COALITION OF

Wound Care Manufacturers

July 11, 2011

United States Department of Health and Human Services
Centers for Medicare and Medicaid Services
Room 445G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: File Code: CMS-5507-C
Comments on Proposed Rule –
"Medicare and Medicaid Programs; Opportunity for Alignment Under Medicaid and Medicare"

Dear Dr. Berwick:

The Coalition of Wound Care Manufacturers ("Coalition") is pleased to submit comments to the Centers for Medicare and Medicaid Services ("CMS") on its proposed rule regarding ""Medicare and Medicaid Programs; Opportunity for Alignment Under Medicaid and Medicare" 76 Fed. Reg. 28196 (May 16, 2011). The Coalition represents leading manufacturers of surgical dressings, negative pressure wound therapy and other medical devices and supplies used by Medicare beneficiaries for the treatment of wounds.

There are three aspects of this proposed rule on which we would like to comment.

1. Under "Identify existing rules that may create barriers to care and to create and implement solutions", we have two issues:

    a. Prior Authorization (PA) - Currently, all State Medicaid programs require PA for most if not all durable medical equipment, orthotics and prosthetic supplies (DMEPOS). However, in most States, a PA cannot be submitted for dual eligible clients until Medicare has been billed and a final determination regarding coverage and payment has been made.

    Resulting Barrier: Suppliers are not willing to provide costly technology including time-intensive services without any recourse to ensure payment.

    Recommendation*:* Develop and implement a dual eligible prior authorization process that synchronizes the documentation requirements and allows suppliers to submit all require documentation to Medicare for a

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Medicare determination and then the claim would automatically cross-over to Medicaid for PA. This would allow the supplier to know whether the beneficiary meets all coverage criteria as well as the amount of total reimbursement from both Medicare and Medicaid.

b. Balance billing for qualified Medicare beneficiary (QMB)- Suppliers are not allowed to bill QMBs for coinsurance, copayments or deductibles

***Resulting Barrier*:** Inadequate HCPCS codes to describe and adequately reimburse for durable medical equipment prosthetics, orthotics and supplies (DMEPOS). Suppliers routinely use an ABN for non-assigned claims to allow receiving additional payment from beneficiaries that require features that exceed what a supplier could provide given the Medicare allowable for a given code. This is particularly problematic for DMEPOS products as many of the codes are generic and includes many technologies within the same code.

Medicaid mandates include "equal access" requirement, state Medicaid plans must: provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan . . . as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the same extent that such care and services are available to the general population in the service area. State Medicaid programs have attempted to help resolve coding issues resulting in access issues by allowing suppliers to use different codes or miscellaneous codes for billing the more expensive DMEPOS products but this strategy adds difficulty in cross-over claims, adds complexity and confusion for audits and potential cost-shifting.

In addition, while CMS has established a modified process which allows Medicaid agencies to request new codes, many Medicaid staffs have reported they do not employ individuals with the necessary expertise or knowledge or in general do not have the necessary human resources to follow the process. In addition, the current process is burdensome and one of the requirements is for the States to obtain a "national program operating need" which has never been adequately defined by Medicare. Moreover, reportedly, working with manufacturers to obtain information needed to complete applications creates a level of distrust regarding the request which results in many cases in the code not being issued.

Recommendation: Create a workgroup including Medicaid DMEPOS staffs, clinicians, suppliers and manufacturers to complete a comprehensive review of current HCPCS codes to identify barriers to access. This involvement may include individuals representing health care providers, health industry trade associations and coalitions, health care manufacturers and patient advocacy groups who have the knowledge and experience in the coding, use of and the furnishing of health care services related to durable medical equipment prosthetics, orthotics and supplies as well as complex rehab technology.

State Medicaid staff would retain the authority to determine which codes they believe are ultimately needed. Then, revise the current process and implement a simple process for Medicaid agencies to request new codes they determine to be needed and allow them to work with manufacturers to obtain information they would not routinely have access to on their own such as, utilization, FDA information and other information CMS may require in order to approve a new HCPCS code.

2. Identify differences in eligibility, payment and coverage benefits that may be barriers to high quality, seamless and cost-effective care.

    a. "In the Home" restriction in the Medicare program

    Resulting Barrier: Medicare has, at least since the inception of the four Durable Medical Equipment Regional Carriers (DMERC), interpreted and applied "appropriate for use in the home" to mean that only items that meet the needs of an individual within their home are covered. For example, a beneficiary that qualifies for power mobility within their home is only covered for the wheelchair and related accessories that are required within the four walls of the home. The individual cannot obtain the level of technology that would allow them to be functional within their community unless they are willing to pay the difference out of their own pocket. As already stated above, dual eligible clients do not have this option. To further deny access, numerous Medicaid programs have attempted to adopt Medicare policy related to DME and CRT items, even though States are not allowed to deny request for items based on the grounds that they are for use outside of the home. Oftentimes, if Medicare denies based on an item not being reasonable and necessary, Medicaid will deny as well. This results in a decrease in the functional status and level of independent living of Medicaid beneficiaries

    Recommendation: CMS is attempting to address this issue as part of another proposed rule- CMS- 2348-P. Statements in the proposed rule agree that individuals with disabilities can and do live and function in the community. And, these individuals, with appropriate technologies can

maintain and recover more independence and higher levels of function. The Coalition recommends that the application of "appropriate for use in the home" be applied to the technology for determining whether an item meets the definition of DME. But, for coverage purposes, as long as there is a documented need within the home, beneficiaries should be allowed access for the product(s) that meet their medical and functional needs in all settings that they routinely encounter to perform daily activities. This would allow for a common interpretation between the Medicare and Medicaid programs.

In summary, aligning Medicare and Medicaid policies to improve access, quality and cost of care for people who are in need of such programs is necessary. The Coalition has only identified a few areas of concern that directly impact dual eligible beneficiaries – but these are critical issues and we ask that the Agency help resolve them.

The Coalition would be happy to serve as a resource to you for assistance or to provide any additional information.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director