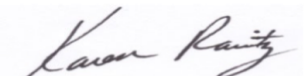
## Conclusion

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

- CMS should utilize ASP pricing for ALL skin substitute products as is currently required by law.
- CMS should utilize its enforcement authority to ensure that ASP is being submitted appropriately.
- CMS should publish all skin substitute ASPs in the data file.
- CMS should include in its final OPPS rule the five Advisory Panel on Hospital Outpatient Payment (HOP) recommendations overwhelming approved during its August 21, 2023, meeting including:
    - 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.
    - CMS should assign all new CTPs with both Q and A HCPCS codes to the low-cost APC groups until a manufacturer provides cost information to CMS.
    - CMS should realign both the high-cost and low-cost application procedure codes to higher paying APC groups that reflect the current average sales prices of all CTPs.
    - CMS should not assign CTPs that are not in sheet form (e.g., gel, powder, ointment, foam, liquid, or injected) to any APC group.
- CMS should not automatically assign "A" code products to the high-cost bucket and
- Require all skin substitute products to submit pricing data to be considered by the Agency for placement in the high or low-cost group.
- CMS should ensure that their contractors, notably CGS, FCSO and Novitas are adhering to regulatory requirements when issuing LCDs and LCAs and should notify the MACs to delay implementation of recently issued final policies for skin substitutes to ensure there is no disruption in care as well as adequate time to obtain necessary documentation (i.e., TRG letters) for coverage consideration.

The Coalition appreciates the opportunity to provide our comments to the Agency on these very important issues. We request that CMS consider and adopt all of our recommendations as well as those of the Advisory Panel on Hospital Outpatient Payment (HOP). If you have any additional questions or would like further information, please do not hesitate to contact me.

Sincerely,



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[i] *78 Fed. Reg. 74,826, 74,931 (Dec.10, 2013)*
[ii] *42 U.S.C. § 1395w- 3a(f)(2)(A)*
[iii] *Manufacturers May Need Additional Guidance To Ensure Consistent Average Sales Price Calculations (OEI-BL-21-00330)*
[iv] *CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data To Ensure Accurate Part B Drug Payments (OEI-03-21-00390)*
[v] *Some Skin Substitute Manufacturers Did Not Comply With New ASP Reporting Requirements (OEI-BL-23-00010)*
[vi] *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports jun19_medpac_reporttocongress_sec-pdf/ at 64.*
[vii] *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/hospital-outpatient-payment*