ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

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 Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the Hospital Outpatient Prospective Payment Proposed Rule 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.

Our comments and concerns are regarding skin substitutes which are included but may not be limited to pages 43571-2, 43604 and 43703 of the proposed rule. We appreciate the opportunity to have met with Director McInnes and his staff to discuss our concerns regarding recently. We have sent him under separate cover the answers to the questions that he and his staff brought up during our meeting. Except for certain proprietary information, the remaining information is also contained in our comments below. We recognize that CMS is concerned about current payment policies and potential incentives toward inappropriate utilization of some skin substitute products. We also realize the need to protect beneficiaries and the Medicare trust fund. Our concerns revolve around how the approach CMS is taking might impact patient care. The Alliance is willing to serve as a resource to CMS as the Agency moves forward to address alternative solutions to the issues at hand.

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In addition, we understand that CMS has made technical corrections to the proposed rule. Since there has not been sufficient time for us to review them, we reserve the right to revise our comments should these technical corrections impact any of our statements or recommendations.

Comments

The Alliance will describe in detail below our concerns with the proposed rule. As a technical matter, the Alliance has concerns with CMS's using the term "skin substitutes" or "wound dressings" to describe the products being packaged within the "skin substitute" section of the proposed rule. We submit that "skin substitutes" is not a clinically accurate term to describe the products in this proposed 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 such, we will be using the acronym "CTPs" when referring to Cellular and/or tissue-based products for wounds in this document. We recognize, however, that since skin substitutes is the term CMS has used for code descriptors and in its rulemaking, CMS may be continuing, at least in the near-term, to use the term skin substitutes.

Our comments center around the following issues:

1. "Skin Substitutes" (CTPs) must continue to be separately payable
2. CMS's data could not be replicated
3. CMS would create serious financial impact in the wound care community by packaging CTPs and add-on codes
4. CTPs are not clinically comparable to wound dressings or wound supplies
5. CTPs are not clinically comparable to implantable biological products
6. CMS should not use the FDA framework for CTPs to justify exclusion from the packaging provision
7. CMS should consider adopting the more clinically accurate term "CTPs" in place of "skin substitutes"
8. CMS did not follow appropriate procedural requirements when establishing these new packaged rates

1. "Skin Substitutes" (CTPs) Must Continue to Be Separately Payable

a. CMS Lacks the Statutory Basis to Package Skin Substitutes

The Alliance questions CMS's authority to unconditionally package one category of biologicals because CMS believes these function as supplies or devices when used in a surgical procedure. The Alliance 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 Alliance strongly urges CMS to reconsider its legal authority to package skin substitute biologicals. Packaging of these products is not consistent with congressional intent when it instructed CMS on the method of payment for former pass-through drugs and biologicals by enacting Section 621 of the Medicare Modernization Act (MMA), which added paragraphs 14 and 15 and subparagraph 16(B) to Section 1833(t) of the Social Security Act.[1]

In order to understand CMS's legal authority regarding packaging of drugs and biologicals, it is important to consider the history of payments for drugs and biologicals under the Outpatient Prospective Payment System. When OPPS was first implemented, Congress required that CMS pay separately for 4 categories of drugs and biologicals: (1) current cancer chemotherapy agents, (2) current orphan drugs, (3) current radiopharmaceuticals, and (4) new drugs (those not paid as a hospital outpatient service before January 1, 1997). These products were to be paid at 95-percent of average wholesale price (AWP) for a period of at least 2 but not more than 3 years.[2]

As OPPS was first implemented in August 2000, the first group of pass-through products "graduated" from pass-through status beginning January 1, 2003. CMS continued to pay separately for these drugs and biologicals as long as the cost exceeded the packaging threshold of $150. However, there were serious concerns about the payment rates implemented in January 2003 for former pass-through drugs and biologicals. Instead of tying payments to publicly available reference data like the pricing compendia, as had been the case during the pass-through period, CMS used hospital charges reduced to estimated costs via cost-to-charge ratios to set the payment rates for those drugs that were formerly pass-through drugs and biologicals. For many products, the estimated costs based upon hospital charges were substantially below costs. In fact, in the Final Rulemaking for CY2004 OPPS (published before the Medicare Modernization Act was enacted), CMS acknowledged that manufacturers of several products had provided credible data based upon actual hospital sales data showing that the CMS estimated costs were substantially below costs.[3]

To assure that payments would be sufficient to cover hospital acquisition costs for the former pass-through products, Congress enacted Section 621 of the MMA adding paragraphs 14 and 15 and subparagraph 16(B) to Section 1833(t) of the Social Security Act. These paragraphs must be read in their entirety and in the context of OPPS payment policies in effect in 2003 to understand at what Congress was aiming. Specifically, at the time Congress added paragraphs (14) and (15) and subparagraph 16(B) to Section 1833(t), there were 2 categories of pass-through drugs whose payment Congress needed to address: (1) former pass-through drugs and biologicals whose pass-through status expired as of January 1, 2003; (2) ongoing or new pass-through products—i.e., new drugs that were not part of the initial pass-through pool in August 2000, and which were being paid as pass-through products on or after January 1, 2003.

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[1] Section 621 of the Medicare Modernization Act. H.R. Rep. No. 108-391. At 247-252 (Section 621 included additional amendments to section 1833(t).

[2] Soc. Sec. Act 1833(t)(6). *See* 65 Fed. Reg. 18,434, 18,478-82 (Apr. 7, 2000). Separate payments were made at 95-percent of average wholesale price offset by the amount, if any, of payment for the product in the associated administration service. In addition, the overall pass-through pool was capped at a fixed percentage of OPPS payments. In addition, for new drugs and biologicals to be eligible for pass-through status, aside from meeting the newness criterion of not having been an outpatient hospital service before January 1, 1997, the cost of the product had to be "not insignificant in relation to the payment for the APC to which it was assigned."

[3] Medicare Program; Changes to the Hospital Outpatient Prospective Payment System and Calendar Year 2004 Payment Rates, 68 Fed. Reg. 63,398, 63,447 (Nov. 7, 2003).

At the time the MMA passed, the concern with payment was with the first category—former pass-through drugs and biologicals that were being paid in 2003 based upon hospital charges reduced to estimated costs where there was evidence that many of these products were being paid below hospital acquisition cost. Then current pass-through products were being paid under the pass-through rules at 95-percent of AWP, so there were no concerns about the adequacy of payment or impact on access for those products.

Congress addressed 3 key concerns about payment for separately payable drugs and biologicals in Section 621 of the MMA: (1) assuring that the former pass-through products would be paid based upon hospital acquisition costs or, if such data were not available, at the same rate as the drugs and biologicals are paid in the non-hospital setting, (2) establishing a basis for payment of new drugs and biologicals before pass-through applications could be reviewed and approved, and (3) establishing a threshold for packaging that was lower than the $150 threshold CMS had adopted by rulemaking prior to the MMA. Paragraph 14 addressed the first concern, paragraph 15 addressed the second concern, and subparagraph 16(B) addressed the third concern.

Relevant for the skin substitute biologicals are paragraphs 14 and 16(B), which are discussed below.

b. Soc. Sec. Act Section 1833(t)(14) Was Intended to Establish a New Payment Methodology for Drugs and Biologicals that Were Separately Paid in 2003 Following "Graduation" from Pass-through Status

As explained above, the key concern which paragraph 14 addressed was the adequacy of payment for separately payable drugs and biologicals—those drugs that had been pass-throughs as current chemotherapy drugs, current orphan drugs, current radiopharmaceuticals, or new drugs first paid as hospital outpatient services between January 1, 1997 and August 1, 2000. Those drugs were being paid separately as long as their costs exceeded a threshold of $150 per claim, but rates were frequently below costs because these were based upon hospital charges reduced to estimated costs using department-wide cost-to-charge ratios. Congress required that the Comptroller General conduct surveys in 2004 and 2005 to determine hospital acquisition costs for these drugs, which Congress identified by the newly coined terminology "specified covered outpatient drugs" ("SCODs"). Congress instructed CMS to conduct such surveys thereafter. Payment was then to be based upon hospital acquisition costs determined under such surveys, or if hospital acquisition costs were not available, then under the payment method applicable in the non-hospital setting (i.e., ASP+6% under Soc. Sec. Act 1842(o) and Soc. Sec. Act 1847A or the now defunct competitive acquisition program for Part B drugs and biologicals under Soc. Sec. Act 1847B).

Congress's intent was revealed clearly in the Report of the Committee on Ways and Means on the MMA. Specifically, the report explains that the reason for the provision was to adjust reimbursement because of "significant problems with the reimbursement for drugs and biologicals under the hospital outpatient system."[4] Most notably, the House Report highlights the issue of charge compression, and the fact that hospital charges cannot capture the costs for specific items. As such, Section 621 was designed to create a "level playing field" for reimbursement of SCODs.[5]

[4] H.R. REP. NO. 108-178, pt. 2, at 229 (2003).
[5] *Id.*

c. Although Not Drafted Clearly, the Definition of SCODs Was Not Intended to Limit the Scope of Separately Payable Drugs and Biologicals to Products Paid as Pass-throughs Before January 1, 2003

We agree that the definition of SCODs in paragraph 14 was not crafted clearly. First, insofar as SCODs included drugs paid as pass-throughs before January 1, 2003, then ongoing pass-through drugs and biologicals which had not graduated out of pass-through status as of January 1, 2004 were subject to conflicting payment policies under the SCOD rules and the pass-through rules. CMS appropriately continued to pay such drugs as pass-throughs in January 2004. Moreover, the 2005 cost acquisition survey described above explicitly refers to two of the skin substitute products covered under this proposed packaging policy as distinct and separate categories of SCODs. Finally, by limiting the SCOD definition to those products that were pass-throughs prior to January 1, 2003, the definition did not explain how CMS was to pay for current or future pass-through drugs and biologicals once those products graduated from pass-through status.

Although Congress did not provide clear instructions as to how products first paid as pass-throughs on or after January 1, 2003 were to be paid after the enactment of the MMA, it is clear that it was not Congress's intent that these products would be eligible for packaging if they exceeded the threshold for packaging. The reason CMS excluded from the definition of SCODs those products that were new on or after January 1, 2003, was because Congress did not want to provide conflicting payment instructions to CMS for those products. For new products introduced on or after January 1, 2003, Congress instructed CMS to pay either at 95-percent of AWP, prior to obtaining approval as pass-through, or at ASP+6% following approval as a pass-through. If Congress had included these drugs under the definition of SCODs, there would have been conflicting instructions for payment—i.e., payment under the SCOD rules and payment under the pass-through (or pre-pass-through) rules. For that reason, the definition of SCODs specifically included products that were paid as pass-throughs prior to January 1, 2003 and excluded products paid as pass-throughs after January 1, 2003.

Congress did not need expressly to say that drugs then eligible for pass-through were to be paid separately beginning in 2004 because all new drugs and biologicals were separately payable as pre-pass-through or as pass-through drugs and biologicals. Congress probably should have clarified that these drugs would remain separately payable once they graduated from pass-through after January 1, 2004, but it is not surprising that Congress did not think to do so because, at that time, CMS's packaging policy was limited to drugs exceeding a cost threshold—then $150. CMS was not picking and choosing among categories of drugs and biologicals and policy packaging whole categories without regard for the cost threshold. Remember that paragraph 14 was addressing a problem with the method by which CMS was setting payment for those drugs it was paying separately. Since at the time, CMS was not policy packaging categories of products that had been paid as pass-throughs previously, there was no consideration that Congress needed to specify that then and forevermore products paid as pass-throughs would remain separately payable as long as they exceeded a cost threshold—that was simply not an issue in 2003.

In fact, Congress did acknowledge the policy to threshold package drugs and biologicals by reducing the packaging threshold to $50 for 2005 and 2006 under paragraph 16(B). Again, although Congress probably should have made it clear that it intended for CMS to implement only threshold packaging for drugs and biologicals coming off pass-through after January 2003, Congress would not have thought to

add that to the amendments made by MMA Section 621 because CMS did not propose at that time packaging policies that would package an entire category of drugs and biologicals that previously were eligible for separate payment as pass-throughs.

d. To Identify the Scope of SCODs Under Paragraph 14, One Must Read the Paragraph in its Entirety—Not Simply Focusing on the Definition in Subparagraph (B)

The SCOD definition in subparagraph B (Soc. Sec. Act 1833(t)(14)(B)) identifies eligible products by reference to the definitions of covered outpatient drugs under Soc. Sec. Act 1927(k)(2) (i.e., under the Medicaid Drug Rebate Law). Under Soc. Sec. Act 1927(k)(2), covered outpatient drugs include prescription drugs approved under a New Drug Application (section 505 of the Federal Food, Drug and Cosmetic Act [FFDCA]) and biologicals approved under a Biologics Licensing Application (section 351 of the Public Health Service Act [PHSA]). Skin substitute biologicals are cleared or approved by FDA either as medical devices (section 510(k) or 515 of the Federal Food, Drug, and Cosmetic Act) or as human cells, tissues, or cellular and tissue-based products (under section 361 of the PHSA). Therefore, looking strictly at the definition of SCODs under subparagraph B, one would conclude that skin substitute biologicals are not SCODs.

However, other parts of paragraph 14, which also refer to SCODs, define biologicals by reference to Soc. Sec. Act 1861(t)(1) (i.e., the definition of biologicals under Medicare Part B). In subparagraph A, Congress instructs CMS how to pay for SCODs in 2004 and 2005—the period before the anticipated GAO surveys would be available. In that subparagraph, Congress provides different instructions for setting payment for sole source drugs, innovator multiple source drugs and noninnovator multiple source drugs. These terms are defined in subparagraph F. Specifically, the definition of sole source drugs under subparagraph F is:

> *''(F) CLASSES OF DRUGS.—For purposes of this paragraph:*
> *''(i) SOLE SOURCE DRUGS.—The term 'sole source drug' means—*
> *''(I) a biological product (as defined under section 1861(t)(1)); or*
> *''(II) a single source drug (as defined in section 1927(k)(7)(A)(iv)).*

When referring to payment for SCODs in 2004 and 2005, Congress makes it clear that the reference for identifying biological products as sole source drugs is Soc. Sec. Act 1861(t)(1)—not Soc. Sec. Act 1927(k)(2). Congress could have been more artful in drafting the definition of SCODs under subparagraph B, but if it intended for biologics to be limited to products under BLAs, it would not have needed to define biologicals under Soc. Sec. Act 1861(t)(1) as sole source drugs. Soc. Sec. Act 1861(t)(1) defines biologicals by reference to their status in the U.S. Pharmacopoeia or on hospital formularies—not by reference to approval under Section 351 of the Public Health Service Act.

Therefore, when looking at paragraph 14 as a whole, it seems clear that Congress considered biologicals to be those products meeting the definition under Soc. Sec. Act 1861(t)(1). Most cellular and tissue-based products for wounds (CTPs) that currently are covered have USP monographs, which is why they are covered and paid as biologicals in both the non-hospital and hospital settings.

In summary, Section 621 of the MMA amended Soc. Sec. Act Section 1833(t) by adding paragraph 14 to assure that those products which had been paid as pass-throughs between August 2000 and December 31, 2002 would be paid at rates sufficient to cover hospital acquisition costs. Congress set forth a

mechanism for payment based upon AWP in 2004 and 2005 and by surveys of hospital acquisition cost or manufacturer-reported ASPs in 2006 and beyond. In defining those products that had been pass-throughs prior to 2003, Congress identified biologicals under Soc. Sec. Act Section 1861(t)(1), which includes CTPs with USP monographs or established hospital formulary status. In addition, Congress assured that those products that were new products after August 2000 would continue to be paid separately as pass-through products for 2 to 3 year periods under the pass-through payment methodology. Here too, CTPs substitute products meeting the definition of biologicals under Soc. Sec. 1861(t)(1) were assured separate payment. Although Congress could have been clearer that it intended for then current or new pass-through products (those paid as pass-throughs on or after January 1, 2003) to be paid following graduation from pass-through using the same SCOD methodology as it instructed the pre-2003 pass-through products to be paid, it is not surprising that Congress did not specify this precisely. At that time CMS was paying separately for pass-through products once these graduated from pass-through as long as products exceeded the cost threshold for packaging, which Congress reduced for 2005 and 2006. Congress did not need to override or preclude policy packaging of categories of drugs and biologicals because CMS had never suggested that it would implement such policies. Previously pass-through drugs were paid separately, it was simply that the rates were inadequate, and Section 621 sought to correct that by adding paragraph 14 to Section 1833(t).

2. **CMS's Data Could Not Be Replicated**

A thorough analysis of the data for each product and procedure is needed to verify that CMS's data and methodology are appropriate. The Alliance and its member organizations, along with many other patient and clinical organizations are not able to replicate the data. In fact, the American Association for Wound Care Management (AAWCM) attempted to replicate the CMS packaged payment rates for CPT codes 15271, 15273, 15275 and 15277 and they were unable to do so. In order to provide substantive comments on the rates and the proposals contained in this proposed rule, the data needs to be replicated – which we were unable to do.

We are in agreement with one of the final recommendations of the Advisory Panel on Hospital Outpatient Payment which stated:

The Panel recommends that CMS delay implementation of the CY 2014 proposals regarding comprehensive APCs, expanded 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.

As such, the Alliance recommends that CMS delay the implementation of this proposed rule for at least a year to allow stakeholders adequate time to analyze the accuracy and appropriateness of these substantial changes. Otherwise, these dramatic changes could create uncertainty for hospitals and disrupt Medicare beneficiaries' access to high quality wound care.

3. **CMS Would Create Serious Financial Impact in the Wound Care Community by Packaging CTPs and Add-On Codes**

Packaging of Application Product Codes and Add On Codes

As noted above, AAWCM attempted to replicate the CMS packaged payment rates for CPT codes 15271, 15273, 15275 and 15277 and were unable to do so. We believe CMS relied on problematic claims data which were further subjected to a 44% discount because CMS used flawed mean cost data. We are deeply concerned the resulting proposed rate could cause serious clinical impact on patient care and healing outcomes because of restricted access to CTPs, should this rule be implemented as written.

Financial Modeling

AAWCM member companies manage over 730 wound care centers. They conduct education sessions with their hospital based wound centers partners to ensure claims are coded appropriately, and conduct audits of hospital claims to validate correct and appropriate billing. Using data from member companies, AAWCM modeled out several representative claims for the three most commonly used products in wound care centers; Apligraf, Dermagraft, and Oasis. The claim examples evaluated the impact of the proposed rule on a 25 sq. cm wound, 30 sq. cm wound, which included an add-on code, and 100 sq. cm venous and diabetic wounds.

Their analysis found that patients with small wounds (25 sq. cm) would be denied access to all but four skin substitute products. The access problem was further amplified with larger wounds -- the packaged payments for wounds greater than 100 sq. cm eliminated a clinician's ability to use any skin substitute unless the hospital sustained a financial loss.

The claims submitted from the majority of AAWCM member hospitals reflect their modeling. However, in the course of working with hospital based centers across the country, AAWCM members are aware of many potential gaps in the data that would negatively impact the claims data used in the CMS analysis. Those gaps include:

- *Failure to use outpatient edits:* For unclear reasons, some hospitals use the IOCE edits, instead running CTP claims through the *inpatient* edits. As a result, these claims are processed inaccurately.
- *Inability of hospital billing software to report quantities greater than "1"***:** Many hospital based outpatient clinics have a high incidence of CERT errors in *quantity reporting*. Hospital billing software is not flexible with regard to the differences between charge entry and billing. When service units (e.g. 44 or 38) must be entered, they are billed out as "1" unit instead of the appropriate unit.
- *Confusion regarding the way to report amount of product used and wasted*: The fact that these products do not have a standard SIZE contributes to the problem. CMS data can be significantly skewed by several big issues including:
    - *Under reporting the total amount used*: Some facilities report only a unit of "1" for the entire product, even when purchasing a product which comes in 38 or 44 cm2 sizes.

- *Not reporting wastage*: Some facilities report only the number of centimeters used and do not report the amount wasted, thereby under reporting the total cost for use of the product.

Charge Compression

Hospitals typically price high cost items (skin substitutes) with a relatively low price markup. These items are combined with lower cost items with a high markup (bandages etc.) which also may include some services/procedures. These pricing patterns are very common and result in "Charge Compression". This variation in the mark up rates creates a potential bias in the cost based rates resulting in a lower than expected cost to charge ratio and lower payments. We believe CMS used hospital cost to charge ratios where the estimated costs based upon hospital charges are substantially below hospital acquisition costs for skin substitutes. Based on an informal survey of AAWCM member hospital acquisition prices and validation by several product manufacturers of hospital selling prices, AAWCM has stated that they are unable to replicate the 38% difference between the product ASP and the 2012 Median Unit Cost data.

AAWCM contacted several member hospitals to compare hospital acquisition prices to the July 2013 ASP limit for several skin substitutes. Based on this informal survey, they found the hospital acquisition price is equal to or greater than the July 2013 ASP for the same products.

Further, they contacted several manufacturers and asked for their hospital selling price compared to their Q4 2012 ASP. They found that the median unit cost utilized by CMS was nowhere near the actual hospital acquisition cost for those products.

In addition, at the recent Alliance meeting with Director McInnes and his staff, the Alliance members stated that we would be providing under separate cover to CMS information from the CTP manufacturers demonstrating that the ASPs were very similar to the hospital acquisition price for these products. This will show credible data that demonstrates clear evidence of charge compression with CTPs.

This issue again illustrates that if this policy is implemented as proposed, it could have a significant impact on the healing outcomes of wound patients who will be denied access to CTPs since the payment rates would be insufficient to cover their acquisition costs.

4. **CTPs Are Not Clinically Comparable to Wound Dressings or Wound Supplies**

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 43572 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)."*

The Alliance strongly disagrees with the above statements for the following reasons:

1. CTPs are distinct and different from wound dressings or surgical dressings, thus are not clinically comparable to each other.
2. The classification system and terminology used by the FDA to delineate these products are distinctly different from that of CMS and its contractors. Both agencies have separate and unique regulatory processes and their own definitions and terminology.
3. The AMA CPT Editorial Panel made the distinction between these products when they defined that "skin substitutes" would be used in the CPT codes 15271-78 rather than non-graft wound dressings.

1. CTPs are distinct and different from wound dressings or surgical dressings, thus are not clinically comparable to each other.

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".

At the August 28, 2013 Alliance meeting with CMS Director McInnes and his staff, several prominent wound care physicians explained the distinctions clinically of how and when they would use CTPs versus wound care dressings in their practice. One physician addressed the unique clinical use for CTPs stalled and chronic wounds by stating:

"The variability and diversity of CTPs is to deliver different bioactive molecules and to provide an optimal cellular environment which now enables physicians to select the most appropriately tailored product or products to achieve wound closure." (Note: We have enclosed Attachment A that was distributed at the meeting that accompanied his explanation.)

In addition, another prominent wound care physician stated that

> *"Surgical dressings are used in my wound care and surgical practice to do specific things for the wound such as cover the wound to prevent invasion of bacteria, manage wound drainage, help preserve wounds moisture, temperature, and pH, and protect the wound from outside forces. In fact, I use surgical dressings to protect CTPs after they are applied.*
>
> *CTPs have intrinsic biological activity. Therefore, I use CTPs in my practice to influence stalled wounds to progress through the phases of healing to achieve complete closure. This intrinsic biological activity distinguishes the various categories of CTPs from the surgical dressings which can only manage the wound environment."*

2. ***The classification system and terminology used by the FDA to delineate these products are distinctly different from that of CMS and its contractors. Both agencies have separate and unique regulatory processes and their own definitions and terminology.***

Again, in our August meeting at CMS we responded to the statement 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).",* by stating that FDA does use the term " dressing" as a product code to describe many of the CTPs—however, this terminology has a different meaning when 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. In our bullet point #6 below, we address the regulatory process for how FDA classifies CTPs.

3. ***The AMA CPT Editorial Panel made the distinction between these products when they defined that "skin substitutes" would be used in the CPT codes 15271-78 rather than non-graft wound dressings.***

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 Alliance 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 Alliance 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. We urge 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.

5. **Products Are Not Clinically Comparable to Implantable Biological Products**

CMS states on page 43572 of the proposed rule:

> *"Finally, implantable biological products are very similar to (and in some instances the same as) skin substitute products, except that the clinical applications for implantable biologicals are typically an internal surgery versus the application to a wound for a skin substitute. Some products had or have dual uses as both skin substitutes and implantable biologicals, which underscores the similarity of these sometimes overlapping classes of products. Implantable biologicals 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 biologicals for OPPS packaging purposes based on the clinical application of individual products."*

The Alliance strongly disagrees with CMS on this issue. 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. AMA recognized this distinction by creating a separate CPT code for the application of implants.

Some additional distinctions between CPTs and implantable biologicals include the following:

- 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.

- 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.

- 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.

Since CTPs and implantable biologicals are distinct from each other, we submit that CTPs should not be packaged in the surgical procedures in which the products are used.

6. **CMS should not use the FDA framework for CTPs to justify exclusion from the packaging provision**

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)"[6]. 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.[7] 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.

In general, FDA's classification of skin substitute biologicals as 510(k) devices, PMA devices or human tissue products depends upon the source of the product (human or other species), presence or absence of cells, processing of the product (minimal manipulation versus more extensive manipulation), and labeling claims (use in wound management versus use in treatment of wounds). Human tissue products that are minimally manipulated are regulated as human cells, tissues, and cellular and tissue-based products under Section 361 of the PHSA. These products may have relatively broad claims in terms of the types of wounds for which these products may be used, but the FDA does not require clinical evidence to support such claims. Cellular products which have been subject to substantial manipulation are regulated as PMA devices and their claims generally include reference to treatment of specific wounds. Valid scientific evidence is required to support these claims. Acellular products may be eligible for clearance as 510(k) devices if there is a suitable predicate device, and these products are generally labeled for use in wound management. Acellular products which contain components not included in previously cleared 510(k) devices may require PMA approval notwithstanding the lack of cells if FDA believes the new components raise questions about the safety and effectiveness of the products.

Regardless of the FDA classification, products may or may not have high quality clinical evidence supporting their use in the healing of chronic skin wounds (e.g., diabetic foot ulcer and venous stasis ulcer). For some 510(k) products, there is published evidence from randomized controlled trials

[6] *See* 78 Fed. Reg. 43,572 (left column, second paragraph)

[7] §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.

showing that these products are useful in the healing of chronic wounds. These data were generated to support commercialization and coverage of these products regardless of requirements by FDA.

Therefore, there is no simple differentiation that one can make among skin substitute biologics based upon their FDA classification. Human cellular products may be PMA or Section 361 products. Acellular products may be 510(k) or PMA products. And any of these products may or may not have high quality evidence supporting their use in healing of chronic wounds.

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 offered by the Alliance that distinguishes cells and tissue-based products for wounds from synthetic meshes and surgical dressings. In fact, the Alliance would suggest 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.

7. **CMS should consider adopting the more clinically accurate term "CTPs" in place of "skin substitutes"**

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

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

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. We have provided a chart of all the CTP products who have Q codes and their classification in Attachment B which was also provided to CMS staff at our recent meeting.

It is important to state that currently one of the A/B MAC contractors did adopt this nomenclature in its LCD for these products 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 Alliance understands, from our meeting with Director McInnes and his staff that CMS is reluctant to use the term CTPs to describe what is currently being referred to as "skin substitutes," by both CMS and the AMA CPT. In 2012, when the AMA released its current CPT language for skin replacement surgery, the term CTPs was not yet created. The Alliance believes that if the term CTPs was available for consideration at that time, it may have been adopted as a part of the current skin replacement surgery language. The Alliance looks forward to working with the AMA CPT Editorial Panel and CMS in an effort to educate both organizations on the different products and their appropriate classification and to revise the current terminology.

8. **CMS did not follow appropriate procedural requirements when establishing these new packaged rates**

The Alliance is concerned that CMS did not follow their procedural requirements when establishing these new packaged rates. CMS is required to meet with outside experts. – the advisory panel on Hospital Outpatient Payment (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 advisory 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 Alliance is pleased that the HOP advisory panel met before the final rule however, and urge CMS to follow the recommendations of the panel – to delay the implementation of the packaging provisions until the data can be reviewed and the panel can evaluate the interaction between the proposal and its cumulative impact.

Conclusion

The Alliance 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 Alliance recommends the following:

- CMS not proceed with its proposal to package skin substitute products as well as add-on procedures for application of these products to larger wounds. The Alliance believes a decision to package skin substitutes and add on codes for skin substitutes is premature and may be harmful. We urge CMS to reconsider its proposal and encourage the Agency to work with the Alliance to address concerns CMS may have about potential incentives for overutilization or overpayment for skin substitute products.
- The Alliance recommends that CMS continue to treat CTPs as separately payable biologics at ASP plus 6 percent.
- The Alliance recommends that CMS develop a public process to consider codes that may be appropriate for packaging. The codes that are being considered for packaging should be announced at least a year before a proposed rule for packaging.
- 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 lack of detailed information makes it difficult to analyze and in 60 days to provide meaningful comments on the impact and appropriateness of packaging add-on codes and CTPs. While we recommend that CMS not proceed with its proposal for packaging CTPs as detailed in the first bullet point, if this does not happen, we would request a delay for at least one year.
- Since CTPs are not the same as surgical dressings and are not an inconsequential supply cost, CMS should make publicly available the primary procedure, utilization assumptions, mean costs for all packaged services, drugs, and biologics.
- The Alliance recommends that CMS should require HOPDs to report correct units of CTPs and correct add-on codes for surgical procedures that require CTPs since the newness of the CPT codes are causing database inaccuracies. If in fact CMS believes add-on codes are incorrect, CMS should request that the AMA review them and revise them if warranted.

We appreciate the opportunity to comment on this proposed rule. 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.
Executive Director