



October 30, 2018

Ms. Seema Verma  
The Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
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Baltimore, MD 21244-1850

Delivered by e-mail to: [CMSHospitalHarmMeasure@yale.edu](mailto:CMSHospitalHarmMeasure@yale.edu)

SUBJECT: Request for Comments on: "Hospital Harm – Severe Hyperglycemia and Medication-Related Bleeding"

Dear Administrator Verma,

The Federation of American Hospitals (FAH) appreciates the opportunity to submit comments on the draft CMS Hospital Harm electronic clinical quality measures (eCQMs). The FAH recognizes the need to address these important patient safety events and our comments on the proposed measures are outlined below.

If CMS proceeds with further development and testing of these measures, the degree to which each measure yields sufficient variation in performance scores across all hospitals must be determined, particularly for the measure on medication-related bleeding. While each eCQM addresses events that are useful to be tracked for quality improvement, the FAH is concerned that the differences in scores may be minimal and may not yield reliable and valid representations of performance across the hospitals. This question should be examined to ensure that comparisons in the quality of care can be made and are useful to allow patients and families to distinguish higher quality of care and by hospitals for quality improvement.

The FAH also strongly encourages CMS to assess the feasibility of collecting the required data elements from electronic health record systems (EHRs) for each measure beyond soliciting for input during this comment period. The FAH is concerned that the complexity of the measures and, particularly the complexity of the numerators, may significantly impact an individual hospital's ability to successfully collect and report on each measure. Thorough assessments of each data element and the required calculations and logic must be vetted across several hospitals and vendor systems to truly understand whether either measure is ready to be implemented in EHRs. If one or more of the measures are not determined to be feasible in the majority of vendor systems currently used, then it would be prudent for CMS to delay further testing and implementation of the measures until these gaps in EHRs data capture and reporting can be addressed.

In addition to thorough feasibility assessments, determinations on whether these measures are reliable and valid must be completed. As noted above, the numerators of these measures are complex and as a result, there is increased risk for missing data and errors in data capture and calculation that could distort results and misrepresent the truly quality of care provided by hospitals. Comprehensive testing for reliability and validity, including at the individual data element level, must be completed prior to implementation in any federal program.

In addition to these general comments, the FAH requests clarification on the need for the Hospital Harm – Severe Hyperglycemic in Hospitalized Patients measure. As noted in the public comment materials, the National Quality Forum (NQF) endorsed a similar measure, #2362e, Glycemic Control – Hyperglycemia, in 2014. When the FAH reviewed this measure, we noted that it was specified, tested, and currently endorsed as an eCQM. One of the primary rationales given for this new Hospital Harm measure was that NQF #2362e was not an eCQM, which does not appear to be correct. In addition, the differences in specifications between the two measures are not adequately explained. The FAH notes that while the cut-off of >200 mg/dL is not identical to the American Diabetes Association guideline recommendation of >180 mg/dL, it allows room for clinical judgment and the ability to address the event prior to it impacting a hospital's performance. We support the continued use of this cut-off in the newer measure. For example, the numerators and exclusions differ between the two measures and understanding what led the technical expert panel to recommend changes from an existing measure that was vetted by NQF would be helpful in responding to the first question on the measure's usefulness. The FAH did not identify any adequate rationale to explain why the Hospital Harm – Severe Hyperglycemic in Hospitalized Patients eCQM should be developed when a competing measure is currently endorsed by NQF.

If implemented, the FAH recommends that the Hospital Harm – Severe Hyperglycemic in Hospitalized Patients and Hospital Harm – Hypoglycemia measures be reported together. This pairing will minimize the risk of increasing hypoglycemia events, which might occur if the focus is solely on preventing severe hyperglycemia. Additional stratification by critical vs. non-critical care, concurrent steroid administration, medical vs. surgical patients and other relevant variables may also provide valuable information to hospitals for quality improvement purposes.

In conclusion, the FAH urges CMS to carefully assess the feasibility, reliability, and validity of each of these eCQMs prior to implementation in a federal program. Misrepresenting the quality of care must be avoided and careful evaluations of each testing area must be completed to ensure that it does not occur.

The FAH appreciates the opportunity to comment on these quality measures. If you have any questions regarding our comments, please do not hesitate to contact me or a member of the FAH staff at (202)624-1500.

Sincerely,



Claudia A. Salzberg  
Vice President, Quality  
Federation of American Hospitals