ALLIANCE OF
WOUND CARE
STAKEHOLDERS
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September 6, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1770-P; Mail Stop C4-26-05
7500 Security Boulevard, Baltimore, MD 21244-1850

Submitted Electronically to Regulations.gov

RE: Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts [CMS-1770-P]

Dear Administrator Brooks-LaSure,

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit comments on the CY 2023 proposed Medicare Physician Fee Schedule (CMS-1770-P). The Alliance is a non-profit multidisciplinary trade association representing physician specialty societies, clinical and patient associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. Our members possess expert knowledge in complex chronic wounds, and in wound care research. These clinicians treat patients with wounds and utilize "skin substitutes" or rather the more technically and clinically correct term, "cellular and/or tissue-based products for skin wounds" (CTPs) – which are subject to provisions within this proposed rule. Please be aware that while the ASTM definition of CTPs is inclusive of synthetic products, some Alliance members who manufacture synthetic products would also recommend the inclusion of synthetics to the descriptor e.g. Cellular, Synthetic and/or Tissue-based products (CSTPs) as they believe it would more adequately encompass the evolving field of products in this space.

That said, throughout this letter the Alliance will utilize the term "CTP" when addressing this product sector as we have since 2013 and validated when ASTM published its original standard guide for "Categories and Terminology of Cellular and/or Tissue-Based Products (CTPs) for Skin Wounds in 2016.[i] A list of our members can be found on our website: www.woundcarestakeholders.org.

The Alliance is extremely concerned with the proposals which address new nomenclature, coding, and payment for CTPs. **The seismic change that CMS is proposing will impact patient access and potentially increase the number of amputations and infection for patients with chronic non-healing wounds.** The Alliance addresses all of our concerns in our specific comments below, and **urges CMS not to move forward to finalize its CTP policies proposed for CY 2023 and CY 2024.**

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EXECUTIVE SUMMARY

The Alliance submits that the CY 2023 proposed Medicare Physician Fee Schedule departs from the existing statutory and regulatory framework for determining Part B payment amounts for CTP products, with insufficient detail or explanation to allow for the provision of meaningful comment and justify a wholesale change to the longstanding classification of CTP products. The potential impact on patients, particularly those with large/complex wounds and many vulnerable populations (including minorities and patients with diabetes) is that they will have less access to advanced therapies as payments will not match costs with the very real possibility of increased amputations and infection. We recommend that CMS adhere to the Consolidated Appropriations Act, requiring manufacturers to submit ASP so that CMS can publish ASP for all CTP and synthetic products. Given the concerns below, the entire CTP portion of this Physician Fee Schedule proposed rule should not be implemented, but at a minimum delayed, until patient access issues can be studied further and more detailed proposals are provided to afford stakeholders the opportunity to submit meaningful comment.

We have divided our comments into the following sections:

- **Section I: Alliance Concerns Relating to CTPs and Wound Care**

    A. Delay Implementation of CTP Proposed Changes
        1. Impact of CMS' Proposal to Package Payment for All CTP Products Into the Practice Expenses
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        3. Administrative Procedure Concerns With CMS's Reclassifying CTPs As "Incident To Supplies"
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    B. Request for CMS to Publish ASPs for all CTPs and Maintain ASP Pricing Methodology for CTP

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        1. Current Quality Measures and Amputation
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    E. Disagreement With Proposed Elimination of Q codes

- **Section II: Additional Alliance Concerns on Provisions Impacting our Clinical Community**

    A. Global Surgical Package

B. Opposition to Clinical Labor Update
C. Clarification if CTPs Subjected to this Discarded Drugs Requirement
D. Remote Therapeutic Monitoring
E. Telehealth

SECTION I:

CONCERNS ON PROVISIONS RELATING TO CTPS AND WOUND CARE

A. DELAY IMPLEMENTATION OF CTP PROPOSED CHANGES

1. Impact of CMS' Proposal to Package Payment for All CTP Products Into the Practice Expenses

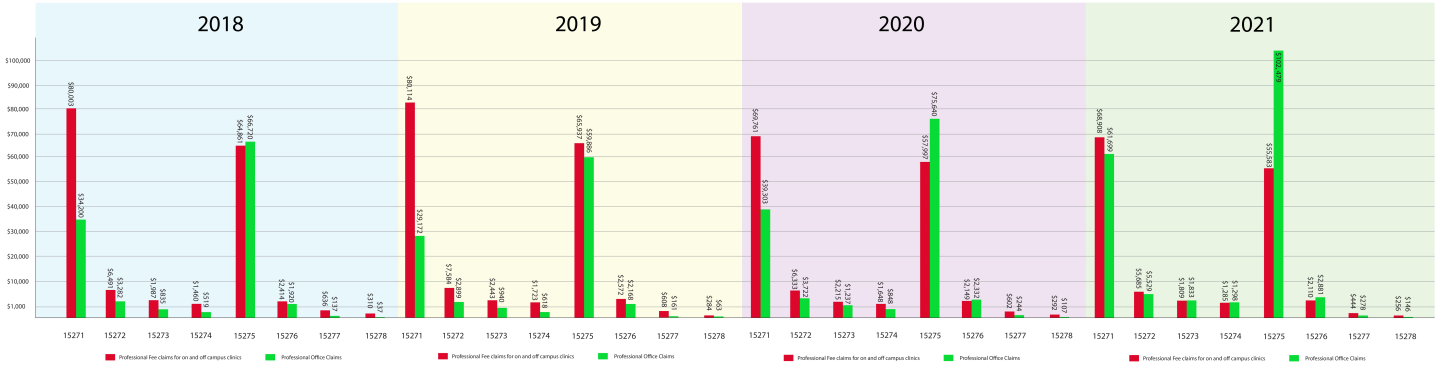
The Alliance has concerns that the proposed rule does not discuss at all the practical issue of shifting payment for CTPs into the PFS as a supply and the very real impact that it would have. Specifically, it would further compress physician payment across all procedures at a time when providers are contending with COVID and a highly inflationary environment. Physicians will not be able to absorb the cost of purchasing CTPs and not receiving adequate payment to provide this advanced therapy. Mid-level providers will realize an even greater impact of this change, as they will only get reimbursed at 85% of the proposed packaged rate for physicians. This will result in a lack of access for patients who could benefit from receiving a CTP when provided in the physician office and as a result an increase in infections as well as amputations – both major and minor.

The Alliance believes that it is helpful for CMS's Division of Practitioner Services and Division of Outpatient Care (HAPG) which has responsibility for the physician fee schedule payment to understand why we believe that there will be an access to care issue. In the hospital outpatient setting when the payment for CTPs were packaged into the payment for the application, the add on codes were also packaged. Because the add on codes represent wounds and ulcers that require the purchase of additional product, patients with wounds larger than 25 sq. cm. up to 99 sq. cm. and also those greater than 100 sq. cm., are not being offered medically necessary CTPs by clinicians in the Provider Based Departments (PBDs). The reason is that the add-on codes that are packaged into the OPPS bundled rates are not adequate to allow the PBDs to purchase the sizes of CTPs necessary to apply to all wound sizes. In fact, none of the add-on codes have been available for additional payment. PBDs can not nor are they willing to incur prohibitive costs and financial losses if they provide CTPs to patients with larger medically necessary wounds/ulcers. Instead, these patients are being treated in either the operating room (OR) defined as same day surgery in which the 2 midnight rule would apply for packaging or they are treated in physician offices. Treating the patients in the operating room (OR) can be problematic for the following reasons: not all patients can undergo anesthesia (or want to), surgeons do not like to do "minor" CTP applications in the OR as there are significant hurdles that have to be navigated in terms of pre procedural testing and anesthesia clearance, OR time can be very hard to obtain in the current climate of over flowing hospitals and finally, there is a significant cost incurred when shifting this procedure to the OR. Thus, a majority of patients have been treated in the physician office for these larger wounds.

To validate this, the Alliance analyzed Medicare claims data from 2018 – 2021 and according to the data provided in Table 1, there has been a steady increase of claims submitted by physician providers. In fact, procedure codes 15271 – 15277 were billed more frequently in the physician office than in PBD and for

more of the larger sized wounds (wounds over 25 sq. cm. – 99 sq. cm. as well as wounds over 100 sq. cm.). There has been an increase every year in the number of claims, largely due to physicians being able to treat larger and more complex wounds in the office and being reimbursed appropriately for the application of the CTP and the CTP itself.

Table 1: Medicare Claims Data for CTP Application Code Claims 2018-2021



*Medicare data analysis completed by Dobson and DaVanzo
** The data in Table 1 is also being provided in larger size as Attachment A

We were also able to confirm based on the same Medicare data analysis completed by Dobson and DaVanzo:

- Roughly $500M would need to get absorbed into the practice expense payment pool which would likely create a decrease in practice expense payment for other areas. This will impact whether a physician will provide this type of advanced therapy to their patients in their office thus impacting access to care and we believe will lead to an increase in infection as well as amputations.
- As stated above, the reimbursement in provider based departments is not adequate to treat these wounds. Outpatient facilities under the prospective payment system are losing money on these larger wounds. In fact the current APC rate of $1,749 payment for most CTPs does not even cover the cost of a majority of CTPs in the market place today. Thus, the steady shift/increase in the number of claims submitted in this physician office setting.

If CMS moves to package payment for all CTP products furnished in the physician office as supplies incident to a physician service, the very payment mechanisms allowing advanced technologies to be appropriately provided in the physician's office likely will reduce physician office use of these products since they were receiving invoice or ASP +6% as a separate payment. CMS, as stated before, has not explained how the products will be bundled thus, it is difficult for the public to provide meaningful comment. This supports our request for delay of implementation until this is explained in detail. Physicians will no longer be able to afford to provide these successful treatments to their patients and therefore in addition to the PBDs, patients may be pushed to seek access in the hospital emergency department creating a cost burden to CMS or have very limited access to this treatment in yet another site of service.

Recommendation: The Alliance recommends that CMS **not** move forward reclassifying all CTP products as "supplies incident to a physician service" and packaging payment into the services' practice expenses in a physician office.

2. CTPs Are Not Supplies

CTPs are not supplies both for technological reasons and also on how they are used clinically.
First, CTPs are affixed to a wound and become incorporated into the wound bed. This demonstrates that they are not supplies that are used and disposed of. To better understand this concept as well as this product category, we have provided an excerpt from the Wounds International Journal which describes CTPs.[ii] Specifically, the journal states,

> *CTPs provide an extracellular matrix (ECM) to a chronic wound, which plays an important role in tissue regeneration and is the major component of the dermal skin layer. The composition of ECM includes proteoglycans, hyaluronic acid, collagen, fibronectin, and elastin. As well as providing a structural support for cells, some components of the ECM bind to growth factors, creating a reservoir of active molecules that can be rapidly mobilized following injury to stimulate cell proliferation and migration. In many chronic wounds, increased levels of inflammatory cells lead to elevated levels of proteases that appear to degrade the ECM components, growth factors, protein and receptors that are essential for patient healing.*
>
> *Recognition of the importance of the ECM to wound repair has led manufacturers to introduce CTPs that work with the patient's body to replace the ECM. These CPTs comprise a reconstituted or natural collagen matrix that aims to mimic the structural and functional characteristics of native ECM[4]. When placed in the wound bed, the three-dimensional matrix provides a temporary scaffold or support into which cells can migrate and proliferate in an organized manner.*
>
> *These products are not passive – they are not gauze or a band aid. They are not a surgical dressing. These products (in contrast to dressings/supplies) are not applied by a patient or caregiver and are typically not removed post-application. There is biologic effect that takes place as a result of the incorporation of these products into a wound bed.*

Furthermore, CTPs have regulatory requirements placed on them that NO other supply has, specifically, tissue tracking requirements. There are rigorous requirements that clinics have to adhere to in order to pass their Joint Commission accreditation inspections.[iii] [ivv] These include but are not limited to documenting:

- Who delivered the CTP
- What time the CTP was delivered
- What condition the CTP arrived
- How the CTP is being stored
- Where they are stored
- Monitoring and logging daily temperatures in storing the CTP
- Each staff member who has come into contact with each tissue needs to be tracked and documented
- Maintain a 10 year implantation record retention

PBDs are in jeopardy of losing their accreditation based on failure to comply with these requirements. No supply has the same type of documentation requirements as CTPs or have any specifically identified Joint Commission requirements as stringent as CTPs. The reason – CTPs are not supplies and are not treated as such through the accreditation process.

Recommendation: We submit that CMS not describe CTP products as "supplies" and not to move forward reclassifying all CTP products as "supplies incident to a physician service" and packaging payment into the services' practice expenses in a physician office.

3. Administrative Procedure Concerns With Reclassifying CTPs As "Incident To Supplies"

CMS' proposal to reclassify skin substitute products (referred to as cellular and /or tissue-based products for skin wounds, or CTPs, throughout this letter as stated above) as "incident to supplies" would depart from the longstanding classification of these products as "biological products," as well as the existing statutory and regulatory framework under which Part B payment amounts for these products are determined. This framework has been consistently applied by the Agency for decades to provide separate Medicare Part B payments for CTP products 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 Administrative Procedures Act (APA) requires that the public be given the opportunity to comment as part of the rulemaking process, prior to CMS adopting a final policy.[vi] Therefore, the lack of explanation or analysis supporting this proposed reclassification leaves stakeholders such as the Alliance with an insufficient basis to evaluate and provide meaningful comment on the Agency's reasoning and the evidence on which it relied.

Moreover, **CMS has not offered any data, analysis, or evidence of any type that supports CMS's proposed position to now classify all CTPs as supplies incident to a physician service, packaged into the practice expense associated with that service, rather than their longstanding treatment as biological products**. Under well-established principles of Administrative Law, CMS must provide support in the administrative record for this reversal of prior policy. In the absence of such an explanation prior to finalizing this proposal, reversing the Agency's longstanding treatment of CTPs as biologicals would be inconsistent with established law.[vii]

All of these issues raise concerns under the Administrative Procedures Act (APA), should CMS move forward to finalize its policies proposed for CY 2023 and CY 2024.[viii] The Alliance believes moving forward with the proposal will significantly impact patient care and patient access (as described throughout our comments) to technologies which providers and patients have relied upon for decades. Moreover, the proposal lacks adequate detail for 2023 and 2024; thus, the impact to patients care will be immediate and detrimental.

Additionally, the proposed timeline for implementation is problematic from a logistical standpoint. Each manufacturer will have to submit a request to the FDA's Tissue Reference Group (TRG) in order to obtain a letter confirming whether their product(s) are regulated solely under section 361 of the Public Health Service (PHS) Act and the regulations in 21 CFR part 1271. While the FDA states their goal is to respond to all such requests within 60 days, that standard is not being met. Many manufacturers have had to wait over 9 months after submission to receive a response to their TRG request. This response letter needs to be received by the manufacturer before they can file a HCPCS code re-application to transition from their existing Q-code to a new A-code. If the TRG takes 9 months to provide a letter to the manufacturer, and since CMS only issues HCPCS codes bi-annually for this category, many products that are currently used to treat patients, and for which Medicare reimburses, will no longer be available for use, thus disrupting patient care.

Recommendation: At minimum, the Alliance urges CMS to delay finalizing the entire proposal related to CTPs to enable further engagement with key stakeholders and to provide further explanation of CMS'

proposed reversal of its prior determination and longstanding position with respect to CTP products so that the public has a meaningful opportunity to comment on the entirety of the proposals. However, as our comments demonstrate, we recommend that CMS not move forward with the bundling of CTPs in a physician's office as we expect that it will impact patient access adversely and potentially increase amputations and infection, not to mention will intensify health care disparities experienced by minorities.

4. CMS' Proposal to Package Payment for All CTP Products Furnished in the Physician Office Setting is Inconsistent With Applicable Laws and Policies

For more than 30 years, CMS has appropriately classified CTP products as biological products, applying Medicare Part B payment policy to these products in the physician office setting. The Alliance appreciates CMS's interest in adopting a consistent payment policy across all CTP products and settings of care in which these products are used. But we have serious concerns that CMS's proposal to abruptly reclassify all products as "supplies incident to a physician service" and package payment into the services' practice expenses – without regard for the products' FDA classification, USP monograph status, and applicable payment laws and policies for biologicals under sections 1842 and 1847A of the Social Security Act (SSA) – would be inconsistent with applicable law.

As CMS is aware, 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 suppliers' 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.[ix] Under Section 1847A, payment for drugs and biologicals provided incident to a physician 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).[x]

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, many CTPs or "skin substitutes" should 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.[xi] This longstanding classification and payment framework under Part B is consistent with the characteristics of many products recognized as "skin substitutes" or CTPs by CMS, including human-derived products regulated as human cells, tissues, and cellular and tissue-based products (HCT/Ps) under Section 361 of the Public Health Service Act (PHS Act) and the related regulations at 21 C.F.R. Part 1271. 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). Examples include: Integra Dermal regeneration, Integra wound matrix, Dermacell, Epifix, Apligraf, Dermagraft, Oasis, Grafix Core and Prime just to name a few. In addition, HCT/P manufacturers must register and list their HCT/Ps with FDA's Center for Biologics Evaluation and Research (CBER). Other CTP products, which consistently derive from donated human tissue, are authorized for marketing by FDA as 510(k) cleared products or through premarket approval (PMA) as medical devices. 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 all CTP products that complies with section 1847A.

CMS' proposal to reverse its longstanding policy, and instead package payment for all CTP products provided in the physician office setting with the service provided by the physician, would be inconsistent with the applicable payment framework for biologicals provided in a physician clinic, as set out in sections 1842 and 1847A. While CMS states the Agency would like to adopt a single, consistent payment policy across all types of CTPs furnished in all outpatient settings of care, this proposed initiative would not consistently apply 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, CMS 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 billed by a physician simply does not authorize the same comprehensive packaging policy found in the hospital OPPS.

Because many CTP products meet the statutory definition of a biological, and the vast majority of others are derived from human or animal biological tissue and/or cells, the Alliance and its members have agreed with CMS' prior determination to provide separate payment for CTPs consistent with the pricing rules established by section 1847A. **The Alliance strongly believes that Medicare coding and payment policies must continue to facilitate separate payment for all CTP and synthetic products, consistent with the requirements of section 1847A, when they are furnished and billed by a physician clinic.** The continuation of this longstanding policy would achieve CMS' goal of applying a uniform payment policy to all CTP products in the physician office setting. That goal would not be achieved, and the payment requirements of sections 1842 and 1847A would not be met if all CTP products were packaged as supply costs into the practice expense of CTP application procedures. Accordingly, the Alliance strongly opposes

CMS proposed change in payment policy and product classification for CTPs and urges CMS to not finalize its proposals for CY 2023 and CY 2024 for these items.

The Alliance notes that other commenters, including the AMA RUC and the SVS, have consistently recommended that high-cost supplies – a term that would apply to the vast majority of the CTP products – be coded and reimbursed separately from the associated physician service. We agree with these commenters' recommendations, which aligns both with the longstanding position of CMS for CTP products and our concerns (as stated above) with the negative impact on patient access to product availability that would come with treating CTP products as supplies included in the practice expense RVUs of a physician service. While the AMA RUC also appeared to lend support to CMS' proposal for skin substitutes, we would note that this statement is specifically limited to a policy that "conforms to the RUC policy on high-cost disposable supplies"— a policy that recommends separate identification and payment for supplies priced more than $500. Based on current pricing, and read together, the Alliance believes this comment effectively recommends that the vast majority of CTP products (those more than $500) be identified and paid separately from the service.

Finally, the proposal fails to provide commenters with sufficient notice and explanation, as required under the Administrative Procedure Act (APA), for this proposed reversal in policy. We have grave concerns that CMS did not include or conduct an impact analysis on this issue. While the Agency suggests that they are not required to provide this type of analysis since most of the provisions will not be implemented until 2024, the Alliance disagrees with this premise as some of the provisions will begin being implemented in 2023 which will impact the policy provision/regulations moving forward. Before CMS can implement any of the provisions related to CTPs, we submit that an impact analysis must be provided given the seismic change.

Recommendation: For these reasons, among others, the Alliance urges that CMS not finalize its proposal to reclassify all skin substitute products as supplies and package payment for all CTP products into the physician service practice expense when they are applied in the physician office setting.

B. Request for CMS to Publish ASPs for all CTPs and Maintain ASP Pricing Methodology for CTPs

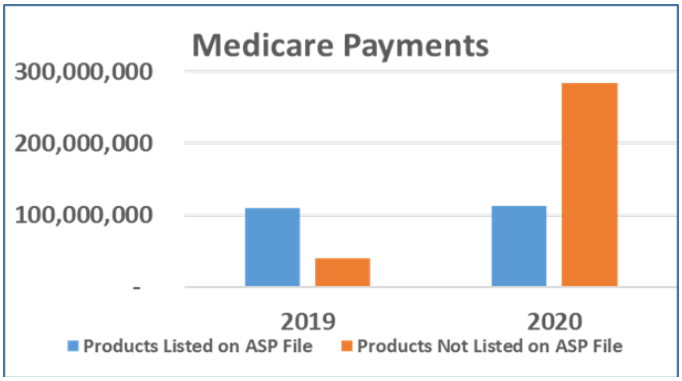
CMS has also proposed to no longer require CTPs to submit ASP pricing. Instead, CTPs would be contractor priced for an interim period until the products are worked into the practice expense. To ensure these products are subject to a consistent payment policy when furnished in the physician office, the Alliance strongly believes CMS should continue its longstanding policy of recognizing and providing separate payment for these products under the ASP methodology described in section 1847A of the SSA. As we will address below, this approach holds significant promise to advance CMS goals of reduced spending and lower out-of-pocket copayment for Medicare beneficiaries.

The Alliance acknowledges that synthetic products are not part of the category defined as drugs or biologics, and as such, do not currently required to report ASP. Therefore, synthetics are not reimbursed based on ASP payment methodology. As such, to accommodate all products, the Alliance recommends that CMS also require synthetics to report ASP. Using ASP methodology would allow CMS to ensure that there is differentiated payment for differentiated products. Furthermore, the Agency would not be overpaying at list or invoice price. According to the data in Tables 2-4 below, when ASP pricing is used for products contained in the Part B pricing data file, there were savings associated with those products as opposed to those not on the Part B pricing data file. If the Agency is interested in controlling costs and providing

savings to the Medicare Trust Fund, while applying a consistent payment policy across all CTP products, it should maintain ASP pricing and all products should be published within this data file. To illustrate the savings impact that the Medicare Trust Fund would realize if CMS would publish all CTP products on the Part B Drug file, we have provided below 2019 and 2020 data analyzed from the Medicare Part B National Summary Data File from one of our Alliance members

Table 2 represents Medicare payments of CTP products.[xii] As demonstrated, Medicare payments for products not on the ASP Part B file increased significantly from 2019 to 2020.

Table 2: Medicare Payments of CTP Products



As shown in Table 3, payments for CTP products listed on the ASP file increased by 2% however, products not listed on the ASP file increased 597% or $243 million dollars in 2020.

Table 3: CTP Product Percent Increase

	Medicare Part B Payment*	
	% Increase 2019 vs 2020	$ Increase 2019 vs 2020
Products on Medicare Part B ASP File	2%	$2,406,233
Products not on Medicare Part B ASP File	597%	$243,417,824

Moreover, in Table 4, we demonstrate that the payment per unit actually decreased by 5% for products listed on the ASP file, while the payment per unit for products not listed increased 59% per unit.

Table 4: CTP Medicare Payment Per Unit

	Payment Per Allowed Service (UNITS)		
	2019	2020	
Products Listed on ASP File	$ 82	$ 77	-5%
Products Not Listed on ASP File	$ 146	$ 232	59%

Congress recently emphasized the need for all products paid as drugs and biologicals under section 1847A by mandating ASP reporting for all such products, effective January 1, 2022, under the Consolidated Appropriations Act.[xiii] By packaging payment and eliminating the ASP reporting requirement for these products, we believe CMS would be undermining Congress' intent to apply a broad, ASP-based payment framework to all drugs and biological products, including CTPs.

Recommendation: The Alliance highly recommends that CMS publish ASPs, and pay per the ASP methodology, for all CTPs in order to achieve the savings and consistency discussed above.

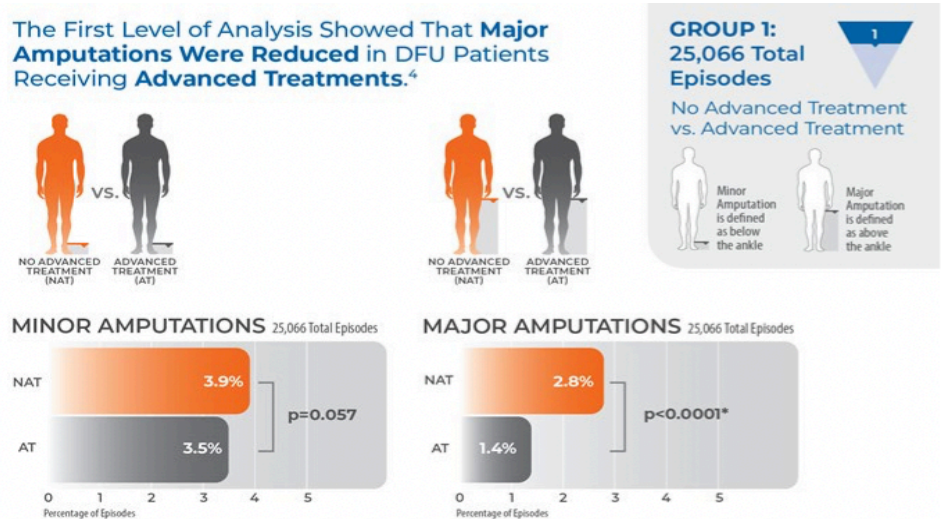
C. Amputation Avoidance in Patients With Diabetes and Quality Measures that Either Are or Could be Developed to Address this Important Issue

In the rule, CMS has indicated that it is so concerned with the number of amputations with diabetic patients that the Agency has put forward a Request for Information seeking quality measures to address amputation avoidance. CMS has specifically stated that "amputation avoidance in diabetic patients is a priority clinical topic, particularly in the measurement of underserved populations, as there are substantial equity concerns related to racial disparity in diabetes-related amputation." CMS may spend as much as $98 billion a year on the treatment of chronic wounds, and they impact 15% of Medicare beneficiaries.[xiv] There are profound healthcare disparities in the outcome of chronic wounds, not the least of which is that **persons of color are more likely to suffer amputations from a diabetic foot ulcer. Chronic wounds disproportionately affect minority populations, and primarily affect persons with multiple comorbid conditions and the disabled.**

We agree that amputation avoidance is and should be a priority topic and will provide information below addressing quality measures. However, we are very concerned that **the proposal to package payment of CTPs will likely increase the number of major and minor amputations, impacting minority populations disproportionately.** As we have repeatedly stated in our comments, there will be access to care issues when physicians do not provide services to patients with larger sized wounds as discussed above as well as a reduction in product choice which will result in an increase in infection and amputations. CTPs are a medically necessary and successful advanced therapy.

In fact, Dr. David Armstrong's study, "Observed impact of skin substitutes in lower extremity diabetic ulcers-lessons from the Medicare Database (2015-2018)"[xv] uses CMS data and validates our point. Specifically, the study, which we have provided as Attachment B, looked at over 900,000 patients and has found **when advanced therapies such as CTPs are used on patients with diabetes, there are lower incidence of minor and major amputations for patients with lower extremity diabetic ulcers.** As such, it is concerning that the Agency, by proposing these significant changes in payment, will in fact lead to more patients receiving amputations. The packaging of payment will likely lead to less access to this advanced therapy - which has been shown to be effective - and could lead to increased amputations.

Table 5: Major and Minor Amputations Reduced When Using Advanced Therapies



*Information presented to CMS by the Alliance at June 27, 2022 meeting

Similarly, CMS is also seeking input from stakeholders on identifying measure concepts that would lead to improved patient outcomes and proactive care in an attempt to avoid amputation. **The Alliance is thrilled that CMS is concerned about amputation avoidance measures for patients with diabetes. We have been concerned about this issue for a number of years and in 2014 collaborated with the US Wound Registry to develop a suite of measures focused on reducing amputation** among diabetics with lower extremity wounds, some of which have been reported by physicians for 8 years. Currently, these measures are only reportable through a Qualified Clinical Data Registry (QCDR) but lack of engagement by most electronic health record vendors has limited their availability. However, the measures are well tested. We have provided a link to the 2022 measure set here: https://uswoundregistry.com/quality-measures/ Furthermore, of note, the "Limb Loss and Preservation Registry" (LLPR) has been set up with Federal Funding to document the outcomes of the population of patients with amputations. Website: Limb Loss and Preservation Registry (llpregistry.org)

1. **Current Quality Measures and Amputation**

Currently CMS approved QCDR measures aimed at reducing amputation among diabetics are:

- Adequate Off-loading of DFU at Each Visit
- Non-Invasive Arterial Assessment of patients with lower extremity wounds or ulcers for determination of healing potential
  - The USWR quality measure requiring arterial screening of all patients with a lower extremity foot ulcer is responsible for improved healing rates and reduced failure rates among the 500 physicians participating in the USWR. We strongly urge CMS to utilize a measure directed at arterial screening of all patients with diabetic foot ulcers.
- DFU Healing or Closure
  - This is risk stratified by the Wound Healing Index to ensure that physicians caring for the sickest patients with the most severe wounds will not appear to have worse outcomes then their peers
- Appropriate use of Hyperbaric Oxygen Therapy (HBOT) for Patients with DFUs

- This measure incorporates several different quality measures all of which represent the basic requirements for the use of HBOT according to the National Coverage Determination for HBOT In DFUs
- Patient Reported Nutritional Assessment and Intervention Plan in Patients with Wounds and Ulcers

We believe that the well-tested measures described above represent the foundation of a suite of quality measures able to address amputation avoidance in DFUs. All of these measures could work at the national level, but the wound care community, which lacks a medical specialty organization or significant financial support from industry, is not able to fund their development into national MIPS measures, nor has there been past support by CMS for the development of measures targeting the diabetic foot ulcer patient.

2. Previous Quality Measures Focusing on Diabetic Foot Ulcer Amputation Avoidance

Previous QCDR measures focused on DFU amputation avoidance (these were approved and later rejected by CMS for reasons stated below):

- Major amputation in patients with diabetic foot ulcers

  - For three years, CMS approved the US Wound Registry's QCDR outcome measure of Major Amputation in patients with diabetic foot ulcers.
  - The measure was eventually rejected by CMS because it did not meet CMS reporting thresholds which require that each doctor reporting the measure have at least 20 patients to whom the measure is relevant (meaning, an individual physician must have 20 patients who suffer a major amputation each calendar year), and that the registry have at least 20 such physicians who meet the measure. (Note: toe and partial foot amputations were not included in this outcome measure because patients are not likely to lose ambulatory status afterwards). This measure was aimed at wound care practitioners because it would be unfair for an amputation measure to be reported by the surgeons whose only involvement was to perform the major amputation and who were not responsible for the clinical care that led up to the amputation.

After discussions with CMS, the US Wound Registry agreed that a "major amputation" quality measure was not feasible as a physician reported measure because, despite their worrisome frequency at the population level, major amputations occurred too infrequently at the physician level to be a measure of quality of care. Based on the frequency rate of major amputations, a major amputation measure would have to be population based.

- Preservation of ambulatory status after minor amputation

  - We submit that a far more useful concept was the USWR measure called, "Preservation of ambulatory status after minor amputation". Many patients' diabetic foot ulcers are at risk for a major amputation (meaning, above or below the knee) but, *as a result of timely arterial revascularization and optimal wound care*, suffer only a "minor" amputation of a toe or toes or partial foot. <u>These minor amputations preserve ambulatory status</u>. We consider "minor" amputations to be a measure of success rather than failure when the patient's ambulatory status is preserved.

    Although CMS did approve this as a QCDR measure for two years, the USWR withdrew this measure when CMS staff insisted the following year that minor amputations be included in the major amputation measure and thus considered "poor outcomes". The USWR refused to

classify "minor amputation(s) with preservation of ambulatory function" as "bad" outcomes equivalent to a major amputation and thus withdrew the measure.

The Alliance maintains that an approach which evaluates preservation of ambulatory status after a minor amputation is a good way to reduce measure quality of care and reduce major amputations in patients with DFUs. We believe CMS should perform a more informed review of this concept.

3. Potential Quality Measures that Could be Developed to Help with Amputation Avoidance

So far, the Alliance has provided the Agency with measures that have already been developed and utilized but there are still others that could be developed which could help with amputation avoidance. These include the following:

- Ulcer free days among patients with a healed DFU
  - DFUs represent a recurring condition. Thus, a potentially workable concept is "ulcer free days" among patients with a previous diabetic foot ulcer. The barrier to this measure is identifying what clinician should report it. Many different physicians are involved in the care of patients with current or healed DFUs. The logical individual to report such a measure is the patient's podiatrist and we would suggest linking it to a quality measure focused on preventive podiatric foot care.
- % of Diabetic patients provided with preventive podiatric services annually
  - Preventive podiatric care may reduce amputation rate. Podiatrists could perform Practice Improvement activities to identify diabetics and work proactively to see them for preventive podiatric care.
- Population measure of amputations based on number of treatment days for lower extremity diabetic ulcer (LEDU) episodes [xvi]
- Hospitalizations for patients with an LEDU[xvii]
- Emergency room visits for patients with an LEDU [xviii]

4. Chronic Wounds Impact on Minority Population - Possibility of Creating a MIPS Value Pathway for Wound Care or Diabetic Foot Ulcers

With respect to quality measures, the Alliance points to the following:

- There are no national MIPS quality measures relevant to the management of patients with chronic wounds and ulcers, and among the quality programs in all healthcare sectors, there is only one measure relevant to chronic wounds (the counting and staging of pressure injuries).
- The GAO reports that CMS has spent an average of $43 million a year on quality measurement programs over the past 11 years, **none of which was spent to fill the measure gap in chronic wound management**.

Furthermore, there is no "Meaningful Measures" initiative around chronic wounds, a problem which impacts 5 times more individuals than heart failure and may cost twice as much. The Alliance has partnered with the US Wound Registry (USWR), a CMS recognized QCDR, to develop a suite of evidence based QCDR quality measures focused on chronic wound care. Three of them were selected for inclusion on *Physician Compare* including: adequate offloading of diabetic foot ulcers at each visit; adequate compression of venous leg ulcers at each visit; and arterial assessment of patients with lower extremity wounds and ulcers at the first visit. Since all wounds are symptoms of disease, they are invariably associated with conditions such as

diabetes, heart failure, chronic kidney disease, paralysis, and cardiovascular disease. Physicians practicing wound care full time have no specialty code and since they often provide the plurality of visits for patients with wounds, are allocated the cost of hospital readmission for conditions like diabetes and heart failure.

Thus, while we understand the evolving focus of the Quality Payment Program (QPP) away from quality to cost measures, in the area of wound care, the current QPP methodology fails to identify quality (since there are no relevant measures) and incorrectly allocates cost. It is possible that the creation of a MIPS Value Pathway (MVP) would be of benefit in chronic wound care or diabetic foot management. If QCDR measures relevant to wound care were included (e.g., diabetic foot ulcer off-loading, arterial assessment, nutritional assessment, etc.), an MVP might make it possible for the many different types of practitioners involved (e.g., surgeons, vascular experts, podiatrists, physical therapists, nutritionists, etc.) to collaborate in such a way as to properly associate quality and cost which currently is not possible.

Chronic wounds have a disproportionate impact on minority populations. As CMS continues to focus on and place importance in health equity and on amputation avoidance for patients with a diabetes - as is evident in the request for information contained in this proposed rule, we would appreciate knowing whether CMS would support an MVP for chronic wound care. We recognize the significant effort that would be needed to create an MVP, and seek feedback from CMS with regard to its support and what resources may be available to help assist us in creating one should the Agency find value in doing so.

The Alliance is supportive and agrees with the Agency that amputation avoidance for patients with diabetes is and should be a priority. The Alliance has always supported the use of quality measures for amputation avoidance for patients with diabetes. Quality measures are a valuable tool to ensure that improved patient outcomes and proactive care in an attempt to avoid amputation is being provided. However, **the proposal to package CTPs in the physician's office will in fact lead to more amputations and should not be finalized.**

Recommendations: The Alliance has provided some recommendations for quality measures for CMS to consider related to wound care and amputation avoidance. Furthermore, the Alliance recommends that CMS not finalize this proposed rule which reclassifies all products as "supplies incident to a physician service" and package payment into the services' practice expenses as this proposal will directly contradict amputation avoidance.

D. Opposition To CMS Renaming the term "Skin Substitutes" To "Wound Care Management Products"

The Alliance agrees with the Agency that the term "skin substitute" is misleading and inaccurate to describe the class of products that are the subject of this proposed rule. We have been advocating for this change for over 10 years. In fact, as the Agency stated, skin substitutes do not substitute for skin. They have evolved and the term is no longer representative of the products in the marketplace or what the products are designed to do. However, the Alliance **strongly disagrees with the Agency that "skin substitutes" should be renamed "wound care management products".** The Agency has indicated that the reason for the change of nomenclature is to provide a "more accurate and meaningful term" which will help address confusion among interested parties about how these products are described and how they are paid for. Yet CMS goes through great lengths describing this term by stating what is and is not included. The Agency also had to explain that the E/M codes would not be implicated by this terminology. If the Agency has to go through

such lengths to explain what the nomenclature means – it will not help to provide any clarity especially when clinically the term includes more products than the class of product it is meant to describe.

Furthermore, CMS also indicated that this new term more accurately describes the suite of products that are currently referred to as "skin substitutes" while providing enough specificity to not include bandages or standard dressings, which are not considered skin substitutes. While CMS is correct that bandages are not considered skin substitutes, there are a wide range of additional products and services that are considered "wound care management" products and services. This list includes but not limited to: disposable negative pressure wound therapy Unna Boots, multilayer dressings, total contact casts, casting and strapping products, selective debridement, surgical debridement agents, low-frequency non-contact non-thermal ultrasound, support surfaces, topical oxygen therapy products, and surgical dressings. So realistically, changing to the wound care management product nomenclature would actually cause more confusion in the industry than the CTP or skin substitute nomenclature that currently exists and does not provide the type of clarity that CMS is trying to achieve.

In order to create less confusion, a more accurate term describing the entire suite of products currently marketed as well as prospective ones, **the Alliance recommends that CMS adopt the term "Cellular and/or Tissue-based Products for Skin Wounds" or CTPs.** This nomenclature is already known and being utilized by clinicians, speakers at conferences, in publications as well as several of the CMS A/B MAC contractors and private payers' LCDs.

Additionally, ASTM International (the well respected standards setting development organization) thought so highly of the cellular and/or tissue-based products for skin wounds (CTP) terminology that in February 2016 it published a definitive standard (F3163-16) devoted to the nomenclature for these products titled "Standard Guide for Classification of Cellular and/or Tissue-Based Products for Skin Wounds." It was updated in 2022 (F3163-22.) The workgroup that created this standard as stated above included FDA (who agreed with the term), scientists, engineers and clinicians who worked collaboratively to ensure that the standard is inclusive of all the products in this space. As stated above, according to the ASTM standards document, the definition of a CTP is as follows, "*CTPs are defined primarily by their composition and comprise of cells and/or the extracellular components of tissue. CTPs may contain cells (viable or nonviable), tissues, proteins, and other materials for which there is a rationale for benefit beyond that achievable with conventional wound coverings. CTPs may additionally include synthetic components.* [xix]

The CTP nomenclature is already being utilized, and includes all products that CMS is trying to describe and provides the clarity that the Agency is seeking. CMS should adopt the term "cellular and/or tissue-based products for skin wounds" (CTPs) in place of the words skin substitutes.

Recommendation: The term cellular and or tissue-based products for skin wounds (CTPs) is clinically and technically accurate to describe this class of products. In fact, this term provides the clarity that CMS is seeking by very clearly identifying the products that are included within the definition. As such, **the Alliance recommends that CMS not utilize the confusing and overly broad term "wound care management products" and instead use the more clinically accurate term -"cellular and/or tissue-based products for skin wounds (CTPs)" or as we stated earlier in our comments- Cellular, Synthetic and/or Tissue-based products CSTPs.**

E. DISAGREEMENT WITH PROPOSED ELIMINATION OF Q CODES

The Alliance has already gone on record opposing the HCPCS coding changes from "Q" codes to "A" codes. "A" codes designate supplies, and CTPs are not supplies as we have described throughout our letter. CMS indicates that it is proposing to move an entire class of products out of the HCPCS codes that have been issued to them for over 12 years – HCPCS Q codes – to new A codes in order to uniformly classify these products in the HCPCS code set. According to CMS, Q codes are not appropriate for these products because Q codes are used to identify separately payable drugs and biologicals. CMS's stated rationale for the change from Q codes to A codes is inconsistent with one of its stated objectives in the treatment of skin substitute products (maintaining clarity for interested parties) and is incorrect factually. We ask CMS to recall from the 2014 OPPS Final Rule (CMS-1601-FC) that CMS responded to stakeholder feedback by stating the Agency was not conflating the two benefit categories of skin substitutes and surgical dressings; and, further that CMS assigns A codes to surgical dressings and Q codes to drugs and biologics which are used to describe skin substitutes. CMS has a long-standing precedence in assigning A codes to dressings and Q codes to individual skin substitute products that submit new HCPCS code applications. Therefore, CMS' latest proposals that Q codes be eliminated in the future and that skin substitute products which are already appropriately assigned Q codes should apply instead for an A code (meant for surgical dressings) is inappropriate**.**

In terms of maintaining clarity for interested parties on coding for skin substitute products, CMS's proposal does just the opposite. CMS made the decision to issue Q codes in 2010 when CMS abandoned the term "skin substitutes" in the code descriptors for these products and instead required an individual product/brand specific descriptor. At that time, the Agency agreed that these products were not "skin substitutes" and instead issued Q codes for each individual product by its brand name – rather than the "J" codes that they were being issued. Q code designation for these products are more appropriate. Thus, for more than a dozen years, most skin substitute products have had HCPCS codes in the Q41XX or Q42XX series, which has enabled physicians, providers, contractors, and coders to know where to look in the HCPCS code set for such products.

CMS has disturbed this clarity in coding by first assigning certain skin substitute products A codes within the past year and now by proposing to move all skin substitute products to A codes. These actions taken and proposed create confusion and unnecessary work for all involved, instead of maintaining clarity. CMS is forcing physicians, providers, coders, and Medicare contractors to adapt their mindsets and their systems to a new set of codes. Further, the proposal would further burden the HCPCS process, which based on consistent missing of time frames for release of code decisions, seems overburdened already. The proposal would significantly increase the number of HCPCS applications the Agency will have to process. Clarity would be maintained by having all skin substitute products assigned Q codes, and that would spare considerable resources for all these components of the system.

The rationale for skin substitute products not maintaining Q codes is factually incorrect. The Q codes do not just include separately payable drugs and biologicals. There are dozens of Q codes for cast supplies and about 10 codes for hospice or home care services. Moreover, if one thinks about what is contained in the set of Q code, skin substitute products make sense to be included therein. The majority of CTPs are either biological or have strong biological components, and in many cases are the result of humans who have donated their tissue. CMS has stated numerous times in rulemaking that these products "*stimulate the host to regenerate lost tissue."* This class of products are therefore most accurately captured by a Q code. **The CMS proposal to transition to A codes not only creates unneeded work and confusion in light of the many years of the use of Q codes for such products, but A codes for skin substitutes does not capture the therapeutic significance of these treatments. Therefore, we strongly recommend that all CTPs be assigned a Q code when meeting the requirements of the HCPCS application.**

Recommendation: CMS should have all the CTP codes issued or remain as "Q" codes. In addition, all CTPs inappropriately issued an A code beginning in 2021 should be re-assigned a proper Q code.

SECTION II:

ALLIANCE CONCERNS ON PROVISIONS IMPACTING OUR CLINICAL COMMUNITY

A. GLOBAL SURGICAL PACKAGE

As part of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Congress mandated that CMS collect data on the number and level of post-operative visits for surgical global codes provided to Medicare beneficiaries. The Act specified that CMS should use this data and other available data, as appropriate, to improve the valuation of surgical global services. CMS contracted with the RAND Corporation to comply with the data collection requirements. The three RAND reports were utilized by the Agency resulting in CMS paying surgeons at a different rate from other physicians and distorted the relativity within the established RBRVS. The Alliance had significant concerns with the RAND reports when they were released and continue to have the same issues with CMS utilizing the data from these reports, including the following:

- The RAND analysis utilized incomplete claims data
- The RUC has indicated that the RAND reports are outdated
- The data utilized in the reports as well as the resulting analysis is significantly flawed

The Alliance urges the Agency to follow the RUC recommendation that "CMS instead indicate specific codes for which they believe are potentially misvalued so that the RUC may address individual services without penalizing all surgeons and all services with a global period." Furthermore, APMA, an Alliance member, has submitted very detailed comments to the Agency. The Alliance agrees with the comments developed by APMA and urges CMS to adopt their recommendations.

CMS has also requested specific comments on the three RAND reports. The specific Alliance comments follow:

> *RAND Report 1: Claims-Based Reporting of Post-Operative Visits for Procedures with 10- or 90-Day Global Periods*

As stated, the Alliance believes that there are several flaws in the reports. The flaws in this report include, but are not limited to the following:

- 54% of physicians eligible for this project were not aware that they were required to participate or they were unable to participate. Thus, the dataset utilized by RAND cannot reasonably be used to forecast any overall trends, given the limited and likely intermittent participation of eligible physicians as well as the current difficulty CMS and RAND researchers have implied in matching up procedures to CPT code 99024.
- RAND concluded that only 39 percent of 090-day global visits and 4 percent of 010-day global visits were performed**.** However, as stated above, 54 percent of physicians in the nine states who were

eligible to participate, did not do so. Additionally, RAND inappropriately assumes that each of these physicians did not provide any office visits in any surgery's global period.
- Participation varied widely by both specialty and state which impacted data collection and thus the analysis and conclusions reached.
- The study used physician time files that are several years old thus making the reports outdated. RAND definition to categorize study participants as robust reporters as , "ten or more 90-day global procedures performed and half of those procedures include at least one reported visit reported during the global period..." which excludes any providers that only perform 010-day global procedures. The top three 010-day global codes, CPT 17000, 17004 and 17110, make up 65 percent of the utilization for all 010-day global services in the study. These three codes are typically performed by the same specialty, Dermatology, and are all from the same destruction of benign or premalignant lesions code family.

RAND Report 2: Survey-Based Reporting of Post-Operative Visits for Select Procedures with 10- or 90-Day Global Periods

The flaws in this report include, but are not limited to the following:

- RAND's main conclusion in the second report was that the average visits were somewhat longer for complex wound repair [21.8 minutes vs 16 minutes] and lower for other areas. However, RAND may have misinterpreted the findings of their survey data. It appears that RAND only compared the survey physician time "on the day of the visit" to the CMS physician time file, but the pre-service and post-service time of E/M services is not specific to the date of the encounter. This is an example of why CMS should be utilizing the RUC recommendations .
- RAND also inappropriately excluded nurse practitioner (NP) and physician assistant (PA) time from their visit time comparison analysis and the wound repair time analyses., which would have led to the observed times being much more similar to the average CMS time cited in the comparison analyses.
- RAND categorized NP/PA survey data as "staff time" and incorrectly observed that "*...such staff time would be considered as part of PE in the RUC process and not contribute to the physician time component nor to the level of the visit."*
- The researchers did not account for Medicare rules on "incident to" and split/shared E/M services.
- Comparing day of service time to the CMS time file was not accurate.
- Survey respondents were provided with completed examples of the surveys. While acknowledging "... that providing sample surveys could potentially affect survey responses...", RAND still included this tool to help the survey respondents understand the survey burden.
- Most importantly, the new E/M office / outpatient visit framework allows for a physician to report a CPT 99212 if 10 minutes is spent on the date of encounter. Most all surgical post-operative office visits are attributed as CPT 99212 in the surgical global period in determining physician work, physician time and practice expense. The new coding structure appears to render this RAND report moot.

Rand Report 3: Using Claims-Based Estimates of Post-Operative Visits to Revalue Procedures with 10- and 90-Day Global Periods

The flaws in this report include but are not limited to the following:

- This study utilized the flawed reverse building block methodology to estimate the change in Medicare payment relative to the first study. The RUC has stated that reverse building block methodology, or any other purely formulaic approach, should never be used as the primary methodology to value services. The Alliance supports and agrees with the RUC's assessment.
- The "robust reporters" concept highlighted in the first study was disregarded and there was no attempt to filter out the 54 percent of eligible providers that did not participate in the data collection initiative.
- No specialty achieved a 100 percent participation rate, and therefore all codes included in the study would have been undercounted.
- Applying an overall ratio from a pool of data where all non-participants were categorized as physicians that never perform post-operative services is not appropriate and skews the analysis.
- The researchers "computed the total post-operative visit time by subtracting pre- and intra-service time from the total physician time." However, this method would have included immediate post-service time, which does not coincide with any bundled visits, as part of the bundled post-operative visit time.

Implementation of the methodology outlined in the RAND reports have resulted in unreasonable reductions in total Medicare payment for many surgical specialties. The RUC, which represents the entire medical profession, voted overwhelmingly (27-1) to recommend that the full increase of work and physician time for office visits be incorporated into the global periods for each CPT code with a global period of 10-day, 90-day and MMM (maternity). The RUC also recommended that the practice expense inputs should be modified for the office visits within the global periods. The Alliance agrees with and supports the RUC and we urge CMS to incorporate into the global codes the adjusted values for the office/outpatient E/M codes that were revised effective January 1, 2021.

As stated above, the Alliance **recommends that CMS follow the RUC recommendation that "CMS instead indicate specific codes for which they believe are potentially misvalued so that the RUC may address individual services without penalizing all surgeons and all services with a global period.** CMS should continue to rely on AMA's Relativity Assessment Workgroup process, utilizing objective screens to identify any potential mis-valuation of services with global periods.

B. OPPOSITION TO THE CLINICAL LABOR UPDATE

The Alliance is opposed to the clinical labor update. Physician practices that have increased wages for their clinical labor staff over the past 20 years, to keep up with the market, with no corresponding rate increases in the PFS, are now suffering paralyzing cuts from a policy intended to align the wages with the current market. The cuts in the proposed rule "undermine the long-term financial viability of physician practices and seniors' access to critical treatments and procedures, by implementing significant cuts in physician reimbursement. Community-based office setting specialty care is a critical part of the nation's healthcare infrastructure, and we are certain CMS' reimbursement policy will have repercussions for the future, impacting access and value.

These Medicare cuts are particularly harmful to the community-based practices that treat medically- complex patients whose conditions often put them at risk of severe health outcomes from COVID-19, and whose conditions have worsened due to delays in diagnosis and treatment as a result of the COVID-19 public health emergency. These cuts will also further exacerbate disparities in access to care and health outcomes among rural and minority populations by constraining - and in some cases preventing - these community-based practices from providing critical patient care to underserved populations. CMS is so concerned with issues

impacting health equity and yet the very policies that are proposed are creating further divide. Therefore, the Alliance is opposed to these provisions in the Medicare Physician Fee schedule which once again undermines the long-term financial viability of physician practices and patient seniors' access to critical treatments and procedures, by generating significant cuts in physician reimbursement.

C. CLARIFICATION IF CTPS SUBJECTED TO THIS DISCARDED DRUGS REQUIREMENT

Under the Infrastructure Investment and Jobs Act, beginning January 1, 2023 quarterly reports on discarded units for affected drugs, manufacturers are required to furnish a refund to CMS for discarded amounts of certain single-dose containers or single-use drugs that are single source drugs, biologicals, and biosimilar biological products – including several CTP products. The refund amount is the amount of discarded drug above a certain percentage (required to be at least 10 percent) of total charges for the drug per calendar quarter.

CMS proposes to use the current JW modifier or its successor to determine the quantity of units of a refundable single-dose container or single-use package that were discarded during the relevant quarter in order to calculate the refund amount. CMS proposes that a separate modifier – the JZ modifier – be included on claims for drugs with no discarded amounts.

In the policy provisions above related to CTPs, CMS proposes to reclassify CTPs as "supplies" – yet in this section of the policy, CMS has identified three CTP products that would be subjected to the proposed discarded drug requirements. There are inconsistencies in this proposed rule from one section to another that need to be remedied. The Alliance seeks clarification if CTPs are subject to the discarded drug requirement. If they are then CMS is classifying them as a class of products as a biologic and can not move forward stating they are a supply in another section of this proposal.

D. REMOTE THERAPEUTIC MONITORING (RTM)

The Alliance supports CMS in its efforts to expand RTM services. The ability to monitor therapeutic data should enable a wide range of use by physician and non-physician practitioners.

However, the Alliance opposes CMS' proposed reduction of payments for RTM (via the proposed a non-Facility PE RVU of 0.24 for both HCPCS G-codes GRTM3 and GRTM4) that will significantly lessen the valuation provided for CPT codes 98980 and 98981, which does not reflect the services provided by a non-physician provider under GRTM3 and GRTM4 which will not differ.

E. TELEHEALTH

There are several areas within the telehealth proposals in which the Alliance would like to comment. Specifically:

Virtual Presence/Remote Supervision: The Alliance recommends that CMS permanently allow the supervision of professionals through real-time audio/video technology across as many services as possible. We oppose CMS' proposal to discontinue virtual direct supervision at the end of the calendar year in which the Public Health Emergency (PHE) ends and urge for permanent support for expanded virtual presence/remote supervision, including for non-face-to- face care management services, remote therapeutic monitoring, and communication technology- based services.

Medicare Telehealth Services: The Alliance recommends that CMS continue its expanded support for telehealth services for the duration of the PHE, and beyond the end of the PHE to the maximum extent possible.

Audio Only Telehealth: The Alliance recommends that CMS enable permanent support for audio-only telehealth. Audio-only telehealth services during the PHE has clearly enabled better care, many of which are beneficiaries in the same underserved communities that CMS is prioritizing support for (and particularly for those who lack access to adequate connectivity to support a live video visit). Reverting audio-only telehealth to pre-PHE bundled treatment would be a disservice to the most underserved Medicare beneficiaries and contrary to its focus on health equity.

CONCLUSION

The Alliance appreciates the opportunity to provide our comments and recommends that CMS delays implementation of the CTP provisions. We continue to be very concerned about the impact on patent access as well as the detriment to patient care should any of the CTP provisions move forward as currently written. The Alliance has and continues to offer to be a resource to CMS as they navigate the very complex issues surrounding CTPs.

Thank you for your consideration.

Sincerely,

Caroline E. Fife, MD, CWS, FUHM Matthew G. Garoufalis, DPM, FASPS, FACFAOM, CWS
Alliance of Wound Care Stakeholders Co-chairs

Marcia Nusgart, R.Ph.
Chief Executive Officer

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[i] *This guide defines terminology for description of cellular and/or tissue-based products (CTPs) for skin wounds. CTPs are TEMPs (tissue-engineered medical products) that are primarily defined by their composition and comprise viable and/or nonviable human or animal cells, viable and/or nonviable tissues, and may include extracellular matrix components. CTPs may additionally include synthetic components.*
[ii] *International consensus. Acellular matrices for the treatment of wounds. An expert working group review. London: Wounds International, 2010.*
[iii] *Joint Commission Standard PC.17.10*
[iv] *Joint Commission Standard PC.17.20*

[v] *Joint Commission Standard PC.17.30*

[vi] *5 U.S.C. § 553(c) (requiring that the public be given an opportunity to comment as part of the rulemaking process).*

[vii] *See, e.g., Encino Motorcars, LLC v. Navarro, 136 S. Ct. 2117, 2126 (2016) (explaining that when making a change to an existing policy, "the agency must at least display awareness that it is changing position," "show that there are good reasons for the new policy," and "be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account") (internal quotation marks omitted); see Smiley v. Citibank (South Dakota), N.A., 517 U.S. 735, 742 (1996) (explaining that "[s]udden and unexplained change, or a change that does not take account of legitimate reliance on prior interpretation may be 'arbitrary, capricious [or] an abuse of discretion'" (quoting 5 U.S.C. § 706(2)(A)) (internal citations omitted).*

[viii] *5 U.S.C. § 706(2)(B) (requiring agency action to not be arbitrary or capricious); See, e.g., Motor Vehicle Manufacturers Ass'n v. State Farm Auto. Ins., 463 U.S. 29, 43 (1983) ("Normally, an agency rule would be arbitrary and capricious if the agency has relied on factors which Congress has not intended it to consider, entirely failed to consider an important aspect of the problem, offered an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the product of agency expertise") (emphases added).*

[ix] *See SSA § 1842(o)(1)(C).*

[x] *See SSA § 1847A(b) and (c).*

[xi] *See 87 Fed. Reg. at 46,028.*

[xii] *Reference: https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Part-B-National-Summary-Data-File/Overview*

[xiii] *Consolidated Appropriations Act, 2021*

[xiv] *Nussbaum et al, "An Economic Evaluation of the Impact, Cost and Medicare Policy Implications of Chronic Nonhealing Wounds", Value in Health Vol. 21, Issue 1, pg. 27-32 2018*

[xv] *David G Armstrong MD, PhD, DPM, MS; William H Tettelbach MD, FACP, FIDSA, FUHM, FAPWCS, CWS; Thomas J Chang DPM; Julie L De Jong MS; Paul M Glat MD, FACS; Jeffrey H Hsu MD, FACS; Martha R Kelso RN, LNC, HBOT; Jeffrey A Niezgoda MD, FACHM, MAPWCA, CHWS; Travis L Tucker MA, MBA; Jonathan M Labovitz DPM, FACFAS, CHCQM, "Observed impact of CTPs in lower extremity diabetic ulcers-lessons from the Medicare Database (2015-2018)", Journal of Wound Care, North American Supplement Vol 30, No. 7, July 2021*

[xvi] *Ibid.*

[xvii] *Ibid.*

[xviii] *Ibid.*

[xix] *Standard Guide for Classification of Cellular and/or Tissue-based Products (CTPs) for Skin Wounds. ASTM International. Current edition approved Feb15, 2022. Published March 2022 Last previous edition approved in 2016 as F3163-16DOI:10.1520/F3163-22*