AAMC

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Via Electronic Submission ***(eCQM Tracker JIRA Website)***

October 30, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
P.O. Box 8011
Baltimore, MD 21244-1850

Re: ***CMS Quality Initiatives Project Title: Hospital Harm – Medication-Related Bleeding and Hospital Harm – Severe Hyperglycemia***

Dear Administrator Verma:

The Association of American Medical Colleges (AAMC or the Association) welcomes this opportunity to comment on the Centers for Medicare and Medicaid Services' (CMS' or the Agency's) measure development under contract HHSM-500-2013-13018I, "Development, Reevaluation, and Implementation of Outcome/Efficiency Measures for Hospital and Eligible Clinicians, Option Year 4." In particular, we submit these comments on the project developing four hospital-level electronic clinical quality measures (eCQMs) entitled Hospital Harm – Medication-Related Bleeding and Hospital Harm – Severe Hyperglycemia.

AAMC is a not-for-profit association dedicated to transforming health care through innovative medical education, cutting-edge patient care, and groundbreaking medical research. Its members are all 151 accredited U.S. and 17 accredited Canadian medical schools; nearly 400 major teaching hospitals and health systems, including 51 Department of Veterans Affairs medical centers; and more than 80 academic societies. Through these institutions and organizations, the AAMC serves the leaders of America's medical schools and teaching hospitals and their more than 173,000 full-time faculty members, 89,000 medical students, 129,000 resident physicians, and more than 60,000 graduate students and postdoctoral researchers in the biomedical sciences. AAMC member hospitals are just 5 percent of all acute care hospitals but have 20 percent of all Medicare inpatient days.

Challenges with eCQMs in General

The AAMC is supportive of CMS' efforts to improve the quality of care by developing measures on dimensions of patient harm or adverse patient safety events, but notes that CMS has previously recognized and responded to the challenges regarding the feasibility of electronically-submitted measures and has reduced the number of eCQMs hospitals must report for FY 2019 and 2020 payment. There is considerable burden required to map the necessary data elements from the EHR to the appropriate Quality Reporting Data Architecture (QRDA) format, and some vendors are not properly equipped to collect and transmit such data through the CMS portal.

Mandatory eCQM reporting depends on hospitals using the correct version of specifications, which is generally in the control of the EHR vendors, not the hospitals. The AAMC urges CMS to continue outreach to EHR vendors, hospital quality staff, and other affected stakeholders to identify underlying

structural problems and barriers to successful reporting of these measures. With this in mind, the Association continues to have concerns that hospitals and vendors may not be adequately prepared to fully report eCQMs and asks CMS to focus resources on sufficiently addressing current concerns with eCQM reporting rather than on developing additional eCQMs for inclusion in hospital reporting programs for the future. Focusing on the inclusion of a small number of measures in the eCQM program that are meaningful and not overly burdensome will provide hospitals with additional time and bandwidth to address the considerable challenges of electronic data reporting.

Finally, the AAMC advises that completed testing of these eCQMs under development should demonstrate reliability and validity in the acute care setting and these measures should be submitted to National Quality (NQF) for review and endorsement. CMS should vet these new eCQMs across a selection of vendors and hospitals prior to considering the measures for addition to a CMS quality reporting program for implementation.

Measure Comments: Medication-Related Bleeding

The AAMC does not support the measure as currently developed to measure medication related bleeding of admitted patients. The measure is flawed for several reasons, including significant concerns of unintended consequences and ensuring that the measure is better tailored to measure medication-related bleeding so that it is meaningful for patients and provides appropriate incentives for hospital improvement. As currently proposed, the measure is overly inclusive, by both defining bleeding too broadly (and with a lack of precision) and by not excluding trauma patients.

Bleeding is defined broadly, notably by looking at an absolute decrease in hemoglobin of at least 2 g/dL. A drop of 2 grams is not necessarily a bleeding event; for example, a patient who presents with severe dehydration and is treated will likely see such a "drop." The relativity of the drop would be more precise – that is a patient who goes from 7 grams to 5 grams is far more significant than a patient who goes from 14 to 12 grams. Defining both as a severe bleeding event is imprecise and could cause hospitals to significantly limit their use of anticoagulants to the detriment of many patients. Another example of the problems with the definition is that it includes any diagnosis code indicating new onset bleeding that starts during the qualifying encounter as a bleeding event, when that bleeding event could be anything from a common nose bleed to something far more serious and worthier of measurement.

In regard to exclusions, the measure does exclude surgical patients and patients on dialysis during the encounter who were administered at least one anticoagulant or thrombolytic medication during the encounter and within 7 days prior to a subsequent bleeding event. The exclusions should also include trauma patients because the vast majority of trauma patients are non-surgical. In addition, the time limits on drop in hemoglobin (excluding first 24 hours of arrival in hospital) or transfusion (excluding first 48 hours after arrival) may not be sufficient to prevent a more defensive practice of using anticoagulants on trauma patients. Also the limited use of new anticoagulants could be more potent and potentially effective for patient care but are less predictable and/or immediately reversible. For example, heparin and coumadin are standard single factor anticoagulants in use that have immediate reversal agents, whereas newer anticoagulants work on multiple factors and thus can be more effective when there is less certainty on the factor causing the need for an anticoagulant but are more challenging to reverse if necessary.

These issues with measure specification lead to significant concerns of unintended consequences, most notably that the measure could lead to hospitals reducing use of anticoagulants, which would be ultimately lead to greater harm to patients.

Measure Comments: Severe Hyperglycemia

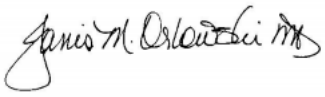
The Association agrees that hospitals should implement protocols to manage hyperglycemia for critically ill patients. That said, this measure as currently developed does not appear to be useful in assessing and improving the care for patients with severe hyperglycemia primarily because of the timing and manner of the glucose measurement. The majority of blood glucose tests are done with a glucometer at the bedside (point-of-care testing) because it is cost effective and expedient and not from a drawn blood sample that goes to the lab. Point of care testing results may not always be included in the electronic health record (EHR), but instead kept in a nurse's notes, whereas lab test results will always be included in the EHR. By measuring only lab tests, and not including point-of-care testing, the measure removes the majority of blood glucose testing from measure. This may result in an inaccurate picture of severe hyperglycemia events, especially as the measure specifies that *no data* is a *de facto* instance of a severe hyperglycemic event. This is because it includes an assumption of severe hyperglycemia in the event that a lab measurement was not captured one day and not preceded by two consecutive days where the glucose values were less than 200 mg/dL.

It should also be noted that generally the measure is still structured to encourage providers to chase a number, rather than focus on patient care. This was an issue in prior specifications of the measure, which led to significant unintended consequences and resulted in the prior measure's removal from the Hospital Inpatient Quality Reporting Program and de-endorsement by the National Quality Forum. In considering ways to re-specify the measure, developers should ensure that the measure incentives care workflows to ensure that there is appropriate glucose monitoring and proper glycemic management for all patients.

Conclusion

We appreciate your attention to these comments and would welcome the opportunity to discuss them with you further. If you have questions regarding the issues discussed please feel free to contact Gayle Lee, galee@aamc.org or 202-741-6429, and Phoebe Ramsey, pramsey@aamc.org or 202-448-6636.

Sincerely,



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Chief Health Care Officer

Cc: Gayle Lee, AAMC
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