COALITION OF
Wound
Care
Manufacturers

September 6, 2013

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

Submitted Electronically

RE: CMS-1601-P: 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 Coalition of Wound Care Manufacturers ("Coalition"), we are pleased to submit the following comments in response to the Hospital Outpatient Prospective Payment Proposed Rule for CY 2014. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those products that are subject to this proposed rule. The Coalition appreciates the opportunity to offer our comments.

General Comments

As a procedural matter, the Coalition is concerned that CMS did not follow their procedural requirements when establishing these new packaged rates. CMS is required to meet with outside experts – a Hospital Outpatient Panel ("HOP") - on the clinical integrity of the APC groups and weights – so that CMS can consider the technical advice provided by the Panel as proposed and final rules are prepared. While we understand that CMS finally held a public meeting on August 26, 2013 to discuss the HOPPS packaging requirements – among other provisions – CMS should have consulted with the HOP panel before the proposed rule was issued and not after the fact so that their advice could have been considered before developing these proposals. The Coalition is pleased that the HOP panel met before the final rule however, and urges CMS to follow one of the recommendations of the panel. Specifically, the Panel recommended that CMS delay the implementation of the CY 2014 proposals regarding comprehensive APCs, expanded

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packaging, visit reconfiguration, and cost center based reimbursement changes for computed tomography (CT) and magnetic resonance imaging (MRI) until data can be reviewed by the Panel at its spring 2014 meeting regarding interactions between the proposals and their potential cumulative impact.

Furthermore, the Coalition is concerned with CMS using the term "skin substitutes" since it is not a clinically accurate term and does not describe the technology that is either currently or will be in the marketplace. Instead, the Coalition recommends that CMS adopt 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. A clinical, non-profit, multidisciplinary association (the Alliance of Wound Care Stakeholders) – of which the Coalition is a non-voting business entity member - recently voted positively on the adoption of this term – and we agree with the new term as it describes these products more accurately. As a result, as mentioned above, we will be using the acronym "CTPs" when referring to Cellular and/or tissue-based products for wounds in this document.

Specifically, we believe that the term "skin substitute" is misleading and inaccurate to describe the products that are the subject of this LCD for the following reasons:

1. This term is not used by either regulatory agency--FDA in its classification of these biologic products nor by CMS in its coding descriptors.

2. 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.

3. In addition, 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."

Based on the information provided above, the Coalition recommends that CMS consider changing their nomenclature to describe these products in the future, as the current term – skin substitutes – is misleading.

The Coalitions specific comments follow. Our comments and concerns are mostly focused on the skin substitute provisions that are included but may not be limited to pages 43571-2, 43604 and 43703 of the proposed rule.

Specific Comments

1. Reconfiguring APCs

Issue: The proposed regulation includes a proposal to convert 29 device-dependent APCs into "comprehensive APCs" that would encompass the procedures billed with the device dependent APC along with any other charges that would typically appear on a claim associated with the APC. A change from device-dependent APCs to the proposed comprehensive APCs represents a significant shift from how APCs are developed and paid. The Coalition is concerned about the potential impact that this change to comprehensive APCs could have on payment rates and on the ability of patients to continue to receive the technology and care that they required.

We are also concerned that the proposed rule includes little information regarding the impact of this significant change or the criteria that CMS will use to establish payment rates of the comprehensive APCs. This lack of information makes it difficult to provide meaningful comments on this portion of the proposed rule.

Furthermore, the proposed rule includes a recommendation to eliminate procedure-to-device and device-to-procedure edits for all APCs. The rule however does not include any information to suggest that the problems that led to the creation of the device edits, no longer persist. Device edits have been very useful historically in ensuring the collection of accurate cost data. The Coalition is concerned that the elimination of these edits, especially in an environment of increased bundling, will jeopardize data accuracy.

Recommendation: The Coalition recommends that CMS provide all necessary data and other information to the public related to the proposed comprehensive APCs allowing for the development of meaningful comments by stakeholders. We also recommend that CMS maintain the device edits in CY 2014 to ensure continued accuracy of the data reported by hospitals and captured by CMS.

2. Packaging Items and Services into APCs

Issue: The Coalition is extremely concerned that CMS is proposing new packaging policies without providing detailed information regarding the impact of these changes on payment rates or patients access. The payment development process for packaged procedures is not transparent and may lead to inappropriate payments and could compromise patient access to high quality care. The Coalition believes that CMS should provide this information and should ensure the accuracy of the data on which packaging decisions are based.

Recommendation: The Coalition recommends that CMS delay the implementation of these provisions until CMS can provide detailed information on the impact that these changes will have on the payment rates as well as on patient access.

3. FDA Framework to Justify Packaging of Skin Substitutes is Erroneous

Issue: In the Proposed Rule, CMS states that "*many skin substitutes are classified by the FDA as wound dressings, which make them the same or similar to surgical dressings that are packaged under §419.2(b) (4)".*

None of these CTP products are wound dressings. All of these products are CTPs and should be separately payable**.** The FDA published the "Proposed Approach to the Regulation of Cellular and Tissue-Based Products" on February 28, 1997. This document described FDA's planned regulatory framework for human cellular and tissue product regulation. Subsequently, FDA put this framework in place through publication of a series of proposed and final rules. The Interim rule was made final, with some modification, on July 29, 1997, now Title 21, Code of Federal Regulations (21 CFR) Part 1270.1.

In developing the regulatory framework for HCT/P products, the FDA considered the long history of clinical use of tissue products and the existing body of clinical evidence for minimally manipulated human tissue. Based on this body of evidence, the FDA determined that these products were safe and effective when minimally manipulated, intended for a homologous use, not combined with other articles and do not have a systemic effect. Most of the CTP products meet these criteria; therefore, the FDA considers them to be safe and effective when they are procured, processed, stored and delivered to clinicians for use in accordance with FDA regulations and guidelines.

Tissues that are manipulated such that their biological characteristics or relevant functions are altered, that are used for purposes other than those they normally perform, that are combined with non-tissue components, or that are used for a metabolic purpose generally are subject to more comprehensive regulatory requirements than other tissues. Such products would be regulated as biologics or devices subject to premarket approval. Sponsors of such products would have to provide submissions to the agency documenting use of processing controls aimed at ensuring clinical safety and effectiveness, and submissions of clinical trial data demonstrating safety and effectiveness.

All currently covered products are regulated by the FDA as HCT/Ps. Some of the products - because they contain animal and synthetic materials and because their human cells that are more than minimally manipulated - must undergo additional regulation by the FDA through the Premarket Approval process to demonstrate safety and efficacy. Many of the other HCT/Ps has also demonstrated safety and efficacy through clinical trials that have been conducted. But these products did not need to go through the PMA process based on the level of their manipulation. The products described in this section of the proposed rule are not fungible; in fact, they vary widely in terms of biological activity, cellularity, and clinical use but they all have active biologic agents that stimulate wound healing.

Notwithstanding how some of these products may be classified by the FDA, those skin substitutes that have USP monographs or are recognized as biologicals on hospital formularies meet the statutory definition of a biological under §1861(t)(1) of the Social Security Act.[1] This section does not distinguish among products that may be cleared as devices under Section 510(k) of the FFDCA, approved as devices under Section 515 of FFDCA (pre-market approval), or marketed as human cells, tissues, or cellular and tissue-based products under Section 361 of the PHSA.

Rather than focusing on the regulatory classification by FDA, which we would argue is impermissible under the Soc. Sec. Act, we would recommend that CMS: (1) treat as separately payable biologicals all products that meet the Soc. Sec. Act definition of biological by having USP monograph status or formulary status at hospitals, and (2) use the framework provided to CMS by the Alliance of Wound Care Stakeholders that distinguishes cells and tissue-based products for wounds from synthetic meshes and surgical dressings.

Recommendation: The Coalition recommends that none of these products should be packaged. All of these products are CTPs and considered, by definition, as biological. As such they should all be separately payable items based on the statute.

4. CTPs Are NOT Wound Dressings

Issue: CMS makes a number of erroneous assumptions and statements in this proposed rule to justify CTPs being a "supply" and therefore eligible for packaging. CMS states on page 43571 of the proposed rule, "*Although the term "skin substitute" has been adopted to refer to this category of products in certain contexts, these products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are various types of* ***wound dressings*** *(emphasis added) that through various mechanisms of action stimulate the host to regenerate lost tissue and replace the wound with functional skin"…Because a skin substitute must be used to perform any of the procedures described by CPT code in the range 15271 through 15278 and conversely because it is the surgical procedure of treating the wound and* ***applying a covering*** *(emphasis added) to the wound that is the independent service,* ***skin substitute products serve as a necessary supply*** *(emphasis added) for these surgical repair procedures. In addition, many skin substitutes are classified by the FDA as wound dressings which make them the* ***same or similar to surgical dressings*** *(emphasis added) that are packaged under 419.2 (b)(4)."*

It is inaccurate to describe the devices/products identified in this proposed rule as "wound dressings" since this term is neither used by CMS or FDA to describe these biologic products. These products are not "covers", "biologic wound dressings" "wound

[1] §1861(t)(1) "The term 'drugs' and the term 'biologicals', except for purposes of subsection (m)(5) and paragraph (2), include only such drugs (including contrast agents) and biologicals, respectively, as are included (or approved for inclusion) in the United States Pharmacopoeia, 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 approved by the pharmacy and drugs therapeutic committee (or equivalent committee) of the medical staff of the hospital furnishing such drugs or biologicals for use in such hospital." This definition makes no reference to the status of these products under FDA.

dressings" or "surgical dressings" in function or technology. CTPs 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 and are uniquely utilized for their biological influence on the healing process. These cellular and acellular tissues or cell treatments interact with the body to enable repair. 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.

On the other hand, wound dressings or surgical dressings are materials that are utilized for covering and protecting a wound from contamination, and for managing the wound condition such as exudate, necrotic tissue or excess dryness. Wound dressings are even utilized to protect CTPs after they are applied.

In addition, CMS makes a distinction between these two products in both their coding and coverage policies by classifying CTPs as "Q codes" and surgical dressings as "A codes".

CMS also states in the proposed rule *"In addition, many skin substitutes are classified by the FDA as wound dressings which make them the **same or similar to surgical dressings** (emphasis added) that are packaged under 419.2 (b)(4)."*

The FDA does use the term "dressing" as a product code to describe many of the CTPs—however, this terminology has a different meaning when the FDA uses the term versus when CMS uses it in its coding and coverage policies due to their unique regulatory processes. As stated above, both the FDA and CMS have distinct terminology, definitions and classification systems for CTPs and surgical (wound) dressings and cannot be used interchangeably.

CMS states that skin substitutes described by CPT codes 15271-15278 do not function like human skin that is grafted onto a wound and instead are various types of wound dressings that stimulate the host to regenerate lost tissue and replace the wound with functional skin. The Coalition strongly disagrees with this assessment.

In fact, in 2012, the AMA CPT Editorial Panel, and several medical associations' worked to develop new skin substitute CPT codes. As a result, codes 15271-15278 were created to describe the work of placing skin substitute grafts. A new subheading called "definitions" was added to the CPT manual that provides a more thorough explanation of surgical preparation, autografts/tissue cultured autografts, and skin substitute grafts. CPT states that skin substitute grafts include non-autologous human skin (dermal or epidermal, cellular and acellular) grafts (such as homograft, allograft), non-human skin substitute grafts (for example, xenograft), and biological products. **CPT explicitly states that codes 15271-15278 are not used to report the application of non-graft wound dressings** (e.g., gel, ointment, foam, and liquid) or injected skin substitutes.

The Coalition submits that the definitions in the CPT manual accurately represent the use of codes 15271-15278 and CMS's assumption that "these products are various types of wound dressings," is inaccurate.

Recommendation: The Coalition urges CMS not to implement these inaccurate definitions of skin substitutes and to review the CPT definitions and guidelines for the use of these codes and the products associated with them. CTPs are not "wound dressings or coverings". As such we recommend that CTPs continue to be classified as separately payable items.

5. CTPs Are NOT Implantable Biologicals

Issue: CMS erroneously states, "*implantable biological products are very similar to (and in some instances the same as) skin substitute products, except that the clinical applications for implantable biological are typically an internal surgery versus the application to a wound for a skin substitute. Some products have had or have dual uses as both skin substitutes and implantable biological, which underscores the similarity of these sometime overlapping classes of products. Implantable biological and skin substitutes both function as supplies or devices that are used in surgical procedures and therefore should be packaged with the surgical procedure in which the products are used. We see no reason to distinguish skin substitutes from implantable biological for OPPS packaging purposes based on the clinical application of individual products".*

The Coalition strongly disagrees with CMS. CTPs are not implantable in that they are not inserted through an incision or into a natural body orifice. They are applied topically after the wound bed is properly prepared. The AMA recognized this distinction by creating a separate CPT code for the application of implants.

There are additional differences between CTPs and implantable biological including the following:

1. Implantable biologicals provide specific physiologic functions, which are different and distinct from CTPs such as:
    - an anti-inflammatory response
    - prevent tissue or structure 'adhesions' which can delay repair and/ or causing scarring with resultant functional loss
    - provide a scaffold for the movement of new blood vessels, nerves, ligaments and other structures in and around the operative site

2. Implantable biologicals are wrapped or applied (injected) near or over a structure (bone, tendon, ligament, muscle, nerve) to provide an immediate anti-inflammatory response and to act as a barrier to the development of adhesions. Once applied onto or around the internal structure or at the repair site during a specific surgical operation (spinal, orthopedic, hernia repair, breast reconstruction), the operative site is then surgically closed. They are not intended to develop full cellular layers of skin as an outer structure of the body.

3. CTPs are cellular and acellular, human tissue based or non-human tissue based. They may have active epidermal and/ or dermal cells, have collagen or polysaccharide layers, may be cryopreserved or irradiated to retain the growth factors and other key components which can stimulate the production of cells for the repair of outer skin. The material sources are widely varied, the processing is widely varied, their shelf

life is widely varied, their indications vary and frequency of application varies. CTPs are dispensed as a sterile, prepared (thawed, reconstituted or hydrated for application) sheet of biological material, not in a centimeter (cm) multi-use package or vial. They come in various sizes and cannot be 'saved' for multiple applications, such as a drug in a multi-use vial.

Recommendation: Since CTPs and implantable biologicals are distinct from each other, we recommend that CTPs should not be packaged in the surgical procedures in which the products are use and should continue to be separately payable items.

6. Skin Substitutes Should Not Be Packaged – They Are Separately Payable Items

I**ssue**: CMS proposes to package all skin substitutes. CMS erroneously believes that these products function as supplies. As a member of the Alliance of Wound Care Stakeholders ("Alliance"), the Coalition would like to go on record that we are in agreement with the longer and more detailed legal arguments presented by the Alliance in their comments to CMS on this provision. Specifically, the Coalition questions CMS's authority to unconditionally package one category of biologicals because CMS believes that these product function as supplies or devices when used in a surgical procedure. The Coalition urges CMS to determine that these products should be reimbursed consistent with specified covered outpatient drugs (SCODs) or biologicals with daily costs that exceed the packaging threshold.

The Coalition believes that CTPs should continue to be separately payable. It is our opinion that these products meet the statutory definition of a SCOD and thus are subject to specific statutory payment provisions. The proposal to package CTPs is inconsistent with the statute and Congressional intent and will harm access to appropriate CTPs and therefore the Coalition urges CMS not to package these products.

Congress did not intend for CMS to circumvent the statutory payment provisions for SCODS by packaging entire classes of therapies. Where Congress allows CMS to package drugs and biologicals – they did so based on cost and not on function. To package these products based on function would render the statute's explicit payment instructions meaningless.

Recommendation: The Coalition therefore strongly recommends that CMS make separate payment at ASP +6% for all of these CTP products, as it does for other SCODs and drugs and biologicals treated as SCODs.

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In summary, the Coalition has significant concerns with the proposed rule and specifically with the packaging of skin substitutes and add on codes for the skin grafting procedures as written.

The Coalition recommends that CMS not proceed with its proposal to package CTP ("skin substitute") products as well as add-on procedures for application of these products to larger wounds. The Coalition believes a decision to package CTPs and add on codes

for CTPs is premature and may be harmful. We urge CMS to reconsider its proposal and encourage the Agency to work with all wound care stakeholders to address concerns CMS may have about potential incentives for overutilization or overpayment for CTP products.

Furthermore, the Coalition recommends that CMS continue to treat CTPs as separately payable biologics at ASP plus 6 percent.

On behalf of the Coalition of Wound Care Manufacturers, we appreciate the opportunity to submit these comments. If you have any questions of would like further information, please do not hesitate to contact me.

Sincerely,

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