ALLIANCE OF

Wound Care Stakeholders

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

Sent Electronically

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

Dear Administrator Berwick:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit the following comments in response to the Proposed Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2012. The Alliance is a 501 (c)(6) multidisciplinary trade association consisting of 19 physician, clinical, provider, 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 that not only possess expert knowledge in complex acute and chronic wounds, but also in wound care research. We appreciate the opportunity to offer our comments.

Our comments center around the section entitled, Proposed OPPS Ambulatory Payment Classification (APC) Group Policies, and specifically, the two proposed wound care quality measures entitled, "**Chronic Wound care: Use of wound surface culture technique in patients with chronic skin ulcers**" and "**Chronic Wound Care: Use of wet to dry dressings in patients with chronic skin ulcers**". While the Alliance *strongly* supports the inclusion and need for wound care quality measures which impact chronic wound care conditions, **we have serious concerns that the two measures proposed will not succeed in improving quality of care among patients with non-healing skin ulcers, nor will they succeed in reducing the "overuse" of inappropriate interventions**.

Data overwhelmingly show that of the billions of Medicare dollars spent on wound care, wastage primarily results from care which is not appropriately PERFORMED, such as

5225 Pooks Hill Rd. | Suite 1626N
Bethesda, MD 20814
301 530 7846 T | 301 730 7946 F
marcia@woundcarestakeholders.org
www.woundcarestakeholders.org

diabetic foot off-loading and vascular screening. The Alliance has separated our comments into three distinct areas: 1) general comments, 2) areas of concern, and 3) summary and conclusion. Our comments follow.

General Comments

The Alliance fully supports the need for CMS to adopt wound care measures since as expressed below, there are more patients with wounds than ever before in the United States. Data presented at the 2005 Medicare Coverage Advisory Committee (MCAC) meeting confirmed that there are 6 million chronic wound patients in the United States, affecting 2% of our population. 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. 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. Venous ulcers are the most common chronic wound with an 80% likelihood of recurrence. (*CMS Medicare Coverage Advisory Committee, 29 March 2005.)*

Wound care is often perceived as being a problem of acute or long term care facilities; however, this is largely because the cost of outpatient wound care has been ignored. Hospital based outpatient wound centers are increasing at a rapid rate in order to provide care that can shorten healing times and help prevent in-patient stays. Many individual clinicians such as podiatrists or surgeons also provide a significant percentage of outpatient wound care. Thus, there are many clinicians practicing wound care as a "specialty" who would like to report quality measures relevant to wound care. Sadly, since "Wound Care" is not an American Board of Medical Specialty recognized medical specialty, it does not have a seat on the AMA House of Delegates and thus has no representation within PCPI. It is our understanding that no physicians or clinicians in the full time practice of wound care participated in the development of the wound care PCPI measures.

However, wound care represents an ideal opportunity to demonstrate the effectiveness of quality measures for the following reasons:

a. Wound care is already highly driven by evidence-based protocols. Healing rates of >70% can be achieved among diabetic foot ulcers with appropriate off-loading and > 55% for venous stasis ulcers receiving appropriate compression bandaging.
b. These basic interventions are well established with an excellent evidence-base. The major wound care organizations have published exhaustively referenced protocols for each of the major wound categories [diabetic foot ulcers, pressure ulcers, venous ulcers].
c. Despite the existence of evidence based protocols, data suggest that clinician implementation of appropriate protocols remains poor. These interventions can be easily extrapolated into quality measures.

Of the 175 current Physician Quality Reporting System (PQRS) measures, only one is directly relevant to wound care (Measure #186, 2011 PQRS Reporting Manual). Wound care physicians and clinicians are anxious to participate fully in PQRS. The two wound care measures that we will be commenting on are:

- Chronic Wound Care: Use of wound surface culture technique in patients with chronic skin ulcers

- Chronic Wound Care: Use of wet-to-dry dressings in patients with chronic skin ulcers

We understand that the two measures were taken from the 2008 Chronic Wound Care Physician Performance Measurement Set that was approved by the Physician Consortium for Performance Improvement (PCPI). While the Alliance is pleased that two wound care measures are included, we have serious concerns that the two measures proposed will not succeed in improving quality of care among patients with non-healing skin ulcers, nor will they succeed in reducing the "overuse" of inappropriate interventions.

There are absolutely no data to support the assertion that "overuse" of wound culture is a significant contributor to the escalating cost of wound care. However, data is abundant that FAILURE to off-load diabetic foot ulcers or identify significant arterial disease are the primary reasons for amputation and extended courses of futile treatment among diabetic foot ulcers and are directly linked to quality and cost.

Furthermore, while we heartily agree that saline wet-to-dry dressings represent an antiquated model of wound care, this "overuse" measure does nothing to drive the clinician to use dressings which are appropriate to the particular wound, but only encourages the use of "anything else but saline." A choice of "anything else" is in fact, a more expensive choice. Thus, this overuse measure, not linked to quality, will have the effect of **increasing cost**, without specifically improving quality. This is particularly true if clinicians are not encouraged to off-load diabetic foot ulcers or perform vascular screening.

Specific Comments

Comments Regarding Measure #1: Use of wound surface culture technique in patients with chronic skin ulcers

The Alliance has concerns that in this measure:

1) The denominator does not reflect the intent of the measure.
2) The numerator is incorrect in stating that there are no exclusions

The measure purports to try to decrease the use of superficial swab culture. 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. Instead, the denominator is all visits in <u>patients with wounds</u>.** The implication of the measure as written is that every time a clinician sees a patient with a wound, a culture is potentially necessary. And thus, 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. The measure effectively rewards clinicians for "doing nothing," rather than for doing the right thing.

Furthermore, the measure as written describes an exclusion for the <u>numerator.</u> Specifically, "The numerator will be met if there is documentation that a technique other than superficial swab of the wound exudate has been used to acquire the wound culture [e.g., Levine/deep swab technique (Levine et al., 1976), semi-quantitative or quantitative swab technique]." However, the measure itself specifically states that the numerator has no exclusions: "Numerator Inclusions/Exclusions: None".

<u>Recommendations</u>: While the measure may have been well intended, if implemented as written, it will not measure what it purports to measure, and thus will not improve quality of care in wound center patients.

The Alliance does not believe that this particular measure can be redeemed. In fact, since the initial attempt to create this measure, polymerase chain reaction (PCR) technology and other advanced swab culture methods have improved the information available from superficial wound cultures. Given the rapid and controversial advances occurring in this area, we recommend that this measure not be implemented. Instead we would recommend using Measure #6 in the PCPI Chronic Wound Care Physician Performance Measurement Set:

- ***Measure #6: Offloading (pressure relief) of diabetic foot ulcers***

The major wound care organizations have published exhaustively referenced protocols for each of the major wound categories, including diabetic foot ulcers. These interventions are directed to correct underlying factors which caused the wound or ulcer (e.g. compression for venous ulcers, off-loading for diabetic foot ulcers, and vascular screening for other leg ulcers). **It is our opinion that quality measures which encourage the implementation of national evidence-based practice guidelines are the best way to engage wound clinicians in PQRS**. Therefore, we believe Measure # 6 would be more appropriate for CMS to adopt.

We note that as written, **The Numerator was defined as:** Patients who were prescribed an appropriate* method of offloading (pressure relief) within the 12 month reporting period, and the **Performance Denominator (PD) is simply all patients 18 and older with a diabetic foot ulcer.** However, for the negative measure of wound culture, the denominator was determined as, "***All patient <u>visits</u>*** with the diagnosis of chronic skin ulcer." We find this discrepancy very ironic. Patients with non-healing skin ulcers

followed in a practice may only be in need of a culture once or twice per year. However, in the event that a diabetic foot ulcer develops, off-loading will be required CONTINUOUSLY until the wound heals. Despite this on-going requirement, the off-loading measure can be passed if it is only prescribed one time.

We strongly urge CMS and the measure developers to reconsider the structure of this measure. Off-loading of diabetic foot ulcers should be performed at each visit. Thus, **the denominator is all visits of patients with diabetic foot ulcers, and the numerator is the prescription of off-loading at each visit**.

The revision of this measure to a "per visit" measure would substantially improve the quality of care of diabetic foot ulcers, and represent a true measure of the quality of care provided by the clinician.

Comments Regarding Measure #2: Use of wet-to-dry dressings in patients with chronic skin ulcers

While this measure is implementable, we believe it falls short of improving the overall quality of care for patients with non-healing ulcers. This "overuse" measure does nothing to drive the clinician to dressings which are appropriate to the particular wound, but only encourages the use of "anything else but saline." A choice of "anything else" is a more expensive choice. Thus, this overuse measure, not linked specifically to quality of care, will have the effect of INCREASING COST. This is particularly true if clinicians are not encouraged to off-load diabetic foot ulcers or perform vascular screening.

The major wound care organizations have published referenced protocols for each of the major wound categories. While all of these protocols emphasize the use of moist wound healing dressings, **the essential element for healing is correction of the underlying factors which caused the wound or ulcer in the first place (e.g. compression for venous ulcers, off-loading for diabetic foot ulcers, vascular screening for other leg ulcers).**

It is our opinion that quality measures which encourage the implementation of national practice guidelines are the best way to engage wound clinicians in PQRS.

Recommendations: Therefore, we urge CMS to implement a "Vascular screening of non-healing leg ulcers" measure, rather than a negative measure of the use of wet-to-dry dressings which will have the very odd effect of driving up cost. If a vascular screening measure were adopted, along with a diabetic foot ulcer "off-loading measure," there would at last be three measures directed at correcting the three most common etiologies for non-healing lower extremity ulcerations (uncontrolled edema, uncontrolled plantar pressure and undiagnosed ischemia). **These three measures could significantly improve quality of care for patients with non-healing leg ulcers and lead to a significant decrease in COST.**

We would be pleased to submit a complete description of a vascular screening measure.

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 Measure #6: *Offloading (pressure relief) of diabetic foot ulcers.*

    a. This measure will improve quality and reduce cost of diabetic foot ulcer care which represents a substantial portion of the Medicare budget.
    b. We recommend that Measure #6 be corrected to a "per visit" measure since proper care of a diabetic foot ulcer cannot be achieved by prescribing off-loading once in a 12 month period. Off-loading must be prescribed with each *visit* (just as Measures #1 and #2 were designed on a per-visit basis).

3) We believe that Measure #2: *"Use of wet-to-dry dressings in patients with chronic skin ulcers"* is a poor way to encourage quality in wound care. Although this measure at least is implementable, we maintain that it will **increase costs** without increasing quality by driving clinicians to more expensive dressings but not linking this choice to quality in any other way.

    a. Instead, we urge CMS to implement a "Vascular screening" measure which might make a significant impact on the escalating number of non-traumatic amputations.

We appreciate the opportunity to submit these comments and would be pleased to serve as a resource to CMS to address any questions or to give further information.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director