COALITION OF

Wound Care Manufacturers

August 30, 2011

Donald Berwick, M.D.
Administrator
Center for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1524-P
Mail Stop: C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted Electronically

Re: Medicare Program; Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2012

Administrator Berwick:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am submitting the following comments in response to the Proposed Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2012. I serve as the Executive Director of the Coalition. The Coalition represents leading manufacturers of surgical dressings and other medical devices and supplies used by Medicare beneficiaries for the treatment of wounds, including skin substitutes.

The Coalition comments do not focus on any specific provisions contained in this proposed rule, but rather what is lacking. Last year, CMS proposed - and implemented - temporary codes for skin substitutes. Specifically, CMS proposed and implemented two temporary codes G0440 and G0441 and eliminated the 90-day global period for the products which fell under these codes. In doing so, only two specific products; Apligraf® and Dermagraft® were impacted. All other grafting procedures and skin substitute products were not affected and still continue with a 90-day global period. As a result, all other grafting materials and skin substitute products are at a distinct disadvantage with the global day assignments.

The Coalition is concerned that CMS did not address the G codes in this proposed rule as the codes were meant to be temporary, created an unlevel playing field (in which the two products are gaining an unfair market advantage) and other products have since come into the marketplace that are similar to those products yet not afforded any instruction on how they too can obtain G codes (along with the 0 day global period).

5225 Pooks Hill Rd. • Suite 1626 N
Bethesda, MD 20814
301 530 7846 T • 301 530 7946 F
marcia@nusgartconsulting.com
www.nusgartconsulting.com

CMS indicated that the rationale for creating these codes was to level the playing field and to eliminate financial incentives. However, the reverse has occurred as a result. As we are sure CMS is aware, since the rule was implemented last year, providers have been changing the skin substitute products they use to treat patients to use the two more expensive products, that have no global period, rather than other less expensive products that will still have 90-day global periods. The Coalition is extremely concerned about this pattern of "abuse" as we believe that decisions are not being made based on the most clinically appropriate product, but rather on the financial incentives being afforded to providers to utilize Apligraf and Dermagraft.

As such, the Coalition would like CMS to address the following prior to this proposed rule becoming final:

- Will the two temporary codes G0440 and G0441 continue to be active in 2012?
- At what point will permanent codes be developed for these products?
- If the G codes are to remain for CY 2012, how can other products that have or will enter the marketplace be afforded the same status as those skin substitutes which were awarded G codes with a 0 day global?
- Will CMS create a level playing field by eliminating the 90 day global period for all other skin substitute products? .

The Coalition would like to recommend that CMS address the G code issue in this regulation prior to it becoming final. Specifically, we would like CMS to eliminate the 90 day global period and afford all skin substitute products with the 0 day global period. The Coalition would also like for CMS to ensure that clinical decision making is based on the most clinically appropriate product for the patient and eliminate financial incentives to select tissue cultured products over any other clinically appropriate skin substitute. The creation of the G-codes has not facilitated clinical decision making based on the most clinically appropriate product. In fact, the addition of the 0-day global has created a finical incentive to select ***only*** these two bioengineered skin substitutes over any other skin substitute whether biologically active, acellular or xenograft.

The Coalition appreciates the opportunity to provide CMS with our comments on the proposed physician fee schedule regulation for CY 2012. 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.

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director