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-1784-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically to www.regulations.gov

RE: Calendar Year 2024 Payment Policies under the Physician Fee Schedule and Other Change to Part B Payment Policies, etc. (CMS-1784-P)

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 Physician Fee Schedule (CMS-1784-P). The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including skin substitutes, also referred to as cellular and/or tissue-based products (CTPs). CTPs are an effective advanced treatment for patients with chronic wounds which clinicians consider important to use. As such, our members have a vested interest in ensuring that CMS creates a sound policy which does not negatively impact patient access to these products which are known to reduce infection and amputations in patients with diabetic foot ulcers.

In this proposed rule, CMS is recommending an overhaul of the payment of CPT products. CMS proposes to treat CTPs as "incident to supplies" when furnished in non-facility settings and to include the costs of these products as resource inputs in establishing practice expense RVUs for associated physician's services, rather than reimburse them separately. The Coalition fears these changes will impact patient access and increase the number of amputations and infections for patients with chronic non-healing wounds. The Coalition does not support CMS' proposed policy and requests CMS to withdraw the proposal.

We submit that CMS's proposal for CTPs is a radical departure from the existing statutory and regulatory framework for determining Part B payment amounts for these products as biologicals covered under section 1861(s)(2)(A) of the Act—a framework which has been consistently applied by CMS for decades to provide separate Medicare Part B payments for CTPs determined using the methodology described in section 1847A for drugs or biologicals. CMS fails to provide a clear statement of the basis for reversing this longstanding position for all CTP products, regardless of their classification by FDA or under definitions provided in the Social Security Act (SSA). The lack

5225 Pooks Hill Rd | Suite 627S
Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410
www.woundcaremanufacturers.org

of explanation or analysis supporting this proposed reclassification makes it difficult to evaluate and provide comment on the CMS's reasoning and the evidence on which it relied.

CMS has not offered any data, analysis, or evidence of any type that supports the Agency's proposed position to now classify all CTPs as supplies incident to a physician service, packaged into the practice expense associated with that service. For example, CMS has not provided any information on the specific CPT codes into which these products would be bundled, the amount of spending under the existing codes that is expected to be moved into practice expense (PE), the budget neutrality impact on PE Relative Value Units (RVUs), if any, or the impacts of this proposal (on its own or in combination with other proposed policies) on expected allowed charges by specialty. Under well-established principles of Administrative Law, CMS must provide support for this reversal of prior policy in the administrative record. In the absence of such an explanation, reversing CMS's longstanding treatment of CTPs as drugs and biologicals would be inconsistent with established law. All of these issues raise concerns under the Administrative Procedures Act (APA) should CMS move forward with these changes. The Coalition requests that CMS withdraw the proposal and recommends instead that CMS maintain and enforce ASP pricing which is:

- consistent with current policy and statutory language,
- already a mandatory requirement for CTP products
- a cost savings mechanism that can not only be achieved when administered and enforced correctly but recommended by MEDPAC and the OIG.

The Coalition has significant fundamental issues with the proposal to bundle CTP products as "incident to supplies" under the practice expense. Our specific comments will address the following:

- CTPs are not supplies and should not be considered as "incident to supplies" under the proposed payment changes.
- Significant issues with the establishment of an appropriate PE RVU for CPTs.
- The goal of consistent payment utilizing the HOPPS is not advisable.
- ASP is the most consistent pricing for CTPs and should and can be utilized across payment settings.
- Implications of moving forward with bundling payment in the physician fee schedule for CTPs.

"Incident to Supplies"

First and foremost, CMS must understand that CTPs are NOT "supplies." For more than three decades, CMS has appropriately classified CTP products as drug or biological products applying Medicare Part B payment policy to these products in the physician office setting. To abruptly reclassify all products as "supplies incident to a physician service" and package payment into the services' practice expenses – without regard for mandatory payment laws and policies applicable to drugs and biologicals under sections 1842 and 1847A of the Social Security Act (SSA) – conflicts with applicable law.

Sections 1842 and 1847A of the SSA govern the Medicare Part B payment amount that must be provided for drugs and biologicals included on a physician's or supplier's request for payment for services under Medicare Part B, when such drug or biological is not paid on a cost or prospective payment basis. For most drugs and biologicals furnished by physicians and included on those physicians' claims on or after January 1, 2005, the payment amount is established under section 1847A. Under Section 1847A, payment for drugs and biologicals provided incident to a physician's

service and billed by the physician must generally be reimbursed in accordance with the Average Sales Price (ASP) payment methodology, through which Medicare Part B reimbursement is determined based on the ASP, if available, or wholesale acquisition cost (WAC).

Section 1861(t)(1) of the SSA defines the terms "drugs" and "biologicals" to include:

> *"such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia [USP], the National Formulary, or the United States Homeopathic Pharmacopoeia, or in New Drugs or Accepted Dental Remedies (except for any drugs and biologicals unfavorably evaluated therein), or as are approved by the pharmacy and drug therapeutics committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs and biologicals for use in such hospital."*

There is no statutory or regulatory requirement that these products be approved for marketing under a particular pathway, whether under section 351 or 361 of the PHS Act or section 505 of the Federal Food, Drug, and Cosmetics Act.

Furthermore, the FDA defines biological products as:

> *Biologics are isolated from a variety of natural sources - human, animal, or microorganism - and may be produced by biotechnology methods and other cutting-edge technologies. Gene-based and cellular biologics, for example, often are at the forefront of biomedical research, and may be used to treat a variety of medical conditions for which no other treatments are available...*
>
> *In contrast to most drugs that are chemically synthesized and their structure is known, most biologics are complex mixtures that are not easily identified or characterized. Biological products, including those manufactured by biotechnology, tend to be heat sensitive and susceptible to microbial contamination. Therefore, it is necessary to use aseptic principles from initial manufacturing steps, which is also in contrast to most conventional drugs. Biological products often represent the cutting- edge of biomedical research and, in time, may offer the most effective means to treat a variety of medical illnesses and conditions that presently have no other treatments available* (emphasis added).

Based on the FDA and CMS definitions, CTPs have been and should continue to be considered and categorized as a biologic and not a supply.

Furthermore, for over 30 years, CMS has appropriately recognized and paid for CTPs as drugs or biologicals under section 1847A when furnished in the physician clinic. This longstanding classification and payment framework under Part B is consistent with the characteristics of many products recognized as CTPs by CMS, including 361 HCT/Ps. Consistent with the SSA definition of a biological, many of the HCT/Ps and other CTPs are described by monographs included in the US Pharmacopoeia (USP). Other CTPs, which are derived from donated human tissue, are authorized for marketing by FDA as medical devices, as 510(k) cleared products or through premarket approval (PMA). Like other products cleared or approved by FDA as medical devices that are administered by physicians in a manner more consistent with drugs and biologicals (e.g., synthetically derived hyaluronic acid injections used to treat osteoarthritis of the knee), CMS has applied a consistent payment policy for CTPs that complies with section 1847A.

CMS' proposal to reverse its longstanding policy, and instead package payment for all CTPs provided in the physician office setting with the service provided by the physician, will conflict directly with the mandatory payment framework for biologicals provided in a physician clinic, as set out in sections 1842 and 1847A.

In addition to CMS' longstanding policy and categorization of CTPs as biologicals and not supplies, the American Medical Association crafted **application codes for skin substitute/CTP products in the surgical section of the CPT book because they require specific wound bed preparation.** These products must be applied by a physician or nurse practitioner (not by a nurse or physical therapist) and **they must be fixated**. Therefore, in addition to legally incorrect, proposing to consider these products as "incident-to" supplies in the physician office is clinically and definitionally incorrect. These products are in a category unto themselves and payment should be made accordingly.

CTPs are a heterogeneous group of biologic, synthetic, or biosynthetic materials that **can provide temporary or permanent coverage of open skin wounds.** CTP products ideally possess the composition and function of skin or have the potential for autologous regenerative healing when applied to a wound. These **matrixes are affixed to the wound and become incorporated into the wound bed**. They are **not disposable** like other products that are considered "incident to supplies" such as wound dressings or BAND-AIDs®. In fact, **a CTP product interacts, directly or indirectly, with the patient's body tissues.**

CMS has always reimbursed CTP products under the ASP methodology because as the Agency has stated they "were generally considered to be biological products." Although the Coalition recognizes that the Social Security Act does not define the term "CTP," Section 351 of the Public Health Service Act ("PHSA") does, and Congress clearly intended to use that definition. CMS has not articulated the legal basis for its proposed action which we submit is required. We submit, t**here IS NO legal basis for CMS to categorize these products as supplies or to deviate from the definitions provided in the PHSA or even from language used by CMS to describe these products.**

CTP Payment Methodology Under The Practice Expense Does Not Work

CMS determines direct PE for a specific service by adding the costs of the direct resources that are typically involved with furnishing that service. However, it is difficult to accurately assess the cost of CTP products by using the practice expense methodology. **The uses of CTPs vary by size of wound, the intended uses as well as the different product types making is difficult to assess what a typical service would be which is a necessary element of the practice expense calculation.** Furthermore, there are many products reported (currently there are over 170) with each CTP HCPCS code and no single product accounts for more than 50% of the usage. An additional difficulty in accurately assessing the cost of CTP products is due to the fact that these products vary immensely by cost as well. As a result, there are **no similarly resourced groups of products/services that could inform payment stratification without risking access to services**.

CMS has now published two proposed rules and convened a January 2023 town hall meeting yet still has not provided anything more than a proposed conceptual change in a long standing policy. CMS still has not provided any substantive information regarding how the Agency will go about making these complex and substantive changes that stakeholders are opposed to and significant questions remain that make moving forward with any rulemaking impossible for CY2024. These questions include but are not limited to:

1. How will CMS build the cost of CTPs into the procedure payment?
2. What data will CMS utilize to determine the cost of CTPs as a direct practice expense input supply?
3. What data and methodology will CMS use to develop a single practice expense input valuation and quantity for CTP products?
4. What methodology will CMS use to establish different resource input levels given the wide variation in product, pricing and units applied?
5. How will the data be updated?
6. How often will the data be updated?
7. How will CMS translate what is in the data source to the relevant CPT codes – both the initial codes (e.g., CPT code 15271) and the add-on codes (e.g., CPT code 15273)?
8. How will the significant variability in the CTPs along with price, size, and material of the CTP be addressed?
9. How will CMS capture the supply cost in a "typical service" (under the PE methodology, there is a determination of the costs of the direct resources from a "typical service")?
10. How will outliers be addressed?
11. What is the impact on patient access?
12. What is the impact on CTP products and valuation of the application procedure code?
13. What is the impact on any redistribution effects on other PFS services with PE RVUs?
14. Will CMS remove low volume claims or claims with zero units of product from any claims-based determination of resource input levels?
15. How will CMS handle claims reported with the JW modifier for discarded units of CTPs?
16. How will CMS reconcile instances when multiple application procedure codes are reported on the same claim?
17. How will CMS reconcile when multiple units of application procedure add on codes are reported, or when add on codes are reported without a corresponding base code?

The questions above are just a small sample of the information that the Coalition believes is incumbent on the Agency to provide which it still has not. This proposed change is complex and extremely difficult to implement. The Agency should simply use a solution that already exists – implement ASP pricing across settings - which would not conflict with payment rules established by Congress and would meet the desired goal of a consistent payment approach.

Consistent Payment Policy Conflicts With Payment Rules and Should NOT Be Based on the HOPPS

CMS states in the proposed rule its goal is to have a consistent payment approach for CTPs and would like to adopt a single payment policy to span different sites of service. The Agency has cited the HOPPS as the system it would model the bundling in the physician fee schedule. CMS should not try to emulate a failed program in the physician office setting in order to try to achieve consistency. The packaging of CTPs in the OPPS has been a complete failure.

Beginning in CY 2014, almost 10 years ago, CMS began to package CTP 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 CTP products into their associated procedures without accounting for differing resources among the products, CMS created two groups of CTP products for packaging – a low-cost and a high-cost group. **CMS believed that the packaged payments for the procedure including payment for the CTP were "adequate and would not discourage the use of the CTP products used in these procedures." This statement has been incorrect since the inception of this payment**

methodology. Payment was 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 CTP payment policies for CY 2019, and continued the same payment policies for CTPs, including allowing any CTP 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 exceeds or falls below the CY 2019 MUC or PDC threshold. In subsequent rulemakings, CMS continued to discuss the CTP payment methodology, but has not altered the policy, and for CY 2024, it again proposed to continue the current payment mechanism.

The Agency has put out alternative proposals for over 7 years to address the issues being raised. Time and again stakeholders have consistently stated that the Agency needed to correct the flaws in the CTP payment methodology and do what is right. Yet, the Agency continued 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.
- The Agency is overpaying for a majority of the products in the marketplace and not protecting the Medicare trust fund.

The inequities in the current payment system under the HOPPS 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.[ii] The Coalition supported all of these recommendations as they will help correct the flaws that exist in the payment methodology as well as inappropriate APC assignments for cellular and or tissue-based products for skin wounds (CTPs) which have impacted access to care in HOPDs. We request that CMS takes notice that the fourth recommendation addresses the use of ASP. Specifically, the recommendations included:

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 Hospital Outpatient PPS (OPPS) packaging of CTPs has been a failure. It has created artificial inflation, created perverse incentives for the use of higher cost products, significantly decreased the use of low-cost products as a result of inadequate payment, has created access to care problems for patients with larger sized wounds (due to no add on code payment) and has been revised multiple times over the past 7 years. There are issues with packaging in the OPPS which CMS has recognized and tried to address by putting forth multiple proposals for alternative payment methodologies over the past 7 years in order to have a more effective system. We reiterate, **CMS**

should not try to emulate a failed program in the physician office setting in order to try to achieve consistency. The only thing consistent in doing so is that the system would be a failure and patient access would be negatively impacted.

Furthermore, this proposed initiative would conflict with the payment rules established by Congress – which mandate certain statutory payment policies for different types of products (e.g., drugs and biologicals) furnished in different settings of care. As CMS is aware, in the hospital outpatient setting, the Agency has implemented a Congressionally-authorized prospective payment system that packages payment for a wide range of drugs, biologicals, supplies, and other procedures in a single payment amount. Medicare's statutory payment framework for drugs and biologicals submitted by a physician does not authorize the same comprehensive packaging policy found in the hospital OPPS which would be improper for CTPs.

Finally, if CMS really wishes to create a consistent approach, then the Agency should also use the same coding and pricing submission for all CTPs. The Agency has created new A codes for some products when Q codes were already being issued for CTPs. The A codes are largely contractor priced causing huge variations in pricing. Yet, CTPs assigned Q codes are submitting ASP pricing as required. Products being issued A codes are contractor priced – which provides less consistency due to wide variations across the country when using list, invoice, AWP, or WAC. If CMS really wishes to cause less confusion and maintain a consistent approach, then the Agency should issue Q codes for ALL CTPs and continue to use ASP pricing which would be published on the Part B Data File as further discussed below.

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. **There is no consistent equitable criteria that is appropriate for a unified payment rate for these products except for using ASP +6%**. This methodology when appropriately administered and enforced, will not only afford the Agency the consistency it is seeking, it will also achieve the cost savings necessary to help preserve the Medicare Trust Fund. Stakeholders have repeatedly and consistently informed the Agency of this fact - 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 to utilize CMS's enforcement authority to ensure that products are reporting and providing the correct information.

Prior to 2014 when CMS bundled payment in the hospital outpatient setting, CMS did have a consistent payment approach to CTPs. CMS paid separately for the application of the CTP and for the CTP itself using the same payment methodology as biologicals— ASP + 6%. In creating the packaged payment system in the HOPPS, CMS broke from the consistent payment methodology and beginning in 2014, was packaging CTPs 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 – as was described above.

Prior to January 2022, manufacturers of CTPs were not required to report ASP. However, with the passage of the Consolidated Appropriations Act, Congress is now mandating ASP reporting for all "products that are payable under this part as a drug or biological" – which would include CTPs - effective January 1, 2022[iii]. Since reporting is now mandatory for all CTPs, the Coalition strongly urges CMS to give ASP pricing methodology time to remedy abuses in the CTP industry and demonstrate cost savings in this category. The underlying cost control issues that are present today

relates to product pricing versus service pricing and utilizing ASP for all CTPs can and will address CMS' desire to cut costs.

The Agency should simply utilize separate payment for CTPs 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 CTPs, CMS should use the data that is already being provided to it to form the payment for any given CTP.

In addition to the Congressional mandate of ASP reporting for all CTPs, 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."[ivv] The OIG further stated when ASP was reported for CTPs there were cost savings.[vi] It has been recognized by the OIG that CMS has not done a particularly good job at administering the ASP program and with more focus and enforcement, the Agency can see huge cost savings.[vii] Furthermore, 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." [viii] These are important and salient points for the Agency to consider as it not only strives for consistency and fixes the CTP payment methodology but also tries to protect the Medicare Trust Fund.

The existing ASP model needs more time and enforcement by CMS to realize the cost savings while also preserving patient access. ASP reimbursement could potentially save the Medicare trust fund 20 to 50% annually for CTP product reimbursement in the physician office setting.[ix] ASP reimbursement would also allow physician flexibility to treat large complex hard to heal wounds with many product options. **Implementation of any bundled methodology is counter to the importance of CMS efforts to advance health equity and will not serve Medicare beneficiaries including minorities, as intended. CMS needs to allow the mandatory reporting of ASP for CTPs to take hold and for the Agency to not only use its enforcement authority to ensure accurate reporting but to publish all ASP in the data file.** 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 CTPs 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 (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 across settings in order to achieve all the goals they claim to want to achieve – health equity, consistent payment approach, protecting patient financial responsibilities, protecting access, and protecting the trust fund by achieving significant cost savings.

Packaging in the HOPPS 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 and one that CMS should not emulate in the Physician Fee Schedule.

The Coalition recommends that CMS should withdraw its policy to bundle CTPs as part of the physician practice expense under the physician fee schedule payment and utilize ASP +6 for all CTPs and publish all data in the pricing data file.

Implications of Moving Forward With Payment Methodology to Treat CTPs as "Incident to Supplies" Under the Physicians Practice Expense

The Coalition also raises significant concerns with the payment implications of CMS' proposal to treat CTPs and incident supplies under the physician practice expense including but not limited to the following:

- The movement of payments that are currently paid separately based on ASP into the practice expense (PE), which is subject to budget neutrality requirements both within the pool of PE RVUs and across the entire PFS. CMS does not explain whether these added costs will be incorporated on a budget neutral basis or not. The Coalition - as well as clinical associations and/or physician specialty societies – strongly oppose the addition of these separate costs on a budget neutral basis.
- Even assuming costs are added in a non-budget neutral manner, they would be subject to numerous constraints on payment growth that would harm the physicians who rely on CTPs in the treatment of wounds as payments would likely not keep pace with costs over time. These constraints include the budget neutrality requirements within the pool of PE RVUs as identified above and across the PFS as a whole, as well as the zero percent, or otherwise low statutory annual updates that are specified by law.
- Constraints with the PFS will ultimately result in outcomes that contradict CMS' goal of aligning payment across different settings of care, with payments under OPPS likely far exceeding payments under the PFS over the long-term. Such an outcome would then create incentives for physicians to move CTP treatments to the outpatient setting for smaller sized wounds and the hospital inpatient setting for larger sized wounds, rather than the office setting. This would result in even higher spending in more costly settings of care, which would increase Medicare spending and also harm Medicare beneficiaries through higher cost-sharing requirements.
- This change would severely impact access to CTPs in the physician office harming the most vulnerable patients and further the health equity divide.
- Stifle the incentive for manufacturers to innovate and bring to market the kind of new medical products that require millions of dollars of research and development and a lengthy FDA approval process.

The Coalition went on record in 2013 when the Agency had proposed to package payment under the OPPS that perverse incentives would be created and that the cost of CTPs would increase under that program. In fact, that did occur. The Agency created artificial inflation, all but eliminated low-cost CTP use, created incentives for clinicians to utilize higher cost products, created more inconsistency and confusion in the marketplace in the issuance of A codes as well as in different pricing requirements depending on the type of code issued, and due to inadequate payment created barriers to access to care in provider-based departments. So why would the Agency move to create the same types of issues in a more complicated reimbursement system?

CMS has now heard concerns from stakeholders and Members of Congress who have consistently and uniformly informed the Agency about the specific negative impacts that a proposal to treat CTPs as supplies as part of the physicians' practice expense could have on patients' access to these medically necessary treatments that have been and are successfully used to manage and heal patients with diabetic foot ulcers and venous leg ulcers. The negative impact to access to care will be felt by different patient populations including but not limited to: minorities, patients in rural areas and patients with diabetes with increases in infections, amputations and sadly loss of life all of which impact minorities disproportionately. All of these issues were brought to the attention of CMS. Yet, the Agency continues to issue this ill-conceived proposal with virtually no additional details to inform meaningful comments. Why would CMS move forward with such bad policy when ASP is Congressionally mandated, will not create access issues, is not complex to administer, will save valuable cost to the Medicare program, and has uniform support from all stakeholders? The answer – it should not.

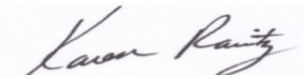
Conclusion

The proposal to create a new payment mechanism in the physician office setting for CTPs needs to be withdrawn. The Coalition recommends that CMS:

- Continue to make separate payment of CTPs in the Physician Fee Schedule until CMS can demonstrate, through rulemaking, that the quality of care and access to beneficiaries is not impacted as well as to demonstrate that this rule will not disproportionately impact underserved patient populations.
- Report the ASP of all CTPs regardless of the HCPCS code issued
- Publish all CTP ASPs in the pricing data file
- Use its enforcement authority to ensure accurate and timely reporting
- Publish guidance per the OIG report on appropriate ASP reporting
- Meet with stakeholders to develop an alternative proposal, if the Agency does not recognize the cost savings that the data suggests will be realized over the course of the next three years.

The Coalition appreciates the opportunity to provide our comments and urges the Agency to adopt our recommendations. If you would like further information or have any questions, please feel free to contact me.

Sincerely,



Karen Ravitz, JD
Health Policy Advisor
Coalition of Wound Care Manufacturers
301 807 5296
Karen.ravitz@comcast.net

[i] *78 Fed. Reg. 74,826, 74,931 (Dec.10, 2013*
[ii] *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/hospital-outpatient-payment*
[iii] *42 U.S.C. § 1395w- 3a(f)(2)(A)*
[iv] *Manufacturers May Need Additional Guidance To Ensure Consistent Average Sales Price Calculations (OEI-BL-21-00330)*
[v] *CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data To Ensure Accurate Part B Drug Payments (OEI-03-21-00390)*
[vi] *id*
[vii] *Some Skin Substitute Manufacturers Did Not Comply With New ASP Reporting Requirements (OEI-BL-23-00010)*
[viii] *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports jun19_medpac_reporttocongress_sec-pdf/ at 64.*
[ix] *CMS. Part B National Summary Data File (Previously known as BESS). https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Part-B-National-Summary- Data-File/Overview 2019 and 2020 data from the Part B National Summary Data File was analyzed*