TO: Cost and Resource Use Standing Committee

FR: NQF Staff

RE: Appeal of Measures for the Cost and Resource Use Standing Committee Ad Hoc Review of the Conceptual and Empirical Analysis of Sociodemographic Variables and Payment Outcomes

DA: July 28, 2016

ACTION REQUIRED

The Cost and Resource Use Standing Committee will provide guidance to CSAC related to appeals of 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 pneumonia (CMS/Yale)

The Standing Committee is being asked to:

- review the conceptual model for the need for SDS adjustment;
- review new analyses using 9-digit ZIP code data;
- consider outstanding attribution issues;
- consider outstanding concerns about the potential for unintended consequences.

BACKGROUND

The National Quality Forum (NQF) has received 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. 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 sociodemographic (SDS) trial period guidance. The Cost and Resource Use Standing Committee reviewed analyses from the developer and recommended the measures continue to be endorsed without the inclusion of SDS factors in their risk adjustment models. The decision was approved by the CSAC and ratified by the Executive Committee of the NQF Board of Directors. Appeals of this decision were submitted by the American Medical Association (AMA) and jointly by four hospital associations, the American Hospital Association, the Federation of American Hospitals, the Association of American Medical Colleges, and America's Essential Hospitals. NQF has responded to the appellants and convened the appellants with representatives from the Centers for Medicare and Medicaid Services (CMS) and the measure developer (Yale/CORE). A summary of the appeals and NQF's response can be found in the Appendix.

ADDITIONAL CONSEUS BUILDING

In June 2016, NQF convened the appellants, CMS, Yale/CORE, the CSAC co-chairs, and one of the chairs of the Cost and Resource Use Standing Committee. The goal of this call was to foster a dialogue between the affected parties and to lay out potential options as the appeal is considered. During the call the appellants asked for clarification for the conceptual basis for the expected effect of adjustment. Yale/CORE agreed to provide a clearer conceptual analysis and to perform additional empirical analyses to examine the impact of SES factors at the nine-digit zip code level to address the concerns raised by the appellants.

NEW EMPIRICAL ANALYSES

CMS/Yale CORE has submitted new analyses using nine-digit ZIP code data included in the CMS/Yale CORE response memo attached to this memo.

STANDING COMMITTEE REVIEW

In light of the new information provided by the developer and outstanding questions of attribution and unintended consequences the Cost and Resource Use Standing Committee is asked to provide additional input to CSAC as they consider these appeals. The Standing Committee will not be asked to vote on the measures at this time.

The Standing Committee is being asked to:

- review the conceptual model for the need for SDS adjustment;
- review new analyses using 9-digit ZIP code data;
- consider outstanding attribution issues;
- consider outstanding concerns about the potential for unintended consequences.

NEXT STEPS

CSAC will review the Standing Committee's input and consider the appeal during their August 9 meeting.

APPENDIX: SUMMARY OF APPEAL AND NQF RESPONSE

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 use 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.

- 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 and 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.
- 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 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 has 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 hospitals 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.

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CENTERS FOR MEDICARE & MEDICAID SERVICES
CENTER FOR MEDICAID & CHIP SERVICES

Memorandum

DATE: **Monday, May 16, 2016**

TO: **The National Quality Forum (NQF)**

FROM: **Lein Han, PhD, Contracting Officer Representative**
Division of Quality Measurement (DQM)
The Centers for Medicare & Medicaid Services (CMS)

Kate Goodrich, MD, MHS, Director
Center for Clinical Standards and Quality
The Centers for Medicare & Medicaid Services (CMS)

SUBJECT: **CMS Response to Appeal of Acute Myocardial Infarction (NQF # 2431), Heart Failure (NQF #2436) and Pneumonia (NQF #2579) 30-Day Episode-Of-Care Payment Measures**

Background

On February 18, 2016, the National Quality Forum's (NQF) Board of Directors ratified NQF #2431: Hospital-level, risk-standardized payment associated with a 30-day episode-of-care for Acute Myocardial Infarction (AMI), NQF #2436: Hospital-level, risk-standardized payment associated with a 30-day episode-of-care for heart failure (HF), and Hospital-level, risk-standardized payment associated with a 30-day episode of care for pneumonia (PN) for continued endorsement, followed by a 30-day appeals period. We received two letters of appeal on the February 18, 2016 endorsement decision. Several stakeholders, including the American Hospital Association (AHA), the Federation of American Hospitals (FAH), the Association of American Medical Colleges (AAMC), the America's Essential Hospitals (AEH), and the American Medical Association (AMA), offered comments addressing the following: use of race variable, consideration of community and environmental factors, and use of additional patient-level variables. We appreciate their interest and thoughtful comments made on the measures. Although some comments will not be addressed in this memo, we have discussed with NQF and the Yale Center for Outcomes Research and Evaluation (CORE). This memo is organized to summarize and respond to the appellant's comments on each issue identified above.

I. Use of Race Variable

Comment: Stakeholders expressed concern on use of the race variable, commenting on the quality of race/ethnicity data and noting that race/ethnicity should not be used as a proxy for socioeconomic status (SES).

Response: In regards to the issue of using race as a proxy for SES, we agree with the appellants that race generally should not serve as a proxy for SES. We feel it is useful to examine race not as a proxy for SES but as an important comparator. Although the NQF Expert Panel on Risk Adjustment for Sociodemographic Factors did not provide clear guidance regarding inclusion of race, the panel did broaden the term from SES to SDS to account for consideration of racial disparities, and we feel it is useful to understand the pattern of racial disparities along with SES disparities in these payment measures. Moreover, the Cost and Resource Use Standing Committee did agree with CORE's analytic plan to examine race. We believe it is helpful to show analyses with race, not because it should be incorporated in risk adjustment models, but as a point of comparison with other SES variables. The conceptual rationale for not adjusting for SES has important parallels with race in that both SES and race are associated with access to high quality care and can lead to differential care within hospitals. These comparisons can be helpful in understanding causal pathways and for making decisions about incorporation of SES in risk adjustment models.

We share concerns regarding the quality of national race/ethnicity data. However, CMS data are not yet specific or sensitive enough to determine race/ethnicity at a more granular level. To be specific, CMS research has shown that "black" and "white" are the only categories of CMS' beneficiary race code variable with high sensitivity and specificity. In the future, when other race/ethnicity categories are more reliable or when other race/ethnicity variables are reliably available, we would certainly support their inclusion in SDS evaluation, but only as a comparator with other SES variables.

II. Consideration of Community and Environmental Factors

Comment: Stakeholders expressed interest in incorporating community-level factors in analyses and risk models.

Response: We appreciate the stakeholder's consideration of community-level factors. We believe the use of ZIP code-linked variables – e.g., the Agency for Healthcare Research and Quality (AHRQ) SES Index that is derived from the American Community Survey (ACS) census block group level data and linked to a patient's ZIP code – can capture community factors and are tested in models at the patient-level as a proxy for patient SES. Additionally, conducting analyses using patient-level variables was consistent with the guidance from NQF: "If a conceptual relationship exists between a *patient-level* sociodemographic factor and outcome, it should be tested empirically."

In terms of using community-level factors that are not at the patient level within the risk adjustment model, we see a few challenges. First there, there is insufficient evidence on which community factors influence health care utilization and episode payment and what would be appropriate to incorporate in risk models. There is also a need to carefully consider the policy implications of incorporating community factors into episode payment models since many potential variables are related to availability of services (such as nursing homes or primary care) which may be driving utilization patterns that the measures are meant to illuminate. So although we are open to considering new approaches to modelling and potential incorporation of community variables, we felt this was not the charge of the NQF guidance, and we do not feel the evidence is sufficient to do so at this time.

III. Use of Additional Patient-Level Variables

Comment: Stakeholders expressed concern with performing analyses using only dual-eligible status and expressed interest in the use of 9-digit zip code data in analyses.

Response: At the time of CORE's meeting with the NQF Cost and Resource Use Standing Committee, CORE identified all feasible variables for use in measures based on the Medicare administrative claims dataset. Among the identified variables, the Committee discouraged CORE from further examination of the AHRQ SES Index linked to a patient's 5-digit ZIP code. (CORE was not able to link the AHRQ SES Index at the 9-digit zip code level at the time of the Standing Committee's in-person meeting.) Secondly, CORE considered the Low-Income Subsidy (LIS) variable and the Supplemental Security Income (SSI) variable. LIS was not used because it has a slightly higher income threshold and does not capture many additional patients above dual eligible status. Patient-level SSI is unavailable for use by developers (only used by CMS to calculate disproportionate share hospital [DSH] status but not otherwise available).

We note that CORE has now completed analyses for the acute myocardial infarction, heart failure, and pneumonia payment measures using 9-digit ZIP code linked to the AHRQ SES Index (a composite of 7 SES variables including housing, income and education from the American Community Survey) at the census block group level. We also adjusted the AHRQ SES Index for cost of living. The results of these analyses are similar to the results of the analyses using the black/non-black and dual-eligible status indicator variables.

CORE Payment Measures: Using 9-digit ZIP Code

Table 1. Relationships between Total Payment and SES or Race Variables

Measure	Variable in the Model	Bivariate Model		Multivariate Model (Current* + SES/Race Variable)	
		Payment Ratio[r]/ Estimate	P-Value	Payment Ratio[r]/ Estimate	P-Value
AMI	Race	1.01	0.0261	0.94	<0.0001
	Dual Eligibility	1.00	0.0657	0.98	<0.0001
	Low SES census block group (AHRQ SES index, linked to 9-digit ZIP – Adjusted for Cost of Living)†	1.01	<0.0001	0.98	<0.0001
HF	Race	1.01	<0.0001	0.97	<0.0001
	Dual Eligibility	1.06	<0.0001	1.01	<0.0001
	Low SES census block group (AHRQ SES index, linked to 9-digit ZIP – Adjusted for Cost of Living)†	1.00	0.4171	0.98	<0.0001
PN	Race	$1,708	<0.0001	$391	<0.0001
	Dual Eligibility	$1,600	<0.0001	$516	<0.0001
	Low SES census block group (AHRQ SES index, linked to 9-digit ZIP – Adjusted for Cost of Living)†	$191	<0.0001	-$134	<0.0001

* Current indicates inclusion of all current risk-adjustment variables (age, comorbidities)

† AHRQ SES index score is less than or equal to 42.7

[r] Payment ratio is equal to exponentiated estimate

Table 2. Distribution of Percent Change in RSPs using the Current Model with Each SES or Race Indicator Added (July 2011-December 2013)

Measure	Distribution	Current* + Race (% RSP Change)	Current* + Dual Eligibility (% RSP Change)	Current* + Low SES census block group (AHRQ SES index, linked to 9-digit ZIP – Adjusted for Cost of Living)† (%RSP Change)
AMI	Minimum	-0.53	-0.38	-0.28
	10th Percentile	**-0.31**	**-0.18**	**-0.15**
	25th Percentile	-0.19	-0.087	-0.071
	Median	-0.064	-0.013	-0.0014
	Mean	0.00084	0.00013	**0.000076**
	75th Percentile	-0.0079	0.054	0.051
	90th Percentile	0.34	0.17	**0.15**
	Maximum	5.06	1.11	0.65
HF	Minimum	-0.45	-0.7	-0.31
	10th Percentile	-0.24	-0.16	**-0.20**
	25th Percentile	-0.19	-0.062	-0.12
	Median	-0.094	0.014	-0.028
	Mean	0.00056	0.000087	**0.00015**
	75th Percentile	0.026	0.089	0.087
	90th Percentile	0.36	0.15	**0.25**
	Maximum	2.59	0.29	0.68
PN	Minimum	-1.09	-2.49	-0.11
	10th Percentile	-0.14	-0.58	**-0.076**
	25th Percentile	-0.004	-0.22	-0.057
	Median	0.048	0.088	-0.016
	Mean	0.0031	0.0059	**-0.00014**
	75th Percentile	0.075	0.32	0.039
	90th Percentile	0.089	0.48	**0.11**
	Maximum	0.19	0.95	0.31