AAMC

Association of
American Medical Colleges
655 K Street, N.W., Suite 100, Washington, D.C. 20001-2399
T 202 828 0400
www.aamc.org

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

February 28, 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 – Acute Kidney Injury, Hospital Harm – Hypoglycemia, and Hospital Harm – Opioid-Related Adverse Events***

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 – Hypoglycemia; Hospital Harm – Hospital-Acquired Pressure Injury; Hospital Harm – Opioid-Related Adverse Events; and Hospital Harm – Acute Kidney Injury."

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 19 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: Acute Kidney Injury

The AAMC does not support the measure as currently developed to measure acute kidney injury (AKI) in hospitalized patients for several reasons, including the need for risk adjustment and ensuring that the measure is better tailored to measure AKI so that it is meaningful for patients and provides appropriate incentives for hospital improvement.

Without adequate risk adjustment, this measure is likely to ensure that any hospital that treats more complex patients and performs more complex surgeries and therapies will have a higher incidence of AKI. Comparing tertiary hospitals, which see these more complex patients and perform more complex procedures, from diagnostic (e.g., image guided studies requiring nephrotoxic contrast agents) to surgical (e.g., trauma and transplant), and more complex medical treatments (e.g., multi-drug chemotherapeutic protocols and septic patients), to community hospitals without adjusting for clinical case mix and co-morbidities will result in teaching hospitals having a greater rate of AKI. The AAMC would also appreciate more clarification on the measure's future use in quality reporting programs.

AKI as measured by an absolute increase in serum creatinine at 1.5 times the baseline is one commonly used definition, though other absolute thresholds also commonly used. The developer should consider using either an absolute threshold or a combination, such as an increase by n% that results in the creatinine level being over a certain threshold level. In addition, creatinine levels may not be the best measure to use as its level varies by muscle mass, race and age. This measure will also need to be adjusted for those medical conditions that result in an overproduction of creatinine without incident acute kidney injury or in those circumstances where one would expect a lower creatinine such as pregnancy. eGFR is often used and most labs calculate it for all patients when creatinine is drawn. Did the measure developer consider using eGFR instead of creatinine value?

Defining a substantial increase in serum creatinine as greater than or equal to 1.5 times the baseline is likely to result in inaccurate reporting of acute kidney injuries. There are cases, such as in the wake of a major operation, with no sequelae where creatinine levels may increase transiently but still remain in the normal range. For example, following a CABG surgery the patient might be treated with diuretics to reduce likelihood of fluid retention in the lungs, resulting in a temporary increase from 0.6 mg/dL to 0.9 mg/dL (noting that the normal levels of creatinine in the blood ranges from 0.6 -1.2 mg/dL for adult males and 0.5-1.1 mg/dL for adult females) that would be reported as AKI even though it was temporary increase within the normal levels with no long-term sequelae as part of a standard clinical intervention post-operation. Including this case in the numerator is not going to reduce AKI (as it is a standard clinical intervention) and is not going to have an impact on reducing mortality or the future need for dialysis. The measure should be more tightly constructed so as to ensure it's truly measuring preventable AKI where the AKI is associated with increased mortality risk and likelihood of the need for dialysis. Finally the

developers have not provided sufficient information on what is considered preventable AKI. There is controversial literature on this particular topic and thus the introduction of this metric into use as an eCQM is troublesome.

Measure Comments: Hypoglycemia

The Association agrees that it is important to develop measures that focus on reducing the most common adverse drug events and that hospitals should implement protocols to manage hypoglycemia 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 hypoglycemia due to the administration of an anti-hyperglycemic medication 24 hours prior to the harm event because of the timing and manner of the glucose measurement. The majority of tests for monitoring blood glucose levels 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. In the event that a drawn blood sample goes to the lab and comes back as less than 40 mg/dL there is no immediate course to provide the sugar and 5-minute glucose measure follow-up because the lab test was often done hours before. By measuring only lab tests, and not including point-of-care testing, the measure removes the majority of blood glucose testing from measure.

Additionally, by measuring quality performance (via removal from the numerator) as a rise from less than 40 mg/dL to greater than 80 mg/dL in 5 minutes, the quality exclusion is essentially only eliminating the false positive test results. That is, the measurement of less than 40 mg/dL was likely not correct, because it is physiologically unlikely that even with administration of glucose that the level will rise that quickly. Was the intention of the measure developer to remove false positives when removing cases with a follow-up of another glucose test within 5 minutes with a result greater than 80 mg/dL?

It should also be noted that administering an anti-hyperglycemic is the standard of care to lower the glucose for a patient that is hyperglycemic and that a measure to incentivize management of hypoglycemia should not have the indirect potential to cause second guessing of that standard of care. Instead, it should incent care workflows to ensure that there is appropriate glucose monitoring after the administration of the anti-hyperglycemic.

Measure Comments: Opioid-Related Adverse Events

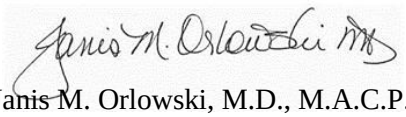
The AAMC is supportive of measure concepts that assess the critical patient safety issues surrounding opioid use, but has reservations about the opioid-related adverse events eCQM under development. We urge the developer to consider potential unintended consequences of the measure that could be mitigated and consider the inclusion of risk adjustment as a component of the measure.

In regards to unintended consequences, including all uses of naloxone is a blunt instrument and may incentivize poor treatment. For example, in cases of an adverse respiratory event after the administration of opioids, it might incentivize the avoidance of naloxone in favor of a more invasive treatment option such as intubation. This is to say that there are important subclinical interactions with opioid administration, and including all uses of naloxone in the numerator for this measure might result in a reduction in the appropriate administration of naloxone, but at the cost of more invasive care for the patient. In addition, the use of naloxone is a standard treatment in hospitalized patients with a change in mental status even if opioids are not the final cause of the condition. Using the use of naloxone as an indicator may reshape currently accepted clinical practice inappropriately. The measure developer should consider ways to remove from the numerator certain cases of the administration of naloxone such to mitigate the unintended consequence of more invasive care in response to quality measurement of the use of naloxone.

It appears there is no consideration for risk adjustment, including for consideration of opioid sensitivity. Physicians should be able to take clinical risk factors into account for the appropriate administration of opioids, and the measure should be nuanced such that it is able to balance measurement with adequate pain control.

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,



Janis M. Orlowski, M.D., M.A.C.P.
Chief Health Care Officer

Cc: Gayle Lee, AAMC
Phoebe Ramsey, AAMC