COALITION OF

Wound Care Manufacturers

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 Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit the following comments in response to the CY 2015 Hospital Outpatient Prospective Payment System (OPPS). The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those that are subject to this propose rule. Since our members have a vested interest in the provision of quality, coverage and payment of wound care, this regulation is of interest and concern to us. The Coalition appreciates the opportunity to offer our comments. Our specific comments follow.

Pass Through of Skin Substitutes

The Coalition 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 OPPS in 2000, and the Agency appropriately has considered skin substitutes and similar products for wounds under the drug/biological pass-through pathway. We do not understand how CMS can now suddenly change course and direct all

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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 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 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 OPPS 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, 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 PHSA. Products approved under Section 351 of the PHSA are biological drugs and are not, in fact, skin substitutes.

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 skin substitute technology – which is why the pass through

process was started in the first place.

The Coalition 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 Coalition recommends that CMS continue to evaluate skin substitutes for pass through status under the drug and biological pass through process.

High/Low Cost Threshold For Skin Substitutes

The Coalition 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 "MUC" methodology. The agency's ability to calculate appropriate payment rates largely depends on the accuracy and completeness of the claims data submitted. To ensure that CMS has the data it needs to set appropriate payment rates, CMS should require complete and correct coding for packaged services – and especially skin substitutes. Facilities are more likely to report all codes – and the correct number of units when there is a requirement to do so. As such, until CMS requires correct coding for skin substitutes, the Coalition recommends that CMS leave the payment rates to be set based on the Average Sales Price (ASP).

Furthermore, although the Coalition opposes any packaging of skin substitutes, if CMS continues with packaging of these treatments, the Coalition requests that CMS retain the current methodology for establishing the high/low cost threshold based upon 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 Coalition comments last year, the claims-derived cost data for skin substitutes was 38 % lower than the product ASPs because of the charge compression phenomenon Coalition members also submitted evidence that ASP data for these products are quite consistent with hospital acquisition cost data. As such, the Coalition 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.

Elimination of Pass Through Applications for CY 2014

The Coalition is also concerned with CMS' proposal to eliminate a pass-through application date for

calendar year 2014. The intent of the pass through status application process is to allow new drugs, biologicals and devices faster access to the market and ultimately to patients. The Coalition disagrees with CMS' assessment that applicants require additional time to adjust to the new policies and procedures. Rather, we believe CMS is inappropriately truncating the pass- through application process for calendar year 2014, which CMS finalized as part of the calendar year 2014 payment policies. Therefore, regardless of whether CMS finalizes the change that skin substitutes should be processed under the device process (which we disagree with as stated above), CMS should still allow submissions for the December 1, 2014 date under the drug and biological pass-through process.

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 Coalition 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. The Coalition 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 Coalition 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 Coalition disagrees with CMS's proposal as we believe that it would only delay the adoption of innovative technology. As such, the Coalition requests that the CMS 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, since CMS issues OPPS updates in January and October, CMS could assign payment in a mid-year cycle or in concert with the OPPS updates that are issued in January and October.

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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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