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WOUND CARE
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March 2, 2018

Alliance of Wound Care Stakeholders Comments re: Hospital Harm – Hospital Acquired Condition: Pressure Injury.
Contract number is HHSM-500-2013-13018I
Task Order HHSM-500-T0001
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On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit the following comments in response to the proposed EHR quality measure – Hospital Harm – Hospital Acquired Condition: Pressure Injury. The Alliance is a 501 (C) (6) nonprofit multidisciplinary trade association of physician medical specialty societies and clinical and patient associations whose mission is to promote quality care and access to products and services for people with chronic wounds (diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers) 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, including pressure ulcers, but also in wound care research. A list of our members can be found at www.woundcarestakeholders.org. Over the years the Alliance has worked with the National Quality Forum (we have been a members since 2015) and we have partnered with the US Wound Registry to create wound care quality measures as part of its Qualified Clinical Data Registry. As such we are very interested in this proposed quality measure.

GENERAL COMMENTS

We strongly support and encourage the continued development of quality measures that assess wound care outcomes, as wound care clinicians should be required to report on measures that relate to the care that they deliver allowing you to effectively track and report the quality of that care. However, any measure being developed needs to be well thought out and designed to achieve the correct objectives. The Alliance is deeply concerned about the Hospital Harm- Hospital Acquired Condition -Pressure Injury measure. The intended objective will not be achieved the way this measure has been crafted. Overall, the specific language as well as the numerator and denominator, contained within this document are not accurate. Furthermore, there are scientifically incorrect statements within this proposed measure. As such, **the Alliance respectfully requests that this measure be withdrawn and that CMS convene meetings with all interested stakeholders to create a well-devised clinically meaningful measure.**

While the Alliance has provided our response to the questions posed in relation to this measure, there are additional issues that need to be stated. These include the following:

1. The Alliance is opposed to the title of this measure. It is very concerning that CMS has tied a Pressure

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Injury Measure to Hospital Harm. As stated throughout our comments – it is possible for a patient to develop or have a pressure ulcer without any harm. If this measure continues as a quality indictor to measure harm, there will be unintended consequences - either an increase in the number of lawsuits, or an increased likelihood that hospitals will be unable to defend themselves against frivolous litigation - despite the best care being provided.

2. The way this measure has been crafted, it appears that CMS and its staff need a better understanding of pressure ulcers in order to develop this type of measure which is critical to capturing quality of patient care. It would be our pleasure to serve as a resource to you to educate the staff on pressure ulcers and wound care. One area that needs education is the fact that many pressure ulcers are not avoidable based on the condition of the patient.

   For instance, most wound care patients have complex and/or chronic medical conditions. In fact, patients with chronic wounds often have serious and multiple co-morbid conditions. Pressure ulcers occur among patients with diabetes, peripheral vascular disease (nearly as common as coronary artery disease and stroke), or as a result of unique medical problems (e.g., sickle cell anemia, vasculitis), or in association with immunosuppression (e.g., AIDS, steroid use or transplantation medications). Many times, these patients may enter the hospital with a primary diagnosis of infection, cardiac disease, diabetes, kidney failure or cognitive deficits and have a pressure ulcer on admission which may not be taken in account. For patients with pressure ulcers, the most common primary diagnoses for hospitalizations include: septicemia, pneumonia, urinary tract infections, congestive heart failure, respiratory failure, and complicated diabetes mellitus.[i]

   This measure presupposes that all pressure ulcers are avoidable/preventable. This simply is not clinically correct. While we certainly agree that some pressure ulcers can be avoided with appropriate care and clinical protocols, it is not accurate to say they all can be avoided.

3. The Alliance recommends that CMS establish an inclusive group of stakeholders to assist CMS in creating a meaningful EHR measure.

4. Finally, there are devices that can support pressure ulcer prevention within the acute care setting, including a variety of support surfaces and surgical dressings, that can be included within an established protocol to reduce the incidence of pressure ulcers in this setting. As we mutually continue to explore this opportunity, many of our members can assist in the development of appropriate tools.

SPECIFIC COMMENTS

When issuing the pressure injury quality measure – CMS specifically requested a response to eight questions. We are responding to the first seven questions as follows:

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

No. There are several issues with this particular question and the way it is written. First, unstageable or Deep Tissue Injury (DTI) wounds do not progress or get worse. The actual depth (stage) of an

unstageable pressure ulcer, either a Stage 3 or 4, is not known until the necrotic debris is removed. A deep tissue injury is damage in deep tissue, therefore, the damage has already occurred. Clinicians have no control over these types of wounds – even when providing the correct treatment. Therefore, the implication that these wounds progress or get worse is inaccurate. Furthermore, patients that are admitted to the hospital with an unstageable pressure ulcer or deep tissue injury usually have serious co-morbid or complex conditions. These patients are considered "high risk" even before any treatment protocols have been established and may or may not respond to effective prevention interventions being provided based on existing prevention guidelines.

Second, CMS has not provided any information regarding the length of stay within the numerator and as such, depending on the length of stay may be counting the same patient multiple times. This will then inaccurately reflect the number of pressure ulcers which have occurred in a facility or deteriorated during hospitalization.

Third, the Alliance is extremely concerned about the word "harm" in the quality measure title. As stated above, some pressure ulcers are unavoidable due to the nature of the wound, the comorbidities of the patient and the condition of the patient. How will CMS account for worsening or unavoidable situations due to comorbidities or conditions that may impact development of a pressure ulcer or wound healing of an existing? Is there anything that can be noted in the patient's EMR to indicate these types of situations – i.e., uncontrolled diabetes, diminished venous circulation in the affected areas? We believe that there should be a mechanism for the hospital to indicate appropriate treatment of pressure ulcers even though/when there are appropriate interventions to treat these wounds. In addition, CMS has not disclosed or discussed how it will monitor the avoidable versus unavoidable pressure ulcers. Until that information has been vetted, this measure should be withdrawn.

Additionally inherent in the quality measure title is the notion that hospital acquired pressure ulcers are a form of hospital harm. The Alliance disagrees with this premise. The assumption CMS is making is that harm has been inflicted on the patient should the patient develop a pressure ulcer in the hospital. However, as discussed above, some pressure ulcers are unavoidable despite the best care being provided. Until there is a clear understanding of what is and is not avoidable, we believe that the word "harm" has no place in the title of any quality measure for pressure ulcers.

Finally, the regulations promulgated by CMS clearly define "hospital acquired conditions" and "serious preventable events." Pressure ulcers can be a "hospital acquired condition" as defined by the regulations. However, they are NOT identified as such in the regulations defining serious preventable events. CMS has acknowledged that some pressure ulcers are unavoidable. So we question why CMS would – across the board – identify pressure ulcers in a hospital harm measure when they have acknowledged that some are unavoidable?

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

The Alliance does not believe this measure is useful at all for many reasons. First and foremost, as stated above, despite the highest quality of care being administered, data clearly show that some pressure ulcers still develop despite the best possible care being provided using all the current interventions available. Since this measure cannot distinguish between ulcers that occur as a result of inadequate care vs. those that develop for reasons beyond our control, it is not helpful in assessing the

quality of care provided.

Second, the measure also does not help or motivate providers to improve care. It appears that CMS is simply finding a different way to extract data which will not change results for hospitals with poor performance in this area. To motivate poor performing hospitals, CMS should develop the measures to incentivize hospitals to improve performance. Rather than reducing payment CMS should consider paying an additional payment to hospitals that perform well.

The measure currently in effect has not necessarily motivated poor performing hospitals to improve. CMS may want to consider publishing a list of poor performing hospitals where the quality of care for pressure ulcers do not meet standards. There must be a meaningful consequence to improve quality of care yet reward those hospitals that are in fact performing well.

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?**

   No. There is no standard template to assess pressure ulcers similarly in each of the different EHR systems and therefore the extractable data is inconsistent from one EHR to another. Currently, there are no guidelines which provide conformity/uniformity in EHR systems. As CMS continues its efforts to improve interoperability this situation maybe improved. Until then, the conformity/uniformity does not exist.

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

   No. As stated above, the thousands of EHR systems have no standard template to assess pressure ulcers, therefore data collection is different from each EHR system. Therefore the extractable data is inconsistent from one EHR to another. Currently, there are no guidelines which provide conformity/uniformity in EHR systems. Moving forward, we would suggest the use of established assessment tools such as the "Braden Scale for Predicting Pressure Sore Risk." In 2011 AHRQ released, "A toolkit for Improving Quality of Care." We would suggest that these tools be considered in continued efforts in the development of a measure and specific tools to support this initiative.

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

   A review of the data would be necessary to better identify exclusions. There may need to be a denominator based on specific risk adjusted patient conditions to identify how the hospitals will be evaluated for pressure ulcers. For example, CMS could exclude all patients receiving palliative care because they are usually receiving this type of care as an end of life care option. Another is to exclude those with metastatic malignancies, or septic shock, as well as other critical illnesses -the thought being that if the organism cannot adequately perfuse critical organs such as the heart, lungs, brain, kidney, then it certainly will not be able to do so with skin.

   Similarly, CMS seems to be including everyone over 18 in the denominator. This inclusion will skew

data collection so refinements will need to be made in order to obtain accurate data collection.

Pressure ulcers that are present on admission must be excluded. A pressure ulcer which is already present cannot be included in a measure that purports to target any "harm" that occurs DURING the hospital stay. Since severe pressure ulcers form from the INSIDE to the outside, any ulcer already present on admission may not have evolved completely and the documentation of its natural evolution will result in the institution being held responsible for events that occurred elsewhere. It is imperative that ulcers present on admission be excluded or hospitals may be unwilling to admit patients with pre-existing ulcers since they know that these ulcers will be counted in their hospital "harm" (sic) data.

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?**

   No. The Alliance does not agree that a 24 hour time frame is adequate. Not all pressure ulcers present immediately. In fact it can take several days for the full extent of a pressure ulcer to manifest – which in part is due to the medical condition of the patient.

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**?

   CMS needs to take into consideration that many EHRs do not have comfort care bundles included in their systems. For those that do have them (and they are limited), the measures are placed and documented within the EHR in many different locations. The measures which exist are not well defined and take on many different forms. There is significant variation from clinician to clinician and facility to facility in what is captured when this information is in fact included in an EHR. It is our opinion that comfort care measures cannot be captured effectively in an EHR at this point in time. There are also still many hospitals that do not use fully functional CEHRT.

CONCLUSIONS

The Alliance appreciates the opportunity to provide you with our comments to this proposed measure. As stated above, since we represent physician specialty societies and clinical and patient associations involved in wound care and pressure ulcers, we would be pleased to serve as a resource to CMS to educate staff on these issues and help to develop a more appropriate and clinically accurate quality measure.