ALLIANCE OF

Wound Care Stakeholders

June 13, 2008

The Honorable Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
U. S. Department of Health and Human Services
Attn: CMS – 1390 – P
Mail Stop C4- 26- 05
7500 Security Boulevard
Baltimore, Maryland 21244-8018

RE: CMS-1390-P: Proposed Changes to the Hospital Inpatient Prospective Payment Systems and for FY 2009 Rates

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, and the Wound Ostomy Continence Nurses Society

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 April 23, 2008, Federal Register titled, "Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems and fiscal Year 2009 Rates".

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 Inpatient Prospective Payment System (IPPS) and appreciates that you have devoted significant resources examining changes that would better reflect patient severity. Our comments focus solely on those areas of the proposed rule that impact wound care. Specifically, the Alliance is concerned with the code descriptions for hospital acquired conditions for pressure ulcers and the proposed quality measures. Our comments follow.

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Hospital Acquired Conditions - Pressure Ulcers

The Hospital Acquired Conditions (HAC) provisions in Medicare regulations required hospitals to begin reporting on their Medicare claims on October 1, 2007, whether certain specified diagnoses were present when the patient was admitted. The first eight conditions were selected last year and included pressure ulcers. In the current proposed rule, CMS proposed to create new codes to better identify pressure ulcers. Accordingly, CMS has identified new codes to replace 707.00–707.09 as 707.20 – 707.22 (non-CCs) and 707.23 and 707.24 (MCCs). CMS requested specific comments on whether the proposed refinements to these existing HACs reflect ICD-9-CM Coordination and Maintenance Committee modification of pressure ulcer codes to capture staging information and comments on the proposed MS-DRG classifications of the codes.

Updating the terminology from "Decubitus Ulcer" to "Pressure Ulcer"

We appreciate the Agency replacing the older term "Decubitus Ulcer" with "Pressure Ulcer" since it reflects the Agency's recognition that pressure can come from many sources, not just a bed, which the term "decubitus" implies.

ICD-9 Coding for Pressure Ulcers

While the Alliance appreciates the efforts that went into the creation of the new codes, we do not believe that the new codes reflect pressure ulcers accurately. The number of codes to identify pressure ulcers is not adequate nor do they reflect current concepts of pressure ulcer pathophysiology and clinical assessments and practice. Specifically, we believe that CMS should have ICD-9 codes established for deep tissue injury and unstageable ulcers which are explained further below. Both of these types of wounds present with very unique characteristics and cannot be accurately captured in the 5 new established codes. Both of these wounds frequently result in a later classification of a Stage III or IV ulcer.

Unstageable ulcers are those in which the true depth, either a stage III or IV, cannot be determined because the lowest portion of the ulcer is covered with necrotic tissue. The term "unstageable" pressure ulcer is a medical diagnosis today and can be an indication for debridement of the wound. There are also some clinical situations in which the necrotic tissue is best left intact; those are called "stable eschar" and frequently occur in elderly patients with severe arterial limb disease. In either case, the current proposed staging codes do not allow for unstageable ulcers to be identified. Unstageable pressure ulcers will be a Stage III or Stage IV if debridement takes place. Yet, debridement is not always indicated in pressure ulcers with stable eschar, so the wound may remain unstageable until it is nearly healed.

Deep tissue injury is a form of pressure ulcers that develops from intense pressures at the bone-muscle interface. The tissue damage forms in the inside of the body and initially is seen as a purple or bruised appearing tissue on a pressure-born area. Deep Tissue Injury

can deteriorate rapidly into Stage III or Stage IV, even with optimal treatment. These ulcers have been described in unpublished case series (Black 2005, Baharestani, 2008) and likely are the cause of almost all stage III and IV pressure ulcers. (Berlowitz & Brienza, 2008)

Since Stage III and IV ulcers will be the focus of quality measures for acute care hospitals, the Alliance supports the tracking of both Unstageable and Deep Tissue Injury pressure ulcers as well. Without specific codes addressing these areas, hospitals will be forced to utilize the "unspecified" code, and thus, will lead to overuse or misuse of this ICD-9 code. The Alliance believes that more codes need to be identified to adequately capture all pressure ulcer types, which has not been captured in the proposed rule.

Therefore, the Alliance recommends that CMS add additional codes to adequately capture all pressure ulcers. Specifically, we recommend the following codes be put into place:

707.25 Pressure Ulcer, Deep Tissue Injury
707.26 Pressure Ulcer, Unstageable

If there is a "shortage" of codes that can be utilized, we urge you to adopt codes for deep tissue injury and unstageable ulcers in exchange for Stage I and II ulcers.

CC/MCC Classification

Additionally, the Alliance supports the classification of 707.23 Pressure Ulcer, Stage III and 707.24 Pressure Ulcer Stage IV as MCCs if they are determined to meet the present on admission indicator. We would also recommend the inclusion of 707.25 Pressure Ulcer Deep Tissue Injury and 707.26 Pressure Ulcer Unstageable as MCCs if they are determined to meet the present on admission indicator. Both 707.25 Deep Tissue Injury and 707.26 Unstageable represent pressure ulcers with the same level of severity and depth of tissue injury as 707.23 Stage III and 707.24 Stage IV, and should be reimbursed as MCCs accordingly.

Unavoidable Pressure Ulcers

The Alliance associations agree with the need to reduce the development of hospital acquired pressure ulcers. We further agree that reducing Stage III and Stage IV pressure ulcers should be a measure of quality care and be considered for non-payment should they occur during a hospitalization. However, not all hospital acquired pressure ulcers can be prevented. Unstable blood pressure or unstable spinal cord injury, for example, may preclude usual preventative measures-as any attempt to turn the patient could worsen their condition. Additionally, some clinical scenarios, such as acute traumatic injuries and complex medical issues, interfere with the required turning and movement off of pressure areas for periods of time to prevent skin breakdown. In all of these scenarios, "skin failure" should be viewed in the same light as temporary renal failure, heart failure, etc.

Skin is an organ and the failure of this organ should not be universally and completely ascribed to iatrogenic or negligent causes.

We would like to offer our assistance as the Agency develops guidance documents on reviewing appeals for payment. We submit that the development of a Stage III or IV pressure ulcers is not always preventable or unavoidable for the severely ill, compromised patient that cannot be moved due to their acute condition. CMS needs to identify ICD-9-CM codes related to these conditions and build into the MS-DRG system a means to eliminate these patients for inclusion in the 'preventable' ulcer non-payment methodology.

RHQDAPU (reporting hospital quality data for annual payment update)

The Alliance has and continues to support efforts to increase the quality of care in Medicare. We do, however, have some concern regarding the increased burden of reporting on these additional measures on smaller institutions. Larger hospitals will likely be able to absorb the costs of the additional work that will result from the requirement of reporting on an increased number off measures, but it is unclear what the impact will be on smaller institutions.

In addition to the general concern raised above, we would like to address the wound care specific quality measures addressed in the proposed rule. For FY 2010, CMS proposes to add 43 new quality measures –several specific to pressure ulcers. We support the measure of pressure ulcer incidence and would support a variation in that measure; hospital acquired pressure ulcers. This is the most accurate term at present. We cannot support using pressure ulcer prevalence as a quality measure. Prevalence is the number of existing pressure ulcers and hospitals admit patients with pressure ulcers. Therefore, measurement of prevalence would include both those patients who were admitted for treatment of the ulcer and those who developed pressure ulcers. Hospitals that admitted patients for treatment of pressure ulcers would appear to be providing poor quality of care, when in fact; they are providing excellent care in an effort to heal these wounds. The collection of incidence can be costly and we would recommend the use of hospital acquired pressure ulcer data with a baseline measure using documentation at the time of admission.

Clarification

The Alliance has a couple of areas in which we seek clarification on this proposal. First, we would like for CMS to define what an “unspecified staged” pressure ulcer is. Does CMS consider this to be a deep tissue injury? Does CMS consider an “unstageable ulcer” an “unspecified staged pressure ulcer? We also would like CMS to define “unspecified”?

The Alliance would also like further clarification on when CMS determines admission. For example, a patient is in the emergency room and has received an order for admission while awaiting a bed in the acute care unit. The patient remains in the ER for 48 hours

before actually being transferred to a hospital bed. In this scenario, when would the POA rules begin – when the patient is actually transferred to the hospital bed or after the order for admission has been received? If a patient is in a holding unit - is the patient's status inpatient or outpatient with respect to POA?

The Alliance would appreciate clarification on these issues.

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

c.c. Donna Pickett, CDC