April 5, 2016

The American Medical Association (AMA) is writing to appeal the endorsement of the following three measures:

- #2431: Hospital-level, risk-standardized payment associated with a 30-day episode-of-care for Acute Myocardial Infarction (AMI) (CMS/Yale)
- #2436: Hospital-level, risk-standardized payment associated with a 30-day episode-of-care for Heart Failure (HF) (CMS/Yale)
- #2579: Hospital-level, risk-standardized payment associated with a 30-day episode of care for pneumonia (CMS/Yale)

The AMA examined the 2016 review of these cost and resource use measures and we believe that the National Quality Forum's (NQF) Consensus Development Process (CDP) was not followed. Specifically, we were unable to identify if and when the Consensus Standards Approval Committee (CSAC) approved the updates to the measure evaluation criteria and guidance prior to implementation in CDP projects. We believe that the revised criteria and guidance provided around risk adjustment and the inclusion of sociodemographic variables does not reflect the original intent of the expert panel and these differences impact whether the analyses completed by developers should be considered responsive to what was put forward by that panel. Our second concern relates to the omission of two of the three conditions placed on the three measures at the time of endorsement in February 2015 in this 2016 review.

As a result of these deviations from the CDP, we believe that the integrity of the NQF process has been compromised with respect to these measures. As such, we would ask that NQF:

- Remove endorsement on these measures until such time that all of the conditions can be adequately met and NQF should work with the developer to identify when the measures can be reevaluated;
- Work with developers to ensure that the measures within the SDS Trial Period are consistent with the recommendations from the Expert Panel on Risk Adjustment and Socioeconomic Status; and
- Reconsider the use of "Endorsement with Conditions" on any measures moving forward.

Our specific concerns and rationales for these requests are outlined below.

<u>Omission of two of the three conditions for endorsement during this current review</u>

Until recently, NQF maintained a simple structure regarding the types of endorsement available. Specifically, endorsement was limited to "NQF-endorsed" and for a few years, "time-limited endorsement" was also an available alternative. Previously, endorsement with any caveats or limitations was not considered in the CDP outside of those measures that were time-limited since all measures must meet the minimum set of measure endorsement criteria. These three cost and resource use measures are some of the first measures to our knowledge that have been endorsed with conditions by the NQF Board of Directors (BOD) Executive Committee. This new type of endorsement could be considered a deviation of the CDP as neither the measure

endorsement criteria, guidance to Standing Committees and the Consensus Standards Approval Committee (CSAC) and other documents provide information on what endorsement with conditions means, how measures can achieve this type of endorsement, and what the NQF's processes are to ensure that these conditions are met and reviewed in a timely manner.

We are concerned that due to the lack of clear processes and procedures, there is great potential for NQF to inadvertently omit or inadequately address these conditions around endorsement. We believe that these three measures serve as a good example of this concern.

These three measures according to the final Technical Report for the Cost and Resource Use project released in February 2015 were endorsed with the following conditions:

- One-year look-back assessment of unintended consequences: NQF staff will work with the Cost and Resource Use Standing Committee and CMS to determine a plan for assessing potential unintended consequences of these measures in use. The evaluation of unintended consequences will begin in approximately 1 year, and possible changes to the measures based on these data will be discussed at that time.
- Consideration for the SDS trial period: The Cost and Resource Use Standing Committee will consider whether the measure should be included in the NQF trial period for consideration of sociodemographic status adjustment.
- Attribution: NQF will consider opportunities to address the attribution issue.

Based on what was included in this review of these measures, only the second condition has been addressed. Assessment of any unintended consequences of these measures was not included in the review and to our knowledge a plan to assess the potential unintended consequences has not been released and could not be found on the NQF web site. In fact, materials to the CSAC and BOD Executive Committee on this review no longer list this assessment as one of the conditions. We would also note that the third condition around attribution would not be considered actionable and responsive to the concerns raised by the NQF membership and public and it appears to have been removed completely from the list of conditions by NQF staff in a memo sent to the Cost and Resource Use Standing Committee and measure developer on May 19, 2015.

These omissions demonstrate that the conditions placed by the NQF BOD Executive Committee in February 2015 have not been adequately addressed nor has the CDP been followed. These omissions also are examples of our concerns about the lack of transparency via the NQF web site. Measures that are endorsed with conditions do not carry this label on the NQF measure search engine (QPS) nor are the conditions included in any materials or measure information with the exception of the final technical report. QPS also does not indicate that any of the three measures were included in the SDS Trial Period. This new type of endorsement and the underlying conditions are not sufficiently clear to the NQF membership and public and could have unintended consequences for those seeking to implement NQF-endorsed measures who remain uninformed and unaware of serious concerns around these measures.

Lack of oversight and approval of current measure evaluation criteria by the CSAC

NQF released updated measure evaluation criteria that went into effect in April 2015. Several modifications were made to the criteria including updates to the Scientific Acceptability

subcriterion and specifically to the language around risk adjustment. These modifications included additional guidance to measure developers and Standing Committees on what must be provided and evaluated during the SDS Trial Period and were based on the recommendations made by the Expert Panel on Risk Adjustment and Sociodemographic Status.

While informational items on the SDS Trial Period were provided to the CSAC in April and August of that same year, we were unable to find documentation of any CSAC approvals of these changes and the associated guidance on the NQF web site, which is contrary to the process followed when other modifications were made to the criteria. This lack of oversight and approval by the CSAC is troubling given the degree of interest and support by the NQF membership on the inclusion of these variables in risk adjustment models, the support of the membership of the recommendations of the Expert Panel, and the desire of many stakeholders to sufficiently address this ongoing measure methodology concern.

In addition, we do not believe that the intent of the Expert Panel's recommendations is adequately represented in the SDS Trial Period guidance. In the final report, the Expert Panel stated that of race/ethnicity should not be considered as acceptable proxies for socioeconomic (SES) because SES often confounds their effects. We would expect that this intent and explicit statements around what should be considered acceptable variables or proxies would be included in the SDS Trial Period guidance, but it is not. In the case before us, the developer of these three measures included race as one of the SDS risk variables. This inclusion is not consistent with the original Expert Panel recommendations and raises significant concerns that the important SDS variables for risk adjustment of these measures were not sufficiently identified and tested.

Throughout this review, the Standing Committee explicitly requested that additional variables be included in the analyses such as the expansion of the zip codes from 5-digits to 9-digits and the addition of Low Income Status along with the Medicaid Enrollment/Dual Status. In addition, four variables were initially identified in the conceptual model; yet, one could argue that only one variable was adequately addressed in the empirical analyses and the others were addressed through the use of a proxy.

We are therefore concerned that the empirical analyses provided by the developer were not fully responsive to the Committee's requests and that the use of proxies should not be considered adequate based on the conceptual model provided. For example, as stated by the Committee, 5-digit zip codes do not provide sufficient information around SDS factors. While we understand that access to the 9-digit zip code data is not yet available to the developer, the absence of data should not justify the use of proxies or inadequate data. Other measures such as eMeasures for which validity is directly impacted by availability of the data, have led committees to not recommend endorsement; yet, despite there having been a similar concern raised with these three measures, endorsement continues to be recommended. Also, we do not believe that the developer adequately demonstrated that Medicaid Enrollment/Dual Status could be considered a valid proxy for the variables identified in the conceptual analysis.

While recognizing the challenge with leveraging data sources, the AMA had the expectation that measure developers would be required to obtain new data sources to account for SDS variables. Therefore, we are disappointed that this did not occur and calls into question the effectiveness of the SDS Trial Period. We stand ready to work with the NQF and other relevant

health care stakeholder groups to improve the current quality measure endorsement processes, specifically the SDS Trial Period. Please feel free to contact Koryn Rubin, Assistant Director of Federal Affairs, at koryn.rubin@ama-assn.org or (202) 789-7408 for more information.

Thank you for considering our appeal and concerns.