NATIONAL QUALITY FORUM

TO: Cardiovascular Endorsement Maintenance Steering Committee

FR: Reva Winkler, MD, MPH and Kathryn Streeter, MS

RE: Comments on draft report *National Voluntary Consensus Standards for Cardiovascular Disease: Endorsement Maintenance, 2011*

DA: August 24, 2011

On August 19, 2011, the 45-day comment period concluded for the 38 measures recommended in the draft report. NQF received 215 comments from 23 organizations. The commenters (see attached list) represent a variety of stakeholders:

Consumers – 2	Professionals - 3
Purchasers - 3	Health Plans - 1
Providers - 5	QMRI – 2
Supplier and Industry - 4	Non-NQF members – 3

The comments include general comments or comments that address groups or classes of measures as well as comments specific to individual measures. NQF staff identified the following comments for further discussion:

Assessment measures

Several commenters have identified the following measures as "check-the-box" measures that are inadequate to advance patient care because they "merely ask whether something has been assessed and don't consider appropriate care and desired results."

- **1524: Assessment of Thromboembolic Risk Factors (CHADS2)** – 'the measure should report the patients actual CHADS 2 score -this would allow tracking of a patients stroke risk over time (e.g., did the patient get better or worse) as well as promote accountability. The committee states this measure is meets the usability test because it improves physician documentation -- this is a basic competency of care and is insufficient to merit endorsement in this area."

- **0079: Heart Failure: Left Ventricular Ejection Fraction Assessment (Outpatient Setting)** – "It is a check-the-box measure that simply assesses whether the clinician completed an assessment. Such measures won't improve patient care. Rather, the goal of the measure should report the patients' health status so that the clinician and others can determine whether the patient is improving over time."
- **0135: Evaluation of Left ventricular systolic function (LVS)** –"We do not agree with the committee's decision to maintain endorsement and placement in reserve status --the measure should be removed altogether."

ACTION ITEM: After considering the comments, does the Steering Committee wish to reconsider its recommendation of the three measures? Why or why not?

Broad exclusions

Several commenters object to overly broad exclusions for patient reasons, system reasons, and medical reasons in the following measures noting that "exclusions should always be evidence-based, highly specific, and explicitly defined. This ensures that the removal of a patient from calculations of a provider's performance is appropriate and, moreover, the exact reason for the removal will be clear in an audit. Having rigorous parameters will also result in more informative data." Commenters cite the broad exclusions as reasons for not choosing measures 0067, 0074 among competing measures – see below. The developer has been asked to respond to the comments also.

- **0067: Chronic Stable Coronary Artery Disease: Antiplatelet Therapy (AMA PCPI)**
- **0074: Chronic Stable Coronary Artery Disease: Lipid Control (AMA PCPI)**
- **0081: Heart Failure: Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (AMA PCPI)**
- **0083: Heart Failure : Beta-blocker therapy for Left Ventricular Systolic Dysfunction (AMA PCPI)**

STAFF NOTE: NQF's measure evaluation criteria regarding exclusions:

> ***2b3.*** *Exclusions are supported by the clinical evidence; otherwise, they are supported by evidence of sufficient frequency of occurrence so that results are distorted without the exclusion. Examples of evidence that an exclusion distorts measure results include, but are not limited to: frequency of occurrence, variability of exclusions across providers, and sensitivity analyses with and without the exclusion.*

ACTION ITEM: After reviewing the comments and the measure evaluation criteria, do these measures continue to meet the criteria for endorsement? Does the Committee wish to change their recommendation of these measures?

Competing measures

A commenter asked whether the draft guidance on best-in-class was used to assist this Committee as several measures in this project appear to be competing. "For example, many of the CAD measures that include blood pressure monitoring, specify different age ranges for patients, and may cause confusion to physicians. Similarly, there appears to be considerable overlap between measures 0068 and 0074, which have a large percentage of members being eligible for both. This issue can pose potential problems in data collection and interpretation of results."

Several commenters identified several pairs of competing measures:

Anti-platelet therapy:

- **0067: Chronic Stable Coronary Artery Disease: Antiplatelet Therapy (AMA PCPI)**
- **0068: Ischemic Vascular Disease (IVD): Use of Aspirin or another Antithrombotic (NCQA)**

Comment: "As the Steering Committee notes, the measure overlaps with NCQA's measure of use of aspirin or anti-thrombotics (measure 0068), which is in wide use in the private sector. To promote alignment with the private sector, we recommend that instead of endorsing measure 0067, the appropriate action would be for the steering committee to obtain NCQA's commitment to broaden the application of its measure (0068) (e.g., to other data collection methods, settings, patients) within a short time frame."

Comment: "We appreciate that these competing measures contain differences with respect to data collection methods, applicable settings, and exclusion criteria; however, it's important that the Steering Committee continue to work with developers of measures #0068, #0067, #0075 to determine the feasibility of harmonizing specifications of these measures where appropriate."

Lipid control:

- **0075 IVD: Complete lipid profile and LDL control 100 (NCQA)**
- **0074 Chronic stable coronary artery disease: Lipid control (PCPI)**

Comment: "The NCQA measure includes a complete lipid profile while the PCPI measure does not require such a profile. It is unclear if it is better to require a complete lipid profile in the measure specification as both measures are seeking to measure LDL-control. We note that the patient population for this denominator is slightly different than the other blood pressure measures, and ask the Steering Committee to provide rationale as to the value of endorsing measures that are not applicable to broad patient populations."

Comment: "We are very concerned about the broad exclusions and believe that instead of endorsing measure 0074, the steering committee should obtain NCQA commitment to broaden its measure (**0075 IVD: complete lipid profile and LDL control 100**) to cover additional areas of interest --this will facilitate alignment with the private sector."

STAFF NOTE: NQF's guidance on competing measures and "best-in-class" was used by the Steering Committee.

ACTION ITEM: After reviewing the comments, the Committee should choose between the competing measures or provide a compelling rationale for endorsing two similar measures.

Composite measures

0076 Optimal vascular care - several comments address issues with the all or none composite measure:

- "As a measurement at a clinical / provider level, there is no apparent exclusion for patients who despite excellent clinical care and provider education, choose to not follow provider best practice recommendations (choose to not fill the statin, choose to continue to smoke, etc)."

- "It importantly includes among its components whether a patient achieved tobacco-free status. All too often, measures of tobacco use only include an assessment and counseling, which fail to report whether a patient quit smoking."
- "Currently the measure is identified for use at the level of the group/practice. We urge the steering committee and the measure developer to specify this measure at the level of the individual physician. There are many good reasons for this. For example, consumers choose individual physicians to be a part of their care team. Additionally, existing NCQA measures that reflect many of the elements in the composite (e.g., blood pressure control, LDL control, daily aspirin use) are specified at the individual clinician level and are widely accepted."

ACTION ITEM: After reviewing the comments, does the Committee wish to change its recommendation of the measure?

Several comments generally support the all or none composites recommended. One commenter noted that "While it may be that all-or-none composites may be optimal for a given circumstance, we support an empiric approach to determining the best composite rather than a reliance on a single approach." One commenter supported recommending the composite measure 0076 only while others supported recommending the individual component measures (0068, 0075) also. A commenter noted that "The value of both individual and composite measures has been demonstrated by CMS pilot studies, however, the current measure set may require harmonization as a number of questions have been raised by the Steering Committee regarding measure harmonization and best-in-class measures."

ACTION ITEM: After considering the comments, does the Committee wish to revisit their discussion of composite measures?

"Topped out" measures

Several commenters support the decision to place the following measures with limited opportunity for improvement in reserve status:

- **0142: Aspirin prescribed at discharge for AMI (CMS)**
- **0160: Beta-blocker prescribed at discharge for AMI (CMS)**

The commenters also identified additional measures that are "topped out" as well and recommend they also be placed in reserve status:

- **0132: Aspirin at arrival for acute myocardial infarction (AMI)** –" CMS is suspending data collection on this measure because it is topped out."
- **0137: ACEI or ARB for left ventricular systolic dysfunction- Acute Myocardial Infarction (AMI) Patients – "**CMS is ending data collection with the understanding that practice has topped out."

STAFF NOTE: The final rule for CMS's Value Based Purchasing (VBP) program identified three measures as "topped out" : 132:AMI–1 Aspirin at Arrival; 160:AMI–5 Beta Blocker at Discharge; and

137: AMI–3 ACEI or ARB at Discharge and are not included in VBP. The developer has been asked to confirm whether data collection for these measures is ending.

ACTION ITEM: After reviewing the comments, does the Committee wish to place measures 132 and 137 in reserve status also? Why or why not?

Mortality measures

Several comments were submitted addressing issues with the mortality measures:

- **0229: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following heart failure (HF) hospitalization (Yale/CMS)**
    - An all-cause mortality rate does not correlate well with AMI mortality.
    - Agree with a mortality measure, but have 2 concerns. First, the validity of risk-standardization adjustment and second, whether it should be all cause mortality vs cardiovascular mortality. Given the advanced age of many heart failure patients, an increasing proportion of whom are in palliative care programs, many deaths cannot be considered a result of substandard care.
- **0230: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) hospitalization (Yale/CMS)**
    - All cause readmission loses its meaning to clinicians and providers as this does not provide information that could lead to performance improvement.
- **0133: PCI mortality (risk-adjusted)© (ACC)**
    - We have concerns over the inclusion of measures that include a post PCI mortality component. States which have a history of data collection on this issue have had to deal with the issue of cherry-picking of PCI candidates to generate better survival statistics. The measure as described, although risk adjusted, would not adequately distinguish between the urgent, rescue procedure and the elective planned procedure. Additionally, changes in the CathPCI data set are being planned, and it may be advisable to hold off on this measure until the changes are available for review.
    - National Association of Healthcare Quality (NAHQ) expresses concerns about the use of registry data in publicly reported measures. These data bases represent significant burden colletions and expense to hospitals. NAHQ recommends measures that are open sources and able to be reproduced by any vendor or organization.

ACTION ITEM: After reviewing the comments, does the Committee wish to change its recommendations on these measures?

Medication measures

Several commenters suggested improvements to measures:

- **0964 Therapy with aspirin, P2Y12 inhibitor and statin (all medications) at discharge**

- **0965 -- Patients with an ICD implant who receive prescriptions for all medications (ACE/ARB and beta blockers) for which they are eligible for at discharge.**

Comment: "We strongly encourage pairing prescription written with prescription filled to strengthen the value of the measure. We encourage the Steering Committee to work with the developer to expand the measure to include prescription filled. We urge the Steering Committee to work with the developer to strengthen the value of this measure by pairing prescription filled with follow through on treatment recommendations."

ACTION ITEM: After reviewing the comments and the measure developers' response, how does the Committee respond to the comments?

Other comments were submitted addressing measures about medication use:

- "As new medication options enter the market, timely inclusion of these new medications and/or drug classes in related quality measure specifications is needed to allow for their appropriate use without delay, where indicated by FDA. Additional alignment (or realignment) of clinical practice guideline-based and quality measure-based recommendations with FDA-approved indications for medications may be necessary to prevent unintended delays or disincentives for use of these new agents by healthcare providers, even though these new agents are FDA approved for the indications represented in the quality measures."
- "There is good evidence in the literature that regular blood pressure monitoring along with regular interaction with health professionals helps patients stay compliant with blood pressure medications and identify changes in the patient's condition. Physician visits monthly would be cost prohibitive but regular visits to a medication management pharmacist may be helpful. Monitoring and documentation could be performed by the pharmacist at a relatively low cost and the results faxed to the patients primary care physician each month to track progress."

ACTION ITEM: Does the Committee wish to include these recommendations in the report?

<u>ICD Measures</u>

1522: ACE/ARB Therapy at Discharge for ICD implant patients with LVSD – "this measure has a very narrow patient population focus, and it would be helpful for the developer to clarify the importance of having so many exclusions for this denominator. Have the measure developers considered including all LVSD patients with documented abnormalities that subsequently received ACE/ARB therapy at discharge?"

1528 Beta blocker at discharge for ICD implant patients with a previous MI (ACCF)
1529 Beta blocker at discharge for ICD implant patients with LVSD (ACCF)
0965 Patients with an ICD implant who receive prescriptions for all medications (ACE/ARB and beta blockers) for which they are eligible for at discharge (ACCF) –"Populations that are eligible for these measures should be captured under either AMI or Heart Failure measures. The need for such a niche measure is unclear."

ACTION ITEM: What is the Committee's response to these comments?

Measures not recommended

Several comments support maintaining endorsement of these measures not recommended:

- **0282--Angina Without Procedure (AHRQ)** – "We ask the steering committee to reevaluate its decision to remove endorsement from this measure. This measure helps to assess overuse of invasive procedures (e.g., PCIs)."

  STAFF NOTE: The developer describes the rationale for this measure: "Admissions for angina are common and there is increasing evidence that the rate of angina admissions is partially a function of the quality of care in a community. Stable angina can be managed in an outpatient setting using drugs such as aspirin and beta blockers, as well as advice to change diet and exercise habits. Effective treatments for coronary artery disease reduce admissions for serious complications of ischemic heart disease, including unstable angina." Committee members believed there are legitimate reasons for admissions for angina that do not involve a procedure and felt that this measure could promote use of procedures. This measure does not assess overuse of procedures.

- **0276 -- Hypertension admission rate (PQI 7)** –"We ask the steering committee to reevaluate its recommendation to remove endorsement from this measure as it could result in the loss of important information."

  STAFF NOTE: The Committee did not recommend this measure because it believed that most admissions for poorly controlled hypertension are not admitted with a primary diagnosis of hypertension but with acute MI or stroke or other complication. The Committee is unsure of the value of this measure when significant numbers of admissions for uncontrolled hypertension are not captured.

ACTION ITEM: After reviewing the comments, does the Committee wish to change their recommendations?

0277: Congestive Heart Failure Admission Rate (PQI 8)

A comment noted that "while ED admissions, per se, are not measured, pressure from medical center administration to reduce admissions of such patients will directly impact ED throughput (and other NQF endorsed measures regarding ED length of stay). This is mentioned in the Steering Committees review but no resolution is suggested. If adopted, one of the unintended consequences will be an increased burden on ED observation units to manage this complex patient population. On the other hand, it will place pressure on hospitals to support outpatient CHF clinics where EDs can send patients for next day follow-up."

ACTION ITEM: What is the Committee's response to this comment?

0330: Hospital 30-day, all-cause, risk-standardized readmission rate following heart failure hospitalization (Yale/CMS)

Several comments were submitted suggesting that the measure does not meet the NQF measure evaluation criteria for endorsement:

- "Exclusions. We urge the steering committee to request an analysis from the measure developer on a list of risk adjustment variables (Appendix A) that should be considered as candidates for measure exclusions. We recommend the steering committee re-examine this measure for scientific acceptability. We are concerned that the criteria included in section *2d: exclusions justified* of the consensus development process has not been properly met. Currently, this measure only includes exclusions in five limited categories: In-hospital death; Without at least 30 days post-discharge enrollment in fee-for-service Medicare; Transferred to another acute care facility; Discharged against medical advice; Admitted with heart failure within 30 days of discharge from an index admission."
- "The measure developer has included a list of risk-adjustment variables (Appendix A) that are applied to claims data. However, these variables are not being applied to ensure that cases that are not truly re admissions are left out of the measures rate. Rather than use these variables in the risk-adjustment methodology, these variables should be considered candidates for additional exclusions. We urge the steering committee to ask the developer to provide evidence that these variables are not distorting the measure results. The developer should provide the following: Count of the frequency of these variables; Sensitivity analysis with and without the exclusions; and Variability of exclusions across hospital types (i.e. teaching and non-teaching)."

- "Risk adjustment. We urge the steering committee to have additional dialogue with the measure developer on the use of stratification to properly risk adjust the HF readmission measure. We recommend the steering committee re-examine this measure for scientific acceptability. We are concerned that the criteria included in section 2e: risk adjustment/stratification of the consensus development process has not properly been met. The NQF criteria in the maintenance report states: It is preferable to stratify measures by race and socioeconomic status rather than adjusting out differences. However, the measure developer states: "The measure is not stratified."
  At a minimum this data must be made publicly available in order for this measure to pass the test of scientific acceptability and remain endorsed under this maintenance review."

- "Disparities. We urge the steering committee to have additional dialogue with the measure developer on stratification to properly account for the disparities underlying the HF readmission measure. We recommend the steering committee re-examine this measure for scientific acceptability. We are concerned that the criteria included in section 2h: disparities of the consensus development process has not been properly met. The NQF criteria in the maintenance report states:
  "If disparities in care have been identified, measure specifications, scoring and analysis allow for identification of disparities through stratification of results (e.g. by race, ethnicity, socioeconomic status, gender); or rationale/data justifies why stratification is not necessary or not feasible."
  However, the measure developer states: "Disparities in race and socio-economic status have been reported at the patient level [for the heart failure readmission measure]."

- "I have real concerns about readmission rates as quality measures. One reason is our data from the VA system showed over a 5 year period in patients who were hospitalized for heart failure that there was a progressive rise in readmission rates associated with a progressive decline in mortality rates. (Heidenreich JACC 2010;56:362-68). A likely reason for this may be that systems which have programs in place to see patients early post-discharge and/or employ various forms of remote monitoring, home visits, and contact with trained NPs will recognize clinical deterioration earlier and admit the patient. This measure has the potential to discourage timely readmissions."
- "All cause readmission loses its meaning to clinicians and providers as this does not provide information that could lead to performance improvement."

STAFF NOTE: The developer has been asked to respond to the comments.

ACTION ITEM: After reviewing the comments and the developer's response, does the Committee wish to change its recommendation of the measure?

Measure developer responses

The measure developers have been asked to respond to comments that pertain to the measure specifications, evidence, data collection, implementation, etc. The responses will be provided to the Committee prior to the September 2 conference call. Committee members should review the comments and responses and identify any comments for further discussion during the conference call.

Organizations Submitting Comments

Consumers:

- Childbirth Connection
- National Partnership for Women and Children

Purchasers:

- Caterpillar, Inc.
- Center for Medicare & Medicaid Services
- Pacific Business Group on Health

Providers:

- American Hospital Association
- Cleveland Clinic
- Intermountain Healthcare
- Mayo Clinic
- University of Pennsylvania

Supplier and Industry:

- Abbott Laboratories
- AstraZeneca
- Boehringer Ingelheim Pharmaceuticals, Inc.
- Ortho-McNeill-Janssen Pharmaceutical, Inc.

Professionals:

- Heart Rhythm Society
- Society for Academic Emergency Medicine
- American College of Cardiology Foundation (ACCF)/American Heart Association (AHA)/Physician Consortium for Performance Improvement (PCPI)

Health Plans:

- America's Health Insurance Plans

QMRI:

- Intermountain Healthcare
- National Association of Healthcare Quality

Non-NQF Members:

- Palmetto Health
- Heart Failure Society of America
- Genentech Inc.