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The Centers for Medicare & Medicaid Services (CMS)
CC: Yale New Haven Health Services Corporation – Center for Outcomes Research and Evaluation (CORE)

RE: [PCQM-677] Public Comment Regarding CMS Draft Measure - Hospital Harm - Hospital Acquired Pressure Injury - Office of the National Coordinator for Health Information Technology

On behalf of The Ohio State University Wexner Medical Center, we would like to submit comments in regards to the Measure Authoring Tool (MAT); eCQM: hospital-acquired pressure injury. We believe that the following suggestions would improve the quality of care for patients by ensuring meaningful data collection and reporting, in order to appropriately capture hospital-acquired pressure injuries.

1.) Does the numerator (as specified) accurately capture hospital-acquired or worsening pressure injuries while minimizing any unintended consequences?

Comment: No. We are concerned about the unintended consequence of inaccurately reporting pressure ulcers such as Deep Tissue Injuries and Unstageable pressure ulcers.

A Deep Tissue Injury (DTI) is not adequately captured within the ICD10 classification, and must be coded as "unstageable". This is problematic because a DTI is not the same as an unstageable pressure ulcer. A DTI often has evolution/change that occurs over 2-4 weeks; therefore, the actual "stage" of this wound is unable to be known at admission. The depth of tissue damage for a DTI wound type can be as shallow as dermis or as deep as bone and the only way to further discover the amount of damage is by ultrasonography that is not typically covered by insurance, and because providers may not have the resources to utilize this least invasive manner, they might have to wait for the wound to evolve, ultimately resulting in inaccurate inflation of diagnosis of stage III and stage IV pressure injuries.

A DTI may appear 2-4 weeks after the mechanism of injury, due to the inflammatory process, which encompasses a time trajectory of 2-4 weeks. That means that these wound types could take up to 4 weeks to declare themselves and that final declaration can be as minimal as a stage 2 in its presentation or be as extensive as a full thickness stage IV wound, precarious and even, life threatening. When this declaration is finally made, the patient, provider, CMS etc. needs to be aware that the wound has not gotten worse, but rather, it has evolved and made known the amount of injury created at the onset of the non-blanchable discoloration of the epidermis.

Because of the difficulty in defining these patients and the uncertainty in ultimate presentation of this wound, these patients who are hospitalized after trauma or periods of immobilization AND later experience a DTI that was from the trauma or immobilization, should be excluded from the numerator if there is no specific ICD10 code to describe them and differentiate them from an unstageable wound.

Additionally, there is need for better classification and understanding of the "unstageable pressure injury" under the current reporting system for CMS. The current system's logic automatically defaults unstageable pressure injuries to stage 3 or 4, but just like the DTI, understanding the physiology of the skin and the pathology of its demise gives support to the idea of necrosis of the dermis with completely viable tissue underneath (ie viable subcutaneous tissue, fascia, muscle etc.) and that a resorbing serous bullae, defined as a stage 2 by the NPUAP, once desiccated, can also present as dry eschar with damage of only the first 2 layers of skin.

Please note that in order to decrease the risk of infection and preserve current skin integrity it is not always best practice to remove eschar as when it is stable eschar for the sole purpose of identification of a stage.

Summary: Due to the interaction of the terms DTI and Unstageable with the numerator as specified, this current measure and the subsequent draft measure will have a secondary outcome of underdocumentation and undertreatment of potentially significant skin changes out of concern for value program related consequences.

Comment: We are concerned about the unintended consequence of inaccurately reporting pressure ulcers that could indeed be unavoidable, skin failure, or Kennedy Ulcers.

There is also no category in the above equation to account for pressure injuries that are defined as **unavoidable** by CMS in the F314 Long Term Care Tag for Survey Guidance. This definition has been endorsed for the acute care setting by the NPUAP in 2010 and again in 2013, but is not being captured in the score card being reported in the acute care setting (DHHS, 2004).

Unavoidable vs. Avoidable Pressure Injuries initially employed by The Center for Medicaid and Medicare (CMS) in their F314 guideline for Long Term Care Facility Surveys was further endorsed by NPUAP in 2010 and again in 2013 advocating expanding the use of this definition to the Acute Care setting. The definition states (1) most but not all pressure injuries are avoidable.(2) pressure redistribution surfaces cannot replace turning or repositioning, (3) if enough pressure was removed from the external body, the skin cannot always survive, and (4) skin failure is not the same as a pressure injury (Black et al, 2011)(Edberg, L.E. et al, 2014). Also included in this definition is the prospect of unavoidability in the presence of hemodynamic instability that prevents a patient from being turned and when life sustaining nutrition and hydrations are held d/t the patient's advanced directives.

Skin failure and Kennedy Terminal Ulcers occur as vital organs begin to fail when blood flow is shunted away from the integument to maintain perfusion to more vital organs such as the heart and lungs resulting in skin necrosis and death of the cutis (Langemo et al., 2006). When reviewing the literature on this topic, evidence show an association of impaired nutrition, multisystem organ failure, sepsis, severe sepsis, septic shock, surgeries lasting greater than 3 hours, prolonged hypotension, vasopressors and prolonged mechanical ventilation to play a role in acute skin breakdown (Delmore et al., 2015). On clinical exam, these wounds can present over boney prominences such as the sacrum and be inadvertently diagnosed as a pressure injury, when indeed, they are not.

2.) How useful is this measure in assessing and improving the quality of care for patients?

This measure, if properly defined and reported, can serve to hold the facility and providers accountable for the care of individual patients, reduce overall healthcare cost and improve patient outcomes. However, the current platform for reporting such the incidence of these wounds needs to be much better defined (as discussed above).

There are limited numbers of certified wound care professionals /clinical experts currently practicing in the field that are familiar with the evidence and able to integrate it into practice. Wound assessment, staging and reporting are complex endeavors that require a knowledge base not available to all institutions and as such, the expertise or lack of expertise contributes to the validity of the data being reported. We believe that improved access to training and certification for clinical expertise in this area of medicine would help to improve the pressure ulcer quality reporting program.

***3*.) Are all clinical concepts related to this measure captured routinely in the normal course of clinical workflow? Specifically, are pressure injuries present on arrival and location (on body) of pressure injury present on arrival, captured routinely and available in structured, extractable fields in EHR systems?**

Yes, with the exceptions of DTI, unstageable pressure ulcers, unavoidable pressure ulcers, skin failure, and evolving pressure injuries not yet declared. These wounds need further definition to appropriately capture “present on admission”. Also, ‘Unstageable” is a catch-all term that represents both extremes of tissue injuries and therefore imparts significant ambiguity in the use of this term.

4.) Are all clinical concepts related to this measure available in structured, extractable fields in EHR systems?

Currently there is no code for DTI pressure injuries. DTI pressure injuries are captured as “unstageable pressure ulcers” which are considered a stage III or stage IV under the current CMS reporting definition. We do not think this is an accurate reflection of these evolving

wounds, especially when DTIs and unstageable pressure injuries can be staged at stage II, once these wounds have declared themselves. DTIs are not established wounds—they behave differently than unstageable wounds, and are often expected to change over a 2 to 4 week trajectory. Separate designation as a DTI is needed in order to appropriately capture this type of wound and differentiate them, appropriately.

5.) Do you suggest any denominator exclusions for this measure, and why?

We suggest excluding patients who experienced mechanisms of immobilization, such as trauma or scenarios of "found on ground" after unknown periods of time, from the denominator, because these patients may have a DTI already developing prior to admission that will declare itself after admission, and therefore be inappropriately captured as developed during hospitalization.

We believe that those with a DTI, unstageable pressure injury, unavoidable pressure injury and skin failure should be placed in a different category and/or further defined within the current category to better reflect the true pathophysiological process of their wounding. Institutions and providers should not be held accountable for skin failure or unavoidable pressure injuries when they have met the criteria outlined in the F314 pressure ulcer guidelines currently being utilized by CMS in the long term care environment until exact guidelines are created specifically for those in the hospital setting. Providers and institutions should also not be penalized by default when a wound is staged DTI or Unstageable due to the assumption that it must be a stage 3-4 when, in fact, these wounds could be a stage 2.

6.) Currently as specified, the measure uses 24 hours as the timeframe within which any pressure injuries that were present on arrival should be documented (in a structured field). Do you agree with this timeframe as a reasonable standard for reporting?

Yes, for pressure injuries that are established and already-declared, or patients that have intact skin and do not develop a DTI. A DTI may take several days or weeks to appear, and therefore could not be captured during the first 24-hour period of hospitalization. Further definition of these pressure ulcers is needed in order to appropriately capture them as present upon admission vs. developed during the hospitalization.

7. While our goal is to include as many patients as possible in the measure, we acknowledge that pressure injuries should be avoided in all patients. However, care practices may change for end-of-life or hospice patients who have a comfort care-only order. Are comfort care-only orders feasible to capture in the EHR systems?

Comfort care orders can be easily captured within an EHR system, however, all patients (or their surrogates for decision making) who decline such a designation will not be captured in the data. It should be noted that a patient may be in the end stages of life or multisystem organ failure or critically ill and still wish to be a "full code". As such, the designation of "comfort-

care" does not fully include the entire population of patients who are actively dying and experiencing situations with different care practices that may impact skin integrity.

Respectfully submitted,

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