ALLIANCE OF

Wound Care Stakeholders

August 31, 2010

Donald Berwick, M.D.
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention CMS 1504- P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Submitted Electronically

Re: CMS-1504-P; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates

Dear Administrator Berwick:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am submitting the following comments in response to the Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates. I serve as the Executive Director of the Alliance, a multidisciplinary consortium of over 15 physician, clinical, provider, manufacturer and patient organizations, whose mission is to promote quality care and patient access to wound care products and services. These comments were written with the advice of Alliance organizations who possess expert knowledge in complex acute and chronic wounds. This proposed rule will have a major impact on our Alliance organizations and as such, we appreciate the opportunity to offer our comments.

Our comments center around the section entitled, Proposed OPPS Ambulatory Payment Classification (APC) Group Policies, and specifically, the proposed OPPS APC related to Skin Repair (APCs 0134 and 0135). The Alliance would like to separate our comments into three distinct areas; 1) areas of concern, 2) areas of agreement, and 3) recommendations.

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AREAS OF CONCERN

Process

The Alliance has concerns regarding this section of the rule. Specifically, while Alliance participants recognize that there may be a need to revise the CPT[1] codes for the products in this category, the procedure by which those codes are developed and ultimately utilized should go through the "normal" process. The Alliance submits that CMS has circumvented the normal process in making CPT coding changes. CMS has proposed to eliminate essentially 6 CPT codes and package site preparation and debridement into procedures where they are not routinely required, as well as create new HCPCS codes without going through the normal process – and specifically without going through the AMA. The Alliance is very concerned about the precedent that this sets. In addition, CMS has inappropriately declared that only 2 of the products, APLIGRAF®[2] and DERMAGRAFT®[3], are indicated for use on lower extremity ulcers, which is not true. While ultimately it may make sense to revise the CPT codes in the skin replacement and skin substitute section of the CPT book and to revalue the revised codes, the **Alliance is concerned about the precedent that CMS is setting by circumventing the exact process under which these and all other procedure codes and HCPCS codes were/are created.**

Level The Playing Field

Furthermore, through these proposed changes, CMS has inadvertently created an "unlevel" playing field. As stated in the Medicare Physician Fee Schedule proposed rule (and cited in this proposal), it is the desire of CMS to create a level playing field and eliminate financial incentives. However, the proposed G codes only impact two specific products: APLIGRAF® and DERMAGRAFT®. All other grafting procedures and skin substitute products are not affected, which does not result in a "level playing field". Therefore, all other grafting materials and skin substitute products are at a distinct disadvantage over Dermagraft and Apligraf. Moreover, as additional products enter the marketplace, the code descriptor may limit their ability to be included in this code.

Unless CMS makes changes that pertain to all the procedure codes in this section of the CPT book, the agency will not achieve its goal of leveling the playing field. In fact, the proposed changes will cause providers to use the two more expensive products.

The G Codes Are Not Appropriate For The APC

In this proposal, CMS created two new codes and bundled debridement and site preparation into the descriptors. Then CMS suggests in the proposed rule to have Apligraf and Dermagraft remain in the same APC. The Alliance submits that it is

[1] CPT is a registered trademark of the American Medical Association
[2] APLIGRAF is a registered trademark of Organogenesis
[3] DERMAGRAFT is a registered trademark of Advanced Biohealing

inappropriate to put the temporary G codes in the Hospital Outpatient Payment System at this time because there are no APCs that have an appropriate value assigned to it that would allow for adequate reimbursement of site preparation, application and debridement. There simply will not be enough reimbursement.

Currently, APC 0134 reimburses a facility around $212 for application of Dermagraft or Apligraf. APC 0135 includes CPT 15002-15005 for site preparation and provides a facility with reimbursement of approximately $299 for that separate, distinct procedure. Both APC 0134 and APC 0135 would be billable to CMS currently. Clearly, placement of the new G codes into APC 0134 provides inadequate reimbursement to providers. Without appropriate reimbursement, the Alliance is concerned that patient access to these products will be significantly hindered.

As such, the Alliance believes it is not appropriate to recognize these proposed new HCPCS G-codes under the OPPS and in their current proposed APC assignments.

AREAS OF AGREEMENT

The Alliance agrees with the following CMS concepts:

• Financial incentives to choose one product over another should be eliminated.
• The sizing provided in the new temporary G code definitions is appropriate. The Alliance agrees that the application descriptions should be in 25 sq cm units rather than 100 sq cm units.

RECOMMENDATIONS

The changes that CMS is seeking to make in the proposed rule will create an unintended advantage for APLIGRAF® and DERMAGRAFT® in the outpatient clinic setting.

The Alliance believes that CMS has not gone through the normal process in making the changes proposed. As we stated earlier in our comments, while ultimately it may make sense to revise the CPT codes in the skin replacement and skin substitute section of the CPT book and to revalue the revised codes through the APC process, CMS has not gone through the AMA prior to issuing this proposed rule.

As such, the Alliance recommends that CMS not go forward with the temporary new codes until they have had the chance to go through the normal process.

Similarly, as stated above, the Alliance believes it is inappropriate to place the G codes into the OPPS because there is no current APC that has an appropriate work value assigned to it that would allow for adequate reimbursement of the site preparation, debridement and the product. As such, the Alliance recommends that hospitals continue to use the 15000 codes until enough data has been collected and work with the AMA to determine appropriate values.

CONCLUSION

The Alliance appreciates the opportunity to provide CMS with input on the proposed HOPPS regulation for CY 2011. As stated earlier in our comments, due to the diversity of organizations with wound care knowledge and experience which comprise the Alliance, we would be pleased to serve as a resource to you now or in the future. We look forward to working with you as you finalize this policy. If you have any questions, or would like further additional information, please feel free to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director

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