COALITION OF
Wound
Care
Manufacturers

June 6, 2011

Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
CMS-1345-P,
7500 Security Boulevard
Baltimore, MD 21244-8013.

Submitted Electronically

Re: CMS-1345; Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations Proposed Rule

Dear Administrator Berwick:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am submitting the following comments in response to the Medicare Shared Savings Program, Accountable Care Organizations Proposed Rule. I serve as the Executive Director of the Coalition. The Coalition represents leading medical device companies who manufacture a wide range of wound care technologies including surgical dressings, skin substitute products, and negative pressure wound therapy devices used by Medicare beneficiaries for the treatment of wounds.

In reviewing the proposed rule, I noticed an important omission. While the proposed rule contains many quality indicators for a variety of disease states, there are no quality indicators for wound care. As CMS is moving towards making payments – as well as assessing penalties - based on whether clinicians are adequately adhering to quality measures, I am concerned that quality measures for wound care were not included in this document.

Since patients with chronic wounds will traverse through the continuum of care within accountable care organizations, the Coalition believes that it is imperative to include quality measures within this document. As you are aware, HHS has been seeking feedback around a framework for developing the National Quality Strategy, including the identification of guiding principles and specific priorities and goals, strategies for stakeholder engagement, and defining the role states play.
The Association for the Advancement of Wound Care submitted a proposed wound care "measures set" to the National Quality Forum (NQF). Unfortunately, the NQF has made

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it clear that their priorities are set by CMS, and in the absence of a directive from CMS, the NQF will not consider quality measures in wound care. Therefore, for this reason, it is even more important that CMS considers adopting wound care measures in this rule. Some examples of proposed measure that CMS should take into consideration include the following:

- Adequate compression for patients with venous insufficiency ulcers
- Adequate offloading for patients with diabetic foot ulcers
- Adequate support surfaces for patients with Stage III-IV pressure ulcers
- HbA1c measurement for patients with diabetic foot ulcers
- Nutritional screening for patients with existing pressure ulcers
- Vascular screening for patients with leg ulcers
- Referral to a wound expert among patients who have failed to respond to conservative care

The rationale for CMS for including wound care measures is the following:

There are 6 million chronic wound patients in the United States, affecting 2% of its population. The United States currently spends$8.5 billion dollars for wound care products and services, and approximately $20 billion dollars annually for wound care treatment. Diabetic foot ulcers, which affect 15% of all diabetics, are the most common cause of non-traumatic amputation in the United States and account for 80% of wound care costs. Pressure ulcers affect 15% of the elderly and are increasing at a rate of 5% per year due to our aging population. (CMS Medicare Coverage Advisory Committee, 29 March 2005.)

These patients are largely from vulnerable populations. Many are of advanced age, and many are minorities. Many, if not most, patients are diabetics, a high percentage are paralyzed, and many are not native English speakers. Extensive coordination of care is needed on most patients, and there is high utilization of ancillary testing. While there are guidelines that wound care organizations such as the Wound Healing Society, National Pressure Ulcer Advisory Panel and Wound Ostomy Incontinence Nurses Society have that address such issues as pressure ulcers and diabetic foot ulcers, there are ***no current national clinical quality measures for wound care.***

The Coalition believes that patients will benefit greatly with the adoption of quality measures and would recommend that CMS adopt the quality measures identified in this document.

Furthermore, the Coalition believes that CMS should ensure that ACOs have sufficient numbers of all health care providers/suppliers (not just PCPs) to treat ACO patients such as physical therapists, home health agencies, rehabilitation agencies, inpatient rehabilitation facilities, skilled nursing facilities and other provider types. Therefore, the CWCM recommends that CMS clarify in the final rule that the expanded list of eligible groups of providers that may participate in the Medicare Shared Savings Program

includes physical therapists, home health agencies, rehabilitation agencies, inpatient rehabilitation facilities, skilled nursing facilities and other provider types.

CONCLUSION

The Coalition appreciates the opportunity to provide CMS with input on the proposed Accountable Care Organization regulation. We look forward to working with you as you finalize this policy. If you have any questions, or would like further additional information on the proposed quality measures, please feel free to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director