ALLIANCE OF

Wound Care Stakeholders

August 29, 2008

The Honorable Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Attn: CMS – 403 – P
Mail Stop C4- 42-05
7500 Security Boulevard
Baltimore, Maryland 21244-8018

RE: CMS-403-P: Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009

Dear Acting Administrator Weems:

I serve as the Executive Director of the Alliance of Wound Care Stakeholders ("Alliance"), a multidisciplinary consortium of over 15 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 the following organizations who possess expert knowledge in wound care: the Association for Advancement of Wound Care, American Professional Wound Care Association, National Pressure Ulcer Advisory Panel, Wound Healing Society, American Association of Wound Care Management, and the Society for Vascular Surgeons.

On behalf of the Alliance, I am submitting the following comments in response to the Centers for Medicare and Medicaid Services [CMS] Proposed Rule published in the July 7, 2008 Federal Register entitled: "Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009".

The Alliance shares CMS's goals of assuring beneficiary access to medical services and technologies – and believes that improving the payment system will help achieve this goal. The Alliance supports your movement toward improved accuracy in reimbursement under the Physician Fee Schedule and appreciates the significant resources devoted to improving quality of care. However, the Alliance is concerned with the code descriptions for negative pressure wound therapy as well as some of the proposed measures to be included in the physician quality reporting initiative. Our specific comments follow.

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A. Payment for Wound Care Procedures

We strongly supported Congressional action to avert the scheduled across-the-board cut in physician payments for 2009, and to ensure that physicians receive a 1.1 percent payment increase for 2009. Nevertheless, we recognize that this is a temporary fix, and it is imperative for CMS, Congress, and the medical community to work together to find a long-term solution to the physician update formula before the forecasted 21 percent reduction in payment rates is triggered in 2010.

As policymakers confront the challenges facing the Medicare system, it is important to ensure that physician payment for wound care procedures are adequate to safeguard beneficiary access to this technology. The wound care community has raised concerns with the growing gap between the costs associated with procedures and Medicare payment levels. As beneficiary demand for these procedures grows, this will only place a larger financial burden on providers, potentially raising patient access issues.

Unfortunately, because Medicare reimbursement for these procedures has not kept pace with the increasingly complex technology, and labor and equipment costs associated with performing these procedures, a patient access challenge is looming.

Unless measures are taken to protect and restore Medicare reimbursement to physicians for these procedures patients will face access issues. We therefore strongly urge CMS to work with the community and other stakeholders to promote payment policies that will adequately compensate physicians for wound care procedures and preserve beneficiary access to these important services. The Alliance would like to offer our assistance to CMS to help develop these payment policies.

B. PQRI - Physician Quality Reporting Initiatives

General Comments

Beginning on page 38559 of the proposed rule, CMS discusses its proposal to to expand the quality measures that eligible professionals may voluntarily report to qualify for incentive payments under the Physician Quality Reporting Initiative ("PQRI"). The Proposed Rule includes a total of 175 measures for reporting in 2009, an increase of 56 measures from 2008. The proposal would allow claims-based reporting either for individual measures or for measures groups.

We are committed to quality care for wound care patients, and we commend CMS' efforts to identify and provide incentives for the adoption of best practices in patient care. In general, we support expanded reporting options that provide physicians with additional opportunities to employ processes that promote the highest quality of care.

In developing and selecting specific reporting measures, it is imperative that CMS work hand-in-hand with the relevant specialty societies and others in the medical community to ensure that measures provide clinically-significant information while being structured in the least administratively-burdensome manner possible. We also encourage CMS to continue its outreach and education initiatives to facilitate provider participation in the quality reporting initiative. CMS also should invite continuing feedback from professionals on ways to improve operational aspects of the program, since physicians ultimately are the best resource for CMS in collecting the types of data that can truly achieve our shared goal of enhancing the quality of services provided to Medicare beneficiaries.

Looking to the future of physician quality reporting, we understand that the Proposed Rule was promulgated before enactment of the "Medicare Improvements for Patients and Providers Act of 2008" ("MIPPA"), which includes a number of reforms designed to improve the PQRI program. We wanted to highlight our support for a process mandated by section 131(b) under which the Secretary must "ensure that eligible professionals have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish," effective beginning with quality measures for 2009. We agree that a physician-driven process is key to developing workable, clinically-effective measures the promote quality of care. We support the AMA's Physicians Consortium for Performance Improvement (PCPI) and their measure development process.

Likewise, MIPPA requires the Secretary to submit a plan to Congress by May 1, 2010 regarding the transition to a value-based purchasing program for Medicare physician services. The framework and details of such a program could have a significant impact on physician reimbursement, quality of care, and beneficiary access to physicians' services. CMS should begin consulting as soon as possible with all affected stakeholders, including specialty societies and other physician organizations and beneficiary representatives, to set forth program goals and quality safeguards. Outreach efforts such as town hall meetings and open door forums should be used to encourage feedback on effective, workable approaches to incorporating value-based purchasing for physician services. We would like to offer our assistance as the Agency develops program goals and quality safeguards as they relate to wound care related services as we represent all stakeholders in this area.

Specific PQRI measures for Chronic Wound Care

As we have stated above, in general, we support expanded reporting options that provide physicians with additional opportunities to employ processes that promote the highest quality of care. However, on Page 38571 of the proposed rule, CMS identifies Additional Proposed Measures Contingent Upon NQF Endorsement or AQA Adoption. Of concern to the Alliance are the following measures:

The Alliance agrees that these measures be part of the PQRI, but CMS has not yet published the final language of these measures and many Alliance members raised several concerns over the language that was used in the drafting of those measures. Prior to placing these proposed measures in the proposed rule, the Alliance believes that CMS or the measure developer must have the detailed specifications of the measures publicly posted. The Alliance believes that CMS was premature in proposing these measures in this fee schedule when the specific language for these measures have not yet been posted or provided to the specialty societies that are impacted. If these measures are adopted, the Alliance urges CMS to ensure that there is more uniformity in the interpretation of the policy for coverage among the CMS contractors.

Comments on the specific measures include the following:

- **Chronic Wound Care: Use of Compression System in Patients with Venous Ulcers**

The concern of many organizations within the Alliance **is** Medicare is a major provider for patients with venous ulcers and currently has conflicting Contractor coverage policies for coding and coverage for high-compression system (three & four layer, short stretch, paste-containing bandages) indicated in the treatment of venous ulcers. This must be addressed to enact this measure and not exclude a significant portion of the population with venous ulcers. To provide an example – Noridian denies access to high compression therapy even when the data supports utilizing this therapy in the literature and endorsed national guidelines.

- **Offloading of diabetic foot ulcers**

The Alliance believes that the measure as written is already the standard of care and is such a low bar that it does not really help with quality of care. This measure, as written, does not move forward in enhancing quality of care in this area. As stated, this measure, as written is already the standard of care and the quality of care enforcement already exists.

- **Diabetes Mellitus: Diabetic Foot & Ankle Care, Peripheral Arterial Disease Ankle Brachial Index**

The Alliance is also concerned about the inclusion of the proposed measure on Diabetes Mellitus: Diabetic Foot & Ankle Care, Peripheral Arterial Disease Ankle Brachial Index. The AQA reviewed this measure at least a year ago and did not pass this measure. Most of the Alliance members opposed this measure. Since

the AQA already reviewed this measure and did not pass it, we do not believe that it is appropriate to include the measure in this proposed rule.

The Alliance urges CMS to issue the detailed specifications of these measures prior to implementing them as part of the PQRI so that interested parties can comment on the measures. The Alliance also urges CMS to ensure that when the measures are adopted, they are clearly identified so that there is more uniformity in contractor interpretation.

C. Potentially Misvalued Services – Need for Increased Transparency in Process

Beginning on page 38582 in the Proposed Rule, CMS outlines its plans to identify and correct potentially misvalued services under the physician fee schedule. As part of this initiative, CMS is requesting that the Relative Value System Update Committee ("RUC") review the fastest growing physician services, as identified by CMS. CMS is undertaking this reassessment to determine why there has been an increase in utilization for such services, noting that there may be a clinical rationale for such increases or changes in the relative resources involved with furnishing the service.

We agree with CMS that it is important to review the reasons behind utilization increases before labeling a service as "misvalued." Utilization increases can be tied to a wide range of appropriate clinical factors, including expanded data indicating improved clinical outcomes associated with a procedure or technology, new clinical evidence supporting additional applications for a procedure or technology, or enhanced physician familiarity with a procedure. Moreover, demographic trends also will impact utilization use. For instance, as the number of "baby boomers" reaching Medicare age increases, an increase in the volume of wound care procedures is to be expected.

We therefore urge CMS to continue to use a transparent approach for examining potentially "misvalued" services. **We believe that physicians and other stakeholders should have an opportunity to review and comment on the RUC's findings and any other related CMS data before any associated Medicare payment or policy changes are adopted.**

The ad-hoc review process that the RUC has recently allowed does not match the cycle that CMS has established and used for 15 years. Section 1848(c)(2)(B)(i) of the Act requires that CMS review all RVUs no less often than every 5 years. Unfortunately, with the recent creation of the RUC Five-Year Review Identification Workgroup, CMS has opted to implement Five-Year Review recommendations as interim values in the Final Rule, thus negating the opportunity for comment or correction for an entire year. It is our position that any potential changes in RVUs based on RUC recommendations should be

published by CMS in the Federal Register in a Proposed Rule with 60-day comment period before they are put into effect.

Without such a process in place, inadvertent errors can be made that cannot be corrected until the following year. Therefore the Alliance recommends that CMS publish any changes in the RVUs based on the RUC recommendations in the Federal Register as a proposed rule with a 60 day comment period.

Conclusion

The Alliance appreciates the opportunity to provide our comments and looks forward to working with you to address the issues discussed in this letter. Please contact me directly

if you have any questions or concerns.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director