ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

September 4, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–1590–P
P.O. Box 8013
Baltimore, MD 21244–8013

Submitted Electronically

RE: CMS-1590-P - Proposed Changes to the Physician Fee Schedule For CY 2013 and for other purposes (DME Face to Face Encounter)

Dear Acting Administrator Tavenner:

The Alliance of Wound Care Stakeholders ("Alliance") is submitting the following comments in response to the "Proposed Changes to the CY 2013 Physician Fee Schedule". The Alliance is a 501 (c) (6) multidisciplinary trade association representing 19 physician and clinical 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 that not only possess expert knowledge in complex acute and chronic wounds, but also in wound care research. A list of our members can be found on www.woundcarestakeholders.org.

The Alliance is submitting comments on two provisions contained in this proposed rule:

- Chronic Wound Care: Use of wound surface culture technique in patients with chronic skin ulcer quality measure
- DME Face to Face requirement issue.

We believe that both provisions pose a problem.

QUALITY MEASURES

The Alliance fully supports the need for more wound care related quality measures in PQRS. The United States currently spent $8.5 billion dollars for wound care products and services, and approximately $20 billion dollars annually for wound care treatment. For example, 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. (*CMS Medicare Coverage Advisory Committee, 29 March 2005.)*

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There are many clinicians practicing wound care as a "specialty" who would like to report quality measures relevant to wound care. However, since "wound care" is not an ABMS recognized medical specialty, it does not have a seat on the AMA House of Delegates and thus physicians in the full time practice of wound care were not represented in the AMA-PCPI initiative directed at wound care measures development.

The sole focus of the Alliance comments is on a wound care measure contained in this proposed rule.

Specifically, the wound care measure that we will be commenting on is:

- Chronic Wound care: Use of wound surface culture technique in patients with chronic skin ulcer

This measure was taken from the 2008 Chronic Wound Care Physician Performance Measurement Set that was approved by the Physician Consortium for Performance Improvement (PCPI).

Our concerns are the following:

1. *In the measure specifications, there is a reference to one survey of wound care specialists that indicated that 54% routinely did a swab culture. There is no indication as to the source of this survey, the number of respondents, the various specialties surveyed or the validity of the survey. This hardly demonstrates a gap in care or significant impact that this measure would have on improving the care provided to people with chronic wounds.*

2. *The denominator does not correctly address the issue raised by the measure, that is, the use of a wound surface culture in a person with a chronic wound.*

   The measure purports to try to eliminate the use of wound surface cultures in chronic wounds. The supporting literature recommends the use of other culture techniques. However**, if the intent of the denominator was to ensure an appropriate culture technique then the denominator is wrong.** If the intent of the measure is to encourage culture techniques other than superficial swabs, the denominator ought to be **all visits in which a culture was performed in the presence of a chronic skin ulcer. Instead, the denominator is all visits in <u>patients with chronic skin ulcers</u>.**

   The implication of the measure as written is that, any time that a swab culture is NOT done the measure is passed. This means that if a clinician NEVER DID A CULTURE OF ANY KIND FOR ANY PATIENT, they would pass the measure even if the appropriate culture were indicated for the patient. The measure effectively rewards clinicians for "doing nothing," rather than for doing the right thing. If the denominator focused on chronic skin ulcers when a culture was taken, then if a wound surface culture was done, they would not meet the numerator of the measure and when they did the appropriate culture they would meet the measure.

<u>Recommendations</u>: **The Alliance recommends that this measure not be implemented**. If implemented as written, this measure will not measure what it purports to measure. This measure does not address any particular gap in care, overuse of care, or do anything to improve the treatment for the person with chronic skin ulceration. As the National Quality Forum (NQF) has identified measures should focus on scientific acceptability, feasibility and usability. This measure does not meet these standards.

As stated, the Alliance recommends that this measure not be implemented. In its place, we would recommend using Measure #6 in the PCPI Chronic Wound Care Physician Performance Measurement Set:

AMA-PCPI Measure #6 Offloading (pressure relief) of diabetic foot ulcers

While there are no data to support the assertion that overuse of wound culture is a major contributor to cost in wound care, **data are abundant that FAILURE to off-load diabetic foot ulcers is a major contributor to cost and failure to heal. It is our opinion that a quality measures which encourages the implementation of a national evidence-based practice guideline such as off-loading is the best way to engage wound clinicians in PQRS**. Therefore, we believe this measurement would be more appropriate for CMS to adopt.

DME FACE TO FACE

While the Alliance does not usually comment on issues related to Durable Medical Equipment (DME), the proposed changes in the DME face to face encounter requirements will impact the physicians/clinicians that order DME to help treat their wound care patients including pneumatic compression devices and accessories and Negative Pressure Wound Therapy (NPWT) – which are subject to this proposed rule.

The Alliance is concerned that these new requirements will unduly burden physicians and will cause delays in providing these necessary items of equipment to their patients. Specifically, adding new items of DME to the list of items that require a written order prior to delivery will delay beneficiaries' access to medically necessary medical equipment, delay hospital discharges and increase administrative burden for physicians and DME providers. Physicians in particular will face new pressure from DME providers and hospitals to complete a written order that meets Medicare requirements in a much shorter time frame than they do now. For busy physician offices, this added burden will not be easily offset by the payment amount proposed under the rule.

The Alliance also is concerned about requiring a separate face to face encounter in order to document the need for an accessory on an already provided item of DME. The primary equipment has already been "vetted" in a face to face encounter and it is unclear why then the accessory to the primary equipment would then also need to have a face to face encounter. The Alliance believes that this is just adding another unnecessary layer in the process and would be unduly burdensome in terms of time and cost to the physicians.

Recommendations: The Alliance recommends that CMS exclude not only NPWT and Pneumatic Compression devices from the face to face requirement, but also the accessories that are utilized for these products.

CONCLUSIONS AND SUMMARY

As experts in the full time practice of wound care, the Alliance member organizations have a unique perspective on issues pertaining to quality of care and thus have the following recommendations for these measures:

1) We urge CMS **not** to adopt ***Measure #1:*** *Use of wound surface culture technique in patients with chronic skin ulcers* because it is **incorrectly designed** and **fails to measure what it is intended to measure**. It will not improve quality and **will not substantially decrease cost of care** since overuse of culture is not a significant cost issue.

2) We recommend that Measure #1 be replaced by AMA-PCPI ***Measure #6: Offloading (pressure relief) of diabetic foot ulcers.*** **This measure will improve quality and reduce cost of diabetic foot ulcer care which represents a substantial portion of the Medicare budget.**

3.) We recommend excluding not only NPWT and Pneumatic Compression from the face to face requirement, but the accessories for these products.

We appreciate the opportunity to comment on this proposed rule. If you need more information or have any questions, please do not hesitate to contact me. The Alliance would be happy to serve as a resource to CMS.

Sincerely,

Marcia Nusgart R.Ph

Marcia Nusgart R.Ph
Executive Director