TO: Koryn Rubin, American Medical Association, Nancy Foster, American Hospital Association, Jayne Hart Chambers, Federation of American Hospitals, Ivy Baer, Association of American Medical Colleges, Beth Feldpush, America's Essential Hospitals

FR: Helen Burstin, Marcia Wilson, Elisa Munthali, National Quality Forum

RE: Appeal of NQF #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)

DA: May 10, 2016

The National Quality Forum (NQF) has received two appeals of its endorsement of the acute myocardial infarction (AMI) (NQF # 2431), heart failure (HF) (NQF #2436) and pneumonia (NQF #2579) 30-day episode-of-care payment measures. NQF takes the concerns of the appellants of these three cost and resource use measures seriously. The Cost and Resource Use Standing Committee has deliberated on the scientific properties of these measures extensively and had made recommendations to CSAC and the Board prior to the start of the trial period, and, upon request from the Board, re-examined the measures using the SDS trial period guidance. NQF recognizes it has an important role important role to build consensus and work though challenging scientific and policy issues such as these. To begin to work through these challenges, NQF will convene the appellants and CMS/Yale on May 10, 2016 to discuss the issues raised. In preparation for that meeting, NQF has outlined its reponses to the concerns raised by the appeallents.

SDS Trial Period Concerns

- The appellants raise concerns about the testing of race as a possible factor for inclusion in the risk adjustment model of the measures. In particular the appellants raise two concerns about the developer's use of race:
    - The appellants believe the developer did not provide an adequate conceptual basis for the use of race as a variable and did not explain why it was appropriate to aggregate individuals into "black or non-black;"
    - The developer tested only one other SDS adjustment variable (dual eligibility). The appellants note the SDS Expert Panel stated that race should not be used as a proxy for SES; rather race is confounded by SES. The appellants believe the developers did not test enough variables to unmask any conceptual relationship and that the relationship between race and the measures' outcomes are likely to remain confounded.
- NQF Response:
    - Guidance was provided to the measure developers and the Standing Committee based on the recommendations of the SDS expert panel that race should not be used as proxy for SDS and should not be used in adjustment unless there is a clear conceptual rationale.

- During its May 21, 2015 webinar to review the developer's conceptual analysis, the Cost and Resource Use Standing Committee raised concerns about the inclusion of race as a variable. The Committee believed that further literature review was needed to determine the within and between effects of race on hospital performance. Some members strongly suggested that between and within hospital differences should be a lens through which this information should be analyzed.
- In a memo dated October 5, 2015, the developer summarizes the results of their expanded literature search. The developer found that most studies uses race and their independent variable with less attention to income or other measures of poverty. The developer concluded that the literature demonstrates that both within and between hospital differences in outcomes among racial/ethnic groups can be partially explained by the use of lower quality hospitals by minorities.
- During the May webinar, the Standing Committee raised similar concerns to the appellants about the aggregation of racial categories. However, in the October 5 memo, the developer confirms that while they considered creating categorizations of black/white/other or black/white/other/Hispanic, data from CMS suggests that black and white race are the only categories with both high sensitivity and specificity in the Beneficiary Race Code variable.
- Race was not included as a variable in the final risk adjustment model; rather it was only explored by the developer.
- NQF agrees with the appellants that race should not be used as proxy for SES. This guidance was explicitly stated in the SDS Expert Panel's final report. The Disparities Standing Committee is currently examining this issue and is in the process of providing additional guidance to measure developers and NQF Standing Committees about the use of race as a variable in risk adjustment models.
- Additionally, the measure developer could clarify their rationale for testing race as a possible variable for inclusion during the May 10, 2016 meeting.

- The appellants note that the Cost and Resource Use Standing Committee urged the measure developer to explore in their conceptual model community and environmental factors, and to separate patient- from community-level resources.
- NQF Response:
  - During its October 27, 2015 webinar to review the developer's empirical analysis, the Committee had extensive discussion about the inclusion of community-level factors into the risk-adjustment model given the inclusion of a 30-day post discharge period in the episode. The Committee acknowledged that for some of the post-hospitalization services, the community context is a critical variable and that these factors may or may not be fully captured by the patient-level SDS adjustment.
  - The developers expressed interest in potentially considering these factors in the model, but sought Committee input and recommendations on how to approach this.
  - This issue could be further explored between the appellants and the developer during the May 10, 2016 meeting.

- The developer did not sufficiently explore the variables included in the conceptual model. Additionally, the appellants raise concerns that the developers did not perform the analyses requested by the Standing Committee. In particular, the developer did not expand the analyses to the nine-digit zip code level and did not include Low Income Status along with the Medicaid enrollment/dual status variable.
- NQF Response:
    - The developer expanded the conceptual model in response to the Cost and Resource Use Standing Committee's concerns. The CMS/Yale team revised the model to broaden the scope of community-level factors included in the model. In doing so, they updated the pre-admission and post discharge phases of the conceptual model to capture the many patient and community factors that reflect differential impact of SDS on episode of care payments. The developer also revised the model to reflect "patient factors" rather than "patient behaviors." Patient factors included variables such as using services provided and adherence to care plan. Community factors included variables such as lack of community services and lack of social supports/caregiver. Finally, the model also was reoriented to capture the potential pathways by which low SDS may impact the care provided to patients. Details of the final memo can be found in the developer's October 5 memo.
    - The Cost and Resource Use Standing Committee noted significant gaps in the literature specific to the impact of SDS on cost, utilization, or payment outcomes. Specifically, the Committee questioned whether the use of standardized payments based on diagnosis-related groups may mitigate the relationship between SDS and costs.
    - In the October 5 memo, the developer clarified they chose to use the Dual Status variable because it best reflected those with the lowest income.
    - The developer and the appellants could discuss the use of additional patient and community level variables at the May 10 meeting as well as the possibility of exploring these variables at the nine-digit zip code level.
- The appellants raise concerns about the implementation of the trial period. Specifically the appellants have concerns about:
    - The guidance provided to Standing Committees on the selection and testing of SDS variables.
    - Consensus Standards Approval Committee (CSAC) approval of the revised measure evaluation criteria.
- NQF Response:
    - NQF recognizes that the SDS trial period marks a significant change the Consensus Development Process. NQF staff have worked to provide guidance to measure developers, Standing Committees, and the public to educate them on the input of the SDS expert panel and on how measures should be reviewed during the trial period. Web meetings have been held with measure developers and Standing Committees are briefed on the changes during their orientation and Question and Answer calls. NQF will

work to improve the clarity and breadth of the educational materials and opportunities provided to developers, Standing Committees, and the public.

- However, NQF maintains a non-prescriptive approach to the selection and testing of variables included in risk adjustment models. NQF does not require that certain variables be tested and does not set requirements around the inclusion of any specific variables. Similarly NQF does not set certain "cut-points" for the statistical testing of a risk adjustment model. The evaluation of the model is the left to the Standing Committee reviewing the measure. This approach applies to both clinical and SDS variables.
- The Disparities Standing Committee is charged with evaluating the trial period. Results to date were presented to the Disparities Standing Committee during their April 26, 2016 webinar. The Committee is currently drafting additional guidance based on the findings and challenges of the trial period to date. This guidance will be provided to the Standing Committees, developers, and public by early summer 2016.
- Updates to the measure evaluation criteria were made as part of the CSAC's approval of the SDS Expert Panel's recommendations during its July 9-10, 2014 meeting. Specifically, the Expert Panel's Recommendation 4 revised the criteria. These recommendations passed with the consensus of the CSAC.

Insufficient Resolution of the Conditions of Endorsement

- The appellants raise concerns that the three conditions for endorsement have not been adequately met. First, the appellants raise concerns about the one-year look back assessment of unintended consequences of these measures in use.
- NQF Response:
  - There is general agreement that these measures need to be monitored as they are endorsed and implemented into federal quality initiative programs. These measures have been recently adopted for the Hospital Inpatient Quality Reporting program for FY 2016 (AMI) and FY 2017 (HF and pneumonia). NQF will need implementation data from CMS as experience with the measures has been demonstrated. The May 10 meeting will allow the appellants and CMS the chance to opportunities to develop a path forward on the look back period issue
- Secondly, the appellants raise concerns about the need to consider issues of attribution.
- NQF Response:
  - With funding from HHS, NQF has launched a project on attribution. The expert panel guiding this work includes representation from both hosptials and the American Medical Association to ensure attribution issues such as the ones illustrated by these measures are addressed. As part of this project, NQF will commission an environmental scan identify different attribution models and examine their strengths and weaknesses. The environmental scan will be used as a foundation for establishing a set of principles and recommendations for applying the models within a complex healthcare delivery system. Throughout this project, NQF will solicit input from NQF's multi-stakeholder audience,

including NQF membership and public stakeholders at key points throughout the project.

Next Steps

The appellants have raised a number of important concerns around the continuing endorsement of these measures. NQF recognizes that the concerns raised around the analytic approach used by the developer will require additional work with the appellants, the developer/CMS, and the leadership of the Standing Committee/CSAC to discuss an agreeable path forward. However, there may be legitimate challenges to leveraging existing data to examine the variables requested by the appellants, but additional work can be undertaken to identify a path forward that explores the issue further. NQF will continue to convene the Disparities Standing Committee to evaluate the trial period and will work with that group to address the concerns and challenges that arise. In the short term, the Disparities Standing Committee will develop additional guidance to the Standing Committees, developers, and the public about the use and testing of SDS variables. Additionally, NQF staff will work to continue to educate Standing Committees, developers, and the public about the SDS trial period and how measures should be evaluated during the trial.

NQF has an important leadership role in building consensus on these issues and will work with the affected parties to determine an agreeable path forward that respects the limitations that may exist in the field, in terms of data and variables, but is also responsive to concerns raised by the appellants.