ALLIANCE OF

# Wound Care Stakeholders

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 Alliance of Wound Care Stakeholders ("Alliance"), 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 Alliance, a 501 (c)(6) multidisciplinary trade association consisting of 21 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.

As we reviewed the proposed rule, we noticed a glaring omission. The proposed rule contains many quality indicators for a variety of disease states. However, there are no quality indicators for wounds. As you are aware, patients with chronic wounds will traverse through the continuum of care for accountable care organizations and therefore, the Alliance believes that it is imperative to include quality measures within this document. As you are also 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 Alliance strongly believes that quality measures for wound care must be developed. The Alliance submitted recommendations to the National Quality Forum (NQF) on this matter.

The Association for the Advancement of Wound Care also submitted a proposed wound care "measures set" to the National Quality Forum. Unfortunately, the NQF has made it

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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. The proposed measures include;

- 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

There are 6 million chronic wound patients in the United States, affecting 2% of its population. We currently spent $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.**

CMS has addressed wound care in a variety of different ways – including but not limited to present on admission, adverse events, MDS, RUGSs etc. The Alliance believes that CMS will align these measures with other quality measures. However, the Alliance would like to recommend that instead of doing an alignment, that CMS simply address accurate and adequate quality measures in this document and adopt the measures identified above.

Excellent protocols for wound care exist but are poorly implemented, in part because of the lack of appropriate measures. As CMS is moving towards making payments – as well as assessing penalties - based on whether clinicians are adequately adhering to quality measures, we hope that CMS will adopt the wound care quality measures recommended by the Alliance prior to final issuance of this proposed rule.

## CONCLUSION

The Alliance appreciates the opportunity to provide CMS with input on the proposed Accountable Care Organization regulation. 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. If you would like further information on the quality measures described above, we are happy to provide it to you for your review. 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