TO: Consensus Standards Approval Committee (CSAC)

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RE: Renal 2015-2017

DA: November 2, 2016

The CSAC will review recommendations from the Renal 2015-2017 project at its November 9-10, 2016 meeting.

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

Accompanying this memo are the following documents:

1. **Renal 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 17 comments received during the post meeting comment period and the NQF/Standing Committee responses.

BACKGROUND

Renal disease is a leading cause of morbidity and mortality in the United States. More than 20 million adults (10 percent of the population) in the United States have chronic kidney disease (CKD). Untreated CKD can result in end-stage renal disease (ESRD) and a host of other health complications. Currently, over half a million people in the United States have received a diagnosis of ESRD, the only chronic disease covered by Medicare for people under the age of 65. Considering the high mortality rates, high healthcare utilization and costs associated with ESRD, the need to focus on quality measures for patients with renal disease is particularly important.

On June 28, 2016, the Renal Standing Committee evaluated 3 newly-submitted measures and 3 measures undergoing maintenance review against NQF's standard evaluation criteria. Four measures were recommended for endorsement and the Committee did not recommend 2 measures. During the post-comment call, the Committee reconsidered the two not recommended measures and altered their decision for one of the measures.

DRAFT REPORT

The Renal 2015-2017 Draft Report presents the results of the evaluation of 6 measures considered under the Consensus Development Process (CDP). Five are recommended for endorsement and one was not recommended.

The measures were evaluated against the 2015 version of the measure evaluation criteria.

	Maintenance	New	Total
Measures under consideration	3	3	6
Measures recommended for endorsement	2	3	5
Measures not recommended for endorsement	1	--	1
Reasons for not recommending	Importance – 0 Scientific Acceptability – 1 Overall – 0 Competing Measure – X	Importance – 0 Scientific Acceptability – 0 Overall – 0 Competing Measure – X	

Pursuant to the CDP, the CSAC may consider approval of five candidate consensus measures.

Renal Measures Recommended for Endorsement:

- #0369 Standardized Mortality Ratio for Dialysis Facilities
  Overall Suitability for Endorsement: Y-17; N-0
- #1463 Standardized Hospitalization Ratio for Dialysis Facilities
  Overall Suitability for Endorsement: Y-19; N-0
- #2977 Hemodialysis Vascular Access: Standardized Fistula Rate
  Overall Suitability for Endorsement: Y-19; N-0
- #2978 Hemodialysis Vascular Access: Long-term Catheter Rate
  Overall Suitability for Endorsement: Y-18; N-0
- #2979 Standardized Transfusion Ratio for Dialysis Facilities
  Overall Suitability for Endorsement: Y-16; N-4

Renal Measures Not Recommended (See Appendix A for the Committee's votes and rationale)

- #0260 Assessment of Health-related Quality of Life in Dialysis Patients

COMMENTS AND THEIR DISPOSITION

NQF received 17 comments from two organizations (both member organizations) 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 Renal project page under the Public and Member Comment section.

Comment Themes and Committee Responses

Comments about specific measure specifications and rationale were forwarded to the developers, who were invited to respond.

The Standing Committee reviewed all of the submitted comments and developer responses. Committee members focused their discussion on measures or topic areas with the most significant and recurring issues.

2977: Hemodialysis Vascular Access: Standardized Fistula Rate

The Kidney Care Partners (KCP) has recommended the developer consider the following modifications to improve the measure going forward:

- Stating that the specifications for #2977 are too imprecise, suggest the numerator specifies the patient must be on maintenance hemodialysis "using an AVF with two needles and without a dialysis catheter present." Additionally, credit should be received for a patient who is using an AVF as the sole means of access, but who also may have a non-functioning AV graft present.
- Suggests that two additional vasculature risk variables that could strengthen the model be added: a history of multiple prior accesses and the presence of a cardiac device.

Committee Response: The Committee discussed the comment submitted and the developer's response. The Committee agreed with the suggestions and recommended that the developer work toward these goals for future iterations of this measure.

2979: Standardized Transfusion Ratio (STrR) for Dialysis Facilities

KCP notes that during the last project, this Standing Committee reviewed the STrR as measure #2699 and did not recommend it. The commenter expresses concerns about the specifications, reliability, validity (risk model), and harmonization. In regards to validity, the commenter does not believe the new measure addressed the Committee's concerns about hospital- and physician-related factors. Overall, they remain concerned about the reliability, as well as the specifications and validity. The commenter strongly encouraged the Committee to reconsider the reliability testing data, which documents reliability issues with the STrR for small facilities, and to comment specifically on the STrR's reliability for such facilities.

Committee Response: The Committee thoroughly reviewed the specifications, reliability, and validity of the measure during the in-person meeting and maintained that the measure meets the NQF criteria.

1463: Standardized Hospitalization Ratio for Dialysis Facilities

KCP believes hospitalization is an important outcome to measure, but has concerns about the specifications, reliability, validity (risk model), and harmonization issues. The commenter strongly encouraged the Committee to reconsider the reliability testing data, which demonstrate significant reliability issues with the one-year SHR for small facilities, and comment specifically on the SHR's reliability for such facilities.

Committee Response: The Committee thoroughly reviewed the specifications, reliability, and validity of the measure during the in-person meeting and maintained that the measure meets the NQF criteria.

NQF MEMBER VOTING RESULTS

Five of the recommended measures were approved with 75% approval or higher. Representatives of 5 member organizations voted; no votes were received from Consumer, Health Plan, Public/Community Health Agency, or Supplier/Industry Councils. Results for each measure are provided below.

Appendix A – Measures Not Recommended for Endorsement

The table below lists the Committee's vote and rationale for measures not recommended for endorsement.

Measure	Voting Results	**Rationale:**
#0260 Assessment of Health-related Quality of Life in Dialysis Patients	**Evidence** H-0; M-5; L-3; I-12 **Insufficient Evidence with Exception** Y-14; N-6 **Gap** H-0; M-12; L-8; I-0 **Reliability** H-3; M-8; L-9; I-0 **Validity** H-0; M-2; L-16; I-2	The developer indicated that several exclusions changed since the last time the measure was reviewed in 2007. Committee members expressed concerns about the exclusions, specifically whether it is appropriate for patients who refuse to complete the survey to be included in the denominator. There were also concerns that the mental status exclusion may be too broad and not well specified, allowing for inappropriate exclusions, and that more clarity for language exclusions may be needed as interpretation and attempts to implement may be highly variable between facilities. The Committee was not able to come to consensus on gap. Some Committee members questioned if facility size indicated variation in reliability and if smaller facilities have lower reliability as compared to large dialysis facilities, although this was not included as part of the developer's analysis. Due to which, the Committee also was not able to come to consensus on reliability. Committee members questioned whether this was the most appropriate method for demonstrating validity of this measure, and noted that the analyses suggested that case mix adjustment may be needed because of the differences in the odds of completion across different populations. A reconsideration request was received. The developer provided clarification of the exclusion criteria and additional data supporting a performance gap; however, the Committee did not feel the additional information substantiated a re-vote on the non-passing criteria. It was noted that assessment of quality of life and specifically if dialysis is making an impact on ESRD patients is important, yet the current process measure was not the best mechanism to move in that direction.

Appendix B – NQF Member Voting Results

NQF MEMBER VOTING RESULTS

Five of the recommended measures were approved with 75% approval or higher. Representatives of 5 member organizations voted; no votes were received from Consumer, Health Plan, Public/Community Health Agency, or Supplier/Industry Councils. Results for each measure are provided below.

Measure #0369 Standardized Mortality Ratio for Dialysis Facilities

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	1	0	0	1	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	0	1	1	2	0%
Supplier/Industry	0	0	0	0	
All Councils	**3**	**1**	**1**	**5**	**75%**
Percentage of councils approving (>60%)					75%
Average council percentage approval					75%

*equation: Yes/ (Total - Abstain)

Voting Comments

DaVita Healthcare Partners: Still an imperfect measure, but the use of claims data for prevalent comorbidities is a significant improvement

Kidney Care Partners: Kidney Care Partners (KCP) continues to be concerned about the testing data, even for the 4-year SMR, which demonstrate significant reliability issues with the SMR for small- and medium-sized facilities. Empirical testing demonstrated that, on average, less than 60% of a facility's score is attributable to between-facility differences for the 4-year SMR. Moreover, 4-year SMR testing results specifically for small- and medium-sized facilities indicate very poor reliability, with IURs of 0.30 and 0.45, respectively. KCP thus believes the specifications must specifically require a minimum sample as identified through the developer's empirical testing.

Measure #1463 Standardized Hospitalization Ratio for Dialysis Facilities

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	1	0	0	1	100%
Provider Organizations	1	0	0	1	100%
Public/Community Health Agency	0	0	0	0	

Purchaser	1	0	0	1	100%
QMRI	0	1	1	2	0%
Supplier/Industry	0	0	0	0	
All Councils	**3**	**1**	**1**	**5**	**75%**
Percentage of councils approving (>60%)					75%
Average council percentage approval					75%

*equation: Yes/ (Total - Abstain)

Voting Comments

DaVita Healthcare Partners: Still an imperfect measure, but the use of claims data for prevalent comorbidities is a significant improvement

Kidney Care Partners: KCP continues to be concerned about the significant reliability issues for the 1-year SHR for small facilities. Specifically, for facilities with <=50 patients, more than half (54%) of a facility's score is due to random noise; even for medium facilities, 43% of a facility's score attributable to random noise and is not a signal of quality. We note that the intended use for the SHR will be for public reporting and the penalty-based QIP; penalizing facilities for performance due to random chance is not appropriate. Given the poor reliability testing results, KCP did not support CMS's proposal to include it in the Quality Incentive Program (QIP) for Payment Year 2020.

Measure #2977 Hemodialysis Vascular Access: Standardized Fistula Rate

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	1	0	0	1	100%
Provider Organizations	0	1	0	1	0%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	**4**	**1**	**0**	**5**	**80%**
Percentage of councils approving (>60%)					75%
Average council percentage approval					75%

Voting Comments

Kidney Care Partners: KCP recommends the developer consider modifications to improve the measure going forward.

- KCP believes the specifications are imprecise as to whether facilities would receive credit for patients using an AVF as the sole means of access, but who also have in place a graft or catheter that is no longer being used. A numerator that specifies the patient must be on maintenance hemodialysis "using an AVF with two needles and without a dialysis catheter present" would remove ambiguity.
- KCP believes two additional vasculature risk variables would strengthen the model: A history of multiple prior accesses and the presence of a cardiac device.

Measure #2978 Hemodialysis Vascular Access: Long-term Catheter Rate

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

*equation: Yes/ (Total - Abstain)

Voting Comments

None.

Measure #2979 Standardized Transfusion Ratio for Dialysis Facilities

Measure Council	Yes	No	Abstain	Total Votes	% Approval*
Consumer	0	0	0	0	
Health Plan	0	0	0	0	
Health Professional	1	0	0	1	100%
Provider Organizations	0	1	0	1	0%
Public/Community Health Agency	0	0	0	0	
Purchaser	1	0	0	1	100%
QMRI	2	0	0	2	100%
Supplier/Industry	0	0	0	0	
All Councils	**4**	**1**	**0**	**5**	**80%**
Percentage of councils approving (>60%)					75%
Average council percentage approval					75%

*equation: Yes/ (Total - Abstain)

Voting Comments

Kidney Care Partners: KCP again expresses concern about the reliability of the STrR for small facilities. Specifically, testing yielded IURs of 0.30-0.41 for small facilities for each of 2011, 2012, 2013, and 2014, indicating approximately 60-70% of a small facility's score is due to random noise. KCP believes the specifications must specifically require a minimum sample as identified through the developer's empirical testing. Additionally, we again note that physicians independently (or following hospital protocols) make decisions about whether or not to transfuse a specific patient; the measure does not adjust for such hospital- and physician-related transfusion practices.

Appendix C – Measure Evaluation Summary Tables

Measures Recommended

0369 Standardized Mortality Ratio for Dialysis Facilities

Submission | Specifications

Description: Standardized mortality ratio for dialysis facility patients. This measure is calculated as a ratio but can also be expressed as a rate.

Numerator Statement: Number of deaths among eligible patients at the facility during the time period.

Denominator Statement: Number of deaths that would be expected among eligible dialysis patients at the facility during the time period, given the national average mortality rate and the patient mix at the facility.

Exclusions: N/A

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Outcome

Data Source: Administrative claims, Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [06/28/2016]

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

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

1a. Evidence: **Y-17; N-2**; 1b. Performance Gap: **H-5; M-13; L-0; I-1**

Rationale:

- The Committee agreed with the developer that there are numerous dialysis care processes that can influence the likelihood of a patient's dying. These processes include:
  - Processes related to fluid management/removal. Inadequate control of total body fluid balance and fluid removal can result in fluid overload and congestive heart failure, increasing the possibility of death.
  - Infection prevention. Inadequate infection prevention processes, including suboptimal management of vascular access, can lead to bacteremia or septicemia, increasing the possibility of death.
  - Dialysis. Failure to maintain processes to ensure adequate dialysis can lead to low Kt/v, increasing the possibility of death.
- The Committee concluded that there was enough of a gap in care to warrant a national performance measure. For the period 2010 – 2013, the 4 year SMR varied from 0.00 to 3.1. The mean value for 4-year SMR was 1.02 and the standard deviation was 0.28.

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-3; L-14; I-1;** 2a. Reliability Revote: **H-2; M-14; L-0; I-0;** 2b. Validity: **H-2; M-14; L-0; I-0**

Rationale:

- The Committee agreed that the developer's changes to the measure were appropriate. The following updates were made since the last submission:
  - The model adjusts for each incident comorbidity separately rather than using a comorbidity index.
  - The indicators for diabetes were modified by consolidating the individual indicators.
  - Adjustments for 210 prevalent comorbidities (identified through Medicare claims) were included
  - The measure is now limited to Medicare patients

0369 Standardized Mortality Ratio for Dialysis Facilities

- However, the Committee did not agree that the measure could be reliably implemented. The reliability of the Standardized Mortality Ratio (SMR) was assessed using data among ESRD dialysis patients during 2010-2013. IURs for the one-year SMR ranged from 0.26-0.32 across the years, which the developer admitted indicates a relatively low degree of reliability.
- The developer found that reliability improved when four-year data were used, with the IUR for the four-year SMR for 2010-2013 being 0.59. However, the Committee did not find this level of reliability to be strong enough for a national standard.
- The Committee suggested that the analysis seemed over-modeled and noted that the developer might consider reducing the included prevalent comorbidities in order to improve reliability. They also recommended that the measure should be reported as rate instead of a ratio to help patients better understand the information they are being provided.
- During the comment period, the developer submitted a request for reconsideration of the measure. After reviewing information provided by the developer, the Committee decided to reconsider the measure and determined the reliability results were acceptable.
- To empirically assess validity, the SMR was compared to other quality of care indicators, including the Standardized Hospitalization Ratio (SHR) – Admissions, the Standardized Readmission Ratio (SRR), the Standardized Transfusion Ratio (STrR), percent of patients dialyzing with a fistula, percent of patients dialyzing with a catheter, and percent of patients with Kt/V >=1.2 to determine validity. Because the correlations were approximately the same for the four years 2010-2013, the developer only reported the 2013 correlations.
- Face validity was assessed by a TEP in 2006 for potential implementation on Dialysis Facility Compare (DFC). In 2015, a TEP was held specifically to consider prevalent comorbidity adjustments for inclusion in the measure. The TEP's recommendations are reflected in the risk adjustment methodology.
- The Committee agreed with the developer that the results indicated higher standardized mortality rates in facilities are associated with higher standardized hospitalization rates, higher standardized readmissions rates and higher standardized transfusion rates, higher values of SMR are associated with increased use of catheters and lower SMRs are associated with a higher percentage of patients receiving adequate dialysis dose.

3. Feasibility: H-13; M-4; L-0; I-0

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

- The Committee agreed all data elements are in defined fields in electronic form and generated or collected by and used by healthcare personnel during the provision of care.

4. Usability and Use: H-17; M-0; L-0; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- This measure is publically reported nationally in Dialysis Facility Compare (DFC).
- The developer states that mortality rates have decreased over time as evidenced by the coefficients for calendar year from the SMR model. The mortality rate for 2011 was 2.6% lower compared to 2010 (p-value<0.0001), and the rates for 2012 and 2013 were lower compared to 2010 at 12.4% and 13.0%, respectively (p-value <0.0001).

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

- One Commenter supported the Committee's decision to not endorse the measure and one commenter felt the measure should have been recommended for endorsement.

0369 Standardized Mortality Ratio for Dialysis Facilities

- The Committee reviewed the comments received and the information provided by the developer. The Committee was satisfied with the additional information provided and decided to reconsider this measure. After discussing and voting on the reliability, validity, feasibility and usability and use criteria, the Committee unanimously recommended the measure for endorsement.

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

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

9. Appeals

1463 Standardized Hospitalization Ratio for Dialysis Facilities

Submission | Specifications

Description: Standardized hospitalization ratio for dialysis facility patients. This measure is calculated as a ratio but can also be expressed as a rate.

Numerator Statement: Number of inpatient hospital admissions among eligible patients at the facility during the reporting period.

Denominator Statement: Number of hospital admissions that would be expected among eligible patients at the facility during the reporting period, given the patient mix at the facility.

Exclusions: None.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Outcome

Data Source: Administrative claims, Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [06/28/2016]

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

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

1a. Evidence: **Y-18; N-1;** 1b. Performance Gap: **H-7; M-12; L-0; I-0**

Rationale:

- The Committee agreed with the developer's rationale for measuring this health outcome:
  - Hospitalization rates remain very high in US chronic dialysis patients relative to the general population, despite a nearly 20% decline from 2005-2013.
  - According to the 2015 USRDS Annual Report, approximately ½ of all dialysis patient hospitalizations continue to be caused by cardiovascular or infectious causes.
  - Programs developed to impact dialysis provider practices have been shown to improve intermediate outcomes (reduced catheter vascular access, small solute adequacy, anemia management) and mortality, modality options, infection prevention, and dialysis organization culture. These practice improvements have been linked to reduced hospitalizations in this population.
- The Committee concluded there was a gap in care that warranted a national performance measure. For 2014, the Standardized Hospitalization Ratio (SHR) varied from 0.07 to 2.92. The mean value was 0.99 and the Standard Deviation (or error) was 0.27.

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-5; M-13; L-1; I-0;** 2b. Validity: **H-6; M-13; L-0; I-0**

Rationale:

1463 Standardized Hospitalization Ratio for Dialysis Facilities

- Inter-unit reliability for the one-year SHRs have a range of 0.70-0.72 for Medicare ESRD dialysis patients across the years 2010, 2011, 2012 and 2013, which the Committee agreed indicated the measure could be reliably implemented.
- The Committee concluded the measure was strengthened by updated empirical validity testing of the measure score with 2010-2013 data and new face validity conducted with a TEP in 2015. The SHR correlates with outcomes, processes of care, and causes of hospitalization that are commonly thought to be potentially related to poor quality of care. Higher rates of hospitalization were associated with higher facility mortality and readmission rates. The developer found higher values of SHR are associated with lower usage of AV Fistulas, higher catheter use, and suboptimal dialysis adequacy.

3. Feasibility: H-14; M-5; L-0; I-0

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

- The Committee agreed all data elements are in defined fields in electronic form and generated or collected by and used by healthcare personnel during the provision of care.

4. Usability and Use: H-8; M-11; L-0; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- This measure is publically reported nationally in Dialysis Facility Compare (DFC).
- The developer states that, as measured by the SHR, hospitalization rates have decreased over time. Compared to 2010, the hospitalization rate was 3% lower for 2011 (p-value <0.0001), 12.7% lower for 2012, and about 16.2% lower for 2013 (p-value<0.0001 for both).

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: **Y-19; N-0**

6. Public and Member Comment

- One commenter, the Kidney Care Partners, believes hospitalization is an important outcome to measure, but has concerns about the specifications, reliability, validity (risk model), and harmonization issues. The commenter strongly encouraged the Committee to reconsider the reliability testing data, which demonstrate significant reliability issues with the one-year SHR for small facilities, and comment specifically on the SHR's reliability for such facilities.
- The Committee thoroughly reviewed the specifications, reliability, and validity of the measure during the in-person and maintained that the measure meets the NQF criteria.

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

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

9. Appeals

2977 Hemodialysis Vascular Access: Standardized Fistula Rate

Submission | Specifications

Description: Adjusted percentage of adult hemodialysis patient-months using an autogenous arteriovenous fistula (AVF) as the sole means of vascular access.

Numerator Statement: The numerator is the adjusted count of adult patient-months using an AVF as the sole means of vascular access as of the last hemodialysis treatment session of the month.

Denominator Statement: All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the entire reporting month at the same facility.

Exclusions: Exclusions that are implicit in the denominator definition include:

•Pediatric patients (<18 years old)

•Patients on Peritoneal Dialysis

•Patient-months with in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

•Patients under hospice care in the current reporting month

•Patients with metastatic cancer in the past 12 months

•Patients with end stage liver disease in the past 12 months

•Patients with coma or anoxic brain injury in the past 12 months

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Intermediate Clinical Outcome

Data Source: Administrative claims, Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [06/28/2016]

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

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

1a. Evidence: **H-5; M-14; L-0; I-0;** 1b. Performance Gap: **H-10; M-8; L-1; I-0**

Rationale:

- The Committee agreed that there is sufficient evidence for measuring this intermediate outcome:
  - There is a definite association between type of vascular access used for hemodialysis and the risk of patient mortality.
  - The developer provided results of a systematic review of the evidence, concluding that a number of epidemiologic studies consistently demonstrate reduced morbidity and mortality associated with greater use of AV fistulas for vascular access in maintenance hemodialysis.
  - The measure is intended to be jointly reported with Hemodialysis Vascular Access: Long-term Catheter Rate. Used together, the two vascular access quality measures consider Arterial Venous Fistula (AVF) use as a positive outcome and prolonged use of a tunneled catheter as a negative outcome.
- Committee members agreed with the developer's rationale that the gap in performance and for disparities is significant. The developer notes that interquartile differences in measure performance from CROWNWeb show substantial disparities across a variety of demographic categories.

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-4; M-15; L-0; I-0;** 2b. Validity: **H-6; M-13; L-0; I-0**

2977 Hemodialysis Vascular Access: Standardized Fistula Rate

Rationale:

- The Committee agreed that the developer's testing results showed sufficient reliability, with an inter-unit reliability analysis showing that about 74 percent of variation in measure scores could be attributable to true differences in performance scores between facilities.
- Validity was tested by assessing the degree to which scores on this measure were correlated with scores on the Standardized Mortality Ratio and Standardized Hospitalization Ratio.
- This analysis showed that Standardized Fistula Rates had a significantly negative association with risks of mortality and hospitalization.
- Some Committee members suggested that the exclusions needed to be defined more specifically (e.g., using specific codes); it was also noted that the rate of exclusions seemed to be low.
- The Committee also expressed concern that exclusions can only be applied to Medicare patients. The developer noted that their analyses showed that facilities' proportion of Medicare patients did not impact performance scores, suggesting there is minimal risk of bias.

3. Feasibility: H-16; M-3; L-0; I-0

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

- Members of the Committee agreed that the data is feasible to collect and most has already been collected. The Committee also agreed that the data elements are generated as part of the care delivery process.

4. Usability and Use: H-7; M-12; L-0; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- The Developer stated that, upon endorsement, CMS will consider retiring the currently-endorsed measure of fistula use (#0257) in favor of this new measure for implementation in the End Stage Renal Disease Quality Improvement Program (ESRD QIP) and Dialysis Facility Compare in future performance years.
- Though the measure is not yet implemented in a public reporting program, CMS expects implementation of the standardized fistula rate measure.
- The Committee had concerns that there may be subsets of patients other than those excluded for which fistula use is not as well correlated with poor outcomes. Additionally, patient choice is not considered, potentially causing pressure for patients to undergo multiple procedures to establish fistulae.

5. Related and Competing Measures

- This measure is related to:
  - 0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement
  - 0256: Hemodialysis Vascular Access-Minimizing use of catheters as Chronic Dialysis Access
  - 0257: Hemodialysis Vascular Access-Maximizing Placement of Arterial Venous Fistula (AVF)
  - 2978: Hemodialysis Vascular Access: Long-term Catheter Rate
- The Committee was unable to discuss related and competing measures during the in-person meeting and will have the opportunity to do so during the post-comment call.

Standing Committee Recommendation for Endorsement: **Y-19; N-0**

6. Public and Member Comment

- The Kidney Care Partners has recommended the developer consider the following modifications to improve the measure going forward:
  - Stating that the specifications for #2977 are too imprecise, suggest the numerator specifies the

2977 Hemodialysis Vascular Access: Standardized Fistula Rate

patient must be on maintenance hemodialysis "using an AVF with two needles and without a dialysis catheter present." Additional, credit should be received for a patient who is using an AVF as the sole means of access, but who also may have a non-functioning AV graft present.

- Suggest that two additional vasculature risk variables that could strengthen the model be added: a history of multiple prior accesses and the presence of a cardiac device.

- The Committee discussed the comment submitted and the developer's response. The Committee agreed with the suggestions and recommended that the developer work toward these goals for future iterations of this measure.

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

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

9. Appeals

2978 Hemodialysis Vascular Access: Long-term Catheter Rate

Submission | Specifications

Description: Percentage of adult hemodialysis patient-months using a catheter continuously for three months or longer for vascular access.

Numerator Statement: The numerator is the number of adult patient-months in the denominator who were on maintenance hemodialysis using a catheter continuously for three months or longer as of the last hemodialysis session of the reporting month.

Denominator Statement: All patients at least 18 years old as of the first day of the reporting month who are determined to be maintenance hemodialysis patients (in-center and home HD) for the complete reporting month at the same facility.

Exclusions: Exclusions that are implicit in the denominator definition include:

-Pediatric patients (<18 years old)

-Patients on Peritoneal Dialysis

-Patient-months under in-center or home hemodialysis for less than a complete reporting month at the same facility

In addition, the following exclusions are applied to the denominator:

Patients with a catheter that have limited life expectancy:

-Patients under hospice care in the current reporting month

-Patients with metastatic cancer in the past 12 months

-Patients with end stage liver disease in the past 12 months

-Patients with coma or anoxic brain injury in the past 12 months

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Intermediate Clinical Outcome

Data Source: Administrative claims, Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [06/28/2016]

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

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

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

Rationale:

- The Committee agreed the evidence establishes the relationship between improved processes of care and

2978 Hemodialysis Vascular Access: Long-term Catheter Rate

health outcomes of interest in this population, but some Committee members suggested that, as a measure of long-term catheter usage in dialysis facilities, the measure may be more appropriately considered a process measure rather than an intermediate clinical outcome.

- The majority of evidence supporting this measure substantiates the importance of decreasing long-term catheter usage in the broader ESRD population; however, there are continued concerns about impact on subpopulations, such as the frail-elderly. The Committee encouraged the developer to continue to assess impact on special population groups.
- The Committee agreed with the Developer that, in general, there is an association between the type of vascular access used for hemodialysis and patient mortality and passed the measure on evidence.
- The Committee noted that data provided by the developer show a decline in chronic catheter use over time. Disparities data showed a number of population groups were more likely to have catheters; these include women, older patients (75 years and older) and those patients who with an ESRD diagnosis for less than a year and those diagnosed for more than 9 years. White patients were less likely to have catheters.
- The Committee generally agreed that the data provided showed there was opportunity for improvement.
- Committee members discussed the developer's finding that 18-25 year olds have higher rates of catheter usage; some Committee members noted that this is also the population with the highest rate of intravenous drug usage, suggesting that surgeons' hesitance to operate on this population may be one reason for their higher rate of catheter usage.

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-8; M-8; L-1; I-0;** 2b. Validity: **H-3; M-13; L-2; I-0**

<u>Rationale</u>:

- To demonstrate reliability, the developer calculated the inter-unit reliability (IUR) for annual performance scores on the measure. This analysis included facilities with at least 11 patients during the entire year. The Committee agreed with the Developer's conclusion that an IUR of 0.765 (76.5%) suggests a high degree of reliability.
- The Developer provided clarification for Committee member concerns that missing fields and other unknown data were counted as catheters.
    - The developer suggested this was done to provide a strong incentive for providers and facilities to report access and make sure that records were kept up-to-date.
- The Committee members took issue with not taking vintage (length of time on dialysis) and insurance coverage into consideration, noting that these factors can contribute to very meaningful differences between certain facilities in any given area.
- The type of insurance a patient has and whether they are capitated to a group that will provide the service may have a significant impact on timely vascular access for that patient.
- The Committee requested the developer clarify information regarding insurance status, noting that many commercial entities are not participating in coverage under the Affordable Care Act (ACA). The Developer suggested that the decision to not risk-adjust the measure was made to avoid giving facilities a pass on issues that may be in their control.

3. Feasibility: H-14; M-4; L-0; I-0

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

<u>Rationale</u>:

- The Committee agreed that the data is feasible to collect and most has already been collected. Committee members also agreed that the data elements are generated as part of the care delivery process.

4. Usability and Use: H-10; M-8; L-0; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh

2978 Hemodialysis Vascular Access: Long-term Catheter Rate

evidence of unintended negative consequences)

Rationale:

- The Developer stated that, upon endorsement, CMS will consider retiring the currently-endorsed measure of catheter use (#0256) in favor of this new measure for implementation in the End Stage Renal Disease Quality Improvement Program (ESRD QIP) and Dialysis Facility Compare in future performance years.

5. Related and Competing Measures

- This measure is related to:
  - 0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement
  - 0256 - Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access
  - 0257 - Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)
  - 2977: Hemodialysis Vascular Access: Standardized Fistula Rate
- The Committee was unable to discuss related and competing measures during the in-person meeting and will have the opportunity to do so during the post-comment call.

Standing Committee Recommendation for Endorsement: **Y-18; N-0**

6. Public and Member Comment

- Three commenters supported the Committee's recommendation to endorse the measure.

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

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

9. Appeals

2979 Standardized Transfusion Ratio for Dialysis Facilities

Submission | Specifications

Description: The risk adjusted facility level transfusion ratio "STrR" is specified for all adult dialysis patients. It is a ratio of the number of eligible red blood cell transfusion events observed in patients dialyzing at a facility, to the number of eligible transfusion events that would be expected under a national norm, after accounting for the patient characteristics within each facility. Eligible transfusions are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window.

This measure is calculated as a ratio, but can also be expressed as a rate.

Numerator Statement: Number of eligible observed red blood cell transfusion events: An event is defined as the transfer of one or more units of blood or blood products into a recipient's blood stream (code set is provided in the numerator details) among patients dialyzing at the facility during the inclusion episodes of the reporting period. Inclusion episodes are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window.

Denominator Statement: Number of eligible red blood cell transfusion events (as defined in the numerator statement) that would be expected among patients at a facility during the reporting period, given the patient mix at the facility. Inclusion episodes are those that do not have any claims pertaining to the comorbidities identified for exclusion, in the one year look back period prior to each observation window.

Exclusions: All transfusions associated with transplant hospitalization are excluded. Patients are also excluded if they have a Medicare claim for: hemolytic and aplastic anemia, solid organ cancer (breast, prostate, lung, digestive tract and others), lymphoma, carcinoma in situ, coagulation disorders, multiple myeloma, myelodysplastic syndrome and myelofibrosis, leukemia, head and neck cancer, other cancers (connective tissue, skin, and others), metastatic cancer, and sickle cell anemia within one year of their patient time at risk. Since these comorbidities are associated with higher risk of transfusion and require different anemia management practices that the measure is not intended to address, every patient's risk window is modified to have at least 1 year free of claims that contain

2979 Standardized Transfusion Ratio for Dialysis Facilities

these exclusion eligible diagnoses.

Adjustment/Stratification: Statistical risk model

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Outcome

Data Source: Administrative claims, Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [06/28/2016]

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

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

1a. Evidence: **Y-18; N-2;** 1b. Performance Gap: **H-2; M-12; L-5; I-1**

Rationale:

- The Committee discussed whether or not this measure would be more appropriately categorized as an intermediate outcome. The Committee discussed how the use of scarce resources, particularly when comparing an event to a non-event--even if it is a relatively scarce event-- is considered an appropriate health outcome metric for the healthcare system, but not for the individual patient. The Committee proceeded to evaluate the measure as an outcome measure.
- The Committee passed the measure on evidence, agreeing that providers can take actions (e.g., utilization of treatments to increase blood cell production) to reduce the occurrence of transfusions.
- Committee members noted that dialysis patients who are eligible for kidney transplant and are transfused risk the development of becoming sensitized to the donor pool, thereby leading to potential negative consequences for kidney transplantation. Monitoring the risk-adjusted transfusion rate at the dialysis facility level, relative to a national standard, allows for detection of treatment patterns in dialysis-related anemia management.
- Some Committee members noted they found the evidence to be most convincing in terms of negative downstream implications for a kidney transplant; others noted that downstream effects are difficult to know, as are the appropriate number of transplants in terms of cost and patient outcomes. Overall, the Committee agreed that the national standard of practice is transfusion avoidance.
- CROWNWeb and Medicare claims data for 2011-2014 showed that standardized transfusion ratios vary across facilities. Analyses of the standardized transfusion ratios (STrR) by race, sex and ethnicity indicate relatively little variation and no disparities substantial to the measure among these groups. The Committee agreed that opportunity for improvement for performance of this measure remains moderate.

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-0; M-15; L-5; I-0;** 2b. Validity: **H-0; M-15; L-5; I-0**

Rationale:

- Some Committee members had concerns about the specifications, specifically the lack of exclusion related to patients who may need transfusions due to acute gastrointestinal bleeds, trauma, or other unplanned surgery.
- Developers provided results of reliability testing of the performance measure score using Medicare claims data from 2011-2014 at the facility level of analysis. Inter-unit reliability (IUR) was estimated using a bootstrap approach, which uses a resampling scheme to estimate the within-facility variation that cannot be directly estimated by a one-way analysis of variance. IURs had a range of 0.60-0.66 across the years 2011, 2012, 2013 and 2014, indicating that around two-thirds of the variation in the one-year STrR can be attributed to the between-facility differences and one-third to within-facility variation. Committee members noted that when stratified by facility size, larger facilities have greater IUR. The Committee agreed that the testing results demonstrate moderate reliability.

2979 Standardized Transfusion Ratio for Dialysis Facilities

- To demonstrate validity of the performance measure score, developers used Poisson regression models to measure the association between STrR and other facility level outcomes, Standardized Mortality Ratio (SMR, NQF #0369) and Standardized Hospitalization Ratio (SHR, NQF 1463). The results from the Poisson model indicated that the StrR tertiles were significantly associated with both SMR and SHR. The developer also noted that a similar analysis was performed to compare StTR scores with facility-achieved hemoglobin levels; the analysis found that the percentage of patients with hemoglobin greater than 10 was positively associated with risk of transfusion.
- In addition, face validity was demonstrated, including a statement from the developers that six out of the six voting members of CMS's 2012 Technical Expert Panel voted to recommend the development of a facility-level standardized transfusion average. Overall, the Committee agreed that the testing results demonstrate moderate validity.

3. Feasibility: H-15; M-4; L-0; I-0

(3a. Data generated during care; 3b. Electronic sources; and 3c. Data collection can be implemented (eMeasure feasibility assessment of data elements and logic)

Rationale:

- The Committee agreed that it is feasible to collect the data. Members also agreed that the data elements are generated as part of the care delivery process.

4. Usability and Use: H-5; M-13; L-1; I-0

(4a. Accountability/transparency; and 4b. Improvement – progress demonstrated; and 4c. Benefits outweigh evidence of unintended negative consequences)

Rationale:

- This measure is publically reported nationally in Dialysis Facility Compare (DFC) and will be in End Stage Renal Disease Quality Incentive Program (ESRD QIP) starting 2018.
- Committee members noted that a potential unintended consequence of the STrR would be to create an incentive for dialysis facilities to target higher hemoglobin levels, as targeting hemoglobin concentrations above 12 to 13 grams per deciliter is associated with elevated risk of cardiac events and related mortality. However, the Committee accepted the developer's rationale that the potential for unintended consequences is low with appropriate provider anemia management practices.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: Y-16; N-4

6. Public and Member Comment

- The Kidney Care Partners notes that during the last project, this Standing Committee reviewed the STrR as #2699 and did not recommend it. The commenter expresses concerns about the specifications, reliability, validity (risk model), and harmonization. In regards to validity, the commenter does not believe the new measure addressed the Committee's concerns about hospital- and physician-related factors. Overall, they remain concerned about the reliability, as well as the specifications and validity. The commenter strongly encourage the Committee to reconsider the reliability testing data, which document reliability issues with the STrR for small facilities, and comment specifically on the STrR's reliability for such facilities.
- The Committee thoroughly reviewed the specifications, reliability, and validity of the measure during the in-person and maintained that the measure meets the NQF criteria.

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

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

9. Appeals

Measures Not Recommended

0260 Assessment of Health-related Quality of Life in Dialysis Patients

Submission | Specifications

Description: Percentage of eligible dialysis patients who complete a health-related quality of life assessment with or without assistance using the KDQOL-36 (36-question survey that assesses patients' functioning and well-being) at least once during a calendar year.

Numerator Statement: Number of eligible (not excluded) individuals with ESRD (ICD-10 N18.6) on dialysis who complete a KDQOL-36 with or without assistance at least once per calendar year

Denominator Statement: Number of individuals with ESRD (ICD-10 N18.6) on peritoneal dialysis, in-center hemodialysis, and home hemodialysis treated by the dialysis facility during the calendar year minus those dialysis patients who meet exclusion criteria in S.10.

Exclusions: Patients with ESRD (ICD-10 N18.6) on dialysis who are <18 years old; who are unable to complete the survey due to mental status that could invalidate the results; who are non-English speaking/reading and no native language translation or interpreter is available; or who have been on dialysis for <3 months. A patient who declines to complete one survey but completes one survey during the calendar year is counted as having a completed survey.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Process

Data Source: Patient Reported Data/Survey

Measure Steward: Witten and Associates, LLC

STANDING COMMITTEE MEETING [06/28/2016]

1. Importance to Measure and Report: Consensus as not reached on the Importance criteria

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

1a. Evidence: **H-0; M-5; L-3; I-12;** Evidence with Exception: **Y-14; N-6;** 1b. Performance Gap: **H-0; M-12; L-8; I-0**

Rationale:

- The developer provided updated evidence for this process measure, which was last reviewed in 2007. During the previous review, the evidence and testing was provided for the KDQOL survey, not the actual measure. For this review, the evidence presented is based on Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines for Chronic Kidney Disease: Evaluation, Classification, and Stratification; GUIDELINE 12. Based on 1989-2001 data, the evidence presented supports the recommendation that: "Patients with GFR <60 mL/min/1.73 m2 should undergo regular assessment for impairment of functioning and well-being: 1)to establish a baseline and monitor changes in functioning and well-being over time, and 2)to assess the effect of interventions on functioning and well-being."
- Committee members raised concerns about the evidence being tangential to the measure as specified with little linkage to patient outcomes. Concerns were also raised about the validation of the KDQOL survey tool. Ultimately, the majority of the Committee voted to rate the measure's evidence as insufficient with exception, noting it is reasonable to assume that in order for a provider to intervene on someone's functioning and well-being, a survey that assesses those items should be completed, and the very first step in that process is attempting to administer and deliver the survey.
- Using 2013-2015 KDQOL-Complete data, the developer tested whether there are statistically significant differences in the performance measure between facilities with at least 10 patients. Data from 2015 showed 1,261 facilities with a median score of 91.8 percent with an interquartile range of 78 to 100 percent. The tenth percentile was 61.2 percent. The Committee was not able reach consensus on whether or not an opportunity for improvement in performance of this measure remains.

2. Scientific Acceptability of Measure Properties: The measure did not meet the Scientific Acceptability criteria

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

0260 Assessment of Health-related Quality of Life in Dialysis Patients

2a. Reliability: **H-3; M-8; L-9; I-0;** 2b. Validity: **H-0; M-2; L-16; I-2**

Rationale:

- The developer indicated that several exclusions changed since the last time the measure was reviewed in 2007. The exclusion of "<3 months at the facility" was revised to "<3 months on dialysis." The exclusion of patients with cognitive impairment, dementia, and psychosis was revised to "unable to complete due to mental status." The measure was also modified so that patients who refuse to complete the survey are not excluded. Lastly, the target population was broadened to include more than just seniors, since dialysis patients also include populations at risk, dual eligible beneficiaries, individuals with multiple chronic illnesses, and veterans.
- Committee members expressed concerns about the exclusions, specifically whether it is appropriate for patients who refuse to complete the survey to be included in the denominator. The developer's rationale for including these patients in the measure is that facilities need to track and make efforts to increase the number of patients completing the survey. There were also concerns that the mental status exclusion may be too broad and not well specified, allowing for inappropriate exclusions, and that more clarity for language exclusions may be needed as interpretation and attempts to implement may be highly variable between facilities.
- The developers provided empirical testing of computed performance scores for reportable clinics, which was conducted using a beta-binomial model. The internal reliability of the measure resulted in Cronbach's alpha of 0.926 for 2013, 0.925 for 2014, and 0.923 for 2015 from KDQOL-Complete data. In terms of understanding reliability in detecting signal to noise, a reliability score of 0.70 or greater is considered acceptable for drawing conclusions about groups. Some Committee members questioned if facility size indicated variation in reliability and if smaller facilities have lower reliability as compared to large dialysis facilities, although this was not included as part of the developer's analysis.
- The Committee was not able reach consensus on the reliability criterion.
- The developer presented validity testing results using linear mixed models with the patient-level quality of life scores for each scale as the dependent variable and facility completion rate as the main independent variable. Results demonstrated that higher completion rates were associated with statistically significantly higher patient-level quality of life scores within the facility.
- The developer also provided results of an exclusions analysis that assessed the odds of survey completion vs. refusal or exclusion across different subgroups, including age, gender, and race. Committee members questioned whether this was the most appropriate method for demonstrating validity of this measure, and noted that the analyses suggested that case mix adjustment may be needed because of the differences in the odds of completion across different populations.
- The Committee did not pass the measure on the validity criterion and provided feedback to the developer.
- A reconsideration request was received. The developer provided clarification of the exclusion criteria and additional data supporting a performance gap; however, the Committee did not feel the additional information substantiated a re-vote on the non-passing criteria. It was noted that assessment of quality of life and specifically if dialysis is making an impact on ESRD patients is important, yet the current process measure was not the best mechanism to move in that direction.

NATIONAL QUALITY FORUM

Renal Measures 2015-2017

Consensus Standards Approval Committee Review and Recommendations

Connie Anderson, BSN, MBA, Standing Committee Co-Chair
Peter Crooks, MD, Standing Committee Co-Chair

November 9, 2016

Renal Measures 2015-2017

- Evaluated measures in the following areas:
  - *Hemodialysis Vascular Access*
  - *Dialysis Monitoring*

- The Committee evaluated 6 measures against NQF's standard evaluation criteria—3 new measures and 3 measures undergoing maintenance review.

Renal Measures 2015-2017
Before Member and Public Commenting

	Maintenance	New	Total
Measures under consideration	3	3	6
Measures recommended for endorsement	1	3	4
Measures not recommended for endorsement	2	--	2
Reasons for not recommending	Importance – 0 Scientific Acceptability –2 Overall – 0 Competing Measure – X	Importance – 0 Scientific Acceptability – 0 Overall – 0 Competing Measure – X	

Recommended Measures *Before* Member and Public Commenting

- *Hemodialysis Vascular Access – 2 measures*
  - *Types of Measures: 2 intermediate outcome; 0 process; 0 composite; 0 outcome*
- *Dialysis Monitoring – 2 measures*
  - *Types of Measures: 0 intermediate outcome; 1 process; 0 composite; 1 outcome*

Comments Received

Renal Measures 2015-2017 Comments Received

- 17 comments received from 2 NQF member organizations.
- Comments received across 3 measures:
  - *2977: Hemodialysis Vascular Access: Standardized Fistula Rate*
  - *2979: Standardized Transfusion Ratio(STrR) for Dialysis Facilities*
  - *1463: Standardized Hospitalization Ratio for Dialysis Facilities*

Committee Recommendations following Member and Public Comment:

Reconsideration requests were received on the 2 measures not recommended for endorsement:

- The Committee re-voted on and recommended measure *0369: Standardized Mortality Ration for Dialysis Facilities* for endorsement.
- The Committee upheld its recommendation to not recommend measure *0260: Assessment of Health-related Quality of Life in Dialysis Patients* for endorsement.

Renal Measures 2015-2017
Post Member and Public Commenting

	Maintenance	New	Total
Measures under consideration	3	3	6
Measures recommended for endorsement	2	3	5
Measures not recommended for endorsement	1	0	1
Reasons for not recommending	Importance – 0 Scientific Acceptability –1 Overall – 1 Competing Measure – X	Importance – 0 Scientific Acceptability – 0 Overall – 0 Competing Measure – X	

Renal Measures 2015-2017
Project Timeline and Next Steps

Executive Committee Review and Ratification	December 8, 2016
Appeals	December 12, 2016 – January 10, 2017
Final Report Due	February 22, 2017

Questions?