TO: Consensus Standards Approval Committee (CSAC)

FR: Melissa Marinelarena, Leslie Vicale, Donna Herring

RE: Cardiovascular 2015 Member Voting Results

DA: January 12, 2016

The CSAC will review recommendations from the *Cardiovascular 2015* project during its January 12, 2016 conference call.

This memo includes a summary of the project, recommended measures, and themes identified from and responses to the public and member comments.

Member voting on these recommended measures ended on January 5, 2016.

Accompanying this memo are the following documents:

1. **Cardiovascular Draft Report.** The draft report has been updated to reflect the changes made following Standing Committee discussion of public and member comments. The complete draft report and supplemental materials are available on the project page.
2. **Comment table**. Staff has identified themes within the comments received. This table lists 86 comments received and the NQF/Standing Committee responses.

CSAC ACTION REQUIRED

Pursuant to the CDP, the CSAC may consider approval of 18 candidate consensus standards. Seventeen measures were recommended for endorsement; one measure was recommended for Approval for Trial Use and one measure was not recommended for endorsement.

Cardiovascular Measures Recommended for Endorsement:

- 0067: Chronic Stable Coronary Artery Disease: Antiplatelet Therapy
- 0068: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet
- 0070: Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)
- 0071: Persistence of Beta-Blocker Treatment After a Heart Attack
- 0079: Heart Failure: Left Ventricular Ejection Fraction Assessment (Outpatient Setting)
- 0081: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
- 0081 eMeasure: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
- 0083: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
- 0083 eMeasure: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

- 0229: Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Heart Failure (HF) Hospitalization for Patients 18 and Older
- 0230: Hospital 30-day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Myocardial Infarction (AMI) Hospitalization for Patients 18 and Older
- 0669: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery
- 0694: Hospital Risk-Standardized Complication Rate following Implantation of Implantable Cardioverter-Defibrillator (ICD)
- 0730: Acute Myocardial Infarction (AMI) Mortality Rate
- 0965: Discharge Medications (ACE/ARB and beta blockers) in Eligible ICD Implant Patients
- 2396: Carotid Artery Stenting: Evaluation of Vital Status and NIH Stroke Scale at Follow Up
- 2712: Statin Use in Persons with Diabetes

Cardiovascular Measures Recommended for Approval for Trial-Use

- 2764: Fixed-Dose Combination Of Hydralazine and Isosorbide Dinitrate Therapy for Self-Identified Black or African American Patients with Heart Failure and LVEF <40% on ACEI or ARB and Beta-Blocker Therapy

Cardiovascular Measures Not Recommended

- 0070 eMeasure: Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)

BACKGROUND

NQF's cardiovascular measures portfolio is one of the largest, with measures for primary prevention and screening, coronary artery disease (CAD), ischemic vascular disease (IVD), acute myocardial infarction (AMI), cardiac catheterization, percutaneous catheterization intervention (PCI), heart failure (HF), rhythm disorders, implantable cardioverter-defibrillators (ICDs), cardiac imaging, cardiac rehabilitation, and high blood pressure. Despite the large number of endorsed measures, gaps remain in patient-reported outcomes and patient-centric composite measures.

In Phase 3 of the Cardiovascular project, the Standing Committee evaluated a total of 26 measures, 13 maintenance measures and 13 new measures against NQF's standard evaluation criteria. (The new measures included three eMeasure versions of previously-endorsed measures; the eMeasures were evaluated separately from their registry-based counterparts.) Seventeen measures were recommended for endorsement by the Committee and one eMeasure was recommended for Approval for Trial Use. The Committee did not reach consensus on one measure, six measures were not recommended for endorsement and one measure (#2763) was deferred to Phase 4.

Measures for reconsideration: NQF received requests for reconsideration for five measures developed by Healthcare Incentives Improvement Institute (HCI3) that were not recommended for endorsement by the Standing Committee. NQF staff will reconvene the Standing Committee on January 28, 2016 to reconsider the five measures that were not recommended (#2740, #2749, #2747, #2748, and #2752)

and the one measure where consensus was not reached for overall suitability (#2751). The results of the reconsideration will be presented to the CSAC during the March 23-24, 2016 in-person meeting.

Ad Hoc Review: In addition to the 26 measures under review in Phase 3, the Cardiovascular Standing Committee also conducted an ad hoc review of measure 0018: Controlling High Blood Pressure. The Committee ultimately did not agree with the changes to the measure evidence and decided not to recommend continuing endorsement of the updated measure. After discussion with the developer following the in-person meeting, the ad hoc review of the revised specifications for 0018 has been deferred pending availability of new evidence. The measure will retain endorsement with the existing specifications.

DRAFT REPORT

The Cardiovascular 2015 Draft Report presents the results of the evaluation of 26 measures considered under the CDP. The measures were evaluated against the 2013 version of the measure evaluation criteria.

	MAINTENANCE	NEW	TOTAL
Measures considered	13	13	26
Measures deferred*	0	1	1
Recommended	13	5	18
Not recommended	0	1	1
Measures where consensus is not yet reached**	0	1	1
Measures under reconsideration**	0	5	5
Reasons not Recommended	Importance- 0 Scientific Acceptability- 0 Overall- 0 Competing Measure- 0	Importance- 0 Scientific Acceptability- 1 Overall- 0 Competing Measure- 0	

* Measure #2763 was identified as a competing measure with NQF #0076, which is scheduled for review during Phase 4. In an effort to foster parsimony and harmony within the CV portfolio and enable the Committee to consider competing measures simultaneously, the Committee agreed to defer their recommendation for this measure until Phase 4 so that a best-in-class determination can be made at that time.

** Five measures will be reconsidered by the Standing Committee on January 28, 2016. One measure from the same developer where consensus was not reached will also be discussed.

COMMENTS AND THEIR DISPOSITION

NQF received 86 comments from 11 organizations (including six member organizations) and 23 members of the public pertaining to the general draft report and to the measures under consideration.

A table of comments submitted during the comment period, with the responses to each comment and the actions taken by the Standing Committee and measure developers, is posted to the Cardiovascular project page under the Public and Member Comment section.

Comment Themes and Committee Responses

The majority of commenters supported the Committee's recommendations. Comments about harmonization, specific measure specifications and rationale, and desire for outcome measures were forwarded to the developers, who were invited to respond.

At its review of all comments, the Standing Committee had the benefit of developer responses. Committee members focused their discussion on measures or topic areas with the most significant and recurring issues.

Theme 1 - Harmonization

Several comments received support the Committee's recommendations for harmonization of the measures identified as related or competing (*0669: Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery and 0670: Cardiac stress imaging not meeting appropriate use criteria: Preoperative evaluation in low risk surgery patients)*. Additional comments received recommend harmonization of three measures (*0081: Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD), 0083: Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD), and 0079: Left Ventricular Ejection Fraction Assessment (Outpatient Setting*).

Committee Response: During the second post In-Person Meeting webinar on October 9, 2015 the Committee considered harmonization of measures within the Cardiovascular portfolio. The Committee encouraged the developers of two competing measures (#0669 and #0670) to harmonize the measure specifications. Harmonization of #0669 and #0670 should be completed prior to the measures' next annual update. The Committee also urged developers to work together in the future to harmonize measures further where possible. Additionally, the Committee will revisit the harmonization discussion of several measures during the next Cardiovascular measure endorsement project in 2016. Measures #0081, #0083, and #0079 were not identified as related or competing based on NQF criteria.

Theme 2 – Request for changes

A number of commenters suggested changes to several measures. The changes included additional exclusions and additional pharmaceutical therapies.

Committee Response: The Committee reviewed the recommended changes and the developer responses, and then discussed the recommended changes during the call. No changes were recommended to the developers at this time.

Theme 3 – Preference of outcome measures

For two measures (*0965: Discharge Medications (ACE/ARB and beta blockers) in Eligible ICD Implant Patients* and *2396: Carotid artery stenting: Evaluation of Vital Status and NIH Stroke Scale at Follow Up*) commenters noted a preference for outcome measures rather than the currently specified process measures.

Committee Response: Generally, the Committee would prefer to recommend the endorsement of outcome measures rather than process or structural measures. However, measuring the process or structure may still be useful for quality improvement or other purposes; these measure types may still be useful where outcomes may be difficult to measure.

Measure Specific Comments

2764: Fixed-dose Combination of Hydralazine and Isosorbide Dinitrate Therapy for Self-identified Black or African American Patients with Heart Failure and LVEF <40% on ACEI or ARB and Beta-blocker Therapy

Description: A high number of comments were received in support of measure #2764 noting the benefits of a fixed-dose combination of hydralazine and isosorbide dinitrate therapy for African-American patients with heart failure (HF). The fixed-dose combination therapy (BiDil) demonstrated a 43 percent reduction in mortality when compared with the placebo during the African-American Heart Failure Trial (A-HeFT). Evidence of the fixed-dose combination's effectiveness in A-HeFT led to a Class 1A recommendation in the American College of Cardiology (ACC) and American Heart Association (AHA) guidelines (2013), making the treatment protocol the standard of care for African-American patients with heart failure (Yancy et al., 2013). Despite the treatment's efficacy and guidelines recommending its use as the standard of care, few African-American patients are being prescribed this FDA-approved treatment. CMS claims data indicates that 90 percent of the eligible black patients meeting the indication do not receive it. Another study notes that only 7 percent of eligible patients received the treatment, leading to an estimated 6,655 avoidable deaths annually (Fonarow et al., 2011).

Three comments received referenced the 2013 ACC/AHA Heart Failure Guideline recommendations that encourage treatment of African-American heart failure patients with the hydralazine and isosorbide dinitrate combination therapy. The commenters state that the guidelines recommend hydralazine and isosorbide dinitrate therapy in African-American patients with heart failure but the guideline recommendation specifically permits use of either the fixed-dose combination or separate

administration of hydralazine and isosorbide dinitrate. The commenters' concern is that the measure could penalize providers who prescribe the separate therapies and the financial burden the fixed-dose combination therapy would place on many patients increasing the likelihood of medical non-compliance.

Committee Response: The Committee considered the ACC/AHA Heart Failure Guidelines during the measure evaluation discussion and determined that a gap in appropriate treatment persists in the African-American subpopulation of heart failure patients warranting a need for this measure. Studies show a significant reduction in mortality of this specific subpopulation with the use of the fixed-dosed combination therapy.

NQF MEMBER VOTING RESULTS

16 of the 18 recommended measures were approved with 60% approval or higher. Two of the 18 measures were measures where consensus was not reached. Representatives of 12 member organizations voted; no votes were received from the Public/Community Health Agency or Consumer Councils. Results for each measure are provided below. (Links are provided to the full measure summary evaluation tables.)

NQF Member Council	Voting Organizations	Eligible to Vote	Rate
Consumer	0	37	0%
Health Plan	2	20	10%
Health Professional	2	100	2%
Provider Organizations	1	110	1%
Public/Community Health Agency	0	19	0%
Purchaser	2	20	10%
QMRI	4	80	5%
Supplier/Industry	1	39	3%
All Councils	**12**	**425**	**4%**

Measure #0067 Chronic Stable Coronary Artery Disease: Antiplatelet Therapy

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	2	0	0	2	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	2	0	2	4	100%
Supplier/Industry	0	0	1	1	

All Councils	**9**	**0**	**3**	**12**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #0068 Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	0	0	2	2	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	3	4	100%
Supplier/Industry	0	0	1	1	
All Councils	**6**	**0**	**6**	**12**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #0070 Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	2	0	0	2	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	2	0	2	4	100%
Supplier/Industry	0	0	1	1	
All Councils	**9**	**0**	**3**	**12**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure # 0071 Persistence of Beta-Blocker Treatment After a Heart Attack

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	0	0	2	2	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	3	4	100%
Supplier/Industry	0	0	1	1	
All Councils	**6**	**0**	**6**	**12**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure # 0079 Heart Failure: Left Ventricular Ejection Fraction Assessment (Outpatient Setting)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	2	0	0	2	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	2	0	2	4	100%
Supplier/Industry	0	0	1	1	
All Councils	**9**	**0**	**3**	**12**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure # 0081 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	2	0	0	2	100%

Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	2	0	2	4	100%
Supplier/Industry	0	0	1	1	
All Councils	**9**	**0**	**3**	**12**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

eMeasure #0081 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	2	0	0	2	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	3	4	100%
Supplier/Industry	0	0	1	1	
All Councils	**8**	**0**	**4**	**12**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #0083 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	2	0	0	2	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	3	4	100%
Supplier/Industry	0	0	1	1	
All Councils	**8**	**0**	**4**	**12**	**100%**

Percentage of councils approving (>60%)	100%
Average council percentage approval	100%

*equation: Yes/ (Total - Abstain)

eMeasure #0083 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	2	0	0	2	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	2	0	2	4	100%
Supplier/Industry	0	0	1	1	
All Councils	**9**	**0**	**3**	**12**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #0229 Hospital 30-day all-cause risk-standardized mortality rate (RSMR) following heart failure (HF) hospitalization for patients 18 and older

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	0	0	2	2	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	0	0	4	4	
Supplier/Industry	0	0	1	1	
All Councils	**5**	**0**	**7**	**12**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #0230 Hospital 30-day all-cause risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) hospitalization for patients 18 and older

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	0	0	2	2	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	3	4	100%
Supplier/Industry	0	0	1	1	
All Councils	**6**	**0**	**6**	**12**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- Adventist Health System: More detailed work should be done on the SDS factors that could impact the performance on this measure.

Measure #0669 Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac Low Risk Surgery

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	0	0	2	2	
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	0	0	4	4	
Supplier/Industry	0	0	1	1	
All Councils	**5**	**0**	**7**	**12**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- Adventist Health System: This measure should be harmonized with 0670.

Measure #0694 Hospital Risk-Standardized Complication Rate following Implantation of Implantable Cardioverter-Defibrillator (ICD)

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	1	0	1	2	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	3	4	100%
Supplier/Industry	0	0	1	1	
All Councils	**7**	**0**	**5**	**12**	**100%**
Percentage of councils approving (>60%)					100%
Average council percentage approval					100%

*equation: Yes/ (Total - Abstain)

Measure #0730 Acute Myocardial Infarction (AMI) Mortality Rate

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	0	0	2	2	
Provider Organizations	0	1	0	1	0%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	0	0	4	4	
Supplier/Industry	0	0	1	1	
All Councils	**4**	**1**	**7**	**12**	**80%**
Percentage of councils approving (>60%)					67%
Average council percentage approval					67%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- Adventist Health System: An empirical analysis of the SDS factors that could have a material impact on this measure was done. In my opinion it is not valid without that study.

Measure #0965 Discharge Medications (ACE/ARB and beta blockers) in Eligible ICD Implant Patients

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	2	0	2	0%
Health Professional	1	0	1	2	100%
Provider Organizations	0	1	0	1	0%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	1	0	2	50%
QMRI	1	0	3	4	100%
Supplier/Industry	0	0	1	1	
All Councils	**3**	**4**	**5**	**12**	**43%**
Percentage of councils approving (>60%)					40%
Average council percentage approval					50%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- Adventist Health System: This measure was developed as a composite construct yet appears to be applied in a different manner.

Measure #2396 Carotid artery stenting: Evaluation of Vital Status and NIH Stroke Scale at Follow Up

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	1	0	1	2	100%
Provider Organizations	0	1	0	1	0%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	3	4	100%
Supplier/Industry	0	0	1	1	
All Councils	**6**	**1**	**5**	**12**	**86%**
Percentage of councils approving (>60%)					80%
Average council percentage approval					80%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- Adventist Health System: This measure appears to be created to force medical professionals to get certification by the American Stroke Association in a particular Stroke Scale. That is not the

purpose of quality measure. If a stroke scale if valid, it would seem that and experience Neurologist could administer it without having to be certified by one particular organization.

Measure #2712 Statin Use in Persons with Diabetes

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	0	1	1	2	0%
Provider Organizations	0	1	0	1	0%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	1	0	3	4	100%
Supplier/Industry	0	1	0	1	0%
All Councils	**5**	**3**	**4**	**12**	**63%**
Percentage of councils approving (>60%)					50%
Average council percentage approval					50%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- Adventist Health System: The research data I reviewed suggests that the use of Statins with Diabetic patients with no history or signs of CVD is not necessarily justified. A consensus on this point has not been reached.

Measure #2764 Fixed-dose Combination of Hydralazine and Isosorbide Dinitrate Therapy for Self-identified Black or African American Patients with Heart Failure and LVEF <40% on ACEI or ARB and Beta-blocker Therapy

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	2	0	0	2	100%
Health Professional	0	1	1	2	0%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	2	0	0	2	100%
QMRI	0	1	3	4	0%
Supplier/Industry	0	0	1	1	
All Councils	**5**	**2**	**5**	**12**	**71%**
Percentage of councils approving (>60%)					60%
Average council percentage approval					60%

*equation: Yes/ (Total - Abstain)

Voting Comments:

- Stanford University School of Medicine: This measure goes against the views of the ACC/AHA clinical practice guideline for heart failure that recommend non-fixed dose or fixed dose. This decision was based on a careful review of all evidence related to fixed vs. non-fixed dosing and their conclusion was that an important benefit exists with non-fixed dosing.

REMOVE ENDORSEMENT OF MEASURES

Seven measures previously endorsed by NQF were not re-submitted, were withdrawn from maintenance of endorsement, or were not recommended for continued endorsement:

Measure	Description	Reason for removal of endorsement
0135 Evaluation of Left Ventricular Systolic Function (LVS) [hospital]	Percentage of heart failure patients with documentation in the hospital record that left ventricular systolic (LVS) function was evaluated before arrival, during hospitalization, or is planned for after discharge.	Developer will no longer be maintaining the measure.
0160 Beta-blocker prescribed at discharge for AMI	Percentage of acute myocardial infarction (AMI) patients who are prescribed a beta-blocker at hospital discharge.	Developer will no longer be maintaining the measure.
0162 ACEI or ARB for left ventricular systolic dysfunction - Heart Failure (HF) Patients	Percentage of heart failure (HF) patients with left ventricular systolic dysfunction (LVSD) who are prescribed an ACEI or ARB at hospital discharge. For purposes of this measure, LVSD is defined as chart documentation of a left ventricular ejection fraction (LVEF) less than 40% or a narrative description of left ventricular systolic (LVS) function consistent with moderate or severe systolic dysfunction.	Developer will no longer be maintaining the measure.
0704 Proportion of Patients Hospitalized with AMI that have a Potentially Avoidable Complication (during the Index Stay or in the 30-day Post Discharge Period)	Percent of adult population aged 18 + years who are admitted to a hospital with acute myocardial infarction (AMI), are followed for one-month after discharge, and have one or more potentially avoidable complications (PACs). PACs may occur during the index stay or during the 30-day post discharge period. Please reference attached document labeled NQF_AMI_all_codes_risk_adjustment_06.30.15.xls, in the tabs labeled PACs I-9 and PAC I-10 for a list of code definitions of PACs relevant to AMI.	Developer will no longer be maintaining the measure.
1522 ACE/ARB Therapy at Discharge for ICD implant	Proportion of ICD implant patients with a diagnosis of LVSD who are prescribed ACE-I or ARB therapy at discharge.	Measure included in composite measure 0965: Patients with an

Measure	Description	Reason for removal of endorsement
patients with Left Ventricular Systolic Dysfunction		ICD implant who receive prescriptions for all medications (ACE/ARB and beta blockers) for which they are eligible for at discharge.
1528 Beta Blocker at Discharge for ICD implant patients with a previous MI	Proportion of ICD implant patients with a diagnosis of previous MI who are prescribed a Beta Blocker at discharge.	Measure included in composite measure 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.
1529 Beta Blocker at Discharge for ICD implant patients with Left Ventricular Systolic Dysfunction	Proportion of ICD implant patients with a diagnosis of Left Ventricular Systolic Dysfunction who are prescribed beta-blocker therapy on discharge.	Measure included in composite measure 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.

Appendix A-Measure Evaluation Summary Tables

LEGEND: Y = Yes; N = No; H = High; M = Moderate; L = Low; I = Insufficient

0067 Chronic Stable Coronary Artery Disease: Antiplatelet Therapy

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who were prescribed aspirin or clopidogrel.

Numerator Statement: Patients who were prescribed* aspirin or clopidogrel within a 12 month period.

*Prescribed may include prescription given to the patient for aspirin or clopidogrel at one or more visits in the measurement period OR patient already taking aspirin or clopidogrel as documented in current medication list.

Denominator Statement: All patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period.

Exclusions: Documentation of medical reason(s) for not prescribing aspirin or clopidogrel (e.g., allergy, intolerance, receiving other thienopyridine therapy, receiving warfarin therapy, bleeding coagulation disorders, other medical reasons)

Documentation of patient reason(s) for not prescribing aspirin or clopidogrel (e.g., patient declined, other patient reasons)

Documentation of system reason(s) for not prescribing aspirin or clopidogrel (e.g., lack of drug availability, other reasons attributable to the health care system)

Adjustment/Stratification:

Level of Analysis: Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: American College of Cardiology

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-12**; **M-0**; **L-0**; **I-0; IE-0**; 1b. Performance Gap: **H-5**; **M-7**; **L-0**; **I-0**

Rationale:

- Based on the guideline recommendations and correlating statements provided by the developer, the Committee agreed that the evidence supports the use of aspirin or clopidogrel in patients with CAD.
- Although there was agreement that a performance gap existed, the Committee questioned whether the measure was topped out since the performance rates from the PINNACLE Registry remained at 86% in 2013 and 2014. Additional literature provided by the developer demonstrated a performance rate of 84% from the PINNACLE Registry. Although, since the numbers were still sub-optimal in certain regions, the Committee agreed a performance gap still existed.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-8**; **M-4**; **L-0**; **I-0** 2b. Validity: **H-8**; **M-4**; **L-0**; **I-0**

Rationale:

- The developer conducted a signal-to-noise analysis using the beta-binomial model to assess the reliability of the measure. The Committee agreed that a score of 0.994 demonstrated high reliability.

0067 Chronic Stable Coronary Artery Disease: Antiplatelet Therapy
• The developers provided content, construct and face validity results for this measure. The Committee agreed that the results adequately demonstrate validity.
3. Feasibility: H-10; M-2; L-0; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • The Committee agreed that the measure is feasible to implement, as the measure has already been in use and collected via registry since 2003.
4. Use and Usability: H-12; M-0; L-0; I-0 *(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)* Rationale: • The measure is currently used in the PINNACLE Registry and PQRS.
5. Related and Competing Measures • This measure is related to: o NQF #0068: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet (NCQA) o The Committee agreed that the different data sources, conditions and medications justify maintaining both measures in the CV portfolio. • No competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-12**; **N-0**
6. Public and Member Comment • Four commenters were generally in support of this measure. Two commenters suggested additional antiplatelet therapies be captured within the measure besides aspirin and clopidogrel. o Developer response: Thank you for your comment and interest in endorsing this measure. The ACC/AHA Taskforce on Performance Measures has plans to revise our entire CAD measure set. At that time will share your recommendation with the writing committee and consider all guideline recommendations that may impact the types of medications (including other antiplatelets) that should be included in this measure when it is updated. o Committee response: The Committee agrees with the developer response and maintains their decision to recommend this measure for endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0068 Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet

Submission | Specifications

Description: The percentage of patients 18 years of age and older who were discharged from an inpatient setting with an acute myocardial infarction (AMI), coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI) during the 12 months prior to the measurement year, or who had a diagnosis of ischemic vascular disease (IVD) during the measurement year and the year prior to the measurement year and who had documentation of routine use of aspirin or another antiplatelet during the measurement year.

Numerator Statement: Patients who had documentation of routine use of aspirin or another antiplatelet during the measurement year.

Denominator Statement: Patients 18 years or older by the end of the measurement year discharged from an inpatient setting with an AMI, CABG, or PCI during the 12 months prior to the measurement year or who had a diagnosis of IVD during both the measurement year and the year prior to the measurement year.

Exclusions: Patients who had documentation of use of anticoagulant medications during the measurement year.

Adjustment/Stratification:

Level of Analysis: Clinician : Group/Practice, Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-14**; **M-1**; **L-0**; **I-0; IE-0**; 1b. Performance Gap: **H-8**; **M-8**; **L-0**; **I-0;**

Rationale:

- The Committee agreed that the developer provided sufficient evidence to support the routine use of aspirin or another antiplatelet in patients with IVD.
- The developer provided performance data from NCQA's Heart/Stroke Recognition Program and CMS' PQRS. The Committee agreed that a performance gap existed but noted that in the PQRS data set as the volume increased the performance rates decreased. The developers explained that this was most likely due to the rapid increase of participating clinicians in the program and it was possible some of them did not have the systems in place to implement the measures.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-11**; **M-5**; **L-0**; **I-0** 2b. Validity: **H-1**; **M-14**; **L-0**; **I-0**

Rationale:

- The Committee agreed that the measure specifications were precisely specified.
- The Committee questioned whether excluding patients on anticoagulation medication, a change in the measure, would affect its reliability.
- Reliability testing for this measure was conducted at the level of the performance measure score using a signal-to-noise test with the overall score being 0.88. The Committee agreed that the results demonstrated high reliability.
- Face validity was systematically assessed through two expert panels that "concluded with good

0068 Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet
agreement that the measure, as specified accurately differentiates quality across clinicians and group practices." The Committee noted that they would have preferred the numerical results from the systematic assessment rather than the general statement provided.
3. Feasibility: H-9; M-7; L-0; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • The Committee agreed that this measure is feasible.
4. Use and Usability: H-12; M-4; L-0; I-0 *(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)* Rationale: • This measure is publicly reported in the PQRS program, the CMS Meaningful Use program, the ACO Shared Savings Program, and the NCQA Stroke Recognition Program.
5. Related and Competing Measures • This measure is related to: o NQF #0067: Chronic Stable Coronary Artery Disease: Antiplatelet Therapy (ACC) o The Committee agreed that the different data sources, conditions and medications justify maintaining both measures in the CV portfolio. • No competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-16**; **N-0**
6. Public and Member Comment • Three commenters generally agreed with this measure. Two commenters suggested an exclusion for those at risk of bleeding be added to the measure. o Developer response: Thank you for your review of the changes to NQF 00068 and this recommendation. NCQA has recently received similar recommendations and we will be reviewing this with our Cardiovascular Measurement Advisory Panel. We will update NQF on our progress. o Committee Response: The Committee agrees with the developer response and maintains their decision to recommend this measure for endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals


NATIONAL
QUALITY FORUM

0070 Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have a prior MI or a current or prior LVEF <40% who were prescribed beta-blocker therapy

Numerator Statement: Patients who were prescribed beta-blocker therapy

Denominator Statement: All patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have a prior MI (within the past 3 years) or a current or prior LVEF <40%

Exclusions: Documentation of medical reason(s) for not prescribing beta-blocker therapy (eg, allergy, intolerance, other medical reasons)

Documentation of patient reason(s) for not prescribing beta-blocker therapy (eg, patient declined, other patient reasons)

Documentation of system reason(s) for not prescribing beta-blocker therapy (eg, other reasons attributable to the health care system)

Adjustment/Stratification:

Level of Analysis: Clinician : Group/Practice, Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Home Health, Post Acute/Long Term Care Facility : Long Term Acute Care Hospital, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry

Measure Steward: AMA-convened Physician Consortium for Performance Improvement

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-16**; **M-0**; **L-0**; **I-0; IE-0**; 1b. Performance Gap: **H-11**; **M-6**; **L-0**; **I-0**

Rationale:

- The discussion and voting on evidence for the eMeasure version of #0070 applies to the Claims/Registry version.
- The developer provided performance data from the PQRS Experience Report from 2010 to 2013. The performance rates ranged from 69.9% to 82.1%. The Committee questioned the variation in performance rates from year to year. The developers explained that variation in performance rates was due to the rate of participating professionals in PQRS changing from year to year. The Committee agreed there continues to be a performance gap with approximately 20-30% of eligible patients not receiving beta-blocker therapy.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-7**; **M-10**; **L-0**; **I-0** 2b. Validity: **H-5**; **M-11**; **L-0**; **I-1**

Rationale:

- The measure was tested for reliability at the level of the measure score using the beta binomial method and assessed 1,724 physicians from the PQRS GPRO database. The reliability at the minimum level of quality reporting events (10) was 0.65. The reliability at the average number of quality reporting events

0070 Coronary Artery Disease (CAD): Beta-Blocker Therapy-Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF <40%)
(61.0) was 0.92. The Committee concluded that overall the results indicated high reliability. • The measure was tested for validity at the level of the measure score by systematic assessment of face validity by the PCPI Measure Advisory Committee of 12 members. The Committee agreed that the results indicated sufficient face validity.
3. Feasibility: H-13; M-4; L-0; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • The Committee expressed no concerns regarding the feasibility of this measure.
4. Use and Usability: H-7; M-8; L-2; I-0 *(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)* Rationale: • The Committee noted this measure is used in PQRS, PINNACLE Registry, and Meaningful Use Stage II.
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-16**; **N-0**
6. Public and Member Comment • Three commenters were generally in support of the measure.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0071 Persistence of Beta-Blocker Treatment After a Heart Attack

Submission | Specifications

Description: The percentage of patients 18 years of age and older during the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with a diagnosis of acute myocardial infarction (AMI) and who received persistent beta-blocker treatment for six months after discharge.

Numerator Statement: Patients who had a 180-day course of treatment with beta-blockers post discharge.

Denominator Statement: Patients 18 years of age and older as of December 31 of the measurement year who were hospitalized and discharged from July 1 of the year prior to the measurement year to June 30 of the measurement year with diagnosis of AMI. See question S.9 Denominator Details for methods to identify patients who qualify for the denominator.

Exclusions: Exclude from the denominator, hospitalizations in which the patient was transferred directly to a nonacute care facility for any diagnosis.

Exclude patients who are identified as having an intolerance or allergy to beta-blocker therapy. Any of the following anytime during the patient's history through the end of the continuous enrollment period meet criteria:

- Asthma (Asthma Value Set).
- COPD (COPD Value Set).
- Obstructive chronic bronchitis (Obstructive Chronic Bronchitis Value Set).
- Chronic respiratory conditions due to fumes and vapors (Chronic Respiratory Conditions Due to Fumes/Vapors Value Set).
- Hypotension, heart block >1 degree or sinus bradycardia (Beta-Blocker Contraindications Value Set).
- A medication dispensing event indicative of a history of asthma (Table PBH-D).
- Intolerance or allergy to beta-blocker therapy.

Adjustment/Stratification:

Level of Analysis: Health Plan, Integrated Delivery System

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Pharmacy

Measure Steward: National Committee for Quality Assurance

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-4**; **M-10**; **L-2**; **I-0; IE-0**; 1b. Performance Gap: **H-3**; **M-13**; **L-0**; **I-0;**

<u>Rationale</u>:

- Evidence provided by the developer included one guideline for a ST-elevation myocardial infarction (STEMI) and one guideline for a non-ST Elevation myocardial infarction (NSTEMI). A Committee noted that the non-STEMI guidelines were graded a level C and stated that the 1999 date of the systematic review was cause for concern. The developer explained that the review was older but the seminal body of work it cited allowed for a large body of evidence which supported the measure best. Other Committee members argued that they were aware of very strong evidence for the use of beta blockers post MI that the developers did not provide.
- The developer provided data from commercial health plans, Medicare, and Medicaid from 2012-2014 that showed that approximately 15% of commercial and Medicaid patients did not receive beta blockers for six months after an MI. Ten percent of Medicare patients did not receive the appropriate treatment.

0071 Persistence of Beta-Blocker Treatment After a Heart Attack

The Committee agreed that there continues to be a gap in performance for this measure.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-2**; **M-13**; **L-1**; **I-0** 2b. Validity: **H-0**; **M-15**; **L-1**; **I-X**
<u>Rationale</u>:

- The Committee questioned how the developer determined that 75% (135 days) of six months (180 days) was the threshold for "persistence". The developer responded that when the measure was originally developed this threshold was thought to be the best way to assign consistent use. However, the developer is aware that the Pharmacy Quality Alliance (PQA) uses 80% of days covered as a threshold and will consider aligning this measure to other PQA adherence measures.
- The developers clarified that all patients discharged with a diagnosis of AMI, regardless of undergoing a revascularization procedure, will be included in this measure.
- Reliability testing for this measure was conducted at the level of the performance measure score using a signal-to-noise test with an overall reliability at the health plan level between 0.78 and 0.81. The Committee agreed this measure is reliable.
- The developer conducted construct validity and a systematic assessment of face validity with three expert panels but did not provide statistical results from the expert panels' review therefore the Committee determined that validity was moderate.

3. Feasibility: H-9; M-7; L-0; I-0
(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)
<u>Rationale</u>:

- The Committee agreed that this measure is feasible.

4. Use and Usability: H-10; M-5; L-1; I-0
(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)
<u>Rationale</u>:

- This measure is currently reported through NCQA Health Plan Rankings, Accreditation, and Quality Compass.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-15**; **N-1**

6. Public and Member Comment

- Four commenters were generally in support of this measure. One commenter noted the feasibility of data may be an issue due to untimely information and data limitations. The same commenter also suggested an exclusion for pregnancy be included in the measure.
    - Developer Response: Thank you for your review of the update to NQF 0071 and this set of recommendations.
      NCQA recognizes the data collection burden this measure presents for individual practices and

0071 Persistence of Beta-Blocker Treatment After a Heart Attack
providers, which is why it is specified for health plan level accountability. Health plans have access to discharge information and pharmacy data, and are in a good position to influence performance on this measure by working with hospitals and practices to ensure data is shared in a timely manner, supporting needed care coordination for these vulnerable patients. With regard to an exclusion for pregnancy, we do not believe this would be appropriate because beta blockers are generally considered safe and although not all beta-blockers are recommended for pregnant women, there are alternatives to choose from. The FDA currently recommends that "women who are pregnant or nursing should talk to their doctor before they start using Beta-Blockers." ▪ http://www.clevelandclinicmeded.com/medicalpubs/diseasemanagement/cardiology/pregnancy-and-heart-disease/ ▪ http://www.fda.gov/forconsumers/byaudience/forwomen/ucm118594.htm ○ Committee Response: The Committee agrees with the developer response and maintains their decision to recommend this measure for endorsement.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0079 Heart Failure: Left Ventricular Ejection Fraction Assessment (Outpatient Setting)

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure for whom the quantitative or qualitative results of a recent or prior (any time in the past) LVEF assessment is documented within a 12 month period.

Numerator Statement: Patients for whom the quantitative or qualitative results of a recent or prior (any time in the past) LVEF assessment is documented* within a 12 month period.

*Documentation must include documentation in a progress note of the results of an LVEF assessment, regardless of when the evaluation of ejection fraction was performed. Qualitative results correspond to numeric equivalents as follows:

Hyperdynamic: corresponds to LVEF greater than 70%

Normal: corresponds to LVEF 50% to 70% (midpoint 60%)

Mild dysfunction: corresponds to LVEF 40% to 49% (midpoint 45%)

Moderate dysfunction: corresponds to LVEF 30% to 39% (midpoint 35%)

Severe dysfunction: corresponds to LVEF less than 30%

Denominator Statement: All patients aged 18 years and older with a diagnosis of heart failure.

Exclusions: None.

Adjustment/Stratification:

Level of Analysis: Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: American College of Cardiology

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-1**; **M-0**; **L-0**; **I-11; IE-12**; 1b. Performance Gap: **H-11**; **M-1**; **L-0**; **I-0**

Rationale:

- The evidence provided for this measure was a heart failure guideline graded Class I: Level of Evidence C (expert opinion). The Committee agreed that although the evidence was insufficient based on NQF's criterion, the measure should be permitted to proceed forward since it is unlikely that any higher level of evidence will become available for this process of care.
- In 2013, the mean compliance rate for this measure was 67% with an increase to 72.5% in 2014. The data also suggests a difference in performance based on insurance type.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-12**; **M-0**; **L-0**; **I-0**; 2b. Validity: **H-10**; **M-2**; **L-0**; **I-0**

Rationale:

- Reliability testing for this measure was conducted at the level of the performance measure score using a signal-to-noise analysis with an overall reliability score of 0.988 for 2013 and 0.989 for 2014.
- Validity testing was conducted at the level of the performance measure score. Face validity was systematically assessed using two expert panels that provided a mean importance rating of 4.24 out of 5.0. The developers also assessed content validity during the development of this measure. The

0079 Heart Failure: Left Ventricular Ejection Fraction Assessment (Outpatient Setting)
Committee did not express any concerns regarding the validity of this measure.
3. Feasibility: H-10; M-2; L-0; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • The Committee identified no concerns regarding the feasibility of this measure.
4. Use and Usability: H-6; M-4; L-1; I-1 *(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)* Rationale: • The Committee noted that this measure has been endorsed for six years and is currently being used in the PINNALE Registry for quality improvement and requested clarification on NQF's policy on use and usability. NQF policy states that performance results are used in at least one accountability application within three years after initial endorsement and are publicly reported within six years after initial endorsement; however, this criterion is not a must-pass criterion.
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-12**; **N-0**
6. Public and Member Comment • Three commenters were generally in support of the measure. One commenter recommended harmonizing this measure with #0081 and #0083.   ○ Committee Response: During the second post In-Person Meeting webinar on October 9, 2015 the Committee considered harmonization of measures within the Cardiovascular portfolio. The Committee urged developers to work together in the future to further harmonize measures where possible. However, measures #0081, #0083, and #0079 were not identified as related or competing based on NQF criteria.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0081 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure with a current or prior LVEF < 40% who were prescribed ACE Inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting or at hospital discharge

Numerator Statement: Patients who were prescribed* ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting or at hospital discharge

*Prescribed may include:

Outpatient setting: prescription given to the patient for ACE inhibitor or ARB therapy at one or more visits in the measurement period OR patient already taking ACE inhibitor or ARB therapy as documented in current medication list

Inpatient setting: prescription given to the patient for ACE inhibitor or ARB therapy at discharge OR ACE inhibitor or ARB therapy to be continued after discharge as documented in the discharge medication list

Denominator Statement: All patients aged 18 years and older with a diagnosis of heart failure with a current or prior LVEF < 40%

Exclusions: Documentation of medical reason(s) for not prescribing ACE inhibitor or ARB therapy (eg, hypotensive patients who are at immediate risk of cardiogenic shock, hospitalized patients who have experienced marked azotemia, allergy, intolerance, other medical reasons)

Documentation of patient reason(s) for not prescribing ACE inhibitor or ARB therapy (eg, patient declined, other patient reasons)

Documentation of system reason(s) for not prescribing ACE inhibitor or ARB therapy (eg, other system reasons)

Adjustment/Stratification:

Level of Analysis: Clinician : Group/Practice, Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Home Health, Hospital/Acute Care Facility, Post Acute/Long Term Care Facility : Long Term Acute Care Hospital, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry

Measure Steward: AMA-PCPI

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-14**; **M-2**; **L-0**; **I-0; IE-0**; 1b. Performance Gap: **H-5**; **M-12**; **L-0**; **I-0**

Rationale:

- The discussion and voting on evidence for the eMeasure version of measure #0081 applies to the Claims/Registry version.
- The developer provided performance data from the PQRS Experience Report from 2010 to 2013. The performance rates ranged from 79.9% to 85.6%. The 2013 Small Group Practice Exception Rate was 1.3%. The Committee agreed there continues to be a performance gap with approximately 80% of eligible patients receiving ACEI/ARB therapy but questioned if this measure has topped out since performance has remained about the same since 2010.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

0081 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-7**; **M-9**; **L-0**; **I-1** 2b. Validity: **H-3**; **M-14**; **L-0**; **I-0**
Rationale:

- The measure was tested for reliability at the level of the measure score using the beta binomial method and assessed 1,244 physicians from the PQRS GPRO database. The reliability at the minimum level of quality reporting events (10) was 0.83. The reliability at the average number of quality reporting events was 0.94. The Committee concluded that overall the results indicated high reliability.
- The measure was tested for validity at the level of the measure score by systematic assessment of face validity by the PCPI Measure Advisory Committee of 12 members. The Committee questioned why the developers were unable to determine the type of exception reported in the PQRS registry. The developers responded that CMS reports exceptions as an overall valid exception rather than breaking down the exceptions into medical, patient, or system reason. The Committee agreed the validity testing to be sufficient.

3. Feasibility: H-10; M-7; L-0; I-0
(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)
Rationale:

- The Committee expressed no concerns regarding the feasibility of this measure.

4. Use and Usability: H-9; M-8; L-0; I-0
(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)
Rationale:

- The Committee noted this measure is used in PQRS, PINNACLE Registry, and Meaningful Use Stage II.

5. Related and Competing Measures

- This measure is related to:
  - NQF #0066: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (American College of Cardiology).
  - These measures both focus on ACE/ARB therapy for patients with heart failure; however, #0066 includes patients with diabetes in the denominator. The Committee will discuss harmonization of these two measures in Phase 4 when #0066 is scheduled for maintenance review.
- No competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-17**; **N-0**

6. Public and Member Comment

- Three commenters were generally in support of this measure. One commenter suggested measure #0081 should be harmonized with measure #0066. The other commenters noted that measure #0083 and measure #0079 should be considered for harmonization with measure #0081. This prompted two separate Committee responses to the commenters:
  - Committee Response: During the second post In-Person Meeting webinar on October 9, 2015

0081 Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
the Committee considered harmonization of measures within the Cardiovascular portfolio. The Committee urged developers to work together in the future to further harmonize measures where possible. Additionally, the Committee will revisit the harmonization discussion of several measures during the next Cardiovascular measure endorsement project in 2016. ○ Committee Response: During the second post In-Person Meeting webinar on October 9, 2015 the Committee considered harmonization of measures within the Cardiovascular portfolio. The Committee urged developers to work together in the future to further harmonize measures where possible. However, measures #0081, #0083, and #0079 were not identified as related or competing based on NQF criteria.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0081 eMeasure Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure with a current or prior LVEF < 40% who were prescribed ACE inhibitor or ARB therapy therapy either within a 12 month period when seen in the outpatient setting or at hospital discharge

Numerator Statement: Patients who were prescribed* ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting or at hospital discharge

*Prescribed may include:

Outpatient setting: prescription given to the patient for ACE inhibitor or ARB therapy at one or more visits in the measurement period OR patient already taking ACE inhibitor or ARB therapy as documented in current medication list

Inpatient setting: prescription given to the patient for ACE inhibitor or ARB therapy at discharge OR ACE inhibitor or ARB therapy to be continued after discharge as documented in the discharge medication list

Denominator Statement: All patients aged 18 years and older with a diagnosis of heart failure with a current or prior LVEF < 40%

Exclusions: Documentation of medical reason(s) for not prescribing ACE inhibitor or ARB therapy (eg, hypotensive patients who are at immediate risk of cardiogenic shock, hospitalized patients who have experienced marked azotemia, allergy, intolerance, other medical reasons)

Documentation of patient reason(s) for not prescribing ACE inhibitor or ARB therapy (eg, patient declined, other patient reasons)

Documentation of system reason(s) for not prescribing ACE inhibitor or ARB therapy (eg, other system reasons)

Adjustment/Stratification:

Level of Analysis: Clinician : Group/Practice, Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Home Health, Hospital/Acute Care Facility, Post Acute/Long Term Care Facility : Long Term Acute Care Hospital, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry

Measure Steward: AMA-PCPI

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-14**; **M-2**; **L-0**; **I-0; IE-0**; 1b. Performance Gap: **H-4**; **M-11**; **L-1**; **I-0**

Rationale:

- The evidence base for angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy prescribed for patients with left ventricular systolic dysfunction (LVSD) is derived the 2013 ACCF/AHA guideline for the management of heart failure. The Committee agreed that the evidence provided demonstrates that initiation of ACE/ARB therapy for patients with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) <40% reduces the risk of death and hospitalization.
- The developers explained that performance data for the eMeasure was not provided because the Meaningful Use federal program does not currently provide performance data. The developer provided

0081 eMeasure Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)

performance data from the PQRS Experience Report from 2010 to 2013. The performance rates ranged from 79.9% to 85.6%. The 2013 Small Group Practice Exception Rate was 1.3%. The Committee agreed that there was an opportunity for improvement based on the data provided from the registry measure but expressed the importance of obtaining performance data from the eMeasure to adequately evaluate this criterion in the future.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-3**; **M-14**; **L-0**; **I-0** 2b. Validity: **H-1**; **M-15**; **L-1**; **I-0**
<u>Rationale</u>:

- The Committee questioned the time frames for the numerator (ACEI/ARB in a 12 month period) and the denominator (documentation of current or history of LVEF <40%). The developer clarified that the denominator is documentation of any historical ejection fraction because ACEI/ARB therapy can normalize a patient's ejection fraction, therefore, this measure should focus on current or prior LVEF <40%.
- Data element validity testing was conducted for this eMeasure (also counts for data element reliability).
- Validity testing for the eMeasure was conducted with data element validity testing at one test site, with the percent agreement at 93.9%. Performance on the measure increased to 98.7% through comparison of automated and manual EHR review.
- The developer provided an exception analysis of 127 exceptions that came from five physician offices using five different EHR systems. The data showed that 99.5% of exceptions were medical reasons for not prescribing ACE inhibitor or ARB therapy. Medical reason exceptions included clinical contraindications, drug allergy and drug intolerance.
- The Committee agreed that many of the challenges discussed with eMeasure #0070 such as evaluating eMeasures with minimal data despite being in use, the use of broad exceptions and the ability to demonstrate validity and reliability based on NQF's current criteria exist with this measure. However, the Committee concluded that testing provided for this measure adequately reflects reliability and variability. The Committee noted that the percent agreement for this eMeasure was 93.9% in comparison to 82.8% for eMeasure #0070 which did not pass on validity.

3. Feasibility: H-4; M-14; L-0; I-0
(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)
<u>Rationale</u>:

- The Committee agreed this measure is feasible. It is specified for several data sources, including eMeasure. A feasibility score card was submitted for the eMeasure with all data elements in defined fields in a combination of electronic sources

4. Use and Usability: H-9; M-8; L-1; I-0
(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)
<u>Rationale</u>:

0081 eMeasure Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD)
• The Committee noted this eMeasure is used in the EHR Incentive Program (Meaningful Use).

5. Related and Competing Measures
• This measure is related to:
  ○ NQF #0066: Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy - Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%) (American College of Cardiology).
  ○ These measures both focus on ACE/ARB therapy for patients with heart failure; however, #0066 includes patients with diabetes in the denominator. The Committee will discuss harmonization of these two measures in Phase 4 when #0066 is scheduled for maintenance review.
• No competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-17**; **N-1**
6. Public and Member Comment • No public comments were received specific to this eMeasure.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0083 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure with a current or prior LVEF < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting or at hospital discharge

Numerator Statement: Patients who were prescribed* beta-blocker therapy** either within a 12 month period when seen in the outpatient setting or at hospital discharge

*Prescribed may include:

Outpatient setting: prescription given to the patient for beta-blocker therapy at one or more visits in the measurement period OR patient already taking beta-blocker therapy as documented in current medication list

Inpatient setting: prescription given to the patient for beta-blocker therapy at discharge OR beta-blocker therapy to be continued after discharge as documented in the discharge medication list

**Beta-blocker therapy should include bisoprolol, carvedilol, or sustained release metoprolol succinate. (see technical specifications for additional information on medications)

Denominator Statement: All patients aged 18 years and older with a diagnosis of heart failure with a current or prior LVEF < 40%

LVEF < 40% corresponds to qualitative documentation of moderate dysfunction or severe dysfunction

Exclusions: Documentation of medical reason(s) for not prescribing beta-blocker therapy (eg, low blood pressure, fluid overload, asthma, patients recently treated with an intravenous positive inotropic agent)

Documentation of patient reason(s) for not prescribing beta-blocker therapy

Documentation of system reason(s) for not prescribing beta-blocker therapy

Adjustment/Stratification:

Level of Analysis: Clinician : Group/Practice, Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Home Health, Hospital/Acute Care Facility, Post Acute/Long Term Care Facility : Long Term Acute Care Hospital, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry

Measure Steward: AMA-PCPI

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-14**; **M-2; L-0**; **I-0; IE-0**; 1b. Performance Gap: **H-6**; **M-11**; **L-0**; **I-0**

Rationale:

- The discussion and voting on evidence for the eMeasure version of measure #0083 applies to the Claims/Registry version.
- The developer provided performance data from the PQRS Experience Report from 2010 to 2013. The performance rates ranged from 75.8% to 86.8%. The 2013 Small Group Practice Exception Rate was 1.04%. The Committee agreed there continues to be a performance gap of eligible patients receiving beta-blocker therapy.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-9**; **M-8**; **L-0**; **I-0** 2b. Validity: **H-4**; **M-12**; **L-1**; **I-0**

0083 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Rationale:

- The Committee agreed that the measure is precisely specified. The measure was tested for reliability at the level of the measure score using the beta binomial method and assessed 684 physicians from the PQRS GPRO database. The reliability at the minimum level of quality reporting events (10) was 0.86. The reliability at the average number of quality reporting events was 0.96. The Committee concluded that overall the results indicated high reliability.
- The measure was tested for validity at the level of the measure score by systematic assessment of face validity by the PCPI Measure Advisory Committee of 12 members.
- Of the 684 physicians with the minimum (10) number of quality reporting events, there were a total of 1,203 exceptions reported. The average number of exceptions per physician in this sample is 1.8. The overall exception rate is 4.9%. As previously discussed with measure #0081, CMS reports exceptions as an overall valid exception rather than breaking down the exceptions into medical, patient, or system reason. The Committee agreed the validity testing to be sufficient.

3. Feasibility: H-11; M-6; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee expressed no concerns regarding the feasibility of this measure.

4. Use and Usability: H-10; M-6; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

- The Committee noted this measure is used in PQRS, PINNACLE Registry, and Meaningful Use Stage II.

5. Related and Competing Measures

- This measure is related to:
  - NQF #2438: Beta-Blocker Therapy (i.e., bisoprolol, carvedilol, or sustained-release metoprolol succinate) for LVSD Prescribed at Discharge (The Joint Commission).
  - The measure focus is the same but the level of analysis is different. The Committee did not make any additional recommendations regarding harmonization.
- No competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-17**; **N-0**

6. Public and Member Comment

- Three commenters were generally in support of this measure. Two commenters suggested this measure be harmonized with measures #0079 and #0081.
  - Committee Response: During the second post In-Person Meeting webinar on October 9, 2015 the Committee considered harmonization of measures within the Cardiovascular portfolio. The Committee urged developers to work together in the future to further harmonize measures where possible. However, measures #0081, #0083, and #0079 were not identified as related or competing based on NQF criteria.

0083 Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0083 eMeasure Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure with a current or prior LVEF < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting or at hospital discharge

Numerator Statement: Patients who were prescribed* beta-blocker therapy** either within a 12 month period when seen in the outpatient setting or at hospital discharge

*Prescribed may include:

Outpatient setting: prescription given to the patient for beta-blocker therapy at one or more visits in the measurement period OR patient already taking beta-blocker therapy as documented in current medication list

Inpatient setting: prescription given to the patient for beta-blocker therapy at discharge OR beta-blocker therapy to be continued after discharge as documented in the discharge medication list

**Beta-blocker therapy should include bisoprolol, carvedilol, or sustained release metoprolol succinate. (see technical specifications for additional information on medications)

Denominator Statement: All patients aged 18 years and older with a diagnosis of heart failure with a current or prior LVEF < 40%

LVEF < 40% corresponds to qualitative documentation of moderate dysfunction or severe dysfunction

Exclusions: Documentation of medical reason(s) for not prescribing beta-blocker therapy (eg, low blood pressure, fluid overload, asthma, patients recently treated with an intravenous positive inotropic agent)

Documentation of patient reason(s) for not prescribing beta-blocker therapy

Documentation of system reason(s) for not prescribing beta-blocker therapy

Adjustment/Stratification:

Level of Analysis: Clinician : Group/Practice, Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Home Health, Hospital/Acute Care Facility, Post Acute/Long Term Care Facility : Long Term Acute Care Hospital, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other

Type of Measure: Process

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry

Measure Steward: AMA-PCPI

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-14**; **M-2**; **L-0**; **I-0; IE-0**; 1b. Performance Gap: **H-4**; **M-12**; **L-0**; **I-1**

Rationale:

- The evidence base for beta-blocker therapy prescribed for patients with a diagnosis of heart failure (HF) with a current or prior LVEF <40% is derived from the 2013 ACCF/AHA guideline for the management of heart failure. One Committee member commented that the guideline supporting this measure recommends long-term treatment with beta-blockers while this measure captures documentation (prescription or discharge medication list) of beta-blockers once during the measurement period. The developer clarified that this measure is designed to capture a point in time (hospital discharge or physician office visit) that the patient is on beta-blocker therapy rather than over a period of time.
- The Committee agreed that initiation of beta-blocker therapy for patients with a diagnosis of heart failure

0083 eMeasure Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)

(HF) with a current or prior LVEF <40% lessens the symptoms of heart failure, improves the clinical status of patients, reduces future clinical deterioration, and decreases the risk of mortality and the combined risk of morality and hospitalization.

- Similar to eMeasures #0070 and #0081, the developers explained that performance data for the eMeasure was not provided because the Meaningful Use federal program does not currently provide performance data. The developer provided performance data from the PQRS Experience Report from 2010 to 2013. The performance rates ranged from 75.8% to 86.8%. The 2013 Small Group Practice Exception Rate was 1.04%. The Committee agreed that there was an opportunity for improvement based on the data provided from the registry measure but expressed the importance of obtaining performance data from the eMeasure to adequately evaluate this criterion in the future.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-0**; **M-17**; **L-0**; **I-0** 2b. Validity: **H-1**; **M-16**; **L-0**; **I-0**
<u>Rationale</u>:

- Data element validity testing was conducted for this eMeasure (also counts for data element reliability).
- Validity testing for the eMeasure was conducted with data element validity testing at one test site, with the percent agreement at 90.9%. Performance on the measure increased to 92.8% through comparison of automated and manual EHR review.
- The developer provided an exception analysis of 118 exceptions that came from five physician offices using five different EHR systems. The data showed that 98.0% of exceptions were medical reasons for not prescribing beta-blocker therapy. Medical reason exceptions included clinical contraindications, drug allergy and drug intolerance.
- The same challenges discussed with eMeasure 0070 and 0081 apply to this measure, however, the Committee agreed that testing provided adequately reflects reliability and variability.

3. Feasibility: H-8; M-9; L-0; I-0
(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)
<u>Rationale</u>:

- The Committee agreed this measure is feasible. It is specified for several data sources, including eMeasure. A feasibility score card was submitted for the eMeasure with all data elements in defined fields in a combination of electronic sources.

4. Use and Usability: H-9; M-8; L-0; I-0
(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)
<u>Rationale</u>:

- The Committee noted this eMeasure is used in the EHR Incentive Program (Meaningful Use).

5. Related and Competing Measures

- This measure is related to:
  - NQF #2438: Beta-Blocker Therapy (i.e., bisoprolol, carvedilol, or sustained-release metoprolol

0083 eMeasure Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD)
succinate) for LVSD Prescribed at Discharge (The Joint Commission). ○ The measure focus is the same but the level of analysis is different. The Committee did not make any additional recommendations regarding harmonization. • No competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-17**; **N-0**
6. Public and Member Comment • No public comments were received specific to this eMeasure.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0229 Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following heart failure (HF) hospitalization for patients 18 and older

Submission | Specifications

Description: The measure estimates a hospital-level 30-day risk-standardized mortality rate (RSMR). Mortality is defined as death for any cause within 30 days after the date of admission for the index admission, for patients 18 and older discharged from the hospital with a principal diagnosis of heart failure (HF). CMS annually reports the measure for patients who are 65 years or older and are either Medicare fee-for-service (FFS) beneficiaries and hospitalized in non-federal hospitals or patients hospitalized in Veterans Health Administration (VA) facilities.

Numerator Statement: The outcome for this measure is 30-day all-cause mortality. We define mortality as death from any cause within 30 days of the index admission date for patients 18 and older discharged from the hospital with a principal diagnosis of HF.

Denominator Statement: This claims-based measure can be used in either of two patient cohorts: (1) patients aged 65 years or older or (2) patients aged 18 years or older. We have explicitly tested the measure in both age groups. The cohort includes admissions for patients aged 18 years and older discharged from the hospital with a principal discharge diagnosis of HF and with a complete claims history for the 12 months prior to admission. The measure is currently publicly reported by CMS for those patients 65 years and older who are either Medicare FFS beneficiaries admitted to non-federal hospitals or patients admitted to VA hospitals. Additional details are provided in S.9 Denominator Details.

Exclusions: The mortality measures exclude index admissions for patients:

1. Discharged alive on the day of admission or the following day who were not transferred to another acute care facility.

2. With inconsistent or unknown vital status or other unreliable demographic (age and gender) data;

3. Enrolled in the Medicare hospice program or used VA hospice services any time in the 12 months prior to the index admission, including the first day of the index admission;

4. Discharged against medical advice (AMA); or

5. Patients undergoing LVAD implantation or heart transplantation during an index admission or who have a history of LVAD or heart transplant in the preceding year.

For patients with more than one admission for a given condition in a given year, only one index admission for that condition is randomly selected for inclusion in the cohort.

For Medicare FFS patients, the measure additionally excludes admissions for patients without at least 30 days post-discharge enrollment in FFS Medicare (because the 30-day mortality outcome cannot be assessed in this group).

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims, Other, Paper Medical Records

Measure Steward: Centers for Medicare & Medicaid Services (CMS)

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1. Importance, 1b. Performance Gap)

1. Importance: **Y-17; N-0** 1b. Performance Gap: **H-13**; **M-4**; **L-0**

Rationale:

- The developer included numerous studies that show that appropriate and timely treatment for heart failure patients can reduce the risk of mortality within 30 days of hospital admission.

0229 Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following heart failure (HF) hospitalization for patients 18 and older

- The performance data provided by the developer showed that the average 30-day risk-standardized heart failure mortality rate was 11.7 percent during the measurement period of 07/2011-06-2014.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-3**; **M-13**; **L-1**; **I-0** 2b. Validity: **H-5**; **M-11**; **L-1**; **I-0**

<u>Rationale</u>:

- The reliability and validity discussion and vote for NQF #0230 was carried over for this measure since they are essentially the same measure with different conditions.

3. Feasibility: H-15; M-2; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

<u>Rationale</u>:

- The discussion and vote for NQF #0230 was carried over to this measure.

4. Use and Usability: H-15; M-2; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

<u>Rationale</u>:

- The discussion and vote for NQF #0230 was carried over to this measure.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-17**; **N-0**

6. Public and Member Comment

- Three commenters were generally in support of this measure.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

0230 Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) hospitalization for patients 18 and older

Submission | Specifications

Description: The measure estimates a hospital-level 30-day risk-standardized mortality rate (RSMR). Mortality is defined as death for any cause within 30 days after the date of admission for the index admission, for patients 18 and older discharged from the hospital with a principal diagnosis of acute myocardial infarction (AMI). CMS annually reports the measure for patients who are 65 years or older and are either Medicare fee-for-service (FFS) beneficiaries and hospitalized in non-federal hospitals or are hospitalized in Veterans Health Administration (VA) facilities.

Numerator Statement: The outcome for this measure is 30-day all-cause mortality. We define mortality as death from any cause within 30 days of the index admission date for patients 18 and older discharged from the hospital with a principal diagnosis of AMI.

Denominator Statement: This claims-based measure can be used in either of two patient cohorts: (1) patients aged 65 years or older or (2) patients aged 18 years or older. The cohort includes admissions for patients discharged from the hospital with a principal discharge diagnosis of AMI and with a complete claims history for the 12 months prior to admission. Currently, the measure is publicly reported by CMS for those patients 65 years and older who are either Medicare FFS beneficiaries admitted to non-federal hospitals or patients admitted to VA hospitals. Additional details are provided in S.9 Denominator Details.

Exclusions: The mortality measures exclude index admissions for patients:

1. Discharged alive on the day of admission or the following day who were not transferred to another acute care facility.

2. With inconsistent or unknown vital status or other unreliable demographic (age and gender) data;

3. Enrolled in the Medicare hospice program or used VA hospice services any time in the 12 months prior to the index admission, including the first day of the index admission; or

4. Discharged against medical advice (AMA).

For patients with more than one admission for a given condition in a given year, only one index admission for that condition is randomly selected for inclusion in the cohort.

For Medicare FFS patients, the measure additionally excludes admissions for patients without at least 30 days post-discharge enrollment in FFS Medicare (because the 30-day mortality outcome cannot be assessed in this group).

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims, Other, Paper Medical Records

Measure Steward: Centers for Medicare & Medicaid Services (CMS)

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1. Importance, 1b. Performance Gap)

1. Importance: **Y-15; N-1** 1b. Performance Gap: **H-11**; **M-5**; **L-0**

<u>Rationale</u>:

- The Committee agreed that the developer provided sufficient evidence suggesting that hospitals are able to influence mortality rates through a broad range of clinical activities, including prevention of complications, use of appropriate medications, timely percutaneous coronary interventions, discharge planning, management of care transitions, medication reconciliation, and patient education.

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- The performance data provided by the developer showed that the average 30-day risk-standardized AMI mortality rates ranged from a minimum of 9.9 percent to a maximum of 20.6 percent during the measurement period of 07/2011-06/2014.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)
2a. Reliability: **H-3**; **M-13**; **L-1**; **I-0** 2b. Validity: **H-5**; **M-11**; **L-1**; **I-0**
<u>Rationale</u>:

- Performance score reliability was assessed using a "test-retest" approach, also called a "split-half" method. A total of 991,007 admissions over a 3-year period were examined, with 494,297 in one sample and 496,710 in the other randomly-selected sample; two risk-standardized mortality rates (RSMR) were calculated for each hospital, one from each of the two separate samples.
- The agreement between the two RSMRs for each hospital (as measured by intra-class correlation coefficient (ICC)) was 0.55; the developer stated that according to the conventional interpretation, this is considered a "moderate" level of agreement.
- One Committee member asked if patients discharged to hospice were excluded because these patients would likely expire within the reporting period. There has been concern that a complication that should have been prevented leads to the patient's condition deteriorating and ultimately admitted into hospice. The developer responded that they do not want to risk adjust or exclude patients based on things that have happened while receiving clinical care.
- The developer conducted a conceptual analysis of SDS factors and found that income, education, and occupational level are the most commonly examined variables linked to worse health status and higher mortality over a lifetime. The literature directly related to 30-day mortality after admission for cardiovascular disease is much more limited. The empirical analysis conducted by the developers found that race (black vs. non-black) and dual-eligible status to be the only two patient level SDS variables available for direct examination. Also considered were a number of neighborhood level variables that could serve as a proxy for patient level SDS such as zip code. Patients were identified as low SDS if they lived in a neighborhood in the lowest quartile of the AHRQ SDS index. The empirical analysis found that the relationship with mortality for dual-eligible patients was small (16.1%) compared to all other patients (14.0%); the mortality rate for black patients was lower (12.6%) compared to patients of all other races (14.4%), and the mortality rate for patients in the lowest SES quartile by AHRQ Index was slightly higher (14.4%) compared to patients in the highest SES quartile (13.9%).
- The developers did not incorporate the SDS factors into the risk adjustment model because the relationship with mortality was small; the relative effect of black race was stronger than the other factors but in the opposite direction than what has been the expressed concern of stakeholders interested in adding such adjustment to models. The developers also compared hospital performance with and without the addition of each SDS variable and found that they had little to no effect on hospital performance. The Committee agreed with the developer's rational for not risk adjusting this measure for SDS factors.
- The developer conducted empirical validity testing of the measure score. To assess validity, the developer compared scores from the administrative claims-based measure to scores derived from

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medical record review in the same patient cohort. The Committee agreed that correlation between the claims-based RSMRs and the record-based RSMRs, which was 0.95, indicated high reliability.

3. Feasibility: H-15; M-2; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- Because the measure is specified for administrative claims data, the Committee identified no concerns regarding the feasibility of this measure.

4. Use and Usability: H-15; M-2; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

- The Committee noted that the measure is currently reported through CMS's Hospital Inpatient Quality Reporting (IQR) Program.
- In addition, measure results are incorporated into the calculation of hospital payment rates through CMS's Hospital Value Based Purchasing (HVBP) Program.

5. Related and Competing Measures

- This measure is related to:
  - NQF #0730: Acute Myocardial Infarction (AMI) Mortality Rate. In-hospital deaths per 1,000 hospital discharges with acute myocardial infarction (AMI) as a principal diagnosis for patients ages 18 years and older. (Agency for Healthcare Research and Quality).
    - The Committee encouraged the developer to harmonize to the extent possible and include the pregnancy exclusion that is currently in #0730.
    - The Committee agreed to maintain both mortality measures in the CV portfolio as this measure captures mortality following hospitalization while #0730 assesses inpatient mortality and both measures are widely used in federal programs.
  - NQF #2473: Hospital 30-Day Risk-Standardized Acute Myocardial Infarction (AMI) Mortality eMeasure. This measure estimates hospital 30-day risk-standardized mortality rates following admission for AMI using clinical information collected at presentation in an electronic health record (EHR). Mortality is defined as death from any cause within 30 days of the index admission date (CMS)
    - This is the eMeasure version of #0230 that was endorsed in Phase 2 of this project. The Committee agreed that the claims-based measure remain in the CV portfolio until the eMeasure is fully implemented. The developers plan to test this eMeasure in the all payer population and include the hospice exclusion currently in #0230 once it is possible to obtain the data element. The developers also plan to further harmonize with #0730 and include the pregnancy exclusion after concluding all payer testing.

Standing Committee Recommendation for Endorsement: **Y-17**; **N-0**

6. Public and Member Comment

- Three commenters were generally in support of this measure. One commenter believed the SDS factors considered in the developer's conceptual analysis does not have a large effect on hospital performance.

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○ Committee Response: The Committee reviewed the developer's measure submission information and agreed that the SDS conceptual framework and empirical analysis provided by the developer was sufficient and agreed that SDS factors should not be included in the risk adjustment model.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0669 Cardiac Imaging for Preoperative Risk Assessment for Non-Cardiac, Low Risk Surgery

Submission | Specifications

Description: This measure calculates the percentage of stress echocardiography, single photon emission computed tomography myocardial perfusion imaging (SPECT MPI), or stress magnetic resonance (MR) imaging studies performed at each facility in the 30 days prior to an ambulatory non-cardiac, low-risk surgery performed at any location. The measure is calculated based on a one-year window of Medicare claims data. The measure has been publicly reported, annually, by the Centers for Medicare & Medicaid Services (CMS), since 2011, as a component of its Hospital Outpatient Quality Reporting (HOQR) Program.

Numerator Statement: The number of stress echocardiography, SPECT MPI, and stress MR studies performed in a hospital outpatient department within 30 days of an ambulatory non-cardiac, low-risk surgery performed at any location (e.g., same hospital, other hospital, or physician office).

Denominator Statement: The number of stress echocardiography, SPECT MPI, and stress MR studies performed in a hospital outpatient department on Medicare beneficiaries within a 12-month time window.

Exclusions: Studies are excluded for any patients with diagnosis codes in at least three of the following categories: diabetes mellitus, renal insufficiency, stroke or transient ischemic attack, prior heart failure, or ischemic heart disease.

Adjustment/Stratification:

Level of Analysis: Facility, Population : National, Population : State

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Hospital/Acute Care Facility, Imaging Facility

Type of Measure: Efficiency

Data Source: Administrative claims

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-12**; **M-4**; **L-1**; **I-0; IE-0**; 1b. Performance Gap: **H-14**; **M-3**; **L-0**; **I-0**

Rationale:

- The evidence provided for this measure included two separate guidelines with nine guideline statements for the recommendation that patients undergoing low-risk, non-cardiac surgery should not have stress image testing.
- The developer provided data based on the Medicare FFS demonstrating performance rates ranging from 14.5% to 18%. In addition, the data suggests that race/ethnicity and facility characteristics had an effect on the appropriate use of preoperative imaging.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-6**; **M-11**; **L-0**; **I-0** 2b. Validity: **H-1**; **M-16**; **L-0**; **I-0**

Rationale:

- The Committee agreed that the measure specifications are clearly defined.
- The developers conducted a signal-to-noise analysis at the level of the performance measure score. The primary analysis was conducted at the facility level using 2013 Medicare FFS data from 2,759 facilities. Reliability was conducted using two tests to identify statistical outliers and a signal-to-noise analysis. Of the 2,759 facilities, 137 were reported as having statistically significant rates of overuse. The beta-binomial model determined moderate reliability with a mean score of 43.0%.

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- The developers clarified that a patient must have three or more of the clinical conditions to be excluded from this measure.
- Face validity of the measure score and data elements was systematically assessed through a seven member technical expert panel (TEP), where 75% agreed the 30-day window to look forward for a low-risk non-cardiac surgery from the date of the imaging procedure accurately captures preoperative testing. The developer noted that the TEP was not able to reach consensus regarding which clinical conditions should be excluded. However, the exclusions are based on the AHA/ACC guidelines, therefore the Committee agreed that this was less important and that the measure is valid.

3. Feasibility: H-12; M-5; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The Committee agreed that the collection of administrative claims data for this measure is feasible.

4. Use and Usability: H-15; M-2; L-0; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

- The measure is currently reported in CMS' Hospital Outpatient Quality Reporting program.

5. Related and Competing Measures

- This measure directly competes with:
  - NQF #0670: Cardiac stress imaging not meeting appropriate use criteria: Preoperative evaluation in low risk surgery patients. Percentage of stress SPECT MPI, stress echo, CCTA, or CMR performed in low risk surgery patients for preoperative evaluation. (American College of Cardiologists)
  - The developers stated that it is difficult to harmonize these measures because they have different data sources and different target populations. The developers agreed that as EHRs continue to evolve and data collection burden decreases they will continue to discuss ways to harmonize these measures over the next couple of years. In the meantime, the Committee encouraged the developers to harmonize and include the cardiac imaging procedures, cardiac computed tomography angiography (CCTA) and cardiac magnetic resonance (CMR) that are included in #0670.

Standing Committee Recommendation for Endorsement: **Y-17**; **N-0**

6. Public and Member Comment

- Four commenters were generally in support of this measure. Two commenters believed this measure should be harmonized with measure #0670.
  - Committee Response: During the second post In-Person Meeting webinar on October 9, 2015 the Committee considered harmonization of measures within the Cardiovascular portfolio. The Committee encouraged the developers of two competing measures to harmonize the measure specifications. Harmonization of #0669 and #0670 should be completed prior to the measures' next annual update. The Committee also urged developers to work together in the future to further harmonize measures where possible. Additionally, the Committee will revisit the

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harmonization discussion of several measures during the next Cardiovascular measure endorsement project in 2016.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0694 Hospital Risk-Standardized Complication Rate following Implantation of Implantable Cardioverter-Defibrillator (ICD)

Submission | Specifications

Description: This measure provides hospital specific risk-standardized rates of procedural complications following the implantation of an ICD in patients at least 65 years of age. The measure uses clinical data available in the National Cardiovascular Data Registry (NCDR) ICD Registry for risk adjustment linked with administrative claims data using indirect patient identifiers to identify procedural complications.

Numerator Statement: The outcome for this measure is one or more complications within 30 or 90 days (depending on the complication) following initial ICD implantation. The measure treats complications as a dichotomous (yes/no) variable; we are interested in whether or not a complication has occurred and not how many complications occurred in each hospital.

Denominator Statement: The target population for this measure includes inpatient and outpatient hospital stays with ICD implants for patients at least 65 years of age who have matching information in the National Cardiovascular Disease Registry (NCDR) ICD Registry. The time window can be specified from one to three years. This measure was developed with Medicare claims and CathPCI Registry data from one calendar year (2007).

Exclusions: (1) Previous ICD placement. Hospital stays in which the patient had an ICD implanted prior to the index hospital stay are excluded.

Rationale: Ideally, the measure would include patients with a prior ICD, as this is a population known to be at high risk of adverse outcomes. However, for these patients it is difficult to distinguish in the administrative data whether adverse events such as infection were present on admission or complications of the second ICD placement. In order to avoid misclassification, we exclude these patients from the measure.

(2) Previous pacemaker placement, Hospital stays in which the patient had a previous pacemaker placement prior to the index hospital stay are excluded.

Rationale: Some complications (infection or mechanical complication) may be related to a pacemaker that was removed prior to placement of an ICD. Ideally, the measure would include patients with a prior pacemaker, as this is a population known to be at higher risk of adverse outcomes. However, for these patients it is difficult to distinguish in the administrative data whether adverse events such as infection were present on admission or complications of the ICD placement. In order to avoid misclassification, we exclude these patients from the measure.

(3) Not Medicare FFS patient on admission. Patient admissions in which the patient is not enrolled in Medicare FFS at the time of the ICD procedure.

Rationale: Outcome data are being derived only for Medicare fee-for-service patients.

(4) Lack 90-day follow-up in Medicare FFS post-discharge. Patients who cannot be tracked for 90 days following discharge are excluded.

Rationale: There will not be adequate follow-up data to assess complications

(5) Not the first claim in the same claim bundle. There are cases when several claims in the same hospital representing a single episode of care exist in the data together. These claims are bundled together and any claim other than the first is excluded.

Rationale: Inclusion of additional claims could lead to double counting of an index ICD procedure.

Adjustment/Stratification:

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility, Ambulatory Care : Urgent Care

Type of Measure: Composite

Data Source: Administrative claims, Electronic Clinical Data : Registry

Measure Steward: American College of Cardiology

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

0694 Hospital Risk-Standardized Complication Rate following Implantation of Implantable Cardioverter-Defibrillator (ICD)

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap, 1c. High Impact, 1d. Composite- Quality Construct and Rationale)

1a. Evidence: **Y-17, N-0**; 1b. Performance Gap: **H-13**; **M-4**; **L-0**; **I-0;** 1d. Composite: **H-10**; **M-7**; **L-0**; **I-0**

<u>Rationale</u>:

- The Committee agreed that a complication following placement of an implantable cardioverter defibrillator (ICD) is an undesirable outcome and that a comprehensive, personalized risk assessment and competency of the physician and hospital treating the patient can lead to decreased complications.
- As part of this measure's development, the developer analyzed unadjusted rates of ICD-related complications in 2007 Medicare Inpatient claims data which included 67,652 ICD admissions for 67,080 patients at 1,792 hospitals. In these preliminary analyses, complications were seen in 5.7% of ICD admissions and the median complication rate following ICD implantation ranged from 0% to 17.8% across deciles of hospitals grouped by their all-cause complication rate. The Committee agreed that there was a performance gap but questioned if it was possible for a hospital to have zero complications. The developer clarified that the complications are not self-reported but calculated using Medicare claims data and include only serious complications such as pneumothorax or hemothorax requiring a chest tube.
- The Committee agreed overall with the quality construct and rationale for this any-or-none composite measure but questioned why death was weighted equally to the other complications. The developer responded that death was a relatively low frequency event therefore they decided to include it in the measure but weight it equally.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity, 2d. Composite construction)

2a. Reliability: **H-4**; **M-12**; **L-0**; **I-0** 2b. Validity: **H-2**; **M-15**; **L-0**; **I-0** **2d. Composite: H-4; M-12; L-0, I-1**

<u>Rationale</u>:

- Reliability testing was conducted at the level of the critical data elements and the performance measure score. Data element reliability was assessed by comparing model variable frequencies and odds ratios in two years of data to determine their degree of consistency over time, and the combined 2 year sample included a total of 43,711 admissions to 1,279 hospitals. Data were drawn from the National Cardiovascular Data Registry (NCDR) ICD Registry and from Medicare Part A claims over the time period 2010Q2-2011Q4. Specific frequencies and odds ratios for each data element were not provided but the developer stated that risk factor frequencies changed little across year and there were no notable differences in the odds ratios across years of data.
- To assess performance score-level reliability the developers performed a "test-retest" approach on the same data set used to assess the critical data elements. The developer randomly split this sample into two groups and calculated the measure for each hospital in the first sample, and then repeated the calculation using the second sample; thus, each hospital was measured twice, but each measurement was made using an entirely different distinct set of patients. Agreement was calculated using an intra-class correlation coefficient (ICC). The agreement between the two risk-standardized complication rates for each hospital was 0.1494. The Committee questioned the low level of agreement between the two hospitals but the developer responded that it was due to the sample size and the frequency of events.

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- To assess validity the developer conducted a chart validation study to determine whether ICD-9 diagnosis and procedure codes reported on Medicare claims and used in the measure specifications accurately identify patients experiencing ICD complications within 30 or 90 days of ICD implantation as reported in the medical charts. The developer provided an analysis of 411 medical records from eight hospitals to report the degree of agreement of 91.5%, with a kappa coefficient of 0.83.
- The developer clarified that no mathematical analysis was provided for the quality construct and they rely on the literature for support in this measure submission, with the intent of provided results from empirical analysis will be provided for the next maintenance review. The Committee agreed that although mathematical scores were not provided, the rationale was sufficient to support the quality construct. After the in-person meeting the developer provided the Committee with the distribution of the various complications at 30 and 90 days.

3. Feasibility: H-6; M-11; L-0; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The data sources for this measure are ICD-9 diagnosis and procedure codes, HCPCS/CPT procedure codes, and vital status data from the Medicare Enrollment Database. The Committee agreed that this measure is feasible.

4. Use and Usability: H-6; M-10; L-1; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

- The Committee raised concern over the access to CMS data necessary for this measure as a main limitation, and therefore is currently not in use.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-17**; **N-0**

6. Public and Member Comment

- Three commenters were generally in support of this measure. One commenter suggested that death be included but the cause of death should be elucidated.
    - Developer Response: Causes of death are not available in the data sources used to ascertain this endpoint in large populations. This approach is consistent with other post-procedural measures (e.g. STS). Finally, deaths comprise a very small proportion of the overall events (2011 - 1.38%).
    - Committee Response: The Committee agrees with the developer response and maintains their decision to recommend this measure for endorsement.
- One commenter stated that NQF should note the expense of registry data and the lack of availability of electronic clinical data from smaller facilities.
    - NQF Response: NQF has reviewed your comment and appreciates your input. Your comment has

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been shared with the Standing Committee and the Developer for consideration. ○ Committee Response: The Committee agrees that feasibility of data collection is an important component of measurement performance and considers this when evaluating measure recommendations.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0730 Acute Myocardial Infarction (AMI) Mortality Rate

Submission | Specifications

Description: In-hospital deaths per 1,000 hospital discharges with acute myocardial infarction (AMI) as a principal diagnosis for patients ages 18 years and older.

Numerator Statement: Number of in-hospital deaths among cases meeting the inclusion and exclusion rules for the denominator.

Denominator Statement: Discharges, for patients ages 18 years and older, with a principal ICD-9-CM diagnosis code for AMI.

Exclusions: Exclude cases:

- transferred to another short-term hospital, for whom the outcome at hospital discharge was unknown
- admitted for treatment of pregnancy, childbirth, and puerperium
- with missing discharge disposition, gender, age, quarter, year, or principal diagnosis

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: Agency for Healthcare Research and Quality

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1. Importance, 1b. Performance Gap)

1. Importance: **Y-17; N-X** 1b. Performance Gap: **H-14**; **M-3**; **L-0**

Rationale:

- In support of the evidence for the measure, the developer provided numerous clinical practice guidelines for the evaluation, management and treatment of AMI, and noted that this measure is a component for the Inpatient Quality Indicators #91 (IQI #91) Mortality for Selected Conditions measure. The Committee agreed that the developer provided a well-established process of care that indicates this measures impacts performance and outcome.
- The developer cited several large databases of overall AMI inpatient mortalities per 1,000 discharges for over 2,800 hospitals with declining mortality rates of 68.94 in 2008 to 56.37 in 2012 using the Healthcare Cost and Utilization Project (HCUP) State Inpatient Databases (SID).
- The Committee also noted that the developer provided disparities data for several factors, showing disparities increasing with age, expected to go up; gender, showing association with an increased rate in mortality; zip codes in low income areas, large central metropolitan hospitals, and Medicare payers.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-14**; **M-3**; **L-0**; **I-0** 2b. Validity: **H-10**; **M-6**; **L-0**; **I-0**

Rationale:

- The Committee agreed that the measure is accurately specified at the facility level with clearly defined measure specifications.
- Reliability testing was conducted at the level of the performance measure score. The developer assessed 2,664 hospitals in a hospital network, with an average of 165.6 discharges per year, with an overall signal-

0730 Acute Myocardial Infarction (AMI) Mortality Rate
to-noise ratio of 0.75. • The developer conducted critical data element testing that included a systematic review of Canadian inpatients records, resulting in a positive predictive value of 84.0% and sensitivity of 81.1%. • Empiric validity testing was performed between hospital-level Spearman rank correlation between IQI 15 risk-adjusted rates and adherence for 6 process measures. The analyses found that hospitals with higher risk-adjusted inpatient mortality, according to IQI 15, also reported poorer adherence on most process measures. • The developer conducted a conceptual analysis of SDS factors and noted that observed disparities such as race, ethnicity, and income, appeared to be attributed to differences in access to care and by utilization of specific hospital services, including early intervention with PCI for patients with a STEMI; therefore, the developer opted not to include those additional factors or provide any additional empirical analysis. • The Committee requested that the developer consider stratifying this measure by education level and other SDS factors.
3. Feasibility: H-16; M-1; L-0; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • The Committee agreed that this measure is feasible.
4. Use and Usability: H-17; M-0; L-0; I-0 *(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)* Rationale: • The Committee agreed that the measure is usable noting that the measure was first released in 2003 and is broadly used in public and private accountability and quality improvement programs, and is publically reported.
5. Related and Competing Measures • This measure is related to: o 0230: Hospital 30-day, all-cause, risk-standardized mortality rate (RSMR) following acute myocardial infarction (AMI) hospitalization for patients 18 and older o The Committee agreed to maintain both mortality measures in the CV portfolio since this measure captures in-patient mortality and measure 0230 assesses mortality after hospital discharge and both measures are widely used in federal programs. • No competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-17**; **N-0**
6. Public and Member Comment • Three commenters were generally in support of this measure.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

0730 Acute Myocardial Infarction (AMI) Mortality Rate
8. Board of Directors Vote: Y-X; N-X
9. Appeals

0965 Discharge Medications (ACE/ARB and beta blockers) in Eligible ICD Implant Patients

Submission | Specifications

Description: Proportion of patients undergoing ICD implant who received prescriptions for all medications (ACE/ARB and beta blockers) for which they are eligible for at discharge.

Numerator Statement: Patients who receive ACE/ARB and Beta blockers for which they are eligible.

1. ACE/ARB prescribed at discharge (if eligible for ACE/ARB as described in denominator)

AND

2. Beta blockers prescribed at discharge (if eligible for beta blockers as described in denominator)

Denominator Statement: All patients with an ICD implant surviving hospitalization who are eligible to receive any one of the two medication classes:

1) Eligiblility for ACE/ARB: Patients who have an ejection fraction (EF) of <40% AND do not have a documented contraindication to ACE/ARB documented

OR

2) Eligibility for beta blockers: Patients who do not have a documented contraindication to beta blocker therapy and have either:

a. EF of <40% OR

b. a previous myocardial infarction (MI)

Exclusions: Discharge status of expired; not eligible for either ACE/ARB or beta blockers

Adjustment/Stratification:

Level of Analysis: Facility

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Composite

Data Source: Electronic Clinical Data : Registry

Measure Steward: American College of Cardiology

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: <u>The measure meets the Importance criteria</u>

(1a. Evidence, 1b. Performance Gap, 1c. Composite – Quality Construct and Rationale)

1a. Evidence: **H-6**; **M-9**; **L-2**; **I-0; IE-0**; 1b. Performance Gap: **H-12**; **M-5**; **L-0**; **I-0;** 1c. Composite: **H-11**; **M-6**; **L-0**; **I-0**

<u>Rationale</u>:

- The evidence base for this composite measure constructed of two process measures is derived from multiple clinical practice guidelines. The 2014 AHA/ACA, 2013 ACCF/AHA, 2011 AHA/ACCF update and the 2012 ACCF/AHA/ACP/AATS/PCNA/SCAI/STS guidelines recommend beta-blocker therapy for patients with a prior myocardial infarction (MI). The 2013 ACCF/AHA and 2011 AHA/ACCF update also recommends beta-blocker and angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy for patients with heart failure (HF).
- While the Committee acknowledged that the evidence provided by the developer sufficiently supports medical therapy for patients with heart failure or a previous MI, the evidence does not support medical therapy for patients who have undergone implantable cardioverter-defibrillator (ICD) implantation. The developer responded that this measure applies to patients with heart failure or a previous MI, as recommended by the guidelines, who have also undergone ICD implantation. The developer also stated that patients with these medical conditions that are undergoing ICD implantation are not receiving the appropriate medical therapy.
- The developer provided performance data from the NCDR ICD Registry from 2011-2012 and 2013-2014. In 2011-2012 a total of 243,186 patients from 1,552 hospitals were analyzed. The mean (average) compliance rate was 74% with a standard deviation (SD) of 16%. The 50th percentile (median) was 76%. In 2013-2014 a 195,563 patients from 1,606 hospitals were analyzed. The mean (average) compliance rate

was 78% with a standard deviation (SD) of 17%. The 50th percentile (median) was 79%. The Committee agreed that there is an opportunity for improvement due to the considerable variation in performance scores.

- The Committee expressed no concerns regarding the quality construct and rationale for this composite measure.

2. Scientific Acceptability of Measure Properties: <u>The measure meets the Scientific Acceptability criteria</u>
(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity; 2d. Composite construction)
2a. Reliability: **H-12**; **M-5**; **L-0**; **I-0** 2b. Validity: **H-9**; **M-8**; **L-0**; **I-0** **2d. Composite: H-~~30~~, M-~~10~~~~7~~, L-~~01~~~~3~~, I-~~0~~~~7~~**
<u>Rationale</u>:

- The Committee agreed that the measure is precisely specified.
- The measure was tested for reliability at the level of the measure score using the split sample method and assessed records from 1,606 hospitals. The cohort was split into two random samples and measure scores calculated at hospitals with at least 50 cases in both random samples were compared. The Committee concluded that a correlation coefficient of 0.87 indicates high reliability.
- The measure was tested for validity at the level of the measure score by systematic assessment of face validity by various ACC committee members involved in the development or approval of the measure. Empirical validity testing was conducted to assess the association of patient and hospital performance on the composite measure with adverse outcomes, specifically mortality and readmission at 6 months following hospital discharge. At both the patient and hospital level, performance on the measure was associated with better outcomes at 6 months following hospital discharge.
- One Committee member questioned why this measure does not take into account the sociodemographic status of patients. Although there are generic medications available, there may be patients that cannot afford the two medications that might be prescribed at discharge.
- The empirical analysis to support the composite construction in order to meet the must-pass criterion of Scientific Acceptability was reviewed on the post-meeting call on September 25th. The volume (N) of the composite exceeded the volume (N) of the individual measures. Based on the construction of the measure (all-or-none), the volume of the composite should be less than the lowest volume of the individual measures. The Committee questioned the accuracy of the data provided for the distribution of the composite measure and its medication components. The Committee re-voted on the composite criterion (2d) via SurveyMonkey after the post-meeting call and did not reach consensus on the construction of the composite. The voting results via SurveyMonkey for the composite criterion from the post-meeting call are listed above.
- Due to the previous consensus not reached status, the Committee discussed 0965 during the post-comment call convened on December 7, 2015. The Committee concluded that due to the intent of the measure (i.e. a patient only needs to be eligible for either an ACEI/ARB or a beta blocker) the data in the "Value" columns for the composite and the individual components are accurate. The measure developer confirmed the intent of the measure. The results of a post-call survey are noted in the vote count above. The Committee came to consensus and passed the 2d. criterion.

3. Feasibility: H-15; M-2; L-0; I-0
(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/

0965 Discharge Medications (ACE/ARB and beta blockers) in Eligible ICD Implant Patients
unintended consequences identified 3d. Data collection strategy can be implemented) Rationale: • The Committee had no questions or comments on the feasibility of this measure.
4. Use and Usability: H-16; M-1; L-0; I-0 *(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)* Rationale: • The measure is not currently publically reported but the individual component measures are used in ACC's NCDR Registry.
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-17**; **N-0**
6. Public and Member Comment • Two commenters generally did not support this measure. Both believed that the reception of a prescription should not be considered a quality measure.   ○ Committee Response: Generally, the Committee would prefer to recommend the endorsement of outcome measures rather than process or structural measures. However, measuring the process or structure may still be useful for quality improvement or other purposes; these measure types may still be useful where outcomes may be difficult to measure. During the in-person meeting the Committee questioned the evidence to support medication therapy for patients undergoing ICD implantation; however, the developer underscored that the guidelines support medication therapy following this procedure in heart failure patients or who have had an MI, and that a gap in patients receiving this therapy still exists.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2396 Carotid artery stenting: Evaluation of Vital Status and NIH Stroke Scale at Follow Up

Submission | Specifications

Description: Proportion of patients with carotid artery stenting procedures who had follow up performed for evaluation of Vital Status and neurological assessment with an NIH Stroke Scale (by an examiner who is certified by the American Stroke Association) Occurring between day 21 and the end of day 60 after the procedure. (Days 21-60 inclusive)

Numerator Statement: Patient Status (alive or Deceased) at follow-up AND Neurologic status with an assessment using the NIH Stroke Scale (by an examiner who is certified by the American Stroke Association)

Denominator Statement: Count of CARE Registry patients that had a carotid artery stenting procedure

Exclusions: Patients deceased at discharge, Patients with an acute, evolving stroke and dissection

Adjustment/Stratification:

Level of Analysis: Facility, Population : National

Setting of Care: Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Registry

Measure Steward: American College of Cardiology

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-0**; **M-9**; **L-6**; **I-1; IE-0**; 1b. Performance Gap: **H-8**; **M-6**; **L-1**; **I-1**

Rationale:

- The Committee questioned the evidence of a linkage between performing a neurological assessment with the NIH Stroke Scale and improved outcomes after carotid stenting. The Committee also questioned the evidence supporting the 30-day follow up timeframe. The evidence provided by the developer included a consensus recommendation categorized as a guideline with no grading assigned. The developer responded that although this is not an outcome measure, documentation of the patient's vital status and neurological assessment is a meaningful way to assess neurologic outcomes after carotid revascularization. The developer also clarified that the intent of this process measure is to determine whether patients undergoing a carotid artery stenting procedure are followed-up in the short-term (21 to 60 days).
- During pilot testing which included a total of 18,212 patients, the performance rates varied from 0 – 100%, displaying an opportunity for improvement.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-1**; **M-15**; **L-1**; **I-0** 2b. Validity: **H-1**; **M-11**; **L-4**; **I-1**

Rationale:

- The Committee questioned the precision of the some of the specifications. The age range of patients to be included in the measure is not provided in the specifications, though the narrative in section 3c.1 states adult patients 18 years and older. The specifications also do not include that the NIH Stroke Scale should be completed by a certified examiner who did not perform the procedure as stated in the evidence provided by the developer. The developer clarified that this should be included in the specifications. It was also not clear to the Committee if a patient with a documented NIH Stroke Scale

2396 Carotid artery stenting: Evaluation of Vital Status and NIH Stroke Scale at Follow Up

assessment died prior to the 21 day timeframe if the facility would be compliant for having done something prior to the timeframe starting. The developer responded that if a patient dies before 21 days and it is documented that they have died during this period, they are counted as having satisfied the measure. Another Committee member had concerns with the collection tool which allows patient reasons as a reason for not following up.

- The developer provided 2 types of reliability testing including the signal-to-noise facility-level testing of the measure score for facilities who completed neurological function testing, and a test-retest methodology to test data element reliability of patient characteristics only.
- The developer provided face validity and content validity. The Committee identified no concerns with the validity of this measure.

3. Feasibility: H-3; M-11; L-3; I-0

(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)

Rationale:

- The data source used to collect and calculate measure performance is the NCDR Care Registry. The developer states that ALL data elements are in defined fields in electronic clinical data, and may be collected via third-party vendors. The specifications are available in the public domain; therefore a provider does not need to participate in the registry to collect this data. The Committee identified no concerns with the feasibility of this measure.

4. Use and Usability: H-2; M-13; L-2; I-0

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)

Rationale:

- The developer stated the measure is used in the CARE Registry of the National Cardiovascular Data Registry of the American College of Cardiology.

5. Related and Competing Measures

- This measure directly competes with [NQF # and Title] [Description]. [Summarize the related/competing measure issue here, and the disposition of it]

OR

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-13**; **N-3**

6. Public and Member Comment

- Two commenters were generally in support of this measure. Both commenters suggested the measure be updated to be an outcome-based measure.
    - Developer response: Yes, the intent of the process measure is to set up a standard process of capturing data for a future outcome measure to detect complications in a standardized manner.
    - Committee Response: Generally, the Committee would prefer to recommend the endorsement of outcome measures rather than process or structural measures. However, measuring the

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process or structure may still be useful for quality improvement or other purposes; these measure types may still be useful where outcomes may be difficult to measure.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals

2712 Statin Use in Persons with Diabetes

Submission | Specifications

Description: The percentage of patients ages 40 – 75 years who were dispensed a medication for diabetes that receive a statin medication.

Numerator Statement: The number of patients in the denominator who received a prescription fill for a statin or statin combination during the measurement year.

Denominator Statement: The denominator includes subjects aged 41 years – 75 years as of the last day of the measurement year who are continuously enrolled during the measurement period. Subjects include patients who were dispensed two or more prescription fills for a hypoglycemic agent during the measurement year.

Exclusions: Patients in Hospice (Medicare Part D) are excluded from this measure. Medicare prescription claims for persons in hospice are not covered by Part D.

Adjustment/Stratification:

Level of Analysis: Health Plan, Population : National

Setting of Care: Pharmacy

Type of Measure: Process

Data Source: Administrative claims

Measure Steward: Pharmacy Quality Alliance (PQA, Inc.)

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-4**; **M-11**; **L-2**; **I-0; IE-0**; 1b. Performance Gap: **H-4**; **M-12**; **L-1**; **I-0**

Rationale:

- The evidence for this measure is based on an ACA/AHA guideline for the primary prevention in individuals with diabetes. The Committee agreed with the evidence provided but noted that the focus of this measure does not include diabetics but diabetics on medication therapy.
- The developer provided 2012 Medicare, commercial, and Medicaid data showing a mean performance rate of 62.8% and 2013 Medicare Part D health plan data with a mean performance rate of 66.1%. The Committee recognized the gap in medication adherence. However, it was noted that many minority women have a higher risk for diabetes and may be overlooked with this measure.
- A Committee member identified that while the measure indicates if a prescription is filled, it does not indicate whether the patient complies with taking the medication. The developer acknowledged that there is no way to determine this based on health plan level claims data, and the Committee noted that a movement in a positive direction should still be achievable when measuring statin use in patients with diabetes.

2. Scientific Acceptability of Measure Properties: The measure meets the Scientific Acceptability criteria

(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)

2a. Reliability: **H-2**; **M-14**; **L-1**; **I-0** 2b. Validity: **H-2**; **M-15**; **L-0**; **I-0**

Rationale:

- The developer provided signal to noise analysis with a mixed effect logistic regression model to examine variability in performance measure scores. A likelihood-ratio (LR) test was also performed to determine if a model with random effects would fit the data better than a standard logistic regression model without random effects. The developer did not provide statistical results but stated that there was a significant

2712 Statin Use in Persons with Diabetes
difference in performance measure scores between plans, which allows for discrimination between high performing plans and low performing plans. The Committee noted that they would have preferred to see the data with the measure submission. • The developers provided validity testing via a 7 step consensus based measure development and testing process, and stated that 89.5% members of the PQA workgroup agreed that the measure could differentiate the quality of care. • Exclusions for this measure include persons receiving hospice care at any point during the measurement year, but no testing was performed on this exclusion due to the lack of available prescription claims data for non-Medicare health plans. The Committee identified no concerns regarding face validity.
3. Feasibility: H-16; M-1; L-0; I-0 *(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)* Rationale: • The Committee agreed that this measure is feasible based on the electronically abstracted administrative claims, readily available from health plan prescription and enrollment data, requiring no extra burden or cost to collect the data for this measure.
4. Use and Usability: H-10; M-6; L-1; I-0 *(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)* Rationale: • The measure is currently reported by CMS to all Medicare Part D health plan sponsors in the monthly Patient Safety Reports for quality improvement,
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Endorsement: **Y-16**; **N-1**
6. Public and Member Comment • One commenter suggested including non-statin therapy and other lipid-lowering drugs such as the new FDA approved PCSK-9 therapies. o Developer response: The measure is based on a specific section of the ACC/AHA guidelines, page 31: 4.5. Primary Prevention in Individuals with Diabetes: A high level of evidence supports the use of moderate-intensity statin therapy in persons with diabetes 40 to 75 years of age. Since the guideline only addresses the use of statin therapy for diabetics, the measure only includes those medications. The new PCSK-9 medications are intended for adjunct therapy with a statin. Diabetic patients receiving combination therapy with both a statin and PCSK-9 medication will be compliant with the measure. Each PQA measure is reviewed annually to determine if there is new evidence or new medications that affect the intent of the measure, and revisions to the measure would be considered, as appropriate. o Committee response: During the in-person meeting, the Committee discussed evaluating the intensity of statins prescribed as recommended in the ACC/AHA guidelines and including

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contraindications and/or intolerance to statin therapy as an exclusion. The developer noted that due to the limited data source, pharmacy claims, it is not possible to determine if patients received the appropriate level of statin intensity or if they have contraindications to statin therapy. Additionally, updates to the list of acceptable medications should be submitted by the developer to NQF during the annual update of the measure.

- Several comments focused on the appropriate intensity of statin treatment, which is a key element in the ACC/AHA guidelines, and including pregnancy, allergy, and previous intolerance as an exclusion.
    - Developer response: During the development of the measure, PQA considered whether the measure criteria could specify moderate to high intensity statin therapy. Since the measure is intended for use by Prescription Drug Plans and uses only prescription claims as a source of data, we are not able to identify individuals with side effects to statin therapy who require a lower intensity of statin therapy. The language in the ACC/AHA guideline states to use moderate to high intensity statin therapy, where appropriate. Due to the limitations of the data source, we cannot determine the appropriate level of statin intensity for each person in the denominator.

      Each PQA measure is reviewed annually to determine if there is new evidence that affects the intent of the measure, and revisions to the measure would be considered, as appropriate. During the development of the measure, side effects of statin therapy were discussed. Currently, statin therapy appears to cause only a slight increased risk of side effects compared with placebo, and no increased risk of discontinuation of therapy compared with placebo. So, numbers of intolerant patients is low. Patients with muscle pain and elevated creatine kinase (CK) levels and even patients with rhabdomyolysis can have different statins reintroduced at low doses.

      The measure is intended for use by Prescription Drug Plans that do not have access to diagnosis or other medical data. The measure uses only prescription claims as a source of data resulting in the inability to identify individuals with contraindications to statin therapy or other medical exceptions.

      During the testing of the measure, medical claims data was used to confirm the validity of the inclusion criteria. PQA tested the measure excluding patients with polycystic ovarian syndrome, gestational diabetes and liver insufficiency, and found very little difference in the measure rate when these exclusions were applied. The number of persons with these conditions was less than 0.4% of the total population. Since the limitation of the data source results in the inability to identify individuals with contraindications to statin therapy or other medical exceptions, the performance rate goal for this measure is not intended to reach 100%.
    - Committee Response: The Committee agrees with the developer response and maintains their decision to recommend this measure for endorsement.

7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X

8. Board of Directors Vote: Y-X; N-X

9. Appeals

2764 Fixed-dose Combination of Hydralazine and Isosorbide Dinitrate Therapy for Self-identified Black or African American Patients with Heart Failure and LVEF <40% on ACEI or ARB and Beta-blocker Therapy

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) and a current or prior ejection fraction (EF) <40% who are self-identified Black or African Americans and receiving ACEI or ARB and Beta-blocker therapy who were prescribed a fixed-dose combination of hydralazine and isosorbide dinitrate seen for an office visit in the measurement period in the outpatient setting or at each hospital discharge

Numerator Statement: Patients prescribed a fixed-dose combination of hydralazine and isosorbide dinitrate seen for an office visit in the measurement period in the outpatient setting or at each hospital discharge

Denominator Statement: All patients aged 18 years and older with a diagnosis of heart failure with a current or prior EF <40% who are self-identified Black or African Americans and receiving ACEI or ARB and Beta-blocker therapy

Exclusions: Denominator exclusions include:

- Hypotension (severe or symptomatic)
- Severe lupus erythematosus
- Unstable angina
- Peripheral neuritis
- Patient actively taking Phosphodiesterase Type 5 (PDE5) Inhibitors

Adjustment/Stratification:

Level of Analysis: Clinician : Group/Practice, Clinician : Individual

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Hospital/Acute Care Facility

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record

Measure Steward: National Minority Quality Froum

STANDING COMMITTEE MEETING [09/09/2015-09/10/2015]

1. Importance to Measure and Report: The measure meets the Importance criteria

(1a. Evidence, 1b. Performance Gap)

1a. Evidence: **H-6**; **M-10**; **L-1**; **I-0; IE-0**; 1b. Performance Gap: **H-6**; **M-10**; **L-1**; **I-0;**

Rationale:

- The evidence base the developer provided for prescribing a fixed-dose combination of hydrazaline and isosorbide dinitrate to self-identified Black or African American patients with heart failure who are also receiving ACEI or ARB and beta-blocker therapy is derived from the 2013 ACCF/AHA Guideline for the Management of Heart Failure and the HFSA 2010 Comprehensive Heart Failure Practice Guideline.
- The Committee expressed concern about the use of a fixed-dose combination of hydralazine and isosorbide dinitrate in this measure because the guidelines do not explicitly recommend a fixed-dose combination. The developer responded that the guideline recommendation is based on the African-American Heart Failure Trial (A-HeFT). A-HeFT examined the use of the fixed-dose combination therapy (BiDil) added to standard heart failure therapy in blacks with New York Association functional class III and IV heart failure. BiDil demonstrated a 43% reduction in mortality when compared with the placebo.
- The Committee agreed there is opportunity for improvement with the data the developers presented. Because this is a newly developed eMeasure the developers did not have overall performance data from the measure as specified but provided a summary of data from the literature that demonstrates the

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existence of a significant opportunity for improvement of whether eligible patients are receiving the hydralazine/isosorbide dinitrate combination therapy in the ambulatory setting and at hospital discharge. According to one study cited by the developer, more than 85% of African-American patients are not receiving the hydralazine/isosorbide dinitrate combination therapy.

2. Specifications and Evidence: <u>The measure meets the Specifications criteria</u>
(2b1. Specifications – specifications are consistent with evidence)
2bi. Specifications: **H-3**; **M-12**; **L-2**; **I-0**
<u>Rationale</u>:

- The Committee acknowledged that this eMeasure is currently being considered for Approval for Trial Use, which does not require the measure to have testing for reliability and validity.
- The Committee did agree that the measure is precisely specified but questioned some of the exclusions. The Committee asked if it was possible to capture "severe lupus erythematosus" in an EHR. The developer responded that most ICD-10 codes do not include severity but there is a SNOMED code that can be used instead. Testing will determine if this SNOMED code is accurately identifying "severe lupus erythematosus."
- One of the Committee members asked if the developer considered patient reasons for not prescribing the medication such as "patient cannot afford the medication" as an exclusion/exception. The developer responded that they discussed an exception where the patient was not on the drug and there was documentation that the patient could not afford the medication but, due to the significant underuse of the recommended combination therapy, the developer chose not to include additional exclusions. The developer clarified that if an eligible patient does not receive a prescription then the provider will not get credit for meeting performance for that patient.

3. Feasibility: H-1; M-14; L-2; I-0
(3a. Clinical data generated during care delivery; 3b. Electronic sources; 3c.Susceptibility to inaccuracies/ unintended consequences identified 3d. Data collection strategy can be implemented)
<u>Rationale</u>:

- The developers provided an eMeasure Feasibility Scorecard of 2 EHRs (hospital and outpatient) testing all data elements required to calculate this measure. The Committee agreed that this measure is feasible for implementation with EHR systems.
- Some Committee members voiced their concerns with the cost of the fixed-dose combination therapy, the availability of the medication in hospital formularies, and the burden of cost to the patients.

4. Use and Usability: H-2; M-9; L-6; I-0
(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement)
<u>Rationale</u>:

- The developer noted that a similar measure that does not require a fixed-dose is currently used in the American Heart Association's Get with the Guidelines.
- The developer provided plans for future accountability and quality improvement use for this new

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eMeasure.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-14**; **N-3**

6. Public and Member Comment

- A large number of supportive comments were received for measure #2764. Three comments received referenced the 2013 ACCF/AHA Heart Failure Guideline recommendations that encourage treatment of African-American heart failure patients with the isosorbide dinitrate and hydralazine hydrochloride combination therapy, but do not explicitly recommend the fixed-dose combination. The commenters noted that the guidelines permit the use of the fixed-dose combination or separate therapies. The commenters' concern is that the measure could penalize providers who prescribe the separate therapies and the financial burden the fixed-dose combination therapy would place on many patients increasing the likelihood of medical non-compliance. The three commenters asked the Committee to reconsider its decision to recommend this measure for Approval for Trial Use.
    - Developer response: The developer responded to each comment regarding the ACCF/AHA guidelines. A summary response is provided below. Full responses can be accessed via the excel comment table at this link.
      The National Minority Quality Forum (NMQF) believes this measure is consistent with the 2013 ACCF/AHA guidelines. While the guidelines provide for the two drugs to be administered separately, it is suggested that the two separate drugs constitutes the generic fixed-dose. However, there is a difference between the off-label use of approved drugs, both brand and generic, and the indicated use of an approved generic drug. FDA approval requires a generic drug to contain the same active ingredients, be identical in strength, dose and routes of administration, have the same indications, be bioequivalent, and meet the same batch quality and manufacturing requirements, but there is currently no FDA-approved generic fixed-dose drug.
      While the ACCF/AHA guidelines recommend off label use of isosorbide dinitrate (a generic of Isordil Titradose) and hydralazine hydrochloride (a generic of Apresoline Hydrochloride), two drugs with indications, labeling, dose and administration that are different from those of the fixed-dose approved by FDA, pros and cons of off-label prescribing should be transparent, such as prescription insurance coverage for off-label use.
      The evidence-based science supporting the use of the fixed-dose drug is the strongest and is the basis for how NMQF specified the measure. According to the A-HeFT trial, the 2010 Heart Failure Society of America guidelines, and other peer reviewed resources, specifying the measure to include the separate drugs as equivalent therapy to the fixed-dose would not be consistent with the evidence and would not meet the high NQF quality measure standards. Moreover, transparency of measure development is important and NMQF addressed this during the September 9 meeting, stating that recommending the use of the two component drugs as a "generic" is inconsistent with FDA approvals since a generic fixed-dose drug is currently not available. It is also important to note that neither component drug is indicated for heart failure and, since the ACCF/AHA guideline recommendations appear to be based on professional

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opinion, NMQF believes measure 2764 is an appropriate performance measure. Commenters have not offered additional supportive evidence to uphold the ACCF/AHA guideline recommendations for the generic component use for heart failure patients. While the ACCF/AHA guideline writing committee notes the importance of availability and cost of the generic components, NMQF believe the reason why patients are not receiving the fixed-dose therapy is because it is not being prescribed. Neither separately nor taken together do the separate compounds meet the definition of a generic or an equivalent substitute for the FDA-approved fixed-dose combination. NMQF is concerned about arbitrary and flexible definitions of the components of quality healthcare that may create confusion within both the provider and patient communities and believe that measure 2764 is a step in the right direction. ○ Committee response: The Committee considered the ACC/AHA Heart Failure Guidelines during the measure evaluation discussion and determined that a gap in appropriate treatment persists in the African-American subpopulation of heart failure patients warranting a need for this measure. Studies show a significant reduction in mortality of this specific subpopulation with the use of the fixed-dosed combination therapy, therefore, the Committee does not change its recommendation of this measure for Approval for Trial Use.
7. Consensus Standards Approval Committee (CSAC) Vote: Y-X; N-X; A-X
8. Board of Directors Vote: Y-X; N-X
9. Appeals