ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

September 2, 2014

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

Comments Submitted Electronically to www.regulations.gov

RE: CMS–1613-P: CY 2015 Hospital Outpatient Prospective Payment System

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 proposed CY 2015 Hospital Outpatient Prospective Payment System (HOPPS). 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. Our specific comments follow.

Proposed Change in Pass-Through Application and Qualification of Skin Substitutes

The Alliance respectfully disagrees with the CMS proposal to change the current pass-through application and qualification of all skin substitutes 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 proposal.

Skin substitutes 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 skin substitutes 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 HOPPS in 2000, and the Agency appropriately has considered skin substitutes and similar products for wounds under the drug/biological pass-through pathway.

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We do not understand how CMS can now suddenly change course and direct all pass-through applications for skin substitutes 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 drug, biological, and device are not defined for purposes of pass-through in the statute, it is unclear on what basis CMS would be able to define all skin substitutes 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 biologicals 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 skin substitutes 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 HOPPS 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 skin substitutes 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, as clinicians, we are concerned that new and innovative therapies will be inhibited as a result of requiring skin substitutes go through the pass-through payment process for devices.

The Alliance has serious concerns about this proposal and urges CMS to continue its long-standing practice of evaluating skin substitutes 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 PHSA that are used to aid wound healing

As stated above, not only are there legal reasons to keep skin substitutes 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 skin substitutes for pass-through status under the drug and biological pass-through process.

Proposed High/Low Cost Threshold For Skin Substitutes

The Alliance agrees with the CMS proposal to lower the high/low cost threshold for skin substitutes to $27 however, we do not agree with the proposed weighted average mean unit cost ("MUC") methodology. The Agency's ability to calculate an appropriate threshold for distinguishing high versus low cost products depends on the accuracy and completeness of the data used to make this calculation. Although the Alliance opposes any packaging of skin substitutes, if CMS continues with packaging of these treatments, we request that CMS retain the current methodology for establishing the high/low cost threshold based upon Average Sales Price (ASP) data rather than average MUC.

ASP data comprise manufacturer-certified actual sales prices for these therapies, which provide a more accurate reflection of true market cost than hospital claims data, which estimate costs from product-specific charges reduced by departmental ratios of cost-to-charges overall. It is well established that claims-based cost data are subject to charge compression and do not reflect accurate costs for individual treatments. Per the Alliance comments last year, the claims-derived cost data for skin substitutes was 38 % lower than the product ASPs because of the charge compression phenomenon Alliance members also submitted evidence that ASP data for these products are quite consistent with hospital acquisition cost data.

As such, the Alliance urges CMS to maintain its current practice of using ASP data to set the high/low cost threshold for packaging, and at the very least, CMS should only implement MUC if the Agency determines that the claims data align with ASP data. We also urge CMS to examine ways to ensure transparency of the data being used for these calculations, as well as developing a process to ensure greater predictability of payment amounts.

Epidermal Autograft

CMS is proposing to reassign 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). 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.

The Alliance recommends that CMS leave this procedure in APC 0329. The Alliance questions why CMS would place CPT® 15110 in the lower APC 0327 when the RVU [10.97] for CPT 15110 [Epidermal autograft trunk, arm, leg] is similar to the RVU [11.28] for CPT® 15115 [Epidermal Autograft, face, head, finger, groin] which remains in APC 0329.

Our rationale for keeping CPT 15110 in APC 0329 is as follows:

- CPT 15110 is not clinically similar to the procedures in APC 0327 including – but not limited to:
    - CPT® 11950-11952 Treatment of contour defects
    - CPT® 12035-12307 - Intermediate layer closures
    - CPT® 15002 – 15003 Wound preparation
    - CPT® 15040 - harvesting a cultured skin graft

- CPT® 15050 - Skin pinch graft

The procedures identified above are single procedures yet the epidermal autograft is a dual procedure: the harvesting of the autograft and the grafting. The epidermal autograft is similar to procedures in level 4 skin repair.

- The frequency of the procedure in the Medicare claims is artificially low and the costs are not representative for this procedure. We believe providers may be coding this procedure improperly and that additional provider education is needed. This may result in more accurate information for CMS to use for rule setting in 2015 for a proposed rule in 2016.

- The proposed APC re-assignment of CPT® 15110 significantly lowers the payment for this procedure. This change would have profound impact on providers who could no longer afford to offer this procedure. Patients with venous leg ulcers and diabetic foot ulcers are challenged to find options to effectively close these wounds. Newly developed autologus epidermal harvesting technique allows the practitioner to transfer the patient's own graft to the wound and begin re-epithelialization of these wounds. This treatment is demonstrating positive clinical outcomes and high patient satisfaction. If CPT® 15110 would remain in APC 0327, providers would not be able to provider this therapy as an option to patients. Patients with these challenging wounds would no longer be able to benefit from this clinically effective procedure to close their wounds.

Due to its clinical complexity, the Alliance recommends leaving CPT® 15110 in the current APC 0329.

Disposable Negative Pressure Wound Therapy (NPWT)

For 2015, CMS is proposing to reassign HCPCS codes G0456 and G0457 for application of disposable NPWT from APC 0016 (Level III Debridement and Destruction) to APC 0015 (Level II Debridement and Destruction). The Alliance urges CMS to maintain the current APC assignment for these services. This would preserve access to disposable NPWT and allow more Medicare claims data to be considered before making any APC reassignment.

There is significant confusion among providers regarding the use of G0456 and G0457 with both mechanical and electrical disposable NPWT devices as well as the variance in components billed with distinct products on the market. As a result, the claims data is often inaccurate given they do not accurately reflect the charges for this treatment and the device. Some areas of confusion include:

- The G codes were established in 2013 for the application of disposable NPWT. There was much confusion when the codes were first released, including how to distinguish the services from procedures involving NPWT using durable medical equipment. The descriptors of the G codes list "mechanical" disposable NPWT. Through conversations with stakeholders, CMS advised the new G codes are available for all disposable NPWT devices, both mechanical and electrical. CMS issued policy guidance to the Medicare contractors as of late February 2013, but there were no published Medicare program transmittals or MLN Matters articles on this coding clarification. This has created significant uncertainty in the provider community about when and how to use these codes

- There is additional confusion among providers regarding what is included when a provider bills CPT® codes 97605 and 97606 which covers the service of providing traditional NPWT, but does not include the reusable and disposable supplies paid for through the Durable Medical Equipment Medicare Administrative Contractors (DMEMAC) versus the new G codes (G0456 and G0457) which includes the supplies.

- There are three disposable NPWT devices currently on the market. Some devices are a part of a kit that includes the device and all supplies, and another device is a system that has components that may be purchased separately. Differences in products may have contributed to billing confusion.

There has been a collaborative effort by the three manufacturers of disposable NPWT through the Alliance of Wound Care Stakeholders to provide CMS with detailed information on the costs of devices, so the Agency can incorporate those costs so as to appropriately establish non-facility practice expense relative value units for the new CPT® codes for disposable NPWT that will presumably be created effective January 2015. We would like to recommend that CMS review those paid invoices and consider the costs of these devices in retaining APC 0016 assignment of disposable NPWT for 2015. Furthermore, as described above, in light of the newness and confusion surrounding HCPCS codes G0456 and G0457, the Alliance believes that any APC reassignment would be premature at this time and requests that CMS continue to place disposable NPWT in APC 0016.

CPT® Payment Assignment Process

CMS has proposed to delay the adoption of new and revised CPT® procedures codes. The Alliance disagrees with this CMS proposal as we believe that it would only delay the adoption of innovative technology. As such, the Alliance requests that the Agency not delay adoption for new and revised CPT® codes, effective in October or January, until the next year and include them in the current year process. Alternatively, the Agency could assign payment in a mid-year cycle or in concert with the OPPS updates that are issued in January and October.

Total Contact Casting

Finally, the Alliance would like to applaud CMS in their decision to readjust the CPT procedures in APC 0426 that also includes total contact casting (CPT® procedure code 29445) as APC 0426 better reflects the true costs for the procedures.

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On behalf of the Alliance 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,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director