

December 26, 2014

Marilyn Tavenner  
Administrator  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-1613-FC  
Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

*Comments Submitted Electronically to [www.regulations.gov](http://www.regulations.gov)*

*RE: CMS – 1613-FC - Hospital Outpatient Prospective Payment System with Comment Period*

Dear Ms. Tavenner,

On behalf of the Alliance of Wound Care Stakeholders (“Alliance”), I am pleased to submit the following comments in response to the final CY 2015 Hospital Outpatient Prospective Payment System (HOPPS) with comment period. The Alliance is a nonprofit multidisciplinary trade association of health care professional 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. Our clinical specialty societies and organizations 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](http://www.woundcarestakeholders.org). Our specific comments follow.

## **SKIN SUBSTITUTES – REFERRED TO AS CELLULAR AND/OR TISSUE BASED PRODUCTS FOR WOUNDS (CTPs)**

### ***Packaging of CTPs***

The Alliance does not support the decision by CMS to package price skin substitutes (cellular and tissue based products (CTPs)). Our primary objection to package pricing is that it forces physicians to make treatment decisions based solely on price rather than on the basis of what product might be the most clinically effective for a given wound in a given patient. However, if CMS is going to allow market forces to determine the appropriate use of products, we believe that clinicians should have access to the broadest possible range of products. At this time, there is broad variability with regard to what products are “covered” despite the fact that package pricing is in effect. Allowing clinicians to unfettered access to all FDA cleared products will give clinicians the latitude to seek both the least

costly and the most clinically effective products, thus creating even greater motivation for manufacturers to produce appropriately sized and appropriately priced products.

Package pricing has also further complicated an already complex billing situation for hospitals. It is the responsibility of CMS to ensure that these products are being billed appropriately so that the High/Low threshold is being established correctly. APCs are evaluated every year. It is the Alliance's recommendation that CMS educate facilities on the correct coding and billing of CTPs. This will ensure that appropriate thresholds are being established. CMS should never see one unit being billed for these products. CMS and its contractors do reviews for these services all the time. If one unit is being billed the claim should kick it out of the system the same way that a claim would for an overpayment. The contractor, should request that the facility correctly bill for the products. The Alliance requests that CMS issue a MedLearn Matters (MLM) to describe the proper billing of these products. This will ensure that accurate, appropriate billing is being submitted – which in turn will ensure accurate, appropriate thresholds being established for CTP products.

Furthermore, since CTPs are being packaged in the hospital setting, we would request that the A/B MAC contractors issue more liberal policies in terms of the products that are being covered. This will allow the marketplace to determine which products are successful, provide clinicians more choice of products to treat their patients, and allow more product choices in the lower cost threshold.

### ***Pass Through Status of CTPs***

The Alliance respectfully disagrees with the CMS decision to change the current pass through application and qualification of all CTPs from the current drug and biologicals pathway to now requiring that they follow the medical device pass through pathway. We have serious legal and policy concerns with CMS's decision.

CTPs are regulated by the FDA in a number of ways, including medical devices, biologics, and 361 HCT/Ps. CMS acknowledges this itself by noting in the proposed rule, "Many skin substitutes are FDA-approved or cleared as devices." Implicit in this statement is that not all CPTs are regulated by the FDA as if they were medical devices.

As CMS knows, Congress established separate pass-through pathways for drugs/biologicals and devices. CMS has followed these pathways since the implementation of OPPS in 2000, and the Agency appropriately has considered CTPs and similar products for wounds under the drug/biological pass-through pathway. We do not understand how CMS can now suddenly, unilaterally, and legally change course and direct all pass-through applications for CTPs and similar products for wounds through the device pass-through pathway.

CMS does not have the statutory authority to review drugs and biologicals under the device pass-through process. Although drugs, biologicals, and devices are not defined for purposes of pass-through in the statute, it is unclear on what basis CMS would be able to define all CTPs and similar products for wounds as devices. In the absence of an explicit definition under the pass-through paragraph in the statute, it would appear that the overall definition of drug and biological in Medicare law should govern. As set forth under Soc. Sec. Act § 1861(t)(1), Medicare defines the terms "drugs" and "biologicals" as those products that:

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

Therefore all CTPs or similar products for wounds that meet this definition should be evaluated for pass-through under the drug/biological pass-through pathway.

Even if CMS were to rely on Soc. Sec. Act §1927(k), which is referenced elsewhere under the OPPI section, that would preclude CMS from considering drugs approved by the FDA under Section 505 of the Federal Food, Drug, and Cosmetic Act as well as biologicals licensed under Section 351 of the Public Health Service Act from being considered devices for pass-through purposes.

If CMS treats all CTPs and similar products used for wounds as devices for pass-through purposes without consideration of some legally cognizable standard for distinguishing drugs/biologicals from devices, such as Soc. Sec. Act § 1861(t)(1) or Soc. Sec. Act § 1927(k), CMS's decision would seem to be arbitrary and without lawful basis.

In addition, manufacturers have developed new and innovative therapies relying on the understanding that they would be reimbursed at ASP+6% during their pass-through period. In particular, therapies approved as drugs or biologicals are appropriately paid under this methodology given the substantial cost and burden associated with obtaining an approval from the FDA under a New Drug Application (NDA) under Section 505 of the FFDCA or a BLA under Section 351 of the PHS Act. Products approved under Section 351 of the PHS Act are biological drugs and are not, in fact, CTPs.

Given that pass-through payments are intended to permit hospitals to report and be appropriately reimbursed for new technologies and to assist companies in bringing new technologies to market, it is unclear why CMS would want to add additional barriers to the pass-through payment process. Specifically, unlike the process for biologics, the medical device pass-through application process contains a requirement to provide evidence of "substantial clinical improvement." Such a requirement would impede the development of new CTP technology – which is why the pass through process was started in the first place.

The Alliance has serious concerns about the change in policy and urges CMS to continue its long-standing practice of evaluating CTPs and similar products that aid wound healing as drugs and biologicals for purposes of the pass-through payment review process. This is particularly important for biologics approved under Section 505 of the FFDCA or under Section 351 of the PHS Act that are used to aid wound healing.

As stated above, not only are there legal reasons to keep CTPs within the drugs and biologicals pass through process based on the statutory provisions identified above, it is also sound policy. The Alliance recommends that CMS continue to evaluate CTPs for pass through status under the drug and biological pass through process.

*Epidermal Autograft*

CMS reassigned CPT® 15110 (Epidermal autograft, trunk, arms, legs; first 100 sq cm or less) from APC 0329 (Level IV Skin Procedures) to APC 0327 (Level II Skin Procedures) in the final rule. The Alliance disagrees with this reassignment. The APC reassignment of CPT® code 15110 from 0329 to 0327 is inappropriate due to cost data and clinical similarity of the procedures within APC 0329. This decision results in a drastic 80 percent reduction in reimbursement for an epidermal autograft [CPT 15110] that could negatively impact patient care.

Since CMS has finalized this policy, despite the comments from stakeholders to the contrary, it is the responsibility of CMS to ensure that these products are being billed appropriately so that the APCs are being established correctly. APCs are evaluated every year. It is the Alliance’s recommendation that CMS educate facilities on the correct coding and billing of epidermal autografts. This will ensure that appropriate reimbursement is being established. As such, the Alliance requests that CMS issue a MedLearn Matters (MLM) to describe the proper billing of these products. This will ensure that accurate, appropriate billing is being submitted – which in turn will ensure that epidermal autografts are accurately and appropriately being placed in the correct APC.

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

Sincerely,



Marcia Nusgart, R.Ph  
Executive Director