Society of Hospital Medicine

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October 30, 2018

Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Yale-CORE
1 Church Street, Suite 200
New Haven, CT 06510

Dear Hospital Harm Measures Team:

The Society of Hospital Medicine (SHM), representing the nation's hospitalists, appreciates the opportunity to comment on the two draft Hospital Harm Measures: Medication-related Bleeding and Severe Hyperglycemia in Hospitalized Patients.

Hospitalists focus on the general medical care of hospitalized patients. They are front-line healthcare providers in America's hospitals for millions of patients each year, many of whom are Medicare and Medicaid beneficiaries. They manage the inpatient clinical care of their patients, while working to enhance the performance of their hospitals and health systems. The unique position of hospitalists in the healthcare system affords a distinctive role in facilitating both the physician-level and hospital-level performance agendas.

We share CMS' vision for promoting high quality care, improving outcomes, and aligning quality measures across settings of care. We also agree that medication-related bleeding and hyperglycemia are both important clinical areas to measure and to focus on improvement. However, we have concerns about the structure of both measures and ask CMS to continue refining the measures before implementation.

Medication-related Bleeding

CMS intends to measure the rate of bleeding events after administration of an anticoagulant or thrombolytic medication during the hospitalization. The measure would count as "harm events" any encounter that was preceded by administration of an anticoagulant or thrombolytic medication and that has an absolute decrease of hemoglobin results of 2g/dL or more within a 48-hour period (excluding the first 24 hours after arrival in the hospital), that requires a transfusion of whole or red blood cells (excluding the first 48 hours after arrival in the hospital), or that indicates a new onset of bleeding. SHM has serious concerns about this measure and its ability to measure hospital harms. We

agree that medication-related bleeding is an important area for consideration, but do not believe this measure is a fair or appropriate indicator for these events. **We strongly recommend against finalizing the measure in its current form and encourage CMS to make major revisions to this measure.**

Foundationally, we do not believe that this measure adequately captures preventable harms. Instead, this measure is better understood as an adverse event measure. Bleeding is a known risk of anticoagulants. Anticoagulants are prescribed when the potential benefit of anticoagulation outweighs the risk of bleeding. It would be a serious mistake to develop a measure that indicates that bleeding that occurs on an appropriately dosed and appropriately monitored anticoagulant is somehow an indicator of poor hospital quality. Indeed, many of the patient cases captured in the measure may be receiving high-quality care, despite the negative indication of this measure. By including preventable and unpreventable harms, this measure fails to provide actionable information for hospitals to guide improvement.

The numerator specification currently includes cases where an encounter included administration of an anticoagulant or thrombolytic and one of three indicators of bleeding events. These events (absolute decrease of hemoglobin results of 2g/dL, transfusion of whole or red blood cells, or new onsets of bleeding) are highly non-specific indicators of bleeding events, and as such are not good indicators of a medication-related bleed, much less a preventable bleed. We believe a stronger measure would require meeting two or three out of the three indicator events, or possibly adding additional criteria (such as decreased systolic blood pressure) to further narrow the measure.

We also question the inclusion of thrombolytic administration in the measure. Thrombolytics are not commonly used outside of the emergency department and as such are mainly a treatment given in response to an emergency condition. Including thrombolytics in this measure may create a disincentive for prescribing thrombolytics to some patients, including stroke and certain acute myocardial infarction patients. Given that there may be multiple factors at play during an emergency, we do not believe that including thrombolytics in the measure is a fair or accurate assessment of hospital quality.

Given these concerns, we recommend significant revisions to the measure and another round of public comment prior to finalizing.

Severe Hyperglycemia in Hospitalized Patients

The Severe Hyperglycemia measure calculates the proportion of hyperglycemic days across all eligible encounters in the hospital. **We broadly support the measure but ask CMS to consider some changes to the initial population and exclusions to better focus the measure on hospital harms**.

We have concerns that the initial population criteria of the measure may be overbroad and include cases that confound the intent of the measure. Some drugs used as anti-diabetics may be used for other conditions. For example, metformin can be used in treating polycystic ovary syndrome (PCOS) and insulin may be administered in cases of hyperkalemia. Given the stated intent of the measure, these cases would not be appropriate to include. We recommend CMS consider a tiered methodology for inclusion in the initial population, such as:

> *All patients 18 years or older at the start of the measurement period with a discharged inpatient hospital encounter during the measurement period as well as:*

1. *At least one blood glucose value >200 mg/dL at any time during the encounter; and*
    a. *A diagnosis of diabetes that starts before or during the encounter; or*
    b. *At least one administration of insulin or any anti-diabetic medication overlaps the encounter.*

This would minimize these confounding cases and enable for a more precise measure. It would also serve as a cross-check on potential errors, such as an incorrectly recorded diagnosis of diabetes.

We appreciate the numerator includes a 24-hour exclusion at the admission, as a window for home-related elevated glucose is an important exclusion from the rate of hyperglycemic days. We ask CMS to consider whether an expanded exclusion (longer window or an exclusion for patients who arrive with very high blood sugar) would better mirror clinical realities. For patients who come in with very high blood sugar (>800 mg/dL), treatments will be structured to bring down this level slowly, potentially exceeding the initial 24-hour window. We believe a change here will sharpen the measure to potentially preventable hospital harms.

SHM appreciates the opportunity to provide comments on the development of these measures. If you have any questions or need more information, please contact Joshua Lapps, Senior Manager of Government Relations, at jlapps@hospitalmedicine.org or 267-702-2635.

Sincerely,

Nasim Afsar

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President, Society of Hospital Medicine


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