AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Dear Administrator Verma:

The American Medical Association (AMA) appreciates the opportunity to comment on the Hospital-Wide All-Cause Unplanned Readmission (HWR) and Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty (THA/TKA complication) measures for use in the Merit-based Incentive Payment System (MIPS). The AMA strongly believes that the measures must be evidence based, attributed to the appropriate levels where the greatest influence can occur, and proven to be reliable and valid. Based on the information released for public comment, we do not believe that either measure meets those criteria.

Key principles driving attribution identification and evaluation

The AMA supports many of the principles used to guide the attribution process for both of these measures but we recommend that an additional principle be incorporated. Specifically, attribution must be determined based on the evidence that the accountable unit is able to meaningfully influence the outcome. This principle aligns with the most recent National Quality Forum (NQF) report, Improving Attribution Models.[1] This principle also would support any measures developed by the Centers for Medicare & Medicaid Services (CMS) as they are reviewed during the NQF Consensus Development Process since the evidence requirements for outcome measures now require that there be at least one structure or process that can influence the outcome and this relationship must be demonstrated through empirical evidence.[2] CMS must begin to demonstrate these relationships with the accountable unit prior to implementing these measures in MIPS. As discussed in our comments on the evidence for each measure below, we do not believe that CMS has adequately demonstrated this link.

In addition, we encourage CMS to reconsider Principle #3: Clinician quality reflects hospital quality, as it is very narrowly focused based on the respecification of these two measures and may not be applicable in all circumstances. In addition, this narrow view does not adequately address the nuances and

[1] National Quality Forum. Improving Attribution Models. Final Report. August 31, 2018. Available at: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=88154. Last accessed December 18, 2018.
[2] National Quality Forum. Measure Evaluation Criteria. September 2018. Available at: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=88439. Last accessed December 18, 2018.

complexities that application of a hospital-specific measure to physicians in the outpatient setting may face. For example, we found it difficult to reasonably apply this principle to the HWR measure given the lack of clear relationships between the primary care provider in the outpatient setting who is attributed the readmission based on retrospective assignment of beneficiaries as no information on how this provider can meaningfully influence readmissions was demonstrated. It is unclear that previous care can be assumed to represent a valid association to the readmission.

Evidence base to support either measure

While the AMA agrees that it is useful to understand the rate of complications following THA or TKA and unplanned readmissions particularly for quality improvement, we did not see explicit information outlining how physicians can implement structures or processes that can lead to improved outcomes for these patients. Rather, most of the cited references focused on incidence rates and prevalence of specific risk factors and did not address what factors or processes leveraged by a physician can reduce the occurrence of either outcomes. As CMS continues to expand the types of measures for possible use in MIPS, the underlying evidence used as the basis to attribute a clinical outcome to a specific measured entity, such as, physicians must be established and we do not believe that CMS has provided sufficient information for either measure to support the attribution to physicians.

Rigor of scientific acceptability testing and results

In addition, we were extremely troubled to see that social risk factors were not tested in the risk adjustment models in either measure. The AMA strongly disagrees with the conclusion that because the initial review of the hospital-level measure by NQF did not require the inclusion of these factors, these factors do not need to be re-examined at the physician level. In fact, on review of the Evaluation of the NQF Trial period for Risk Adjustment for Social Risk Factors report,[3] it is clear that NQF did not reach a general conclusion that inclusion of social risk factors in risk models was not supported. Rather, the approaches to testing these data should be revised such as multi-level models or testing of social factors prior to clinical factors and that as access to new data becomes available, it may elucidate more differences that are unrelated to factors within a hospital's or physician's control. We believe that neither measure should be considered for implementation until the need for social risk factors is adequately assessed and the c-statistics are further increased beyond 0.65 for the THA/TKA complication measure and 0.64 for the HWR measure.

Decisions on the inclusion of these risk factors in adjustment models must be made based on data and not assumptions. CMS must begin to identify the degree of social risk factors and availability of services for specific patient populations. Strategies such as applying the American Community Survey or a similar data set to determine whether patients for a specific hospital or other provider live in an area where there are fewer resources available should be explored. We readily acknowledge that there are challenges to this type of approach since it requires linkages of patient panels to communities, which may not be the same area where the admission occurred. Nevertheless, these strategies would provide a more comprehensive assessment of the current state and would allow CMS to adjust the measure based on

[3] National Quality Forum. Evaluation of the NQF Trial period for Risk Adjustment for Social Risk Factors. Final report. July 18, 2017. Available at: http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=85635. Last accessed December 18, 2018.

clinical complexity and social risk. The AMA strongly encourages CMS to continue to explore and incorporate additional risk factors and strategies.

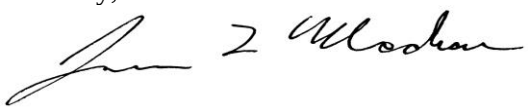
The AMA also encourages CMS to continue to ensure that measures meet minimum acceptable thresholds for testing such as 0.7 for reliability and demonstrate the validity when attributed to the physician, especially when measures are applied to more than one physician. Specifically, we note that while the mean and median signal-to-noise reliability may achieve 0.7, the range when applied to smaller volumes is generally wider than desired. For example, the range when applying the THA/TKA complication measure to eligible clinicians with more than 25 admissions was 0.582 – 0.988 and 0.463 – 0.996 for eligible clinician groups. Higher case minimums should be considered for the THA/TKA complication measure and we support utilizing the higher case minimum of 100 admissions for the HWR measure.

Further testing to demonstrate the validity of the measures as it relates to its application to each of the accountable units to which the measure is attributed must be completed such as predictive and construct validity. Face validity is not sufficient, particularly as the survey did not specifically assess the degree to which the experts agreed that the measure attributed to each accountable unit resulted in scores that were valid and useful. In addition, we encourage CMS to consider broadening those surveyed beyond the Technical Expert Panel as they may have an inherent bias given their participation in developing the measure.

In conclusion, CMS must balance the desire to apply these measures to the broadest number of clinicians possible with the unintended consequences of inappropriately attributing measures to physicians for which they cannot meaningfully influence patient outcomes. The AMA requests that CMS carefully consider the potential misinformation that could be provided to patients and caregivers if the measures do not have a clear evidence base to support attribution of the outcome to a specific physician and could potentially produce scores that are invalid and unreliable.

The AMA appreciates the opportunity to provide our comments and thanks CMS for considering our views. If you should have any questions regarding this letter, please feel free to contact Margaret Garikes, Vice President of Federal Affairs, at margaret.garikes@ama-assn.org or 202-789-7409.

Sincerely,



James L. Madara, MD