ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

June 13, 2017

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1677-P
Mail Stop C4-26-05
7500 Security Boulevard,
Baltimore, MD 21244-1850

Comments Submitted Electronically to www.regulations.gov

RE: CMS-1677-P Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2018 Rates

Dear Administrator Verma:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the proposed regulation entitled, "Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Fiscal Year 2018 Rates". The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies and clinical associations 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.

While the proposed regulation contains many issues in which CMS is seeking comment, the Alliance will solely focus our comments on those that impact wound care and specifically:

- ***Removal of the current pressure ulcer measure (NQF #0678) and replace it with a modified version of the measure entitled "Changes in Skin Integrity Post Acute Care: Pressure Ulcer: Injury***.
- ***Clarification of Terminology Used throughout the Proposed regulation – Pressure Ulcer/Injury***
- ***Patient Safety and Adverse Events (Composite) NQF #5031***
- ***Adoption of Malnutrition eCQMs in the Hospital***

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814
T 301.530.7846 | **C** 301.802.1410 | **F** 301.530.7946
marcia@woundcarestakeholders.org

***Removal of the current pressure ulcer measure (NQF #0678) and replace it with a modified version of the measure entitled "Changes in Skin Integrity Post Acute Care: Pressure Ulcer: Injury*.**

CMS is proposing to remove the current pressure ulcer measure (NQF #0678) and replace it with a modified version of the measure entitled "Changes in Skin Integrity Post Acute Care: Pressure Ulcer: Injury." The newly proposed measure is not NQF endorsed. CMS even notes in the proposed rule that the Agency intends to submit the proposed measure to NQF for endorsement as soon as feasible. The Alliance does not support moving forward with this measure until the measure has been vetted via the NQF endorsement process which examines measures not only for the importance to measure and report, but also for testing regarding feasibility, usability, reliability and validity of the measure, which are critical to accountability. This measure, with the new terminology would not comport to ICD-10 usage and would create confusion among clinicians. As such, the Alliance recommends that CMS delay implementation of this proposed measure modification until it can be vetted with the NQF.

Clarification on the term "pressure ulcer/injury" used in the regulation

The Alliance seeks clarification on the terminology utilized not only in the modified version of the measure but throughout the proposed rule and specifically on the term "pressure ulcer/injury" used in the proposed regulation.

CMS continuously refers to pressure ulcers in the proposed rule as pressure ulcer/injury. The Alliance is seeking clarification on this new terminology. Is the term "injury" being utilized to describe "deep tissue injury" solely? If so, then the Alliance is in support of this modification.

However, many but not all of our members do not support the term "pressure injury" as synonymous for the term "pressure ulcer" in the new measure since they maintain that it is clinically incorrect and inappropriate. It is our understanding from these clinical associations that the "injury" terminology does not have universal support from wound care organizations, has limited scientific evidence, carries with it legal ramifications, and can lead to much confusion not only in the clinical community but also by the public at large. Importantly, the term also does not align with ICD-10 coding terms.

For instance, one of the possible ramifications of changing all "pressure ulcers" to "pressure injuries" is that they may be relocated to the "wound" section of ICD-10 (and future iterations of the system). It is generally agreed that *ulcers* are related to underlying medical conditions, whereas "wounds" are the result of operations or accidents. Pressure injuries *as wounds* will require coding to define the specific injury it is "related to", with the possible creation of codes for "inadequate hospital care," "failure to turn," "injury by [named] medical device," despite the fact that the scientific data to support these assertions are inconclusive. After the pressure wound has failed to heal for 30 days, it will be recoded as a chronic ulcer- but not as a *pressure ulcer*, making it difficult to understand clinical outcomes since these problems will not maintain a unique code structure throughout. Furthermore, because CMS

recognizes the different underlying etiologies of "ulcers" vs. "wounds," CMS often distinguishes between them with regard to the treatments and therapeutic interventions that are covered.

Another confusing issue is while Stage 1 "ulcers," and Deep Tissue Injuries (DTI) are not open skin lesions, the lesions currently referred to as Stage 2, 3, and 4 *pressure ulcers* ARE open lesions with drainage requiring a dressing. If all of these lesions are now referred to as *injuries*, it is not clear how we are to know which ones are open wounds requiring a dressing, unless that information is to be conveyed via the National Pressure Ulcer Advisory Panel numbering system, whereby injuries numbered 2, 3, and 4 indicate an open sore, and injuries numbered with 1 and DTIs are not. This information would not be obviously apparent from the terminology, and would require *a priori* knowledge (e.g. all Stage 3 pressure injuries are actually open sores that require a dressing, but Stage 1 injuries are not open sores and thus may not require a dressing).

In summary, due to the lack of actual consensus on the scientific argument for this change, and the difficulties it creates for coding and clinical documentation, many but not all of our clinical association members have requested that CMS not change the term "pressure ulcer" universally to "pressure injury." However, if CMS is simply utilizing the term to describe deep tissue injury, then the Alliance recommends that CMS instead utilize the term "Pressure Ulcer/Deep Tissue Injury." This terminology is clearer and would not cause any confusion in the clinical community and would continue to align with ICD-10 coding. We would appreciate having the opportunity to discuss this issue with CMS staff before the implementation of the final rule.

Inclusion of Patient Safety Measure Acute Care

The Centers for Medicare and Medicaid Services (CMS) have proposed a new measure for the FY 2023 Program Year and Subsequent years***: Patient Safety and Adverse Events (Composite) NQF #5031***. This measure would replace the current claims-based Patient Safety Indicator (PSI) #90 measure from the Hospital program beginning with the FY 2019 program. The specific component in which we are commenting relates to the PSI 02 Pressure Ulcer Rate - which is one of the 10 individual PSI components. According to the proposed rule, CMS will calculate this composite using administrative claims data. CMS will use a Generalized Estimating Equation hierarchical modeling approach that will for demographic and clinical characteristics. While the Alliance agrees that improving patient care/safety and providing hospitals incentives to ensure patients are not harmed by the medical care they receive is important and necessary, we do not agree with including this measure as a composite nor do we agree that claims data is the method by which CMS should calculate the composite if CMS moves forward with this proposal.

We also seek clarification as to why CMS has created NQF 5031 for IPPS yet there are other different measures included in this proposed rule for LTCH. The Alliance is trying to understand why CMS would create so many different measures to measure the same thing – quality of care for treating patients with pressure ulcers. The LTCH measure is not a composite measure – it is a free-standing measure which has already been vetted with the National Quality Forum. Pressure ulcers are complex and due to

the incidence and the interest of the community, the development of evidence based protocols should be used and not minimized in a composite measure with other factors.

As such, the Alliance recommends that the PSI O2 for Pressure Ulcers be removed from the NQF 5031 and instead CMS utilize the quality measure being put forward in the LTCH portion of this proposed rule - which has already been vetted by the NQF - to address pressure ulcers. This way there will be more uniformity across care settings in the delivery of quality pressure ulcer treatment.

Adoption of Malnutrition eCQMs in the Hospital IQR

Finally, CMS proposed 4 new malnutrition focused electronic clinical quality measures (eCQMs). Malnutrition is often a precursor for pressure ulcers therefore implementation of an effective care and discharge plan for patients diagnosed with malnutrition is absolutely critical in improving outcomes by reducing complications including but certainly not limited to pressure ulcers. As such the Alliance supports these proposed measures. Preventing and treating malnutrition is so critical in these patients that the malnutrition eCQMs are "measures that matter" for patients, families and providers. The Alliance supports these measures as stated but would recommend that CMS adopt these measures in the CY 2018 reporting cycle rather than a future year as stated in the proposal.

In addition to the comments provided above, one of our member organizations, the Academy of Nutrition and Dietetics, submitted comments to CMS as well. While their comments do not focus specifically on wound care, malnutrition is a big component of wound care. In their comments, they stated the following:

As malnutrition is an independent risk factor for poor patient outcomes[1] we recommend CMS adopt the malnutrition eCQMs in the Hospital IQR with reporting starting in CY 2018 to address potential patient-safety risks, facilitate care coordination and to improve patient outcomes. We also support adopting a future malnutrition composite measure in the Hospital IQR, when available.

While people may be at-risk or become malnourished in any care setting, the trigger of a hospitalization can exacerbate and accelerate disease-associated malnutrition or the risk of malnutrition. With 33-54% of patients at risk of or malnourished upon hospital admission and only 3-5% diagnosed we agree with CMS that this is a gap area and recommend that this issue be addressed as soon as feasible. While recognizing the need to avoid imposing unnecessary burdens on hospitals associated with measure reporting, we support the immediate adoption of these clinically relevant eCQMs as there are currently no malnutrition measures and there is a significant quality improvement opportunity. Malnutrition is associated with many adverse outcomes including depression of the immune system, impaired wound healing, muscle wasting and increased mortality.[2],[3] Patients with malnutrition have also been found to be four times more likely to develop pressure ulcers, two times more likely to develop surgical site infections, 16 times more likely to develop intravascular device infections, and five

[1] Lim, SL, et al. Malnutrition and its impact on cost of hospitalization, length of stay, readmission and 3-year mortality. Clin Nutr. 2012 Jun;31(3):345-50. doi: 10.1016/j.clnu.2011.11.001. Epub 2011 Nov 26.

[2] Corkins MR et al. Malnutrition diagnoses in hospitalized patients: United States, 2010. JPEN J Parenter Enteral Nutr. 2014; 38(2): 186-95.

[3] Barker LA, et al. Hospital malnutrition: prevalence, identification and impact on patients and the healthcare system. Int J Environ Res Public Health. 2011; 8(2): 514-27.

times more likely to develop catheter-associated urinary tract infections. [4] A 2016 AHRQ Statistical Brief estimates the economic impact of malnutrition in the hospital to be $42 billion[5]and that 23% of patients with malnutrition were readmitted to the hospital within 30 days, with an average cost per readmission of $16,900 per patient for those with protein-calorie malnutrition and $17,900 per patient for those with post-surgery non-absorption. [6] Early identification of Medicare beneficiaries at risk for malnutrition, prompt nutrition intervention and implementation of an effective care transition plan has been shown to reduce length of stay, pressure ulcer incidence, and costs.[7,] As recovery and functional independence may be significantly improved by preventing and treating malnutrition, the malnutrition eCQMs are clinically important for patients, families and clinicians.

The Alliance is in support of the 4 eCOM malnutrition measures contained in this proposed rule and also the comments that were submitted by the Academy. The Alliance requests that CMS adopt their recommendations.

Conclusion

The Alliance appreciates the opportunity to provide you with our comments. If the Agency needs further information or has any questions, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R. Ph.

Marcia Nusgart
Executive Director

[4] Guenter P, et al. Addressing Disease-Related Malnutrition in Hospitalized Patients: A Call for a National Goal. The Joint Commission Journal on Quality and Patient Safety, 2015 Oct;41(10):469-73.Oct 2015, Vol. 41, No. 10.

[5] Weiss AJ, et al. Characteristics of Hospital Stays Involving Malnutrition, 2013. HCUP Statistical Brief #210. September 2016. Agency for Healthcare Research and Quality, Rockville, MD.

[6] Fingar KR, et al. All Cause Readmissions Following Hospital Stays For Patients With Malnutrition, 2013. HCUP Statistical Brief #218. December 2016. Agency for Healthcare Research and Quality, Rockville, MD.

[7] Meehan A, et al. Health system quality improvement: Impact of prompt nutrition care on patient outcomes and health care costs. J Nurs Care Qual. 2016; 31(3): 217-23.