ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

January 27, 2014

Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1601-FC,
Mail Stop C4-26-05,
7500 Security Boulevard,
Baltimore, MD 21244-1850

Submitted Electronically

RE: CMS-1601-FC: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Hospital Value-Based Purchasing Program; Organ Procurement Organizations; Quality Improvement Organizations; Electronic Health Records (EHR) Incentive Program; Provider Reimbursement Determinations and Appeals

Dear Administrator Tavenner:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the Hospital Outpatient Prospective Payment Final Rule with comment for CY 2014. The Alliance is a nonprofit multidisciplinary trade association of health care professional and patient organizations 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. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org.

The issuance of the final rule has and will continue to negatively impact our members significantly as products that our clinicians utilize in their practices everyday-"skin substitutes" - were included as packaged items under the final rule. We are beginning to evaluate the impact on this provision to our members—the clinical specialty societies who use these products as well as the patients who may not be able to obtain them We request to meet with your staff regarding this and some further recommendations in the second quarter of this year.

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As such we offer both general and specific comments to the final rule.

General Comments

While the Alliance understands that CMS is aware that there are some inconsistencies between what was published in the text in the final rule and the addendums, we are seeking clarification that the addendum are in fact correct. One example of many inconsistencies is regarding **Code 15275** (trunk arm leg greater than 100 Sq cm). We would like to ensure that CMS will be issuing a technical correction and utilizing the addendum information within the text of the final rule.

Specific Comments

Administrative Procedures Act

The Alliance is concerned that CMS did not follow its procedural requirements under the Administrative Procedures Act (APA) when establishing these new packaged rates. The proposed rule contained a single rate for "skin substitutes" yet in the final rule, without any way for the public to offer meaningful comment, CMS provided for a two-tier system for the packaging of these products. The change from one rate to a two - tiered system was not a logical extension of the rule and therefore violates the APA.

In 2003, Congress amended Title XVIII of the Social Security Act to include an important safeguard against abuses in the Medicare rulemaking process; the law now states that when "a final regulation includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation."[1] Furthermore, the courts have explained that a final rule is the "logical outgrowth" of a proposed rule "if interested parties 'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period."[2] By contrast, a final rule fails the logical outgrowth test and thus violates the APA's notice requirement where "interested parties would have had to 'divine [the agency's] unspoken thoughts,' because the final rule was surprisingly distant from the proposed rule."[3]

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[1] *42 U.S.C.§1395hh(a)(4).*

[2] *Northeast Maryland Waste Disposal Authority v. EPA*, 358 F.3d 936, 952 (D.C. Cir. 2004).

[3] *CSX Transp., Inc. v. Surface Transp. Bd., 584 F.3d 1076, 1080 (D.C.Cir. 2009) (citing Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin., 407 F.3d 1250, 1259-60 (D.C.Cir.2005)). See also Allina Health Services, et al. v. Sebelius, No. 10-1463 (D.D.C. 2012)*

In this case, it is quite clear that the Proposed Rule did not mention a proposal to create two groups of skin substitutes as part of the change in packaging policy or how such a distinction would be determined, nor could this plan have been anticipated by reasonable parties. As a result, this change cannot be deemed to be a logical outgrowth of the Proposed Rule. In order to comply with the law CMS must subject this proposal to a public comment period as required by the APA.

The Alliance recognizes that the packaging provisions have already gone into effect and therefore strongly urges CMS to meet with stakeholders in the second quarter of 2014 in order to hear our feedback, and recommendations for a better more equitable system so CMS can make changes to the packaging provisions in time for the issuance of the proposed 2015 regulation.

The Term "Skin Substitute" is Clinically Inaccurate and Should be Replaced with the More Inclusive Descriptor "Cellular and/or Tissue Based Products for Wounds (CTPs)".

The Alliance also is concerned with CMS using the term "skin substitutes" to describe the products being packaged within the "Skin Substitute" section of the final rule.

The Alliance recommended that CMS utilize the term "Cellular and/or Tissue Based Products for Wounds (CTPs)" when describing these products. CMS, in its response to comments, stated that "CTP" is too close to the abbreviation HCT/P that the FDA uses to refer to human cell, tissue and cellular and tissue based products – which is the regulatory pathway for only some of the skin substitutes. The Agency further acknowledged that there are differences in composition among the various products – which is why each product has its own Q code. This was the rationale for not utilizing a more scientifically and clinically accurate term.

This seems like a rather baseless reason to deny a terminology that scientists, clinicians, and other agencies believe better describe the products being utilized in the marketplace. CMS itself uses acronyms that are similar to one another – yet continue to use them. The FDA terminology for products that maintain a certain pathway should not have any bearing on whether CMS utilizes a scientifically accurate term to describe these products. Furthermore, the very rationale that CMS used to discount the term CTP also applies to the term "skin substitute". Specifically, CMS states, the term CTP is too close to HCT/Ps which is the regulatory pathway for only some of the skin substitutes. However, the term skin substitutes only accurately describes very few of the products in the marketplace. It is CMS responsibility to accurately describe the products in their payment and medical policies. The term CTP does this regardless of whether the acronym is similar to FDA terminology.

As such, we question the CMS rationale for not adopting this term and would like to recommend that CMS start using this terminology so that the term used is more scientifically and clinically accurate.

The Alliance continues to maintain that the term "skin substitute" is not a technically accurate term to describe the products in this rule nor does it describe the technology that is either currently or will be in

the marketplace. The term "Cellular and/or tissue based products for wounds (CTPs)" which does accurately describe and is broad and inclusive of both current and future technology should be utilized instead.

As stated in our original comments - in 2012, the Alliance embarked on a yearlong effort to determine an appropriate term. In order to achieve a fair and inclusive process for determining this new term, a workgroup of scientists, clinical organizations, and business entities was created from the Alliance to address this issue. Such diverse multidisciplinary clinical specialties societies as the American Podiatric Medical Association, Society of Vascular Medicine, American Society of General Surgeons, Association for the Advancement of Wound Care, American Professional Wound Care Association, American Board of Wound Management and the American Physical Therapy Association participated in this process.

The following were the criteria used to select the new term:

- be based on science
- be inclusive of all products in marketplace today with eye towards what is in the "pipeline"
- be neutral in regards to FDA--- nothing that would be offensive and not allow manufacturers to get their products approved in the future if needed
- ensure that all products are eligible for Medicare coverage as drugs and biologicals consistent with their USP monographs
- easily understood by clinicians
- easily linked to the existing CPT codes for the application of the products

The Alliance reviewed over 18 different names during this process and selected the term "Cellular and/or tissue based products for wounds (CTPs)" since it met the criteria listed above.

To reiterate our rationale: The Alliance submits that the term "skin substitute" is misleading and inaccurate to describe the products that are the subject of this rule for the following reasons:

1. The biologic products referred to in the final rule as "skin substitutes" are identified by CMS as "Q codes". These products:
    - all contain **viable or non viable cells and/or are derived from biological tissue with intrinsic biological activity;**
    - **are usually not removed from the wound,**
    - **are uniquely utilized for their biological influence on the healing process – whether they have a positive influence on the healing process without incorporation OR have the ability to stabilize or support healing through incorporation in whole or part into the regenerating tissue.** These cellular and acellular tissues or cell treatments interact with the body to enable repair, and are not usually removable. Clinicians use these products to influence stalled wounds to progress through the phases of healing to achieve complete closure.

While all of these products are utilized to achieve closure of the wound, the products themselves are different.

There appears to be a misunderstanding that these products themselves will function as a permanent replacement for the lost or damaged skin. CTPs do not function as a permanent replacement for the lost or damaged skin. This is simply incorrect. None of the CTPs currently on the market or in the development pipeline acts to fully replace skin. They do not "substitute" for skin. CTPs that are incorporated into the wound via degradation and remodeling clearly do not replace skin, but instead act by enabling repair/regeneration of the patients own skin. They provide an interactive component that stimulates the repair process in order to achieve skin closure.

There are four scientific articles which are attached as **Attachment A** that support deleting language that suggests that biologic products function as a "permanent replacement" for lost or damaged skin:

• Hu S, Kirsner RS, Falanga V, Phillips T, Eaglstein WH. Evaluation of Apligraf® persistence and basement membrane restoration in donor site wounds: a pilot study. Wound Repair Regen. 2006 Jul-Aug;14(4):427-33.

- Persistence: No persistence of Apligraf® DNA was found after week 4 (p. 429)

- Conclusion: "Apligraf® DNA persisted in a minority of patients at 4 weeks in acute partial-thickness wounds. Apligraf' s®' success in speeding healing of acute wounds appears to be related to factors other than the persistence of donor DNA or effect on basement membrane restoration."

• Marston WA, Hanft J, Norwood P, Pollak R. The efficacy and safety of Dermagraft in improving the healing of chronic diabetic foot ulcers: results of a prospective randomized trial. Diabetes Care. 2003; 26:1701-1705.

- Statement regarding degradation/remodeling of product: "Dermagraft is a bio-engineered dermal substitute that laboratory data suggest has two principal modes of action. It provides living, human dermal fibroblasts that deposit matrix proteins and facilitate angiogenesis. It also provides a preformed collagen matrix, receptors, and bound growth factors that facilitate the migration of the patients' epithelial cells that close the wound." (p1704)

• Veves A, Falanga V, Armstrong DG, Sabolinski ML. Graftskin, a human skin equivalent, is effective in the management of noninfected neuropathic diabetic foot ulcers: a prospective randomized multicenter clinical trial. Diabetes Care. 2001; 24:290-295.

- Statement regarding degradation/remodeling of product: "Living human skin equivalents (HSEs), which are produced by using tissue-engineering techniques, have been successful in treating chronic wounds, such as venous ulcers. Although their precise mode of action is not known, it is believed that they act by both filling the wound with extracellular matrix and

inducing the expression of growth factors and cytokines that contribute to wound healing." (p290-291)

• Falanga V, Sabolinski M. A bilayered living skin construct (APLIGRAF) accelerates complete closure of hard-to-heal venous ulcers. Wound Repair Regen. 1999; 7:201-207.

- Statement regarding degradation/remodeling of product: "At this point, we still do not know whether the allogenic neonatal cells of Graftskin remain in the wound and for how long. It is likely that they are able to remain in the wound for some time, at least long enough to take over and produce the right signals and substances, or long enough to instruct the resident cells and restore their own program for proper wound healing." (p206)

2. CMS, FDA and AHRQ either do not use or do not believe that the term skin substitute is correct.

- The CMS division that addresses HCPCS coding for these biologic products abandoned the term "skin substitute" effective in 2010 when a manufacturer requested that CMS delete this term since it was an incorrect descriptor. The manufacturer stated at the 2010 CMS HCPCS Public Meeting that that this language was wrong since allografts are mislabeled as "skin substitutes." Allografts differ in structure, tissue origin, and in some cases differ from biologic products in terms of how they are approved by the FDA (human skin for transplantation not devices). CMS thus changed the descriptors and eliminated the term "skin substitutes" from all of its Q codes for these items.

- The term "skin substitute" is also not used by FDA in its classification of these biologic products.

- The Agency for Healthcare Research and Quality (AHRQ), in its 2012 final draft technology assessment on skin substitutes inferred that these products were not "skin substitutes," when the Agency stated: "A true "skin substitute" would act like an autologous skin graft in adhering to the wound bed while providing the physiological and mechanical functions of normal skin. The skin substitutes included in this report contain various combinations of cellular and acellular components intended to stimulate the host to regenerate lost tissue and replace the wound with functional skin. Presumably, successful healing during management with these products would also require maintenance of a moist wound environment and other procedures thought to promote healing."

3. Finally, it is important to state that currently one of the A/B MAC contractors, Cigna Government Services) utilizes the CTP nomenclature in their LCD for these products (another AB MAC is about to release a new policy with this nomenclature) and the USP utilizes nomenclature that is in alignment with the Alliance terminology for these products. The USP refers to these products as Cell and Tissue Based Regenerative Medicine Products. The Wound Care Source book published by Kestral, as well as published articles including Today's Wound Clinic and Ostomy Wound Management, Advances in Wound Care), also uses CTPs to describe

these products. Prominent clinicians are using the term Cellular and/or Tissue Based Products for Wounds (CTPS) when speaking to their colleagues at conferences. The terminology is accurate and reflective of the products and is already being used by the clinical community when describing these products. The Alliance believes that it is important to have consistency when referring to these products as to not cause confusion in the marketplace.

Therefore, since the marketplace, your contractors and scientific publications are already using this term – we would request that CMS stop utilizing a scientifically and clinically incorrect term to describe these products and use a scientifically and clinically accurate term to describe these products. The Alliance recommends the term "cellular and/or tissue based wound care products for wounds (CTPs)". We have provided a chart of all the CTP products and their classification in **Attachment B**.

Impact Analysis

Finally, the Alliance is concerned that CMS has not analyzed the impact of packaging CTPs and the add on codes for skin substitutes on net payments for patient care and are concerned that CMS has not provided detailed information regarding the impact of these changes on payment rates or patient access.

CMS's policy to unconditionally package add-on code procedures completely undermines the AMA CPT coding framework, it does not ensure that hospitals are reimbursed for all medically-necessary services performed, and it ultimately could threaten beneficiary access to important medical services. Add-on codes are distinct clinical procedures that have been valued by the AMA independently from the primary procedure and that the AMA specifies should be listed separately, in addition to the primary procedure. CMS's packaging policy inappropriately voids the AMA's separate valuation of these codes. CMS's policy also essentially results in hospitals not being reimbursed for the additional clinical care and supplies required, including the additional amount of CTPs, that may be required when performing an add-on service, which ultimately could adversely impact patient access to these services. Specifically we are concerned that CMS has not demonstrated how it accounts for the full range of supplies and devices that may be used and/or the typical number of levels furnished to a patient in an outpatient encounter in setting the packaged APC rate.

The Alliance believes that packaging all add-on codes is an overly-broad, indiscriminate proposal that does not promote payment accuracy or advance patient care. As CMS develops the 2015 OPPS rule, we encourage CMS to reassess this policy and defer packaging of all add-on codes until further analysis is performed. Should CMS contemplate continuing packaging add-on codes in 2015, CMS should establish a clear and transparent method for identifying and reviewing add-on codes that could potentially be packaged. As part of this process, CMS should consult with the AMA CPT Editorial Panel for a determination regarding which primary CPT codes should be revised to include add-on procedures and which add-on codes should remain separate codes available for separate billing and payment as appropriate. CMS also should make publicly available more detailed data underlying payments for packaged services, including a cross-walk to utilization assumptions. As long as add-on

codes are packaged, we recommend that CMS instruct hospitals to report add-on codes and codes for all packaged items (including the correct number of units being utilized for CTPs) to ensure that all charges are included on the claims.

CMS should provide detailed information regarding the impact of packaging of add-on codes and CTPs and has to be confident that there will be no negative unintended consequences. CMS cannot assume there will be no patient harm and no patient access problems. The Alliance is concerned that there have already been significant issues impacting clinicians and product choice and CMS did not address any foreseeable impact on hospitals, clinicians, patients or manufacturers in the final rule.

For a variety of reasons, the Alliance does not agree with the APC placement or rates for the newly packaged "skin substitutes"/CTPs. We believe that the APCs that were created – along with the rates associated with them - are very low and arbitrary for the majority of the products that currently have coverage and payment. These products would have been the basis for utilization that CMS should have made their payment rate determination based upon. However, this information was not made available to the public for comment.

Of further concern, CMS can reference the ASP+6% payments from the non-hospital setting, but how will it determine a utilization-weighted mean or median for the packaged CTPs for outpatient hospital rates? And will CMS determine pricing to include non-covered products? This information also needs to be made available to the public for comment.

The Alliance would also like to recommend that CMS conduct an impact analysis. As stated above, we would also like to request a meeting with CMS staff in the second quarter of 2014 to identify the impact on our members and Medicare beneficiaries and address recommendations.
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We appreciate the opportunity to comment on this final rule with comment period. The Alliance would welcome the opportunity to work with CMS to help establish more appropriate and equitable APC's for these CTP products. If you need more information or have any questions, please do not hesitate to contact me. The Alliance would be happy to serve as a resource to CMS.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director