ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

June 24, 2013

Marilyn Tavenner
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue SW
Washington, DC 20201

Submitted electronically

RE: CMS-1599-P Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2014 Rates; Quality Reporting Requirements for Specific Providers; Hospital Conditions of Participation; Medicare Program; FY 2014 Hospice Wage Index and Payment Rate Update; Hospice Quality Reporting Requirements; and Updates on Payment Reform; Proposed Rules

Dear Administrator Tavenner:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the proposed rule on the Inpatient Prospective Payment System FY 2014. The Alliance is a nonprofit multidisciplinary trade association of health care professional and patient organizations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org.

Our specific comments focus on three areas of this proposed rule: The Admission Criteria, Hospital Acquired Conditions and Wound Care Quality Measures. Our specific comments follow.

Specific Comments

Admission and Medical Review Criteria for Hospital Inpatient Services

Issue: The Alliance agrees that prolonged observation periods are having an adverse impact on the financial liability of the beneficiary and provider. Although we support CMS in its efforts to curtail recent increases in the length of time that Medicare beneficiaries spend as outpatients receiving

observation services, the Alliance believes there are significant issues with the proposed policy in this rule.

Length of Stay Presumptions and Patient Access Concerns

Issue: There is a presumption throughout this proposed rule, that an individual is an 'inpatient' if the documentation shows that the patient requires more than two midnights in the hospital following an inpatient admission. The "starting point for this time-based instruction would be when the beneficiary is moved from any outpatient area to a bed in the hospital in which the additional hospital services will be provided." Medicare would presume that hospital services spanning fewer than two midnights should be considered outpatient observation. For patients whose inpatient stay was fewer than two midnights, CMS would pay for inpatient care only if the services were identified on Medicare's inpatient-only list or "in exceptional cases such as beneficiary death or transfer."

Concerns: The Alliance is deeply concerned that these presumptions will adversely affect patient access to medically necessary wound care services, particularly with the presumption that hospital services spanning fewer than two midnights should be considered outpatient observation. We believe that the decision to admit to an inpatient stay should be made by the interdisciplinary team and solely based on the clinical condition of the patient and in which setting their medical needs can be most safely and effectively addressed.

There are many clinical scenarios for which a hospital inpatient stay lasting for less than two midnights is medically necessary and appropriate. For example, when a patient is admitted to the emergency room with a wound with elevated blood sugar, acute cellulitis and possible arterial occlusion of the lower extremity, the patient is usually attended to in observation care for 6 hours and then likely admitted because of unstable blood sugar, wound /skin infection and high risk of clot formation. The patient would be admitted for administration of IV antibiotics, debridement of the wounds, evaluation of vascular and arterial status and control of their blood sugar, which may be managed within 30 hours and the medical team determines the patient is stable, without occlusion and that it is appropriate to discharge to home health services as follow-up care for the wound/cellulitis and diabetic control. The total amount of care could be less than the two midnight requirement in this proposal.

Current CMS policy relies on clinical judgment and evaluation of a patient's needs to determine inpatient admission status. Although Chapter 1 of the Medicare Benefit Policy Manual instructs physicians to use a 24-hour period as a benchmark for inpatient status, consistently Medicare's longstanding policy has been that CMS does not define or pay under Medicare Part A for inpatient admissions solely on the basis of the length of time the beneficiary actually spends in the hospital. By CMS affirming its confidence in the current criteria and planning to continue to apply the inpatient admission criteria when the beneficiary remains hospitalized for fewer than two midnights, CMS is proposing a rule that would establish new time-based medical review criteria, separate and distinct from clinical judgment.

In addition, the policy in the proposed rule would result in a Medicare review contractor denial for the inpatient admission of these patients due to the length of stay presumption, which would in turn deny coverage for medically necessary inpatient rehabilitation services. Further, the proposed rule for Part B Inpatient Billing in Hospitals, CMS-1455-P, indicates that physical therapy services are excluded from

being rebilled as Part B services if denied under Medicare Part A because physical therapy services are defined as "outpatient only" services. Physical therapists do provide wound care in multiple care settings and their services should not be denied.

Therefore, hospitals that admit Medicare beneficiaries for less than two midnights and provide medically necessary services to those patients will not be able to rebill for those services under Part B after receiving a denial due to the presumption. The inability to be reimbursed for medically necessary services creates a disincentive for hospitals to provide these services to patients during the inpatient hospital stay for fear of denials and noncoverage. This may create barriers to access to care for Medicare beneficiaries in the acute care setting, simply because of their length of stay.

Recommendations: The Alliance recommends setting a timeframe for an observation period of no more than 24 hours. This will help to set a bright line standard for hospitals as well as post-acute care providers such as home health agencies and skilled nursing facilities. The Alliance also requests further clarity regarding how transitions of care would affect the two-midnight presumption. It is unclear in the proposed rule how CMS will be addressing this and urges CMS to consider appropriate transitions of care for this policy.

Medicare Review Contractor Accountability

Issue and Concerns: CMS states that the two-midnight presumption was created to decrease hospital hesitancy to admit patients whose inpatient stays are medically necessary for fear of retroactive denials. However, CMS also states that if a hospital is found to be abusing the two-midnight presumption for non-medically necessary inpatient hospital admissions and payment, CMS review contractors would disregard the two-midnight presumption when conducting review of that hospital. The Alliance is concerned with how the Medicare Review Contractors would monitor and implement this provision.

Recommendations: We encourage CMS to further clarify the parameters and expectations for review contractors to set aside the two-midnight presumption. For example, what factors would contribute to evidence that a hospital is systematically delaying the provision of care to surpass the two-midnight timeframe? Without safeguards used systematically across all contractor regions, this new policy may not decrease hospital hesitancy to admit patients if contractors can simply ignore the presumptions.

Further, we encourage CMS to closely monitor the application of these presumptions by review contractors and institute safeguards. For example, if there is evidence that Medicare review contractors are abusing their power to disregard the two-midnight presumption, such as a high percentage of decisions being overturned during the appeals process, CMS should ensure appropriate remedial actions such as termination of the contactor agreement.

Hospital Acquired Conditions

Issue and Concerns: The Alliance understands that CMS is required to penalize hospitals in the lowest-performing 25% for eight hospital-acquired conditions (HACs) including the rates of pressure ulcers. CMS has proposed to divide the HACs into two domains. The first domain would include the

rates of pressure ulcers. The Alliance believes there is already a mechanism in place which reduces payment for the development of a Stage III or IV pressure ulcer which are acquired in a facility.

Recommendation: The Alliance requests clarification on why "rates of pressure ulcers" as a HAC indicator is necessary since there is already a mechanism to reduce payment for the development of certain pressure ulcers in place. It is unclear if CMS is intending to include all pressure ulcers or just Stage III and IV pressure ulcers. It is also unclear in this proposed rule how CMS will factor in a patients age, gender, and any comorbidities related to pressure ulcer development in their calculations. The Alliance would encourage more clarity prior to the rule becoming final.

Additionally, the Alliance sought clarification prior to the deadline for these comments on whether the rate of accidental puncture and laceration criteria includes skin tears. We did not receive a response and would also like clarification on this issue prior to the proposed rule becoming final.

Wound Care Quality Measure

Issue: The Alliance does not agree with the quality measure "Percent of Residents with Pressure Ulcers That are New or Worsened" and does not believe this measure is appropriate for any setting. It is misleading and not based on scientific evidence. Furthermore, it is unclear what the definition of "worsening" is with respect to this measure. There has been no consistent definition of worsening and CMS has not defined this term as it relates to this measure.

Language in the Proposed Rule: We invite public comment on this proposal to adopt NQF #0678 Percent of Residents or Patients with Pressure Ulcers that are New or Worsened (Short- Stay) for the LTCHQR Program.

Concerns: Current CMS policy assumes that all pressure ulcers are preventable, all are caused by faulty care, that pressure ulcers progress through the various numeric stages, and that worsening ulcers are defined as pressure ulcers which increase in Stage. Not one of these statements is based on scientific evidence.

Stage 2 pressure ulcers, which are superficial skin breakdown, can be due to moisture, friction and/or shear forces or to pressure and do not always progress to Stage 3 and 4 lesions. Therefore, the concept of progression through the various stages is incorrect. Evidence is now incontrovertible that Stage 3 and 4 ulcers originate in the deep tissue compartment and progress outward to the dermis [inside out theory], thus begin as a deep tissue injury (DTI). This deep tissue injury initially will not be visible to the naked eye; hours or days will elapse before clinical signs are evident. Once observed, DTIs will evolve along a predictable course such that the tissue will open to become Stage 3 or 4 ulcerations. At the time of clinical presentation, deep tissue injuries may have the appearance of a purple or maroon bruise under intact skin that may resemble and is often mistaken for a Stage 1 pressure ulcer. Thus, the assumption that intervention can reliably prevent Stage 1 pressure ulcers from "progressing" to Stage 4 ulcers is faulty and dangerous.

Equally misleading is the concept that pressure ulcers "worsen" because unstageable ulcerations become Stage 3 or 4 ulcers, or because Stage 3 ulcers are re-classified as Stage 4 ulcers, once the necrotic debris

covering the true ulcer depth is removed. In the NPUAP staging system, ulcers are regarded as unstageable if the base is covered by necrotic tissue. However, if after debridement the ulcer undergoes "re-staging," it will be considered to have worsened when in fact the actual severity of the original ulcer has only become apparent.

No prospective studies have been performed which indicate that the staging system can be reliably utilized and in fact, data show that the reliability of the current classification system is deficient. In one study[1], 473 nurses were asked to classify 56 photographs of skin lesions as normal skin, blanchable erythema, pressure ulcers or incontinence lesions. The multirater-kappa with good agreement should be 0.70 but was only 0.37 ($P < 0.001$). The same pictures were presented to another 86 nurses for classification on two separate occasions with an interval of one month apart. The intrarater agreement was poor with the calculated kappa = 0.38.

The impetus of regulatory changes appears to be fueled by the common misconception that all tissue injury invariably begins with superficial damage (Stage 1 and 2) and progresses to deep ulcers (Stage 3 and 4) due to negligence and poor quality of care. We have already commented on the fact that Stage 1 and 2 ulcers do NOT always progress to become Stage 3 and 4 ulcers. To date, there is also no evidence that pressure ulcers can be completely prevented. In a recent consensus conference that involved 24 stakeholder organizations from various disciplines, it was unanimously agreed that pressure ulcers are largely preventable but not always avoidable[2]. To maintain hemodynamic stability and normal functioning of vital organs during critical conditions and at life's end, circulation is diverted from the skin compromising cutaneous perfusion[3]. Dysfunction and associated skin changes are inevitable when metabolic demand outstrips supply of oxygen and vital nutrients. In other words, the skin will exhibit breakdown in the same way that the other organs do as part of ageing and severe illness. This means that intrinsic factors predispose individuals to the development of pressure ulcers. Some of these key factors are poor nutritional intake, low Body Mass Index (BMI<18.5), hypoproteinemia, low systolic blood pressure, anemia, contractures and prominent bony prominences, vascular disease, neuropathy, and uncontrolled diabetes. Pressure ulcers related to these factors are not due to caregiver neglect.

With regard to the proposed quality measure, there is no consistent definition of "worsening." This is particularly problematic when one considers the following:

1. Stage 1 ulcerations are easily confused with DTIs.
2. Pressure ulcers do not progress through the stages.
3. Stage 2 pressure ulcers form from the outside-in due to moisture, friction/shear or pressure.
4. Stage 3 and 4 pressure ulcers form from the inside out and thus do not represent the "worsening" of ulcers of a lesser stage but an entirely different pathophysiological process.
5. Patient factors make some pressure ulcers medically unpreventable and the medically unpreventable ulcers cannot yet be identified from those which might be caused by caregiver neglect.

Recommendation: The Alliance – as commented on previously – does not agree with the quality measure and does not believe that it is an appropriate measure for any setting. The Alliance recommends that this measure is not adopted in the Inpatient or Long Term Care Hospital Setting – let alone any setting in which wound care is provided. Furthermore, the Alliance urges CMS to make the

development and endorsement of better quality measures for pressure ulcer PREVENTION and TREATMENT a priority for the National Quality Forum.

References

1. Defloor T, Schoonhoven L, Katrien V, Weststrate J, Myny D. Reliability of the European Pressure Ulcer Advisory Panel classification system. *J Adv Nurs* 2006; 54(2):189-98.
2. Black JM, Edsberg LE, Baharestani MM, Langemo D, Goldberg M, McNichol L, Cuddigan J, Npuapv NP. Pressure ulcers: avoidable or unavoidable? Results of the National Pressure Ulcer Advisory Panel consensus conference. *Ostomy Wound Manage* 2011; 57(2):24-37.
3. Sibbald RG, Krasner DL, Lutz J. SCALE: Skin Changes at Life's End: Final Consensus Statement: October 1, 2009. *Adv Skin Wound Care 2010;23*(5):225-36

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On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.
Executive Director