TO: Consensus Standards Approval Committee (CSAC)

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RE: Renal Member Voting Results

DA: September 1, 2015

The CSAC will review recommendations from the Renal project at its September 8th conference call.

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

Voting for Renal measures closes at 6pm on September 2nd. Voting results will follow this memo as an addendum when available.

Accompanying this memo are the following documents:

1. **Renal Draft Report.** The draft report has been updated to reflect the changes made following the 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, these are noted below. This table lists all 97 comments received, developer responses and the NQF/Standing Committee responses.

CSAC ACTION REQUIRED
Pursuant to the CDP, the CSAC may consider approval of 19 candidate consensus standards for endorsement.

Renal Measures Recommended for Endorsement:

- 0251: Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement (Kidney Quality Care Alliance – KCQA)
- 0256: Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access (University of Michigan/Centers for Medicare and Medicaid Services – UM/CMS)
- 0257: Hemodialysis Vascular Access—Maximizing Placement of Arterial Venous Fistula (AVF) (UM/CMS)
- 0318: Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum (UM/CMS)
- 0321: Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute (Renal Physicians Association – RPA)
- 1423: Minimum spKt/V for Pediatric Hemodialysis Patients (UM/CMS)
- 1424: Monthly Hemoglobin Measurement for Pediatric Patients (UM/CMS)
- 1425: Measurement of nPCR for Pediatric Hemodialysis Patients (UM/CMS)

- 1460: Bloodstream Infection in Hemodialysis Outpatients (Centers for Disease Control and Prevention – CDC)
- 1662: Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy (RPA)
- 1667: Pediatric Kidney Disease : ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL (RPA)
- 2594: Optimal End Stage Renal Disease Starts (Kaiser)
- 2701: Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kg/hour) (KCQA)
- 2704: Minimum Delivered Peritoneal Dialysis Dose (UM/CMS)
- 2706: Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V (UM/CMS)

Renal Measures Recommended for Endorsement with Reserve Status:

- 0249: Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy—Minimum Delivered Hemodialysis Dose (UM/CMS)
- 0255: Measurement of Serum Phosphorus Concentration (UM/CMS)
- 0323: Adult Kidney Disease: Hemodialysis Adequacy: Solute (RPA)
- 1454: Proportion of patients with hypercalcemia (UM/CMS)

Committee evaluated and is not recommending the following measures for endorsement:

- 1660: ESRD Patients Receiving Dialysis: Hemoglobin Level <10 g/dL (RPA)
- 2699: Anemia of Chronic Kidney Disease: Dialysis Facility Standardized Transfusion Ratio (UM/CMS)
- 2700: Ultrafiltration rate greater than 13 ml/kg/hr (UM/CMS)
- 2702: Post-Dialysis Weight Above or Below Target Weight (KCQA)
- 2703: Minimum Delivered Hemodialysis Dose (UM/CMS)
- 2705: Delivered Dose of Dialysis Above Minim (UM/CMS)

BACKGROUND

Renal disease is a leading cause of morbidity and mortality in the United States. More than twenty million adults (10% 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 and high healthcare utilization and costs associated with ESRD, the need to focus on quality measures for patients with renal disease is particularly important.

On May 6-7, 2015, NQF convened a new multi-stakeholder Standing Committee composed of 23 individuals to evaluate 14 NQF-endorsed maintenance measures and 11 new measures and make recommendations for endorsement. Fifteen measures were recommended for endorsement, four measures were recommended for endorsement with reserve status, and the Committee did not recommend six measures.

DRAFT REPORT

The Renal Draft Report presents the results of the evaluation of 25 measures considered under the CDP. Fifteen measures were recommended for endorsement as voluntary consensus standards suitable for

accountability and quality improvement, four measures were recommended for endorsement with reserve status, and the Committee did not recommend six measures. The measures were evaluated against the 2013 version of the measure evaluation criteria.

	MAINTENANCE	NEW	TOTAL
Measures considered	14	11	25
Withdrawn from consideration	5	0	5
Recommended	9	6	15
Recommended with reserve status	4	0	4
Not recommended	0	6	6
Reasons not Recommended	Importance- 0 Scientific Acceptability- 0 Overall- 0	Importance- 3 Scientific Acceptability- 1 Overall- 0	

COMMENTS AND THEIR DISPOSITION

NQF received 97 comments from five organizations (including four member organizations) and individuals 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

Staff reviewed all comments and identified themes for the measure portfolio. During their post-comment conference call, the Standing Committee reviewed the comments, developer responses, and proposed NQF and committee responses. Committee members focused their discussion on measures or topic areas with the most significant and recurring issues. Following are the themes identified from the Renal Public Comment:

Theme 1 - Removal of Upper Boundary and Clarification of Frequency Requirements

During the in-person meeting, Committee members supported endorsement of the following measures [#0249 (Delivered Dose of Hemodialysis Above Minimum), #0318 (Delivered Dose of Peritoneal Dialysis Above Minimum), and # 2704 (Minimum Delivered Peritoneal Dialysis Dose)], on the following conditions:

- The upper spKt/V requirement be removed; and
- The frequency of dialysis visits be clarified and consistent across measures: lowered from four visits a week to three visits or greater a week in order for patients to be included in the denominator.

Comments received supported the stipulations made to revise the measures and, thus, supported the Committee's recommendations.

Committee Response: Requested changes have been made and the Standing Committee stands by its original recommendation.

Theme 2 - Dialysis Access Considerations

A number of measures in the Renal Portfolio focus on either minimizing use of catheters as a dialysis access strategy, or increasing the utilization of AV Fistulas or Grafts. Consistent with the Committee discussions, commenters continued to encourage measure developers and stewards to consider patient characteristics when determining appropriateness of dialysis access type. Specifically, concerns were raised around the premise that catheters are clinically appropriate in some populations, and there may be a preference for not using AV Fistulas with patients in hospice or with short life expectancy.

Committee Response: Improving quality measures to accurately identify the clinically appropriate populations for inclusion and exclusion is evolving. There was significant discussion about potential measure revisions from a recently convened vascular access technical panel which may further clarify these efforts. The Committee was charged with evaluating the measures as submitted and, while measure revisions may be forthcoming based on the Technical Expert Panel recommendations, the NQF criteria ahave been met with the information provided.

Theme 3 – Committee Reconsideration Requests

The developers of the following measures requested reconsideration of the Committee's recommendation. Each developer was provided an opportunity to supply additional information that would support their reconsideration request. Following is a list of the measures reconsidered, their disposition based on the reconsideration, and if not recommended, where the measure failed to meet criteria.

- 1460 Bloodstream Infection in Hemodialysis Outpatients
    - Taking into account the Committee's concerns about the adjusted ranking metric (ARM) aspect of the measure, the developer removed it from the measure. After this update, the Committee changed their decision and recommended this measure for endorsement.
- 1660 ESRD Patients Receiving Dialysis: Hemoglobin Level <9g/dL
    - The Committee reconsidered the measure but they stood by their decision that the gap was not sufficient to warrant a national performance measure.
- 2700 Ultrafiltration rate greater than 13 ml/kg/hr
    - The Committee reconsidered the measure and proceeded to move beyond validity, where the measure originally failed, but ultimately voted to not recommend the measure for endorsement. The Committee also noted that while the measure was very similar to measure #2701, which also focused on ultrafiltration rates, there were important differences, specifically the lack of inclusion of time on dialysis in 2700 and using one day of data which may impact reliability.
- 2703 Minimum Delivered Hemodialysis Dose
    - The developer updated the measure and requested reconsideration of this measure. The Committee determined the new information did not justify reconsideration and upheld their original recommendation stating there was a small performance gap and little room for improvement.
- 2705 Delivered Dose of Dialysis Above Minimum

- Originally, the Committee did not pass this measure on Importance to Measure and Report due to concerns with the evidence sub-criterion. After review of the information provided by the developer during the post-comment call, the Committee decided to reconsider this measure and agreed there was evidence to support this measure. However, the Committee did not feel the gap was sufficient enough to warrant a national performance measure.

REMOVE ENDORSEMENT OF MEASURES

Five measures previously endorsed by NQF were withdrawn from maintenance of endorsement:

Measure	Description	Reason for removal of endorsement
0370: Monitoring hemoglobin levels below target minimum	Percentage of all adult (>=18 years old) hemodialysis or peritoneal dialysis patients with ESRD >=3 months and who had Hb values reported for at least 2 of the 3 study months, who have a mean Hb <10.0 g/dL for a 3 month study period, irrespective of ESA use.	Measure Withdrawn from Consideration
1418: Frequency of Adequacy Measurement for Pediatric Hemodialysis Patients	Percentage of all pediatric (less than18 years) patients receiving in-center hemodialysis or home (irrespective of frequency of dialysis) with documented monthly adequacy measurements (spKt/V) or its components in the calendar month.	The developer stated this measure is being recommended for retirement. The process of measurement frequency is already captured in measure #1423 (Minimum spKt/V for Pediatric Hemodialysis Patients) which measures achievement of dialysis adequacy (target Kt/V). #1423 measure requires that Kt/V be measured monthly in pediatric HD patients therefore a separate process measure will not be needed to assess frequency of measurement. NQF #1418 is not implemented in a public reporting program.
1421: Method of Adequacy Measurement for Pediatric Hemodialysis Patients	Percentage of pediatric (less than 18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis) for whom delivered HD dose was measured by spKt/V as calculated using UKM or Daugirdas II during the reporting period.	The developer stated this measure is being recommended for retirement. Information on the method of adequacy measurement is captured in #1423 (Minimum spKt/V for Pediatric Hemodialysis Patients) which measures achievement of dialysis adequacy (target Kt/V). #1423 requires that the method of calculating the Kt/V measurement be UKM or

Measure	Description	Reason for removal of endorsement
		Daugirdas II, therefore a separate process measure is not needed to assess appropriate measurement method. NQF #1421 is not implemented in a public reporting program.
1666: Adult Kidney Disease : Patients on Erythropoiesis Stimulating Agent (ESA)-- Hemoglobin Level > 12.0 g/Dl	Percentage of calendar months within a 12-month period during which a hemoglobin level is measured for patients aged 18 years and older with a diagnosis of advanced chronic kidney disease (CKD) (stage 4 or 5, not receiving Renal Replacement Therapy [RRT]) or End Stage Renal Disease (ESRD) (who are on hemodialysis or peritoneal dialysis) who are also receiving erythropoiesis-stimulating agent (ESA) therapy have a hemoglobin level > 12.0 g/dL.	RPA decided not to submit 1666 for maintenance as that measure has been determined to be topped out by CMS and retired from the PQRS program.
1668: Adult Kidney Disease: Laboratory Testing (Lipid Profile)	Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period.	RPA experts felt that the science (including the latest KDIGO guidelines) no longer supports annual measurement of lipids for patients with diagnosed CKD as indicated in measure 1668.

Appendix A-Measure Evaluation Summary Tables

Rating Scale: H=High; M=Moderate; L=Low; I=Insufficient; NA=Not Applicable; Y=Yes; N=No

0251 Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement
Submission | Specifications
Description: Percentage of end stage renal disease (ESRD) patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >90 days who: 1. have a functional autogenous AVF (defined as two needles used or a single-needle device) [not one needled used in a two-needle device]} (computed and reported separately); 2. have a functional AV graft (computed and reported separately); or 3. have a catheter but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF or AV graft at least once during the 12-month reporting period (computed and reported separately). + Reporting should be stratified by incident versus prevalent patients, as defined by USRDS. Numerator Statement: Number of patients from the denominator who: 1. have a functional autogenous AVF (defined as two needles used or a single-needle d device) [not one needled used in a two-needle device]} (computed and reported separately); 2. have a functional AV graft (computed and reported separately); or 3. have a catheter but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF or AV graft at least once during the 12-month reporting period (computed and reported separately). + Reporting should be stratified by incident versus prevalent patients, as defined by USRDS. Denominator Statement: All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days. This measure includes both in-center and home hemodialysis patients. Exclusions: None. Adjustment/Stratification: No risk adjustment or risk stratification Level of Analysis: Clinician : Individual Setting of Care: Ambulatory Care : Clinician Office/Clinic, Dialysis Facility Type of Measure: Process Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Paper Medical Records Measure Steward: Kidney Care Quality Alliance (KCQA)
STANDING COMMITTEE MEETING [05/06/2015-05/07/2015] 1. Importance to Measure and Report: **The measure meets the Importance criteria** *(1a. Evidence, 1b. Performance Gap)* 1a. Evidence: **2-H; 14-M; 1-L; 5-I**; 1b. Performance Gap: **3-H; 18-M; 1-L; 0-I** Rationale: • The developer cited the following evidence: Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. All related aspects of the guidelines were graded B (moderately strong evidence). The Committee noted the evidence supported AVF and also noted the evidence did not address all the complex factors that may impact the patient receiving an AVF. They concluded there was evidence to support this measure. • The developer presented data showing a 93.8% mean performance from a review of 1057 hemodialysis

0251 Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement

observed patients drawn from a mix of 53 for-profit and not-for-profit dialysis units. The performance for each individual facility in the pilot ranged from 41% to 100%. The Committee agreed that the data presented indicated there is room 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: **2-H; 14-M; 5-L; 1-I**; 2b. Validity: 2-H; 14-M; 5-L; 1-I

Rationale:

- The Committee expressed many concerns about the specifications of the measure:
  - Some committee members requested the developer clarify if vascular access complications were defined only as complications related to hemodialysis catheters or whether complications related to fistulas and grafts were included in their definition. The developer commented that the measure focuses on assessing the degree of placement instead of following and monitoring complications so a definition was not included in the submission; however, the reference was to catheter-related complications due to the higher degree of complication and infections associated with catheters. The Committee agreed with the developer that treatment of vascular access complication was common practice; however, they alluded to a general need to monitor fistula and graft complications as well.
  - The Committee supported the flexibility of the measure in choosing the best option for the patient, be it an AVF or AV Graft. The developer stated this feature of the measure was based on feedback from the last NQF Renal Steering Committee that requested that two separate measures, one that covered AVF and one that looked at AV Graft, be combined. However, committee members voiced concerns that an evaluation by a vascular surgeon or other qualified surgeon was considered equal to the actual placement of a functional AVF or AV Graft in this measure. The developer stressed that this is for the patient's benefit and that documentation of reasons the patient could not support a permanent access is required. While this feature could be seen as an easy route for meeting the requirement of the measure, the Committee agreed encouraging shared decision-making and incorporating patient-informed choice was a positive aspect of the measure.
- The developer provided 2008 – 2009 critical data element testing that assessed data integrity and inter-rater reliability (IUR) from a sample of 53 dialysis facilities and four nephrology offices.
- At the facility level, IUR had a kappa of 0.8880 with a 95% confidence interval of 0.7484 – 1.00. The physician office testing resulted in a kappa of 0.9152 with a 95% confidence interval of 08349-0.9964. Overall, the Committee agreed the measure was reliable.
- Validity was also assessed at the critical data element level. Following data collection, on-site data audits were performed at 11 of the 53 participating field-test sites/facilities.
- Chart validation results showed high validity for sensitivity at 99.38%, specificity at 85.29%, positive predictive value at 96.99%, and negative predictive value at 96.67%.
- There was a meaningful difference that was defined as a significant spread of greater than 20% between minimum and maximum scores. The performance across facilities in the pilot ranged from 41 to 100%, with a mean of 93.8% in those 53 facilities. Based on this data, the Committee agreed that the meaningful differences between reporting entities supported measure validity.

3. Feasibility: **6-H; 15-M; 1-L; 0-I**

(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 developer stated the measure would be monitored through Current Procedural Terminology (CPT)

0251 Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement
codes, End Stage Renal Disease diagnosis codes (International Classification of Diseases (ICD)-9 and 10) and G-codes for hemodialysis. The Committee inquired into the possible use of CROWNWeb in this measure. The developer stated the measure is specified and tested in a way in which it could be used by CROWNWeb. While they are not certain there is currently a field that would capture the vascular surgeon evaluation aspect of the measure, a field can be added into CROWNWeb if it is deemed appropriate. Committee members supported this conclusion. • The developer pointed out an additional change incorporated into the measure since endorsement was the inclusion of G-codes to help capture the evaluation component more clearly. Several committee members noted that they had not encountered G-codes during their work and thus had concerns about its use in this measure. The developer clarified that G-codes were just one of many ways the data could be collected; CPT and ICD 9 and 10 codes can also be used. Overall, the Committee agreed the measure was feasible.
4. Use and Usability: **4-H; 16-M; 0-L; 2-I** (Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified) Rationale: • This measure has been endorsed since 2007 and although it is currently not in use, the developer stated there are plans for it to be used in public reporting and payment programs, and also plans for its use in quality improvement with external benchmarking to multiple organizations.
5. Related and Competing Measures • This measure was identified as potentially related or competing with: ○ NQF #0256 Minimizing Use of Catheters as Chronic Dialysis Access: Percentage of patient months on maintenance hemodialysis during the last hemodialysis treatment of month with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session. ○ NQF #0257 Maximizing Placement of Arterial Venous Fistula (AVF): Percentage of patient months for patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles. ○ NQF #2594 Optimal End Stage Renal Disease (ESRD) Starts: Optimal End Stage Renal Disease (ESRD) Starts is the percentage of new ESRD patients during the measurement period who experience a planned start of renal replacement therapy by receiving a preemptive kidney transplant, by initiating home dialysis, or by initiating outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft. • During the In-Person meeting, the Committee assessed the measures based on the NQF decision logic to identify related and competing measures and determined that 2594 was not related to or competing with 0251, 0256, and 0257. The Committee did determine 0251, 0256 and 0257 were competing measures, however, did not encourage further harmonization at this time. The Committee noted the measures were not incompatible with one another and emphasized the need to not lose some of the value of the individual measures by harmonizing.
Standing Committee Recommendation for Endorsement: 19-Y; 2-N
6. Public and Member Comment • Five commenters were generally in support of this measure.

0256 Minimizing Use of Catheters as Chronic Dialysis Access
Submission | **Specifications**

0256 Minimizing Use of Catheters as Chronic Dialysis Access

Description: Percentage of patient months on maintenance hemodialysis during the last HD treatment of month with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.

Numerator Statement: Number of patient months in the denominator who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the month.

Denominator Statement: Adult hemodialysis patients who have had End Stage Renal Disease (ESRD) for greater than 90 days as of the first day of the reporting month.

Exclusions: Exclusions that are implicit in the denominator definition include pediatric patients (<18 years old), and acute hemodialysis patients (hemodialysis patients who have had ESRD for less than 91 days). There are no additional exclusions for this measure.

Adjustment/Stratification: No risk adjustment or risk stratification

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 (CMS)

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: **21-Y; 0-N**; 1b. Performance Gap: **5-H; 17-M; 0-L; 0-I**

Rationale:

- The developers updated the Committee on continued review of the two paired dialysis access measures, 0256 and 0257. The University of Michigan, on behalf of Center for Medicare and Medicaid Services (CMS), convened a Vascular Access Technical Expert Panel (TEP) that met in late April 2015, shortly before the NQF Renal In-Person meeting, in order to recommend potential revisions to these two measures that would address concerns in the community about unintended consequences of promoting fistula and graft use over catheter use, especially around possible circumstances where facilities should not be penalized for prolonged catheter use. While the general consensus among the TEP members was that chronic catheter use should continue to be discouraged, the developer was not able to share more details since the deliberations report and recommendations were not finalized at the time of the meeting. The developer does not expect the results to be available to share by the post-meeting call.
- The developer provided data that includes a Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines and Clinical Practice Recommendations 2006 Updates and a 2006 TEP review. All related aspects of the guidelines were graded B (moderately strong evidence) except for 2 sections which were graded A (strong evidence). The 2006 TEP was in support of the measure and the Committee agreed there was sufficient evidence to support this measure.
- The developer provided January 2013-December 2013 CROWNWeb performance data indicating that the rate of minimizing catheter use is about 90%.The Committee agreed there is room for improvement.
- Disparities data were provided that imply that there are statistically significant changes in performance scores depending on sex, race, ethnicity, age, and diabetes as primary causes of ESRD. The developer states that in the absence of biological effects explaining these differences, risk adjustment for these factors would potentially mask disparities in care. However, the developer is willing to provide supplementary analyses to allow the Committee to look at variation by socioeconomic status (SES) within the constraints of indicators that are currently available. While the Committee had some concerns about the actual performance and the extent performance could be improved, they concluded there was still room to improve.

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

0256 Minimizing Use of Catheters as Chronic Dialysis Access

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

2a. Reliability: **4-H; 16-M; 2-L; 0-I**; 2b. Validity: **8-H; 14-M; 0-L; 0-I**

Rationale:

- The developer presented testing at the measure score level using January 2013 – December 2013 CROWNWeb and claims data to calculate the inter-unit reliability (IUR) for the 12 month period to assess the reliability of this measure. The analysis showed an IUR of .078, which is high and suggests 78% of variation in the measure is attributed to between-facility variation.
- The Committee requested clarification on the reliability of comparing claims to CROWNWeb stating the submission provided an absolute difference of three percent. Based on concerns during a workgroup call, the developer re-ran the analysis to compare agreement using Medicare claims and CROWNWeb using more current data. When the data were re-run, the absolute difference went away and produced similar statistically significant kappas.. The developer updated the measure submission to include this updated analysis.
- The Committee noted it was appropriate that pediatric patients were not included in the patient population. The Committee agreed the measure was well-defined and that the testing results suggest this measure is reliable.
- The Committee requested information on how missing data are handled. The developer clarified that patients, for whom data are missing are included in the numerator and would be considered non-compliant.
- Empirical validity testing conducted at the performance measure score level was provided by the developer. The developers utilized Poisson regression models to measure the association between facility level quintiles of performance scores and the standardized mortality ratio (SMR) and standardized hospitalization ratio (SHR) measures. The Committee agreed that with the p-value of less than .0001 for SMR and SHR indicated the measure was valid.

3. Feasibility: **21-H; 1-M; 0-L; 0-I**

(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 measure data is collected from administrative claims and CROWNWeb.
- The Committee inquired as to whether the developer intended to migrate from using both claims and CROWNWeb to using CROWNWeb solely. They were advised that while CROWNWeb is the preferred data source, it is still fairly new and will need more time in the field before measures can be completely converted to CROWNWeb. At this time, no decision has been confirmed for a migration thus claims are still incorporated into this measure and other similar measures.
- Committee members agreed that the data elements are generated and used by healthcare personnel as part of the care delivery process.

4. Use and Usability: **22-H; 0-M; 0-L; 0-I**

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified)

Rationale:

- Committee members noted that the measure is publicly reported in Dialysis Facility Compare (DFC) and is used in a payment program, End Stage Renal Disease Quality Incentive Program (ESRD QIP).

5. Related and Competing Measures

- This measure was identified as potentially related or competing with:
    - NQF #0251 Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for

0256 Minimizing Use of Catheters as Chronic Dialysis Access

Placement: Percentage of end stage renal disease (ESRD) patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >90 days who:

- 1. have a functional autogenous AVF (defined as two needles used or a single-needle device [NOT one needle used in a two-needle device]) (computed and reported separately); 2. have a functional AV graft (computed and reported separately); or 3. have a catheter, but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF or AV graft at least once during the 12-month reporting period (computed and reported separately). + Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.
- NQF #0257 Maximizing Placement of Arterial Venous Fistula (AVF): Percentage of patient months for patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles.
- NQF #2594 Optimal End Stage Renal Disease (ESRD) Starts: Optimal End Stage Renal Disease (ESRD) Starts is the percentage of new ESRD patients during the measurement period who experience a planned start of renal replacement therapy by receiving a preemptive kidney transplant, by initiating home dialysis or by initiating outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft.

- During the In-Person meeting, the Committee assessed the measures based on the NQF Decision Logic to Identify Related and Competing Measures and determined that 2594 was not related to or competing with 0251, 0256, and 0257. The Committee did determine 0251, 0256 and 0257 were competing measures, however, did not encourage further harmonization at this time. The Committee noted the measures were not incompatible with one another and emphasized the need to not lose some of the value of the individual measures by harmonizing.

Standing Committee Recommendation for Endorsement: 22-Y; 0-N

6. Public and Member Comment

- Three commenters were generally in support of the measure.
- One commenter raised concerns around the premise that catheters are clinically appropriate in some populations, and there may be the opportunity to exclude patients in hospice or with short life expectancy from receiving an AVF.
  - Developer Response: Ongoing measure development includes the consideration of refinements to this measure that may mitigate the unintended consequences regarding special populations with limited life expectancy. The current NQF-endorsed vascular access quality measures supported by CMS are linked measures, incentivizing AV fistula use as a positive outcome and prolonged use of tunneled catheter as a negative outcome. These linked measures incorporate the clinical equipoise regarding these access types, effectively creating three categories of outcomes (AV fistula=positive; AV graft= neutral; prolonged use of tunneled catheter= negative).
  - Committee Response: Improving quality measures to accurately identify the clinically appropriate populations for inclusion and exclusion is evolving. There was significant discussion about potential measure revisions from a recently convened vascular access technical panel which may further clarify these efforts. The Committee was charged with evaluating the measures as submitted and while measure revisions may be forthcoming based on the Technical Expert Panel recommendations, the NQF criteria are met with the information provided.

0257 Maximizing Placement of Arterial Venous Fistula (AVF)

Submission | **Specifications**

Description: Percentage of patient months for patients on maintenance hemodialysis during the last hemodialysis (HD) treatment of month using an autogenous AV fistula with two needles.

Numerator Statement: Number of patient months in the denominator who were using an autogenous AV fistula with two needles at the last HD treatment of month

Denominator Statement: For both CROWNWeb and Claims data, the denominator will include all hemodialysis patients who are at least 18 years old and have had End Stage Renal Disease (ESRD) for greater than 90 days as of the first day of the reporting month.

Exclusions: Exclusions that are implicit in the denominator definition include pediatric patients (<18 years old) and acute hemodialysis patients (hemodialysis patients who have had ESRDS for less than 91 days). There are no additional exclusions for this measure.

Adjustment/Stratification: No risk adjustment or risk stratification

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 (CMS)

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: **2-H; 19-M; 0-L; 0-I**; 1b. Performance Gap: **5-H; 17-M; 0-L; 0-I**

Rationale:

- The developers updated the Committee on continued review of the two paired dialysis access measures, 0256 and 0257. The University of Michigan, on behalf of CMS, convened a Vascular Access Technical Expert Panel (TEP) that met prior to the NQF Renal In-Person meeting in late April 2015 to recommend potential revisions to these two measures. These revisions would address concerns about unintended consequences of promoting fistula and graft use over catheter use, especially around possible circumstances where facilities should not be penalized for prolonged catheter use. While the general consensus among the TEP members was that chronic catheter use should continue to be discouraged, the developer was not able to share more details since the deliberations report and recommendations were not finalized.
- The developer provided evidence that includes a Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines and Clinical Practice Recommendations 2006 Updates and a 2006 TEP review. All related aspects of the guidelines were graded B (moderately strong evidence) except for 2 sections which were graded A (strong evidence). The 2006 TEP was in support of the measure and the Committee agreed there was sufficient evidence to support this measure. Updates to the evidence form were made by the developer based on Committee discussion.
- Upon review of the evidence submitted, the Committee noted that the measure is an intermediate outcome measure, which correlates AV fistula use to impact on mortality. The evidence, grade B from KDOCI, supports that AV fistula is the primary choice. The evidence does not explicitly address the complexity of the issue of decision-making related to fistula versus graft as it related to minimizing the pain and suffering of the patient over time. But overall, the Committee agreed there was evidence to support this measure.
- Based on the data provided on measure performance, the Committee recognized a disparity in performance gap, although not large. Similar to the other measure in the pair, the Committee felt that it should be listed as a disparity-sensitive gap.

0257 Maximizing Placement of Arterial Venous Fistula (AVF)

- CROWNWeb data from 2013 was presented to demonstrate opportunity for improvement. The mean percentage of patient months with AV fistula was 67%; i.e., 67 percent of patients are dialyzing with AV fistulas. The first quartile was 60% and the third quartile was 75%. No national goal rate is stated, but it can be inferred from the bottom quartile that there is room 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: 0-H; 17-M; 1-L; 2-I; 2b. Validity: 2-H; 12-M; 4-L; 4-I

Rationale:

- The Committee noted the exclusions were consistent with the paired measure, there was no risk adjustment and there seemed to be meaningful difference in terms of quality by looking at fistulas and catheters.
- They further noted that the testing provided indicated inter-unit agreement of 0.76 CROWNWeb versus claims with a kappa of .91 for fistula use. During the In-Person meeting, the UM KECC team indicated they had conducted additional, updated analysis on correlation between claims and CROWNWeb; the Committee asked to see this additional data. The updated data were shared with the Committee and measure submission forms updated to reflect the additional analysis.
- In terms of validity, testing was done at the performance measure level with analysis run to calculate association between facility level quintiles of performance scores with the standardized mortality ratio (SMR) and standardized hospitalization ratio (SHR) measures. Results indicate the percent of patients dialyzing with an AV fistula was significantly associated with both the SMR and SHR.
- As with the catheter measure, the developer was asked if they had done any additional analysis. They confirmed the recalculation of the fistula measure using Medicare claims, calendar year 2013, as well as CROWNWeb data, calendar year 2013. The agreement for the fistula measure in both sources was statistically significant with a kappa of .92 and the correlation between the data sources was .869.
- The developer updated the measure description, numerator statement, numerator details, and calculation algorithm to remove reference to fistula with “two needles” to reflect Committee comments.
- Overall, the Committee agreed the developer provided data indicated the measure was reliable and valid.

3. Feasibility: 14-H; 8-M; 0-L; 0-I

(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 measure is routinely generated via CROWNWeb and Medicare forms so the consensus was that there essentially were no concerns with the feasibility of this measure.

4. Use and Usability: 5-H; 10-M; 4-L; 4-I

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified)

Rationale:

- Committee members noted that the measure is publicly reported in Dialysis Facility Compare (DFC) and is used in a payment program, End Stage Renal Disease Quality Incentive Program (ESRD QIP).
- The developer reports use of fistula increased from 66.8% in January 2013 to 67.9% in December 2013.
- The Committee discussed the possibility of unintended consequences of only measuring fistula rates, however, concluded that this is a factor to consider during development and is not something that can be resolved by the Committee at this time.

- 5. Related and Competing Measures
- This measure was identified as potentially related or competing with:

0257 Maximizing Placement of Arterial Venous Fistula (AVF)

- NQF #0251 Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement: Percentage of end stage renal disease (ESRD) patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >90 days who 1. have a functional autogenous AVF (defined as two needles used or a single-needle device [NOT one needle used in a two-needle device]) (computed and reported separately); 2. have a functional AV graft (computed and reported separately); or 3. have a catheter, but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF or AV graft at least once during the 12-month reporting period (computed and reported separately). + Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.
- NQF #0256 Minimizing Use of Catheters as Chronic Dialysis Access: Percentage of patient months on maintenance hemodialysis during the last hemodialysis (HD) treatment of month with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.
- NQF #2594 Optimal End Stage Renal Disease (ESRD) Starts: Optimal End Stage Renal Disease (ESRD) Starts is the percentage of new ESRD patients during the measurement period who experience a planned start of renal replacement therapy by receiving a preemptive kidney transplant, by initiating home dialysis or by initiating outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft.

- During the In-Person meeting, the Committee assessed the measures based on the NQF Decision Logic to Identify Related and Competing Measures and determined that 2594 was not related to or competing with 0251, 0256, and 0257. The Committee did determine 0251, 0256 and 0257 were competing measures, however, did not encourage further harmonization at this time. The Committee noted the measures were not incompatible with one another and emphasized the need to not lose some of the value of the individual measures by harmonizing.

Standing Committee Recommendation for Endorsement: 17-Y; 5-N

Rationale

- The Committee voiced various concerns about this measure and had some level of discomfort in recommending endorsement without the knowledge of future revisions as an outcome of the TEP. However, the decision was to vote on the measure as presented and allow staff to work with the developer to ensure appropriate monitoring of revisions and need to bring a revised measure back in the future.

6. Public and Member Comment

- Four commenters were generally in support of the measure.
- Two commenter raised concerns around the premise that catheters are clinically appropriate in some populations, and there may be the opportunity to exclude patients in hospice or with short life expectancy from receiving an AVF.
  - Developer Response: Ongoing measure development includes the consideration of refinements to this measure that may mitigate the unintended consequences regarding special populations with limited life expectancy. The current NQF-endorsed vascular access quality measures supported by CMS are linked measures, incentivizing AV fistula use as a positive outcome and prolonged use of tunneled catheter as a negative outcome. These linked measures incorporate the clinical equipoise regarding these access types, effectively creating three categories of outcomes (AV fistula=positive; AV graft= neutral; prolonged use of tunneled catheter= negative).
  - Committee Response: Improving quality measures to accurately identify the clinically appropriate populations for inclusion and exclusion is evolving. There was significant discussion about potential measure revisions from a recently convened vascular access technical panel

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which may further clarify these efforts. The Committee was charged with evaluating the measures as submitted and while measure revisions may be forthcoming based on the Technical Expert Panel recommendations, the NQF criteria are met with the information provided.

0318 Delivered Dose of Peritoneal Dialysis Above Minimum

Submission | **Specifications**

Description: Percentage of all patient months for patients = 18 whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V >= 1.7 and spKt/V =< 8.5. (dialytic + residual)

Numerator Statement: Number of patient months in the denominator whose delivered peritoneal dialysis was a weekly Kt/Vurea of between spKt/V >= 1.7 and spKt/V =< 8.5 (dialytic + residual)

Denominator Statement: To be included in the denominator for a particular month the patient must have had ESRD for greater than 90 days, must be >=18 years old, and must be assigned to that facility for the entire month.

Exclusions: Exclusions that are implicit in the denominator definition include

1) pediatric patients (<18 years old)

2) all patients who have had End Stage Renal Disease (ESRD) for <91 days, and

3) patients who have not been in the facility for the entire month.

There are no additional exclusions for this measure.

Adjustment/Stratification: No risk adjustment or risk stratification

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 (CMS)

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: **3-H; 20-M; 0-L; 0-I**; 1b. Performance Gap: **4-H; 16-M; 1-L; 1-I**

Rationale:

- The developer presented clinical guidelines for peritoneal dialysis adequacy (Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines and Clinical Practice Recommendations 2006 Updates). The guidelines were rated as Grade B. Committee members noted that the evidence supports the lower boundary (spKt/V >= 1.7), but no evidence was presented for the upper bound (spKt/V <= 8.5). The developer clarified that the upper bounds were included in the specifications as an administrative means of ensuring that the data integrity was maintained, and to be transparent with how the measure is calculated. The majority of committee members voted evidence as medium or high with the stipulation that the upper bound be removed.
- The developer indicated that analysis using CROWNWeb and Medicare claims data from January to December 2013 indicate the mean percentage of patients with peritoneal adequacy measurements that achieved the target at least once in four months was 78.6% (SD=17.3%). These results indicate that on average, facilities are meeting the Kt/Vurea guidelines in 79% peritoneal dialysis patients. The sample size included 45,554 peritoneal dialysis patients at 1,528 facilities with at least 11 peritoneal dialysis patients.
- The developer presented data on disparities; the Committee agreed that the test results appear to be statistically significant, but do not appear to be clinically significant.

0318 Delivered Dose of Peritoneal Dialysis Above Minimum

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: 3-H; 17-M; 1-L; 0-I; 2b. Validity: 1-H; 17-M; 3-L; 0-I

Rationale:

- Committee members questioned how a facility would be assessed when patients do not have a spKt/V measured within the four month period. The developer responded that the missing measurement would be counted against the facility; as the intent of the measure is to report and meet a minimum threshold.
- The developer presented January 2013 – December 2013 claims data used to calculate the inter-unit reliability (IUR) for the twelve month period to assess the reliability of this measure; 1528 facilities and 45,554 peritoneal dialysis patients were included in the analysis. The IUR of 0.911 is high and suggests 91% of variation in the measure is attributed to between-facility variation. The confidence interval is (0.905, 0.917). The Committee agreed that the reliability data presented was sufficient.
- Validity was assessed by calculating the Spearman correlation between this measure and the 2013 standardized mortality ratio (SMR) and standardized hospitalization ratio (SHR). The Spearman correlation between this measure and the 2013 standardized mortality ratio as measured by the NQF endorsed SMR (NQF 0369) for the same facility is -0.008 (p-value=0.7744). The Spearman correlation between this measure and the 2013 standardized hospitalization ratio as measured by the 2013 SHR (NQF 1463) is -0.139 (p-value <0.0001).
- The developer reports that the Spearman correlation estimates indicate higher facility level percentages of patients at the facility that achieve the Kt/V target is associated with lower standardized hospitalization, respectively, although the magnitude of the association is low. A very weak association between facility level percentages of patients achieving the Kt/V target and lower standardized mortality was observed and in the expected direction; however, the correlation coefficient was not statistically significant.

3. Feasibility: 14-H; 8-M; 0-L; 0-I

(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 for this measure is CROWNWeb. If a patient's data are missing in CROWNWeb, Medicare claims are used. The Committee agreed that the data are collected and used by healthcare personnel during provision of care and they had no concerns with feasibility.

4. Use and Usability: 16-H; 6-M; 0-L; 0-I

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified)

Rationale:

- The developer described two current uses of the measure for public reporting and payment programs. The Committee did not have any concerns with usability and use of this measure.

5. Related and Competing Measures

- This measure was identified as potentially related or competing with:
    - NQF# 0321 Peritoneal Dialysis Adequacy: Solute: Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease ESRD receiving peritoneal dialysis who have a total Kt/V >= 1.7 per week measured once every 4 months
    - NQF #2704 Minimum Delivered Peritoneal Dialysis Dose: Percentage of all patient months whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V >= 1.7 (adult) or 1.8 (pediatric) and spKt/V =< 8.5. (dialytic + residual)

0318 Delivered Dose of Peritoneal Dialysis Above Minimum

- NQF #2706 Pediatric Peritoneal Dialysis Adequacy-Achievement of Target Kt V: Percent of pediatric peritoneal dialysis patient-months whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V = 1.8 and spKt/V< 8.5. (dialytic + residual)
- NQF #2705 Delivered Dose of Dialysis Above Minimum: Percentage of all patient months for patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.

- The Committee was unable to discuss related and competing measures during the in-person meeting and had the opportunity to do so during the post-comment call. NQF #2705 was not recommended by the Committee so that measure was not included in the discussion. The Committee concluded that the remaining measures were related but not competing. The Committee recommended and the developers agreed to work together to harmonize these measures where possible.

Standing Committee Recommendation for Endorsement: 22-Y; 0-N

6. Public and Member Comment

- Three commenters were generally in support of the measure. Two of these measures requested confirmation that requested changes by the Committee had been made.
  - Developer Response: Based on the discussion that took place at the NQF Standing Committee meeting, CMS has made the following revisions to the measure submission:
    - The upper threshold for spKt/V values has been removed from the specifications
    - The specifications were edited to provide more clear descriptions of the numerator, denominator, exclusions, and calculation algorithm. These calculation clarifications are not material changes with respect to the documentation that the Committee reviewed in May.
    - The evidence form was revised to include the abstracts for the pieces of evidence listed in 1a.8.2.
  - Committee Response: Requested changes have been made and the Standing Committee stands by its original recommendation

0321 Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving peritoneal dialysis who have a total Kt/V >= 1.7 per week measured once every 4 months

Numerator Statement: Patients who have a total Kt/V >= 1.7 per week measured once every 4 months

Denominator Statement: All patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis

Exclusions: There are no denominator exceptions for this measure.

Adjustment/Stratification: No risk adjustment or risk stratification

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

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Dialysis Facility, Home Health, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other (Domiciliary, Rest Home, or Custodial Care Services)

Type of Measure: Outcome

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

Measure Steward: Renal Physicians Association (RPA)

0321 Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: 11-H; 11-M; 0-L; 0-I; 1b. Performance Gap: 4-H; 16-M; 1-L; 1-I

Rationale:

- The evidence presented for this intermediate clinical outcome measure is based on the Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines and Clinical Practice Recommendations, 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access that are rated as Grade B. The guidelines state that for a patient with residual kidney function, the minimal delivered dose of total small solute clearance should be the total peritoneal and kidney Kt/Vurea of at least 1.7 per week. For patients without residual kidney function, the minimal delivered dose of total small solute clearance should be a peritoneal Kt/V urea of at least 1.7 per week measured within the first month after starting dialysis therapy and at least once every four months thereafter. Committee members agreed that there was sufficient evidence presented.
- The developers clarified that per the last United States Renal Data System (USRDS) annual data report, this metric is being met by 87% of patients. Committee members had concerns that this was older data, was not physician or clinician level data, and that more information could be provided. Members questioned if there is room for improvement, however it was noted that there could be a greater gap in care due to the fact that disparities data were not presented. Overall, the Committee agreed there was 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: 2-H; 16-M; 4-L; 0-I; 2b. Validity: 5-H; 16-M; 1-L; 0-I

Rationale:

- Critical data element testing was performed at the individual physician/group practice level. Data abstracted from patient records were used to calculate inter-rater reliability for the measure, and analysis included percent agreement of 99.74% and Kappa statistic of 0.00 with a 95% confidence interval of (-1.93,1.93) to adjust for chance agreement. The Committee agreed that the results presented demonstrate sufficient reliability.
- The Committee recommended that it would be helpful to have clarity on how long the residual kidney function is allowed to carry forward, that perhaps at four months it drops if it hasn't been repeated for the total Kt/V calculation. The developer confirmed residual function is measured every 4 months along with the calculation of Kt/V.
- Members also noted that they would like to see more data on a minimum sample size and whether or not having a minimum number of eleven patients (similar to the facility level measures) could make the measure more meaningful.
- Validity was assessed at the measure score level by expert panel evaluation. Face validity of the measure score as an indicator of quality was consistent. Committee members agreed that the results presented demonstrate sufficient validity.

3. Feasibility: 6-H; 15-M; 1-L; 0-I

(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 for this measure are from administrative claims, clinical database/registry, and abstracted from electronic health record. The required data elements are routinely generated as part of patient care. Committee members agreed that collection of this data is feasible.

0321 Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute

4. Use and Usability: 15-H; 7-M; 0-L; 0-I

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified)

Rationale:

- The developer described three current uses of the measure for public reporting, payment and quality improvement programs (e.g., Physician Quality Reporting System (PQRS), Physician Compare, and Renal Physician Association (RPA) Internal Quality Improvement initiatives). No unintended consequences were identified. The Committee did not have concerns with usability and use of this measure.

5. Related and Competing Measures

- This measure was identified as potentially related or competing with:
    - NQF# 0318 Peritoneal Dialysis Adequacy – Delivered Dose of Peritoneal Dialysis Above Minimum: Percentage of all patient months for patients = 18 whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V >= 1.7 and spKt/V =< 8.5. (dialytic + residual)
    - NQF #2704 Minimum Delivered Peritoneal Dialysis Dose: Percentage of all patient months whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V >= 1.7 (adult) or 1.8 (pediatric) and spKt/V =< 8.5. (dialytic + residual)
    - NQF #2706 Pediatric Peritoneal Dialysis Adequacy-Achievement of Target Kt V: Percent of pediatric peritoneal dialysis patient-months whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V = 1.8 and spKt/V< 8.5. (dialytic + residual)
    - NQF#2705 Delivered Dose of Dialysis Above Minimum: Percentage of all patient months for patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
- The Committee was unable to discuss related and competing measures during the in-person meeting and had the opportunity to do so during the post-comment call. NQF #2705 was not recommended by the Committee so that measure was not included in the discussion. The Committee concluded that the remaining measures were related but not competing. The Committee recommended and the developers agreed to work together to harmonize these measures where possible.

Standing Committee Recommendation for Endorsement: 21-Y; 1-N

6. Public and Member Comment

- Five commenters were generally in support of this measure.

1423 Minimum spKt/V for Pediatric Hemodialysis Patients

Submission | **Specifications**

Description: Percentage of patient months for all pediatric (<18 years old) in-center HD patients who have been on hemodialysis for more than 90 days and dialyzing 3 or 4 times weekly whose average delivered dose of hemodialysis using the UKM or Daugirdas II formula) was between spKt/V = 1.2 and spKt/V<5.0.

Numerator Statement: Number of patient months for patients in the denominator whose delivered dose of hemodialysis (calculated from the last measurement of the month (using the UKM or Daugirdas II formula) was between a spKt/V >= 1.2 and spKt/V =<5.0.

Denominator Statement: To be included in the denominator for particular month, a patient must have been <18 years old, have had ESRD for greater than 90 days, dialyzing 3 or 4 times weekly, and must be assigned to that facility for the entire month.

Exclusions: Exclusions that are implicit in the denominator definition include

1423 Minimum spKt/V for Pediatric Hemodialysis Patients

1) patients on home hemodialysis,
2) patients on ESRD less than 91 days
3) patients receiving dialysis less than 3x/week or greater than 4x/week and
4) patients who have not been in the facility for the entire reporting month
There are no additional exclusions for this measure.
Adjustment/Stratification: No risk adjustment or risk stratification
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 (CMS)

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: **0-H; 9-M; 11-L; 3-I**; Insufficient Evidence with Exception: **14-Y; 9-N**; 1b. Performance Gap: 1-H; 17-M; 2-L; 2-I

Rationale:

- One clinical practice guideline (Clinical Practice Guidelines for Hemodialysis Adequacy: Kidney Disease Outcomes Quality Initiative (KDOQI) Guideline 8. Pediatric Hemodialysis Prescription and Adequacy: 2006) and a systemic review of literature by a technical expert panel (TEP) are referenced. The KDOQI guideline was graded as A (strong evidence).
- The developer clarified that the specifications are for patients dialyzing three or four times a week whose average delivered dose of hemodialysis using urea kinetic modelling (UKM) or Daugirdas II are a single pool Kt/V of 1.2. The rationale is to ensure that children who are dialyzing four times a week would still be evaluated for adequate dialysis.
- The Committee noted that as in many pediatric measures, there is not much evidence for the pediatric population. The measure is based on adult data with the assumption that children should be doing at least as well as adults do, and the Committee noted that is a reasonable position to take. The referenced literature indicates some need for a higher dose of dialysis for children with respect to growth and development. Committee members questioned the evidence for a rationale for an upper limit (spKt/V<5).
- Committee members raised concerns about the measure as constructed and that using a single pool Kt/V in patients dialyzed at different frequencies is the wrong tool. The UKM or Daugirdas formulas are designed for a fixed number of dialysis treatments a week, not "three or four". For a variable number of treatments a method such as weekly standard Kt/V must be used. Committee members noted that when looking at varying frequencies of dialysis, rather than using a single pool Kt/V, the tool that should be used is a continuous tool, like the standard Kt/V. Some Committee members also raised concerns that setting a minimum of 1.2 Kt/V, with whatever frequency, could be a disincentive to put patients on increasing frequency of dialysis because that would not change their Kt/V. The incentive would be to increase time during single sessions instead of more frequent dialysis, and that is not as efficient a treatment as increasing the frequency would be.
- The developer noted that analysis using CROWNWeb and Medicare claims data from January to December 2013 indicate a mean score of 85.6% (13.0. The sample size included 180 hemodialysis patients and 1,195 patient months in facilities with at least 11 eligible pediatric patients.
- The Committee did not reach consensus on the exception to evidence criterion. The major concerns were the evidence supporting three times and not four times per week. Only a small number of patients require

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dialysis more than three times per week and this is a very important measure for pediatricians.
2. Scientific Acceptability of Measure Properties: Consensus not reached on the Scientific Acceptability criteria *(2a. Reliability - precise specifications, testing; 2b. Validity - testing, threats to validity)* 2a. Reliability: 1-H; 11-M; 7-L; 2-I; Second vote: 0-H; 11-M; 11-L; 1-I; 2b. Validity: 0-H; 18-M; 4-L; 1-I Rationale: • The developer used CROWNWeb and Medicare claims data from January 2013 – December 2013 to calculate the inter-unit reliability (IUR) for the 12 month period to assess the reliability of this measure. The IUR is 0.812 with the confidence interval being (0.633, 0.931). This suggests that 81% of variation in the measure is attributed to between facility variance. • The Committee did not reach consensus while voting on reliability. There were concerns with specifications. Members noted that the distinction in the Daugirdas II method and the UKM are fundamentally different and would yield differing inter-unit and inter-organizational variation. One member noted that the lack of specificity in the blood drawing techniques and the timing within a dialysis week all impact the result of the tests. • Validity was assessed at the measure score level and was established on the basis of face validity. Clinical technical expert panel members agreed that this measure will improve quality of care for pediatric hemodialysis patients.
3. Feasibility: 14-H; 8-M; 1-L; 0-I (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 primary data source for this measure is administrative claims and electronic clinical data through CROWNWeb. All data elements are in defined fields in a combination of electronic sources. The Committee had no major concerns with feasibility.
4. Use and Usability: 17-H; 6-M; 0-L; 0-I (Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified) Rationale: • The measure is currently publicly reported in Dialysis Facility Compare and the End Stage Renal Disease Quality Incentive Program (ESRD QID) payment program. All Medicare-certified facilities that are eligible for the measure, and have at least 11 patients are considered accountable entities for QIP. The Committee had no major concerns with use and usability.
5. Related and Competing Measures • This measure was identified as potentially related or competing with: ○ NQF# 0249 Hemodialysis Adequacy Clinical Performance Measure III-Hemodialysis Adequacy--HD Adequacy--Minimum Delivered: Percentage of all adult (>=18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V >= 1.2 during the study period. ○ NQF# 0323 Adult Kidney Disease-Hemodialysis Adequacy-Solute: Percentage of calendar months within a 12-month period during which patients aged 18 years or older with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis three times a week for >= 90 days have a spKt/V >= 1.2 ○ NQF #2703 Minimum Delivered Hemodialysis Dose: Percentage of all patient months for patients whose average delivered dose of hemodialysis using the UKM or Daugirdas II formula) was

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between spKt/V >= 1.2 and spKt/V =< 5.0

- NQF#2705 Delivered Dose of Dialysis Above Minimum: Percentage of all patient months for patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.

- The Committee was unable to discuss related and competing measures during the in-person meeting and had the opportunity to do so during the post-comment call. NQF #2703 and NQF #2705 were not recommended by the Committee, so those measures were included in the discussion. The Committee concluded that the remaining measures were related but not competing. The Committee recommended and the developers agreed to work together to harmonize these measures where possible.

Standing Committee Recommendation for Endorsement: In-Person: 10-Y; 13-N; Post-Comment Call: 20-Y; 0-N

- Based on the updates provided by the developer during the July 30 post-comment call, the Committee was able to reach consensus on this measure and recommended it for endorsement.

6. Public and Member Comment

- Two commenters supported the endorsement of this measure with the condition that the upper limit be removed.
  - Developer Response: The measure has been revised in response to concerns from the NQF Standing Committee regarding the appropriateness of single pool Kt/V for measuring Kt/V in patients who are dialyzing 3 or 4 times per week. The 2010 Technical Expert Panel members that recommended the original measure were contacted and asked to consider a revision to limit the measure to pediatric patients on three times a week dialysis. A majority of the TEP members supported this revision. Further information about the decision to revise the measure is provided in 2b2 (Validity Testing). The upper threshold for spKt/V values has been removed from the specifications. The specifications were edited to provide more clear descriptions of the numerator, denominator, exclusions, and calculation algorithm. These calculation clarifications are not material changes with respect to the documentation that the Committee reviewed in May.

1424 Monthly Hemoglobin Measurement for Pediatric Patients

Submission | **Specifications**

Description: Percentage of patient months of pediatric (less than 18 years) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients who have monthly measures for hemoglobin during the reporting period.

Numerator Statement: Number of patient months of pediatric (less than 18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients with a measurement of hemoglobin during the reporting period. The hemoglobin value reported for the end of each reporting month (end-of-month hemoglobin) is used for the calculation.

Denominator Statement: All patient months for pediatric (less than 18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients under the care of the dialysis facility for the entire reporting month.

Exclusions: Exclusions that are implicit in the denominator definition include all patients >=18 years and those who have not been in the facility the entire reporting month (transient patients). There are no additional exclusions for this measure.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Dialysis Facility

1424 Monthly Hemoglobin Measurement for Pediatric Patients

Type of Measure: Process

Data Source: Electronic Clinical Data

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

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: 3-H; 19-M; 1-L; 0-I; 1b. Performance Gap: 2-H; 18-M; 1-L; 0-I

Rationale:

- For this process measure, the developer provided data that includes a Kidney Disease Outcomes Quality Initiative (KDOQI) clinical guideline and a systematic review of literature. The recommendation is defined as "expert opinion", based on TEP consensus thus was not graded. In addition, the Committee noted a systematic review summary that was supportive of the measure.
- The developer provided 2013 CROWNWeb clinical data (January 2013-December 2013). With a mean performance score of 75%, the Committee acknowledged there was a performance gap.
- The developer indicated, and the Committee agreed, that the sample size used to determine performance scores was too small to display useful disparities data.

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: 0-H; 22-M; 1-L; 0-I; 2b. Validity: 0-H; 22-M; 1-L; 0-I

Rationale:

- Reliability was assessed at the performance measure score by calculating facility-level Pearson correlation coefficients between the current performance month and the preceding month for reporting months during January 2013 – December 2013 at 59 facilities. The Pearson correlation coefficients of each pair of the current and the preceding months ranged from 0.78 to 0.98. All were statistically significant with a p-value less than 0.0001.
- While the Committee expressed some concerns over the small sample size for pediatric practices and CROWNweb data transmission issues described in more detail in the overarching issues section of this report, the Committee concluded that overall this measure was reliable.
- The developer used January 2013 – December 2013 CROWNWeb data to calculate facility level monthly and annual performance scores. Fifty-nine facilities that had at least 11 eligible patients were included in the testing and analysis; a total of 1,280 patients were included. They computed the Spearman correlation to assess the association between the annual performance scores and the NQF endorsed (0369) standardized mortality ratio (SMR) using the 2013 SMR.
- Spearman correlation coefficient was -0.20, p=0.13. The developer notes this suggests that facilities with a higher percentage of pediatric patients (calculated as patient months) with hemoglobin measured is associated with a lower risk of mortality relative to facilities with a lower percentage of pediatric patients with hemoglobin measured. The result is however not statistically significant.
- This measure is being maintained on the basis of face validity. The measurement of hemoglobin as a dialysis quality measure was initially developed and approved by a Clinical Technical Expert Panel (TEP), which agreed that this quality measure is important in the assessment of the quality of care for pediatric dialysis patients. The Committee agreed that the results indicate sufficient face validity.

3. Feasibility: 14-H; 7-M; 1-L; 0-I

(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:

1424 Monthly Hemoglobin Measurement for Pediatric Patients

- The measure data is collected from CROWNWeb. Committee members agreed that the data elements are generated and used by healthcare personnel as part of the care delivery process.

4. Use and Usability: 2-H; 17-M; 1-L; 3-I

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified)

Rationale:

- The Committee voiced concern that the measure is currently not in use in a public program despite being endorsed since 2011. The developer clarified that, while the Center for Medicare and Medicaid Services (CMS) is not currently using the measure and is still considering possible future use, the measure is available for public use and community healthcare networks among other groups are using the measure to collect data for internal quality improvement purposes.
- The Committee agreed the benefits of the measure outweigh any possible unintended consequences.

5. Related and Competing Measures

- This measure was identified as potentially related or competing with:
  - NQF #1667 ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD who are receiving hemodialysis or peritoneal dialysis have a Hemoglobin level <10g/dL
- The Committee concluded the measures were not related or competing and should not be harmonized.

Standing Committee Recommendation for Endorsement: 22-Y; 1-N

6. Public and Member Comment

- Three commenters were generally in support of this measure.

1425 Measurement of nPCR for Pediatric Hemodialysis Patients

Submission | **Specifications**

Description: Percentage of patient months of pediatric (less than 18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements.

Numerator Statement: Number of patient months in the denominator with monthly nPCR measurements.

Denominator Statement: Number of all patient months for pediatric (less than 18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis).

Exclusions: Exclusions that are implicit in the denominator definition include pediatric patients (<18 years old), all patients who have not been in the facility for the entire reporting month, and all home hemodialysis patients. There are no additional exclusions for this measure.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Dialysis Facility

Type of Measure: Process

Data Source: Electronic Clinical Data

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

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1425 Measurement of nPCR for Pediatric Hemodialysis Patients

1a. Evidence: 2-H; 16-M; 0-L; 1-I; 1b. Performance Gap: 2-H; 17-M; 0-L; 0-I

Rationale:

- For this process measure, evidence provided by the developer included two Kidney Disease Outcomes Quality Initiative (KDOQI) clinical guidelines and a 2014 literature review. KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations, 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access: Guideline 8.2.2 was graded as moderately strong evidence (Grade B) and the 2008 KDOQI Clinical Practice Guideline Update for Nutrition in Children with CKD Guideline 1.1 was graded as strong evidence (Grade A). The literature review was supportive of the measure as well.
- While the Committee acknowledged that the evidence and performance gap data were based on the adult population, they concluded the evidence and performance gap could be inferred to support a measure of the pediatric population.
- The developer provided 2013 CROWNWeb clinical data (January 2013-December 2013). With a mean performance score of 80.4%, the Committee acknowledged there was a performance gap.
- The developer indicated, and the Committee agreed, that the sample size used to determine performance scores was too small to display useful disparities data.

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: 2-H; 17-M; 0-L; 0-I; 2b. Validity: 0-H; 19-M; 0-L; 0-I

Rationale:

- Inter-unit reliability (IUR) was calculated using January 2013 – December 2013 CROWNWeb data from a sample of 455 Medicare and non-Medicare pediatric, In-Center Hemodialysis (ICH) patients in 225 facilities. The Committee agreed the overall IUR of 0.985, indicating that 98.5% of the variation in the measure can be attributed to the between-facility differences, suggests the measure is reliable.
- Validity testing was conducted at the measure score level. Face validity was ascertained through review and input from a technical expert panel (TEP). In addition, the developer proved testing data that demonstrated that facilities with at least 11 eligible pediatric patients with recorded nPCR values, had a mean serum albumin of 3.77, while facilities with less than 100% reporting of recorded nPCR values had a mean serum albumin of 4.0. The Committee agreed with the TEP that the measure was statistically significant with a p-value of 0.02.

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

(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 measure data is collected from CROWNWeb. Committee members agreed that the data elements are generated and used by healthcare personnel as part of the care delivery process.

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

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified)

Rationale:

- The Committee voiced concern that the measure is currently not in use in a public program despite receiving time limited endorsement in 2011 and receiving full endorsement in 2014. The developer clarified that, while the Center for Medicaid and Medicare (CMS) is not currently using the measure and is still considering possible future use, the measure is available for public use and community healthcare networks, among other groups, are using the measure to collect data for internal quality improvement purposes.

1425 Measurement of nPCR for Pediatric Hemodialysis Patients

- The Committee agreed the benefits of the measure outweigh any possible unintended consequences.

5. Related and Competing Measures

- No related or competing measures noted.

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

6. Public and Member Comment

- Four commenters were generally supported the measure.

1460 Bloodstream Infection in Hemodialysis Outpatients

Submission | **Specifications**

Description: Standardized Infection Ratio (SIR) of Bloodstream Infections (BSI) will be calculated among patients receiving hemodialysis at outpatient hemodialysis centers.

Numerator Statement: The number of new positive blood culture events based on blood cultures drawn as an outpatient or within 1 calendar day after a hospital admission. A positive blood culture is considered a new event and counted only if it occurred 21 days or more after a previous positive blood culture in the same patient.

Denominator Statement: Number of maintenance hemodialysis patients treated in the outpatient hemodialysis center on the first 2 working days of the month.

Exclusions: Patients receiving inpatient hemodialysis and home hemodialysis are excluded

Adjustment/Stratification: Statistical risk model

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

Setting of Care: Dialysis Facility

Type of Measure: Outcome

Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Imaging/Diagnostic Study, Electronic Clinical Data : Laboratory, Paper Medical Records, Electronic Clinical Data : Pharmacy

Measure Steward: Centers for Disease Control and Prevention (CDC)

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: **19-Y; 0-N**; 1b. Performance Gap: 7-H; 14-M; 0-L; 0-I

Rationale:

- This is a facility-level, endorsed outcome measure that is intended to calculate the Standardized Infection Ratio (SIR) of bloodstream infections amongst patients who receive hemodialysis in outpatient hemodialysis facilities. The National Health and Safety Network (NHSN) allows facilities to calculate and produce their own reports without separate software.
- The developer provides rationale stating that use of this measure is to assist in identifying outbreaks of bloodstream infections, to stimulate improvements in vascular access care, and to stimulate improvements in other infection control practices that have led to subsequent reductions in bloodstream infections.
- Committee members noted that the evidence provided by the developer states that dialysis-related procedures are the cause of many types of blood stream infections. The Committee also noted that the evidence provided for the SIR is as compelling as it was when the measure was initially endorsed in 2011.
- The developer provided 2006 data for performance gap, however, stated that they are currently looking

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at data coming out of the End Stage Renal Disease Quality Incentive Program (ESRD QIP). Developers expect to have more information shortly, but could not provide it at the time of the meeting.

- Committee members noted there is still opportunity to improve the SIR component of the measure and there is significant evidence of a gap in care, specifically when looking at the infection rates listed in the Glomerular Filtration Rate (GFR). The Committee also stated that the renal community has not done their job of decreasing blood stream infection rates as hospitals have done, further emphasizing the gap in care.
- Some committee members noted there would be gaps in African-Americans and elderly patients who receive hemodialysis, but questioned the relatively older data and expressed that the developers may have seen changes occur since 2011, when the measure was endorsed. Ultimately, members of the Committee passed the measure on performance gap.

2. Scientific Acceptability of Measure Properties: <u>The measure does not meet the Scientific Acceptability criteria</u>

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

2a. Reliability: 0-H; 4-M; 3-L; 14-I Reconsideration Reliability: 1-H; 17-M; 0-L; 0-I; Validity: 2-H; 15-M; 1-L; 0-I

<u>Rationale</u>:

- Committee members noted the analysis of performance was completed almost a decade ago and that all analyses completed showed a substantial variation in the rates of reported blood stream infections.
- While the SIR component of the measure is well established, and has clear specifications, the ARM portion of the measure was identified as not well specified. Committee members stated it was challenging to evaluate a measure with the level of specificity on methodology provided by the developer and requested updated data.
- Members of the Committee encouraged developers to use a broader standardization methodology rather than using access alone. Overall, committee members did not find the specifications on the methodology proposed for the Adjusted Ranking Metric (ARM) portion of the measure and data provided by the developer to be insufficient and the measure failed at reliability. Based on these comments, the developer removed the ARM aspect of the measure.
- Committee members also expressed concerns about validity being reassessed now that NHSN is available. The developer was encouraged to provide more current data in order to accurate review many aspects of this measure, including reliability and validity.
- During the August 3rd post-comment call, the Committee decided to reconsider this measure and agreed the measure was reliable and valid once the ARM was removed from the measure. It was noted that with this revision, the measure is much more closely aligned to the originally endorsed specification, with the only revision being the addition of SIR.

3. Feasibility: 2-H; 9-M; 7-L; 0-I

(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 data for this measure's testing was abstracted from paper records and electronic health records. The ongoing data collection for this measure is reported through the NHSN and available via electronic fields.
- Data are collected or generated and used by healthcare personnel during provision of care.

4. Use and Usability: 5-H; 10-M; 3-L; 0-I

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified)

<u>Rationale</u>:

- The Committee noted the measure was currently used for Public Health/Disease Surveillance and public

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reporting. As of January 2015, approximately 6000 outpatient dialysis facilities are reporting to NHSN.

5. Related and Competing Measures

- No related or competing measures noted.

Standing Committee Recommendation for Endorsement: 18-Y; 1-N

6. Public and Member Comment

- While commenters agreed the tracking of bloodstream infection is extremely important, three commenters expressed concerns about the methodology used especially in regards to the inclusion of the Adjusted Ranking Metric (ARM) and Standardized Infection Ratio (SIR). Three commenters supported the Committee's decision to not endorse this measure. One commenter felt the measure should be endorsed despite methodological concerns.
    - Based on public and Committee comments, the developer removed the adjusted ranking metric (ARM) from the measure. Developer Response: Specifically, mention of the ARM will be removed from "De.3. Brief description of the measure" and description of the ARM calculation will be removed from "S.18. Calculation algorithm/measure logic". The standardized infection ratio (SIR) and corresponding calculation of the SIR will remain in the measure. All other elements of the measure and measure specifications will remain unchanged. The sections describing: measure importance, scientific acceptability, usability and use, and related and competing measures will remain unchanged.

1662 Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

Submission | Specifications

Description: Percentage of patients aged 18 years and older with a diagnosis of CKD (not receiving RRT) and proteinuria who were prescribed ACE inhibitor or ARB therapy within a 12-month period

Numerator Statement: Patients who were prescribed ACE inhibitor or ARB therapy within a 12-month period

*The above list of medications/drug names is based on clinical guidelines and other evidence. The specified drugs were selected based on the strength of evidence for their clinical effectiveness. This list of selected drugs may not be all-inclusive or current. Physicians and other health care professionals should refer to the FDA's web site page entitled "Drug Safety Communications" for up-to-date drug recall and alert information when prescribing medications.

Definitions:

Prescribed – May include prescription given to the patient for ACE Inhibitor or ARB therapy OR patient already taking ACE Inhibitor or ARB therapy as documented in the current medication list

Denominator Statement: All patients aged 18 years and older with the diagnosis of CKD (Stages 1-5, not receiving RRT) and proteinuria

Definitions:

Proteinuria:

1. >300mg of albumin in the urine per 24 hours OR

2. ACR >300 mcg/mg creatinine OR

3. Protein to creatinine ratio > 0.3 mg/mg creatinine

RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation

1662 Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

Exclusions: Documentation of medical reason(s) for not prescribing ACE inhibitor or ARB therapy (eg, pregnancy, history of angioedema, cough due to ACE Inhibitor or ARB therapy, allergy to medications, other medical reasons)

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

Adjustment/Stratification: No risk adjustment or risk stratification

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

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Dialysis Facility, Home Health, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other (Domiciliary, Rest Home, or Custodial Care Services)

Type of Measure: Process

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

Measure Steward: Renal Physicians Association (RPA)

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: 1-H; 20-M; 0-L; 0-I; 1b. Performance Gap: 1-H; 20-M; 0-L; 0-I

Rationale:

- Developers provided the update of the 2012 Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines as evidence to support the measure in which the developer's Work Group suggests that an angiotensin receptor blocker (ARB) or angiotensin converting enzyme inhibitor (ACE-I) be used in non-diabetic adults with non-dialysis CKD and urine albumin excretion of 30 to 300 mg per 24 hours (or equivalent) in whom treatment with BP-lowering drugs is indicated. This was graded 2D, very low evidence suggested by the Work Group. Also, the Work Group recommends that an ARB or ACE-I be used in non-diabetic adults with CKD ND and urine albumin excretion >300 mg per 24 hours (or equivalent) in whom treatment with BP-lowering drugs is indicated. This was graded 1B, moderate evidence recommended by the Work Group.
- Committee members discussed the adequacy of evidence provided, noting it is applicable to the process of care measured; however, the measure, as specified, is not limited to those with hypertension.
- The developer notes that among CKD patients, the use of ACEIs/ARBs is 56-57%, which is significantly lower than the 71-76% for those identified as having hypertension or diabetes. Among CKD patients with cardiovascular disease, 61% use a lipid lowering agent.
- The developer reports that, based on Center for Medicare and Medicaid Services (CMS) Physician Quality Reporting Initiative (PQRI) (now known as Physician Quality Reporting System (PQRS)) 2008 claims data, there is a gap in care in that 44.9% of patients reported on did not receive the optimal care.
- It is also noted by developers that African-Americans have the highest rate of hypertension-related End Stage Renal Disease (ESRD), exceeding other racial and ethnic groups resulting in hypertension remaining a close second to Diabetes Mellitus (DM) as the leading cause of ESRD in the African-American community.
- It was noted that the majority of patients that would be included in the denominator may not be under a nephrologist's care, thus the gap is perceived to be relatively high.

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: 0-H; 16-M; 4-L; 1-I; 2b. Validity: 0-H; 20-M; 1-L; 0-I

Rationale:

1662 Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

- Developers provided data abstracted from patient records in 2008 that were used to calculate an inter-rater reliability of the measure. This analysis included a 93.15% agreement and kappa statistic of 0.8047 with the 95% confidence interval between 0.6395- 0.9699 to adjust for chance agreement.
- Committee members noted the specifications of the measure were well defined and precisely specified. The members of the Committee noted that validity presented was based on input by an expert panel, where that panel rated the measure a mean 4.7 on a 5 point scale (with 10 members giving a rating of four and nine members rating it as a five).
- Data were presented from the CMS PRQI claims option. In 2008, 45% of patients failed to receive optimal care and significant variations in performance were noted in the program.
- Based on the data provided, the Committee deemed the measure as both reliable and valid.

3. Feasibility: 0-H; 18-M; 3-L; 0-I

(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:

- Data is generated and used by healthcare personnel during the provision of care. Members of the Committee questioned whether or not urine albumin results could be captured when using electronic health records (EHRs). Developers responded by stating that within the Veterans Health Administration (VHA) EHR the data could be captured but could not specify with respect to any others.
- Committee members noted that having the measure could potentially advance the agenda of making searchable albumin urea results, also making it easier to populate potential patient registries and undertake or advance population management of those with CKD.

4. Use and Usability: 10-H; 8-M; 2-L; 1-I

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified)

Rationale:

- The measure is currently in use and is included in the Renal Physicians Association (RPA) Quality Improvement (QI) registry that uses e-specifications and provides for internal QI to specific organizations. Planned usage provided by the developer includes public reporting, professional certification or a recognition program.
- Committee members noted that the measure was the right type of measure that should be used when evaluating different health plans and could also be linked to accountability and payment.

5. Related and Competing Measures

- This measure was identified as potentially related or competing with:
    - 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%): Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy
- The Committee was unable to discuss related and competing measures during the in-person meeting and had the opportunity to do so during the post-comment call. The Committee concluded that the remaining measures were related but not competing. The Committee recommended and the developers agreed to work together to harmonize these measures where possible.

Standing Committee Recommendation for Endorsement: 20-Y; 1-N

6. Public and Member Comment

- Five commenters were generally in support of this measure. One of these commenters noted the

1662 Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy

measure could be improved by more specificity regarding many aspects of the measure.

- Developer Response: The RPA appreciates ASN's feedback. We agree with the recommendation that the measure should specify a UPCR threshold of 500mg/g or a UACR threshold of 300mg/g.

1667 Pediatric Kidney Disease : ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL

Submission | **Specifications**

Description: Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL

Numerator Statement: Calendar months during which patients have a hemoglobin level < 10 g/dL

Denominator Statement: All calendar months during which patients aged 17 years and younger with a diagnosis of ESRD are receiving hemodialysis or peritoneal dialysis

Exclusions: Documentation of medical reason(s) for patient having a hemoglobin level < 10 g/dL (eg, patients who have non-renal etiologies of anemia [eg, sickle cell anemia or other hemoglobinopathies, hypersplenism, primary bone marrow disease, anemia related to chemotherapy for diagnosis of malignancy, post-operative bleeding, active bloodstream or peritoneal infection], other medical reasons) Note: PCPI recommends that physicians document specific reasons for exception in patient medical record.

Adjustment/Stratification: No risk adjustment or risk stratification

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

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Dialysis Facility, Home Health, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other (Domiciliary, Rest Home (eg Assisted Living Facility), or Custodial Care Services)

Type of Measure: Intermediate Outcome

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

Measure Steward: Renal Physicians Association

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: 5-H; 13-M; 3-L; 1-I; 1b. Performance Gap: 10-H; 13-M; 0-L; 0-I

Rationale:

- For this intermediate outcome measure, the developer provided evidence that includes a Kidney Disease Outcomes Quality Initiative (KDOQI) clinical guideline and a systematic review of literature. Based on the KDOQI evidence the Committee graded this measure as moderately strong.
- The Committee agreed there was strong evidence supporting the measure. Specifically that in dialysis and non-dialysis patients with chronic kidney disease (CKD) receiving erythropoietin-stimulating agent (ESA) therapy, the hemoglobin target should generally be in the range of 11.0 to 12.0 g/dL. This was based on the results of 14 randomized controlled trials (RCTs) in dialysis patients and 15 RCTs in non-dialysis patients. Evidence for setting a Hemoglobin Level less than 10g/dL as the floor was not included in this submission but the Committee noted they were aware of evidence that supported the developer's decision to set the threshold at 10.
- The developer provided data from the 2008 Physician Quality Reporting System (PQRS), which demonstrated a mean of 36.51% of patients did not receive optimal treatment (11 to 12 g/dL). The

1667 Pediatric Kidney Disease : ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL
developers noted disparities in anemia care in the African-American population, which also has a higher prevalence of CKD. • The Committee concluded there was an opportunity for improvement with 20% of patients with hemoglobin less than 10 gm/dL.
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: 1-H; 8-M; 4L; 10-I; Second vote: 1-H; 15-M; 1-L; 6-I; 2b. Validity: 3-H; 18-M; 0-L; 1-I <u>Rationale</u>: • The measure was tested at the critical data element level, using inter-rater reliability for medical record abstraction with a kappa of 0.986 in the adult population. Committee members voiced concern that the measure was not tested in children, the target population of this measure. Additionally, the kappa listed was for a data element that was no longer in the measure so the Committee noted it was not relevant to the review of this measure. • Initially, the Committee failed the measure at the reliability criterion. After further discussion and clarification from the developer that the reliability testing results would not change if tested in a pediatric population because the process was the same for both populations, the Committee requested to revote and passed the measure on reliability. • A technical expert panel was used to assess face validity of the measure with a mean rating of 4.37 out of 5. The Committee agreed the measure was valid.
3. Feasibility: 10-H; 13-M; 0-L; 0-I (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 measure data can be collected from administrative claims, clinical database/registry and abstracted from electronic health record. Committee members agreed that the data elements are generated and used by healthcare personnel as part of the care delivery process.
4. Use and Usability: 14-H; 9-M; 0-L; 0-I (Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified) <u>Rationale</u>: • Committee members noted that the measure is publicly reported and is used in payment and quality improvement programs. • Data submitted by the developer demonstrates a slight improvement over the past 4 years. • The Committee agreed the benefits of the measure outweigh any possible unintended consequences.

5. Related and Competing Measures
• This measure was identified as potentially related or competing with:
  ○ NQF #1660 ESRD Patients Receiving Dialysis: Hemoglobin Level <9g/dL: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD who are receiving hemodialysis or peritoneal dialysis have a Hemoglobin level <9g/dL
  ○ NQF #1424 Monthly Hemoglobin Measurement for Pediatric Patients: Percentage of patient months of pediatric (less than 18 years) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients who have monthly measures for hemoglobin during the reporting period.
• NQF #1660 was not recommended by the Committee, so the Committee will not discuss the harmonization of these two measures. The Committee concluded there was substantial differences

1667 Pediatric Kidney Disease : ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL

between #1667 and #1424, most specifically that #1424 is a process measure and #1660 an intermediate outcome measure. While they have similar focus areas, they were determined not to be related or competing.

Standing Committee Recommendation for Endorsement: 20-Y; 3-N

6. Public and Member Comment

- Four commenters were generally in support of this measure. One of these commenters expressed concerns regarding the population listed.
    - Developer Response: The RPA appreciates APSN's support and feedback. The RPA is willing to modify the age from 17 years or younger to <18 years. The measure numerator is specified as "Calendar months during which patients have a hemoglobin level < 10 g/dL" and the denominator as "All calendar months during which patients aged 17 years and younger with a diagnosis of ESRD are receiving hemodialysis or peritoneal dialysis".

2594 Optimal End Stage Renal Disease (ESRD) Starts

Submission | **Specifications**

Description: Optimal End Stage Renal Disease (ESRD) Starts is the percentage of new ESRD patients during the measurement period who experience a planned start of renal replacement therapy by receiving a preemptive kidney transplant, by initiating home dialysis, or by initiating outpatient in-center hemodialysis via arteriovenous fistula or arteriovenous graft.

Numerator Statement: The number of new ESRD patients who initiate renal replacement therapy in the twelve month measurement period with an optimal ESRD therapy (specific optimal ESRD therapies are defined in section S.6).

Denominator Statement: The number of patients who receive a preemptive kidney transplant or initiate long-term dialysis therapy (do not recover kidney function by 90 days) for the first time in the twelve month measurement period

Exclusions: None

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Integrated Delivery System, Population : Regional, Clinician : Team

Setting of Care: Ambulatory Care : Clinician Office/Clinic, Dialysis Facility

Type of Measure: Process

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

Measure Steward: The Permanente Federation

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: 6-H; 16-M; 0-L; 0-I; 1b. Performance Gap: 18-H; 4-M; 0-L; 0-I

Rationale:

- The evidence is based on four clinical practice guidelines including Kidney Disease Outcomes Quality Initiative (KDOQI) Guidelines 2006 Update – Vascular Access; United Kingdom Renal Association Vascular Access for Hemodialysis 5th Edition, Vascular Access Society guidelines and the Canadian Society of Nephrology. In addition, there was systematic review evidence submitted. In its entirety, the Committee agreed the evidence provided supported this multi-component measure.

2594 Optimal End Stage Renal Disease (ESRD) Starts

- Various committee members stated their support for the importance of the measure and its ability to drive improvements in care prior to initiation of dialysis.
- The Committee questioned if formal adaptation of the measure changed care across the Permanente Federation. The developer indicated improvement has been seen across regions and they have also noticed growth in home peritoneal dialysis as well.
- Performance scores across the Kaiser Permanente (KP) Regions for the last three years are shown in a table and graphically in the appendix in the submission. Over six consecutive semi-annual measurement periods, the KP national mean has improved from 47.0% in December 2011 to 57.7% in June 2014. For the most recent measurement period (July 1, 2013 to June 30, 2014) the total number of new ESRD patients was 2681, ranging from 87 to 1147 patients in the six measured Kaiser Permanente regions. The initial regional minimum was 32% and maximum was 64%; most recently the regional minimum was 48% and maximum was 61%.
- The data submitted by the developer indicated a performance gap and supported the value of creating a national performance measure.

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: 10-H; 10-M; 1-L; 0-I; 2b. Validity: 6-H; 13-M; 2-L; 0-I

Rationale:

- The developer tested the accuracy of the measure by assessing total element accuracy, denominator and numerator accuracy combined, and comparing the match proportion to the developer's hypothesized value of .9 and a 95% confidence interval. Pediatric patients are currently included in the denominator as confirmed by the developer; however, there was considerable discussion about the appropriateness of their inclusion. A good proportion of pediatric patients should be covered by peritoneal dialysis and there is a growing number having pre-emptive transplants. The numbers of pediatric patients are very small and it is not practical to put a fistula or graft in most children. One of the pediatric experts explained that for the pediatric patient, the goal should be pre-emptive transplant rather than fistula or graft. The developer expressed willingness to reconsider the pediatric portion of the measure and to bring the results to the post-comment call. At the post-comment call, the developer confirmed the pediatric portion of the measure was removed.
- The Committee discussed accountability and whether individual clinicians have an opportunity provide optimal starts if they practice in a hospital where 50% of their patients present at the emergency department. The developer indicated that the measure suggests a minimum of 50 patients within a year to report the measure and that it is not appropriate for use in units serving less than 50 patients per a year such as small pediatric units and individual practitioners.
- Overall, the testing data indicated accuracy was very good. The positive predictive value was excellent at 0.94 and negative predictive value at 0.79. The developer demonstrated sufficient validity as an indicator of quality.
- In gaining an understanding of the specification, the Committee asked about use of the Center for Medicare and Medicaid Services (CMS) 2728: End Stage Renal Disease Medical Evidence Report Medicare Entitlement And/Or Patient Registration form. The developer had mentioned in opening statements that all information necessary to calculate the measure is included in that form. It was explained that the information was presented to demonstrate how the measure may be utilized outside of the Kaiser system; however, the 2728 was not utilized and has not been validated for calculation of the measure.

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

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

2594 Optimal End Stage Renal Disease (ESRD) Starts

Rationale:

- Based on the information submitted, there was confusion around the audience for the measure. Specifically clarification was requested on if the measure was intended to assess quality of care provided by integrated delivery systems, hospitals, physicians, or other levels. The developer clarified the measure is currently utilized in an integrated delivery system and re-iterated difficulty in using the measure in any type of unit with less than 50 patients. The developer reports that CMS collects all data required by the measure using Form 2728, thus it could be utilized more broadly by health plans and in Federal programs.

4. Use and Usability: 4-H; 11-M; 6-L; 0-I

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified)

Rationale:

- The measure is currently used in six Kaiser regions for quality improvement and accountability. Kaiser plans to submit it to CMS where there is potential for the measure to be used as a Physician Quality Reporting System (PQRS) measure.
- A potential unintended consequence of the measure is that it could drive programs with a lot of urgent starts to doing urgent start peritoneal dialysis, which may or may not be clinically appropriate, and drive clinical behaviors where the result is unknown. The developer indicated this has not been the case in their history of measure use, but it would be something that would require consideration in future adaptations of the measure outside of Kaiser Permanente.

5. Related and Competing Measures

- This measure was identified as potentially related or competing with:
    - NQF #0251 Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement: Percentage of end stage renal disease (ESRD) patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis >90 days who 1. have a functional autogenous AVF (defined as two needles used or a single-needle device [NOT one needle used in a two-needle device]) (computed and reported separately); 2. have a functional AV graft (computed and reported separately); or 3. have a catheter, but have been seen/evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for a functional autogenous AVF or AV graft at least once during the 12-month reporting period (computed and reported separately). + Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.
    - NQF #0256 Minimizing Use of Catheters as Chronic Dialysis Access: Percentage of patient months on maintenance hemodialysis during the last HD treatment of month with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.
    - NQF #0257 Maximizing Placement of Arterial Venous Fistula (AVF): Percentage of patient months for patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles.
- During the In-Person meeting, the Committee assessed the measures based on the NQF Decision Logic to Identify Related and Competing Measures and determined that 2594 was not related to or competing with 0251, 0256, and 0257. The Committee did determine 0251, 0256 and 0257 were competing measures, however, did not encourage further harmonization at this time. The Committee noted the measures were not incompatible with one another and emphasized the need to not lose some of the value of the individual measures by harmonizing.

Standing Committee Recommendation for Endorsement: 17-Y; 3-N

Rationale

2594 Optimal End Stage Renal Disease (ESRD) Starts

- The Committee requested the developer assess potential revisions to the measure submission related to inclusion of the pediatric population and also greater clarity of level of analysis. They specifically indicated the measure should not be reported at the individual clinician level.

6. Public and Member Comment

- One commenter supported the measure for endorsement and one did not.
- Three additional commenters supported the concept of the measure but had concerns with the construction of the measure. They expressed the measure was only feasible in fully integrated delivery care systems or large physician groups and could not be applied to dialysis facilities, or even ESRD Seamless Care Organizations (ESCOs), because neither includes CKD patients. Commenters suggested exclusions that address scenarios in which a permanent access may not be appropriately identified and also listed potential unintended consequences of implementing this measure.
    - Developer Response:
        - Intended level of analysis (health care entities appropriate to measure): Due to the check box nature of the online application process, it is difficult to describe on the application how this measure can best be used to improve outcomes for patients who are approaching ESRD. As pointed out by both KCP and RPA and also as stated several times in the application, the use is neither appropriate nor intended for dialysis providers who generally do not see patients before ESRD and have little or no opportunity to educate and coordinate care before ESRD. The entities that can impact Optimal ESRD Starts are CMS, commercial health plans, integrated care systems with CKD patients (not ESCOs) and large nephrology practices/nephrology associations with more than 50 new ESRD patients per year.
        - Patients not previously managed by nephrologists: The 40% of patients not assigned to a nephrologist until they start dialysis, as noted by KCP and RPA, are the exact patients this measure can help address when applied at the payer level. In America today, with the presence of electronic laboratory data, every patient with advanced chronic kidney disease can be identified, and then educated about dialysis modalities and kidney transplantation, referred to a nephrologist and be prepared before ESRD. In most cases, the abnormal labs (creatinine, urine protein) were paid for by CMS or a health insurance plan and it is in their best interest and is their responsibility to reach out to these patients and bring them into a process leading to an Optimal ESRD Start.
        - At the nephrologist level, patients who reach ESRD without seeing a nephrologist may not be attributed to the nephrologist who takes on their care. Pre-ESRD patients under the management of a nephrologist and team however, share the responsibility to help patients have an Optimal ESRD Start. And when sufficient numbers of new ESRD patients can be grouped together (50 or more per year), the performance of the nephrologist and their teams may be measured.
        - Additional exclusions: Before discussing individual proposed denominator exclusions, we would like to point out that the Optimal ESRD Starts target could never be 100% for a number of reasons, but that the 2012 35.5% US outcome is far below what can be accomplished. The goal is to have systems in place to identify and support the majority of patients approaching ESRD, and we must keep an eye to the larger mission. Furthermore, every exclusion means more data elements must be collected, as well as tested for reliability and validity.
        - The third exclusion suggested by both KCP and RPA is actually in place, not as an exclusion but defined in the denominator statement: “The population being measured are patients age 18 and over who 1) receive a preemptive kidney transplant (having

2594 Optimal End Stage Renal Disease (ESRD) Starts

never received outpatient dialysis), including simultaneous pancreas and kidney transplant, plus 2) patients age 18 and over initiating long-term maintenance dialysis who do not recover kidney function by 90 days." This is 90 days as opposed to the suggested 4 months. Of course the longer the waiting time, the more patients will recover GFR and be able to stop dialysis. However, the calculation of the metric already requires a 90 day waiting period for acute renal failure recovery, and there needs to be a compromise to keep the results more current and meaningful. Since the vast majority of patients who will recover have recovered by 90 days, we feel that is an adequate time period.

- The first two proposed exclusions from both the KCP and the RPA involve decisions for the frail elderly which is an area of much interest in the renal literature in the last couple years. We agree that Fistula First is not the correct approach for all patients and that the frail elderly probably do need a different pathway to ESRD, including the option to not start dialysis (such patients are not in the denominator), and the use of grafts or even catheters for a trial or for a planned short duration of dialysis. At this time the medical evidence is not clear about an ideal pathway for such patients. Within KP, we are discussing alternative programs for the frail elderly. We expect that if this measure is endorsed, by the time this measure is up for re-endorsement in 3 years there may be sufficient medical evidence and global agreement to provide an exclusion for these patients. We would be happy to work with your organizations on this.
- In the area of unintended consequences, we agree that these specific situations bear close monitoring. 1) In the case of promoting urgent start PD, we view this as a very good thing and it is included in the numerator definition. We believe in Home Dialysis first unless patients clearly are incapable. It is difficult to imagine urgent start PD being inappropriately used in an unqualified candidate in order to game the system. But even if such a patient quickly failed PD, there is no penalty in the measure for switching to in-center hemodialysis later. 2) Single needle in fistula with second line in catheter – our view is that this is not optimal, exposes the patient to catheter sepsis and is a failure of the system to prepare the patient. We recognize that sometimes the fistula is not quite ready when the patient has to start hemodialysis and recognize that the perfect algorithm for fistula placement may never be discovered. This is one reason why the measure's target will never be 100%, but such failures should be looked at as opportunities to improve the system for future patients. 3) Low socioeconomic status: All patients deserve the chance for an Optimal ESRD Start, regardless of their socioeconomic status. We recognize the reality of current disparities in care but hope that if they do exist in this process and are brought into the light, that there will be an opportunity for better outcomes in the future.

2701 Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kg/hour)

Submission | **Specifications**

Description: Percentage of adult in-center hemodialysis patients in the facility whose average ultrafiltration rate (UFR) is >/= 13 ml/kg/hour.

Numerator Statement: Number of patients* from the denominator whose average UFR >13 ml/kg/hour who receive an average of <240 minutes per treatment during the calculation period.**

*To address the fact that patients may contribute varying amounts of time to the annual denominator population, results will be reported using a "patient-month" construction.

2701 Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kg/hour)

** The calculation period is defined as the same week that the monthly Kt/V is drawn.

Denominator Statement: Number of adult in-center hemodialysis patients in an outpatient dialysis facility undergoing chronic maintenance hemodialysis during the calculation period.

Exclusions: The following patients are excluded from the denominator population:

1. Patients <18 years of age (implicit in denominator definition).
2. Home dialysis patients (implicit in denominator definition).
3. Patients in a facility <30 days.
4. Patients with >4 hemodialysis treatments during the calculation period.
5. Patients with <7 hemodialysis treatments in the facility during the reporting month.
6. Patients without a completed CMS Medical Evidence Form (Form CMS-2728) in the reporting month.
7. Kidney transplant recipients with a functioning graft.
8. Facilities treating <XX adult in-center hemodialysis patients during the reporting month. (Number currently being evaluated.)

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Other– Dialysis facility

Type of Measure: Process

Data Source: Electronic Clinical Data

Measure Steward: Kidney Care Quality Alliance (KCQA)

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: 0-H; 17-M; 2-L; 1-I; 1b. Performance Gap: 3-H; 16-M; 1-L; 0-I

Rationale:

- The measure is based on one Kidney Disease Outcomes Quality Initiative (KDOQI) clinical guideline and a systematic review of the evidence. The KDOQI clinical practice guidelines for hemodialysis adequacy: Achievement of optimal “dry” weight (CPG 5.1) gave the evidence a grade of A (high quality of evidence).
- The developer clarified that the measure requires either having dialyzing patients at an average UFR ≤13 ml/kg/hour and/or dialyzing patients for an average of >240 minutes per session during the reporting period. Upon review of the evidence submitted, the Committee noted that none of the articles reviewed during the systemic review addressed those specific requirements and different cutoffs are listed for both the timeframe and UFR.
- While voicing concerns about evidence, the Committee also noted that many of the dialysis measures focused on renal replacement dose have been recommended for movement into reserve status. In contrast, this measure, focused on a discrete intermediate clinical outcome, begins to breakdown in a more granular way some of the issues that are components of what the original Kt/V intended. The concern is there is not much known about this specific aspect of care because the industry has been concentrating on the more global measure. Upon review of performance gap, the Committee indicated data from 4,252 hemodialysis facilities, with over 412,000 patients, shows that there is significant gap with a median of 10.8%.
- Overall, the Committee agreed there was evidence to support the measure and there was a need for a national performance standard.

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

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

2701 Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kg/hour)

2a. Reliability: 0-H; 19-M; 0-L; 0-I; 2b. Validity: 2-H; 16-M; 1-L; 0-I

Rationale:

- The reliability of the measure was assessed using a repeated measures analysis of variance (ANOVA) test. Using data from 4,252 dialysis facilities, the developer provided data that demonstrated an intra-class correlation coefficient between 0.6 and 0.7, indicating a good level of reliability within facilities over the course of the 12 months They also provided ratios of between-to within- facility correlation ranging 1.7 to 2.3; there is more variation between facilities than within facilities.
- Clarification was requested on the exclusions. The measure excludes four or more treatments per month so it would count three maximum submissions for compliance. Overall, the Committee concluded the measure was reliable and differentiates between facilities.
- The validity of the measure was evaluated by correlating facility-specific scores with each facility's 2013 Standardized Hospitalization Ratio for Admissions measure (SHR, NQF #1463) and Standardized Mortality Ratio* measure (SMR, NQF #0369) scores, using Pearson's Correlation Coefficient. The correlations were in the expected direction and statistically significant. The measure was also tested for validity at the level of the measure score by systematic assessment of face validity by a technical expert panel advising the measure developers. (*SMR specifications are based on a 4-year rolling period.)

3. Feasibility: 2-H; 15-M; 1-L; 1-I

(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 for this measure is CROWNWeb. The measure was tested using data from three KCQA member dialysis organizations, each with the capacity to provide retrospective analyses from a data warehouse/repository. The Committee expressed concerns that CROWNWeb currently only collect one data point and thus would need to be expanded to the three submissions during the week that the monthly Kt/V is drawn in order to monitor this measure. The developer reassured the Committee that they are in conversation with the Centers for Medicare and Medicaid Services (CMS) about adding the two extra data points so batch submitters could batch them together to form the three needed data points and all other facilities would have to manually enter the additional two in the manner they currently manually enter the one data point.
- Overall, the Committee agreed data is being collected or generated and used by healthcare personnel during provision of care.

4. Use and Usability: 2-H; 15-M; 1-L; 1-I

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified)

Rationale:

- While the measure is not currently in use, the Committee agreed it has the potential to be used in public reporting, payment and quality improvement programs.

5. Related and Competing Measures

- This measure was identified as potentially related or competing with:
  - NQF #2700 Ultrafiltration rate greater than 13 ml kg hr: Percentage of patients months for patients an ultrafiltration rate greater than 13 ml/kg/hr
- NQF #2700 was not recommended by the Committee, so the Committee did not discuss the harmonization of these two measures.

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

6. Public and Member Comment

2701 Avoidance of Utilization of High Ultrafiltration Rate (>/= 13 ml/kg/hour)

- Five commenters were generally in support of this measure.

2704 Minimum Delivered Peritoneal Dialysis Dose

Submission | **Specifications**

Description: Percentage of all patient months whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V >= 1.7 (adult) or 1.8 (pediatric) and spKt/V =< 8.5. (dialytic + residual)

Numerator Statement: Number of patient months in the denominator whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V >= 1.7 (adult) or 1.8 (pediatric) and spKt/V =< 8.5. (dialytic + residual)

Denominator Statement: To be included in the denominator for a particular month, the patient must have had ESRD for greater than 90 days, and must be assigned to the facility for the entire month.

Exclusions: Exclusions that are implicit in the denominator definition include

1) all patients who have had ESRD for <91 days and

2) patients who were not assigned to the facility for the entire month.

There are no additional exclusions for this measure.

Adjustment/Stratification: No risk adjustment or risk stratification

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 and Medicaid Services (CMS)

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: 1-H; 18-M; 1-L; 3-I; 1b. Performance Gap: 5-H; 18-M; 0-L; 0-I

Rationale:

- This intermediate clinical outcome measure is supported by Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines (KDOQI CPG) and clinical practice recommendations, 2006 Updates (hemodialysis adequacy, peritoneal adequacy); and KDOQI 2006 Updates CPG for Peritoneal Dialysis Adequacy for pediatrics. The Committee agreed that the body of evidence shows a strong correlation between total solute clearance for urea and morbidity and mortality.
- Committee members noted that the pediatric patient data is based primarily on expert opinion. Members also questioned if there is a difference between the 1.7 Kt/V and 1.8 Kt/V clearance thresholds (in evidence) with pediatric and adults and why there are multiple measures. The developer clarified that they do not report on measures at facilities with fewer than eleven patients; however, many facilities with only a small number of pediatric patients that would not be included in reporting want to report on dialysis adequacy. Committee members questioned why there are minimum case requirements and the developer explained the issue of patient identification where such small samples creates the potential for identity of patients from could be breached and the relevant Center for Medicare and Medicaid Services (CMS) policy. Members expressed concern that the alternative is to have no measurements for pediatric patients.
- The developer presented CROWNWeb and Medicare claims data from January to December 2013 that indicated the mean percentage of patients with peritoneal dialysis adequacy measurements that achieved the target at least once in four months (adult) and six months (pediatric) was 78.1% (SD=17.9%).

2704 Minimum Delivered Peritoneal Dialysis Dose

Committee members agreed that gaps exist.

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: 5-H; 18-M; 0-L; 0-I; 2b. Validity: 0-H; 18-M; 4-L; 0-I

Rationale:

- The developer confirmed that the numerator includes the number of adults who achieved the 1.7 Kt/V threshold within four months, and the number of children who achieve the 1.8 Kt/V threshold within six months. Committee members agreed that the data elements are clearly defined. Again, clinics with less than 11 peritoneal dialysis patients are excluded. If the Kt/V is not measured, the case(s) are still included in the denominator.
- The developer presented testing at the measure score level using January 2013 – December 2013 claims data to calculate the inter-unit reliability (IUR) for the 12 month period to assess the reliability of this measure. The analysis showed IUR is 0.914, which is high and suggests 91% of variation in the measure is attributed to between-facility variation. The confidence interval is (0.908, 0.920).The Committee agreed that the testing results suggest this measure is reliable.
- Validity was assessed by calculating the Spearman correlation between this measure and the 2013 standardized mortality ratio (SMR) and standardized hospitalization ratio (SHR). This measure is also established on the basis of face validity. The measure is a combination of the individual adult and pediatric peritoneal dialysis (PD) Kt/V measures that have been reviewed and approved by Clinical TEPs in 2006, and 2013, respectively.
- The Spearman correlation between this measure and the SMR for the same facility is -0.01 (p-value=0.7169). The Spearman correlation between this measure and the SHR is -0.118 (p-value <0.0001).
- The Spearman correlation estimates indicate higher facility level percentages of patients at the facility that achieve the Kt/V target is associated with lower SHR, although the magnitude of the association is low. A very weak association between facility level percentages of patients achieving the PD Kt/V target and lower SMR was observed and in the expected direction, however the correlation coefficient was not statistically significant. The Committee agreed that the validity testing provided was sufficient.

3. Feasibility: 15-H; 8-M; 0-L; 0-I

(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 noted that the data elements are routinely collected or generated by healthcare personnel during provision of care and are available electronically through CROWNWeb or claims data and they had no major concerns with feasibility.

4. Use and Usability: 8-H; 12-M; 1-L; 1-I

(Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified)

Rationale:

- This measure is a combination of individual adult and pediatric Kt/V measures. The existing NQF endorsed adult PD Kt/V measure (NQF #0318) is currently included in the End Stage Renal Disease Quality Improvement Program (ESRD QIP) beginning with payment year (PY) 2015, and has been reported on Dialysis Facility Compare since January 2013. The Pediatric PD Kt/V (NQF #2705) measure is finalized for ESRD QIP for PY 2018. Both measures were recommended for endorsement by the Committee.
- While the measure is not currently in use, the Committee agreed it has the potential to be used in public reporting, payment and quality improvement programs.

5. Related and Competing Measures

2704 Minimum Delivered Peritoneal Dialysis Dose

- This measure was identified as potentially related or competing with:
  - NQF# 0318 Peritoneal Dialysis Adequacy – Delivered Dose of Peritoneal Dialysis Above Minimum: Percentage of all patient months for patients = 18 whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V >= 1.7 and spKt/V =< 8.5. (dialytic + residual)
  - NQF# 0321 Peritoneal Dialysis Adequacy: Solute: Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease receiving peritoneal dialysis who have a total Kt/V >= 1.7 per week measured once every 4 months
  - NQF #2706 Pediatric Peritoneal Dialysis Adequacy-Achievement of Target Kt V: Percent of pediatric peritoneal dialysis patient-months whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V = 1.8 and spKt/V< 8.5. (dialytic + residual)
  - NQF#2705 Delivered Dose of Dialysis Above Minimum: Percentage of all patient months for patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.
- The Committee was unable to discuss related and competing measures during the in-person meeting and had the opportunity to do so during the post-comment call. NQF #2705 was not recommended by the Committee so that measure was not included in the discussion. The Committee concluded that the remaining measures were related but not competing. The Committee recommended and the developers agreed to work together to harmonize these measures where possible.

Standing Committee Recommendation for Endorsement: 21-Y; 1-N

6. Public and Member Comment

- Three commenters were generally in support of this measure. Two of these commenters requested information on stipulations made by the Standing Committee during the In-Person.
  - Developer Response: The specifications have been revised to use the term "weekly Kt/Vurea" instead of "spKt/V", and we have clarified the measurement period for pediatric patients (within the past 6 months). Allowing facilities to exclude those patients for which RRF cannot be measured could potentially encourage gaming of this measure. This is consistent with the way missing data are treated in this measure (missing Kt/V values are counted against the facility). In addition, our ability to assess whether a facility evaluated RRF is not currently feasible using the data available in CROWNWeb or Medicare Claims.

2706 Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V

Submission | **Specifications**

Description: Percent of pediatric peritoneal dialysis patient-months whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V = 1.8 and spKt/V< 8.5. (dialytic + residual)

Numerator Statement: Percent of pediatric peritoneal dialysis patient-months whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V >= 1.8 and spKt/V =< 8.5. (dialytic + residual)

Denominator Statement: To be included in the denominator for a particular month the patient must have had ESRD for greater than 90 days, must be <18 years old, and must be assigned to that facility for the entire month.

Exclusions: Exclusions that are implicit in the denominator definition include

1) all patients >=18 years old

2) all patients who have had ESRD for <91 days, and

3) patients who have not been in the facility for the entire reporting month

There are no additional exclusions for this measure.

2706 Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V

Adjustment/Stratification: No risk adjustment or risk stratification

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 and Medicaid Services

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

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

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

1a. Evidence: 0-H; 18-M; 2-L; 1-I; 1b. Performance Gap: 14-H; 8-M; 1-L; 0-I

Rationale:

- Evidence for this intermediate clinical outcome measure is supported by the Kidney Disease Outcomes Quality Initiative (KDOQI) 2006 Clinical Practice Guidelines for Peritoneal Dialysis Adequacy. This measure is based on studies in adult peritoneal dialysis patients because an equivalent evidence base does not exist for children. Committee members agreed that when no pediatric-specific data exists, performance measures for adults should serve as the minimum of standard.
- Committee members raised a question regarding residual renal function being measured using combined creatinine clearance and urea clearance. The developer responded that the original intention was for the residual renal function assessment to comport with the adult approach, which is measuring urea clearance, and that would be consistent with the clinical performance recommendations for pediatric measures. However, as currently specified, the pediatric measure is not aligned with the adult approach which is measuring urea clearance only. The pediatric specialists on the Committee indicated that when the combined Kt/V is calculated for either children or adults, they are only using urea. The developers were unable to explain the variation in the specifications from the intention and thus agreed to modify the pediatric measure to be consistent with the adult measures (NQF #2704 and #0318) which use urea clearance to measure residual kidney function.
- The Committee noted the evidence is largely based on the inference from adults that adequate measurement of adequate peritoneal dialysis results in better outcomes. Along with the consensus that when no pediatric specific data exists, performance measures for adults should serve as the minimum of standard.
- The developer presented CROWNWeb data from 2013 showing that only about 50 percent of pediatric patients had a measure of peritoneal dialysis adequacy during the six months of data analyzed. The Committee agreed there was a gap in care.

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: 3-H; 19-M; 0-L; 0-I; 2b. Validity: 0-H; 23-M; 0-L; 0-I

Rationale:

- Committee members questioned how often adequacy is supposed to be measured and the developer clarified that it should be within six months to be consistent with the KDOQI Clinical Practice Recommendations (CPRs). The developers agreed to update the specifications and address the interval of measurement and also correct spKt/V >= 1.7 to spKt/V >= 1.8.
- The developer presented testing at the measure score level using January 2013 – December 2013 claims data to calculate the inter-unit reliability (IUR) for the 12 month period to assess the reliability of this measure. The method for calculating the IUR was developed for measures that are approximately normally distributed across facilities. The IUR is 0.961, which is high and suggests 96% of variation in the measure is attributed to between-facility variation. The confidence interval is (0.936, 0.979).The

2706 Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V
Committee agreed that the testing results suggest this measure is reliable. • Face validity is used to substantiate the validity of this measure. Committee members noted that the small sample size used for validity testing is due to lower numbers of pediatric patients to include in a study. Members agreed that the validity testing results reflect the quality of care provided, and adequately distinguishes good and poor quality.
3. Feasibility: 16-H; 6-M; 0-L; 0-I (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 noted that the data elements are routinely collected or generated by healthcare personnel during provision of care and are available electronically through CROWNWEB or claims data and they had no major concerns with feasibility.
4. Use and Usability: 6-H; 15-M; 1-L; 1-I (Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified) Rationale: • This is a new measure that is not currently in use; however the measure has been finalized for use for payment year (PY) 2018 End Stage Renal Disease Quality Incentive Program (ESRD QIP) in the future. The Committee had no major concerns with use and usability.
5. Related and Competing Measures • This measure was identified as potentially related or competing with: ○ NQF# 0318 Peritoneal Dialysis Adequacy – Delivered Dose of Peritoneal Dialysis Above Minimum: Percentage of all patient months for patients = 18 whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V >= 1.7 and spKt/V =< 8.5. (dialytic + residual) ○ NQF# 0321 Peritoneal Dialysis Adequacy: Solute: Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving peritoneal dialysis who have a total Kt/V >= 1.7 per week measured once every 4 months ○ NQF #2704 Minimum Delivered Peritoneal Dialysis Dose: Percentage of all patient months whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of between spKt/V >= 1.7 (adult) or 1.8 (pediatric) and spKt/V =< 8.5. (dialytic + residual) ○ NQF#2705 Delivered Dose of Dialysis Above Minimum: Percentage of all patient months for patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period • The Committee was unable to discuss related and compet006ing measures during the in-person meeting and had the opportunity to do so during the post-comment call. NQF #2705 was not recommended by the Committee so that measure was not included in the discussion. The Committee concluded that the remaining measures were related but not competing. The Committee recommended and the developers agreed to work together to harmonize these measures where possible.
Standing Committee Recommendation for Endorsement: 23-Y; 0-N Rationale • The developer has agreed to update the specifications as recommended by the Committee.
6. Public and Member Comment • Three commenters were generally in support of this measure. Two of these commenters requested information on stipulations made by the Standing Committee during the In-Person. ○ Developer Response: The specifications have been revised to use the term "weekly Kt/Vurea"

2706 Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V
instead of "spKt/V", and we have clarified the measurement period for pediatric patients (within the past 6 months). Allowing facilities to exclude those patients for which RRF cannot be measured could potentially encourage gaming of this measure. This is consistent with the way missing data are treated in this measure (missing Kt/V values are counted against the facility). In addition, our ability to assess whether a facility evaluated RRF is not currently feasible using the data available in CROWNWeb or Medicare Claims.

Measures Recommended With Reserve Status

0249 Delivered Dose of Hemodialysis Above Minimum
Submission | **Specifications**
Description: Percentage of all patient months for adult patients (>= 18years old) whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was between spKt/V >= 1.2 and spKt/V =< 5.0. Numerator Statement: Number of patient months in denominator whose delivered dose of hemodialysis (calculated from the last measurement of the month (using the UKM or Daugirdas II formula) was between a spKt/V >= 1.2 and spKt/V =<5.0. Denominator Statement: To be included in the denominator for a particular month, the patient must be >= 18 years old, must have had ESRD for greater than 90 days, must be dialyzing thrice weekly during the month, and must be assigned to that facility for the entire month. Exclusions: Exclusions that are implicit in the denominator definition include 1) pediatric patients (<18 years old) 2) those patients receiving dialysis less than 3 times weekly 3) all patients who have had ESRD for <91 days, and 4) patients at the facility for less than one month. There are no additional exclusions for this measure. Adjustment/Stratification: No risk adjustment or risk stratification 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 (CMS)
STANDING COMMITTEE MEETING [05/06/2015-05/07/2015] 1. Importance to Measure and Report: **The measure meets the Importance criteria** *(1a. Evidence, 1b. Performance Gap)* 1a. Evidence: 6-H; 15-M; 0-L; 0-I; 1b. Performance Gap: 0-H; 6-M; 16-L; 1-I Rationale: • The developer presented 2006 Kidney Disease Outcomes Quality Initiative Clinical Practice Guidelines (KDOQI CPG) and Clinical Practice Recommendations (CPRs) that were rated as Grade A for evidence to support this intermediate clinical outcome measure. The Committee noted that the guidelines from 2006 had a grade A but are dated. There are a number of studies showing clearance correlations with outcomes, and there is the hemodialysis study showing that higher clearances are not necessarily helpful, at least overall. • The developer agreed to remove the upper threshold of spKt/v <= 5.0 as there is a lack of evidence to support this. The developer confirmed this change was made during the post-comment call. • The performance data is based on 2013 CROWNWeb and Medicare claims data. Out of about 5,500 facilities, the mean performance score was 93.5 percent, with a standard deviation of seven percent. The

0249 Delivered Dose of Hemodialysis Above Minimum
Committee questioned whether or not there is opportunity for improvement and voted to consider the measure for endorsement with reserve status.
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: 4-H; 18-M; 0-L; 0-I; 2b. Validity: 3-H; 19-M; 1-L; 0-I <u>Rationale</u>: • The data elements were defined based on a treatment file for patients who are on dialysis. Testing was performed using the data from calendar year 2013, CROWNWeb and Medicare claims from over 5,500 facilities that had at least 11 eligible patients. The inter-unit reliability (IUR) for the 12 month period was 0.942, which is considered high. • Validity testing was performed using the Spearman correlations to measure association between facility level performance scores and the 2013 standardized mortality ratio (SMR) and standardized hospitalization ratio (SHR). The Committee agreed that the coefficients are statistically significant, although the magnitude is relatively small. SMR was -0.085, and the SHR was -0.159.
3. Feasibility: 18-H; 5-M; 0-L; 0-I (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 data source for this measure is CROWNWeb. If a patient's data is missing in CROWNWeb, Medicare claims are used. Data is collected or generated and used by healthcare personnel during provision of care. The Committee had no major concerns with feasibility.
4. Use and Usability: 17-H; 6-M; 0-L; 0-I (Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified) <u>Rationale</u>: • The measure is currently reported in the Dialysis Facility Compare public reporting program and End Stage Renal Disease Quality Incentive Program (ESRD QIP) payment program. All Medicare-certified dialysis facilities that are eligible for this measure, and have at least 11 patients are "accountable entities". The Committee had no major concerns with use and usability.
5. Related and Competing Measures • This measure was identified as potentially related or competing with: ○ NQF# 0323 Adult Kidney Disease-Hemodialysis Adequacy-Solute: Percentage of calendar months within a 12-month period suring which patients aged 18 years or older with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis three times a week for >= 90 days have a spKt/V >= 1.2 ○ NQF# 1423 Minimum spKt V for Pediatric Hemodialysis Patients: Percentage of patient months for all pediatric (<18 years old) in-center HD patients who have been on hemodialysis for more than 90 days and dialyzing 3 or 4 times weekly whose average delivered dose of hemodialysis using the UKM or Daugirdas II formula) was between spKt/V = 1.2 and spKt/V<5.0. ○ NQF #2703 Minimum Delivered Hemodialysis Dose: Percentage of all patient months for patients whose average delivered dose of hemodialysis using the UKM or Daugirdas II formula) was between spKt/V >= 1.2 and spKt/V =< 5.0 ○ NQF#2705 Delivered Dose of Dialysis Above Minimum: Percentage of all patient months for patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.

0249 Delivered Dose of Hemodialysis Above Minimum
• The Committee was unable to discuss related and competing measures during the in-person meeting and had the opportunity to do so during the post-comment call. NQF #2703 and NQF #2705 were not recommended by the Committee so were not included in the discussion. The Committee concluded that the remaining measures were related but not competing. The Committee recommended and the developers agreed to work together to harmonize these measures where possible.
Standing Committee Recommendation for Endorsement with Potential for Reserve Status: 22-Y; 0-N
6. Public and Member Comment • Three commenters were generally in support of this measure for reserve status. Two of these commenters requested information on stipulations made by the Standing Committee during the In-Person.   ○ Developer Response: The specifications have been revised to use the term "weekly Kt/Vurea" instead of "spKt/V", and we have clarified the measurement period for pediatric patients (within the past 6 months). Allowing facilities to exclude those patients for which RRF cannot be measured could potentially encourage gaming of this measure. This is consistent with the way missing data are treated in this measure (missing Kt/V values are counted against the facility). In addition, our ability to assess whether a facility evaluated RRF is not currently feasible using the data available in CROWNWeb or Medicare Claims. We have revised the evidence form for this measure to remove the reference to pediatric patients.

0255 Measurement of Serum Phosphorus Concentration
Submission | **Specifications**
Description: Percentage of all peritoneal dialysis and hemodialysis patient months with serum or plasma phosphorus measured at least once within the month. Numerator Statement: Number of dialysis patient months in the denominator with serum or plasma phosphorus measured at least once within the reporting month. Denominator Statement: Number of patient-months among in-center hemodialysis, home hemodialysis, or peritoneal dialysis patients under the care of the dialysis facility for the entire reporting month Exclusions: Exclusions that are implicit in the denominator definition include all patients who have not been in the facility the entire reporting month. There are no additional exclusions for this measure. Adjustment/Stratification: No risk adjustment or risk stratification Level of Analysis: Facility Setting of Care: Dialysis Facility Type of Measure: Process Data Source: Electronic Clinical Data Measure Steward: Centers for Medicare & Medicaid Services (CMS)
STANDING COMMITTEE MEETING [05/06/2015-05/07/2015] 1. Importance to Measure and Report: **The measure meets the Importance criteria** *(1a. Evidence, 1b. Performance Gap)* 1a. Evidence: 6-H; 15-M; 0-L; 0-I; 1b. Performance Gap: 0-H; 6-M; 16-L; 1-I Rationale: • The developer presents the measure focus as the facility´s process of measuring serum or plasma phosphorus each month for End Stage Renal Disease (ESRD) dialysis patients. They provided the following path as the process leads to the improvement of mortality: Measure serum or plasma phosphorus-->

0255 Measurement of Serum Phosphorus Concentration

Assess value-->Identify problem-->Identify treatment options-->Administer the appropriate treatment-->Patient experiences improvement in mortality.

- Developers also reference The Kidney Disease: Improving Global Outcomes (KDIGO) clinical practice guidelines, and cites additional sources of evidence. Three separate Technical Expert Panels (TEPs) were involved in the development and maintenance of the measure. The TEPs found no randomized control trials providing strong evidence to inform healthcare providers as to the efficacy of phosphorus lowering strategies on improvement in clinical outcomes.
- The Committee discussed the measure evidence and found that the KDIGO guidelines provided did not match the measure specifications. KDIGO guidelines state for chronic kidney disease (CKD), phosphorous levels should be measured every one to three months and the measure requires a monthly phosphorous. The evidential data provided is largely focused around phosphate levels and not the act of measuring phosphate levels. Despite the discrepancy in the actual process of measuring phosphorous levels, the Committee rated this measure as moderately satisfying the evidence criteria.
- Performance gap data provided by the developer noted that consistently monitoring phosphorous levels helps to ensure the regulation of patient morbidity and mortality. Additionally, routine blood tests will assist in the detection and monitoring for abnormal phosphorous balance.
- Developers provided information on the performance scores of the more than 6,000 facilities that housed at least a single eligible patient. Using the 2013 CROWNWeb data, the median data were calculated at 92%.
- Committee members noted the high percentage of performance at the 50th percentile stating there was not much room for improvement. Questioning whether or not there were factors to be improved upon, members agreed that there was only slight opportunity for improvement and voted to consider the measure for endorsement with reserve status.

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: 4-H; 18-M; 0-L; 0-I; 2b. Validity: 3-H; 19-M; 1-L; 0-I

<u>Rationale</u>:

- Some members asked for clarification of whether or not the denominator truly excluded patients who had not been in the facility for the entire month. Developers clarified that a patient must be out of the facility for an entire 30 calendar days during the reporting month to be included in the denominator exclusion.
- The assessment of reliability was based on facility-level Pearson correlation coefficients between the current performance month and the previous month for 2013 reporting months (January – December 2013). Pearson correlation coefficients of each pair of the current and preceding months ranted from 0.72 – 0.90 and were statistically significant ($p<0.0001$). Monthly IURs ranged from 0.95 – 0.97.
- There was confusion among committee members regarding the specifications related to transplant patients with functioning allografts. Additionally, inclusion of pediatric patients was a point of confusion since the evidence provided was only from adult patients.
- Once the developer clarified that pediatric and adult patients were included in the denominator and in the testing, committee members concluded the measure was reliable and valid.

3. Feasibility: 18-H; 5-M; 0-L; 0-I

(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 data source for this measure is CROWNWeb. If patient data is missing in CROWNWeb, Medicare claims are used. Data is collected or generated and used by healthcare personnel during provision of care.

0255 Measurement of Serum Phosphorus Concentration
The Committee had no major concerns with feasibility.
4. Use and Usability: 17-H; 6-M; 0-L; 0-I (Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified) Rationale: • The measure is currently in use in the End Stage Renal Disease Quality Improvement Program (ESRD QIP). The current use for quality improvement is internal and specific to the organization via the Renal Physicians Association (RPA) Quality Improvement Registry. • The measure was first publicly reported in the final QIP PY 2014 scores released in December 2013, so performance data over time cannot be assessed at this time. The Committee did not have any major concerns with the use and usability of this measure.
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Endorsement with Potential for Reserve Status: 22-Y; 0-N
6. Public and Member Comment • Three commenters were generally in support of this measure for reserve status.

0323 Adult Kidney Disease: Hemodialysis Adequacy: Solute
Submission | **Specifications**
Description: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis three times a week for >= 90 days have a spKt/V >= 1.2 Numerator Statement: Calendar months during which patients have a spKt/V >= 1.2 Denominator Statement: All calendar months during which patients aged 18 years and older with a diagnosis of ESRD are receiving hemodialysis three times a week for >= 90 days Exclusions: There are no denominator exceptions. Adjustment/Stratification: No risk adjustment or risk stratification Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team Setting of Care: Ambulatory Care : Clinician Office/Clinic, Dialysis Facility, Home Health, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility, Other (Domiciliary, Rest Home, or Custodial Care Services) Type of Measure: Outcome Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry Measure Steward: Renal Physicians Association
STANDING COMMITTEE MEETING [05/06/2015-05/07/2015] 1. Importance to Measure and Report: **The measure meets the Importance criteria** *(1a. Evidence, 1b. Performance Gap)* 1a. Evidence: 9-H; 12-M; 0-L; 0-I; 1b. Performance Gap: 0-H; 4-M; 14-L; 3-I Rationale: • The developer presented 2006 Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines and Clinical Practice Recommendations, rated Grade A, as evidence to support this intermediate clinical outcome measure. The developer offered the rationale that adequate dialysis dose is

0323 Adult Kidney Disease: Hemodialysis Adequacy: Solute
strongly associated with better outcomes, including decreased mortality, fewer hospitalizations, decreased length of hospitalizations, and decreased hospital costs. The measure is presented as a clinician level measure as contrasted with the Center for Medicare and Medicaid Services (CMS) facility-level measure (NQF# 0249). Similar to measure NQF #0249, the Committee agreed that the evidence is strong. • The developer indicated that United States Renal Data System (USRDS) data has shown that 97% of patients obtaining a single pool Kt/V of greater than or equal to 1.2. Although the Committee noted that there is not much room for improvement, they agreed that the measure would be a good candidate for endorsement with reserve status.
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: 3-H; 17-M; 2-L; 0-I; 2b. Validity: 0-H; 19-M; 0-L; 2-I <u>Rationale</u>: • The developer confirmed that residual kidney function is a denominator exclusion and noted there was an inconsistency between the e-specifications and the measure information form. The Committee encouraged developers to correct this inconsistency and include residual kidney function in the measure. There is a small population of patients for whom this would be useful to include. In the interest of having patient focused care, less hemodialysis would be done on patients who have substantial residual kidney function. Tailoring the therapy appropriately when endogenous kidney function can be counted is a patient oriented and patient specific opportunity. • It was noted that the detailed specifications are not granular enough to account for inter-organizational variability that might occur if one organization chooses an equilibrated Kt/V and they take the single pooled component of that. • Reliability was tested by examining four different nephrology practices, with hemodialysis/peritoneal dialysis patients, participating in the Physician Quality Reporting Initiative (PQRI) (now known as Physician Quality Reporting System (PQRS)) program with hemodialysis/peritoneal dialysis patients. This included multiple visits at multiple sites across the country. Kappa values were calculated for inter-rater reliability and were exceptionally high, one or nearing one. The Committee had no major concerns with reliability. • Validity testing was conducted at the measure score level. An expert panel was used to assess face validity of the measure. Face validity of the measure score as an indicator of quality was consistent and the Committee agreed that the results suggested sufficient validity.
3. Feasibility: 11-H; 11-M; 0-L; 0-I (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 data elements required are routinely measured as part of patient care and can be derived from CROWNWeb and electronic health records. The Committee agreed that collection of this data is feasible.
4. Use and Usability: 15-H; 5-M; 2-L; 0-I (Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified) <u>Rationale</u>: • The measure is currently in use in the Physician Quality Reporting Program (PQRS) and reported in Physician Compare. The current use for quality improvement is internal and specific to the organization via the Renal Physicians Association (RPA) Quality Improvement Registry. The Committee did not have any major concerns with use and usability.
5. Related and Competing Measures • This measure was identified as potentially related or competing with:

0323 Adult Kidney Disease: Hemodialysis Adequacy: Solute

- NQF# 0249 Hemodialysis Adequacy Clinical Performance Measure III-Hemodialysis Adequacy--HD Adequacy--Minimum Delivered: Percentage of all adult (>=18 years old) patients in the sample for analysis who have been on hemodialysis for 90 days or more and dialyzing thrice weekly whose average delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a spKt/V >= 1.2 during the study period.
- NQF# 1423 Minimum spKt V for Pediatric Hemodialysis Patients: Percentage of patient months for all pediatric (<18 years old) in-center HD patients who have been on hemodialysis for more than 90 days and dialyzing 3 or 4 times weekly whose average delivered dose of hemodialysis using the UKM or Daugirdas II formula) was between spKt/V = 1.2 and spKt/V<5.0.
- NQF #2703 Minimum Delivered Hemodialysis Dose: Percentage of all patient months for patients whose average delivered dose of hemodialysis using the UKM or Daugirdas II formula) was between spKt/V >= 1.2 and spKt/V =< 5.0
- NQF#2705 Delivered Dose of Dialysis Above Minimum: Percentage of all patient months for patients whose average delivered dose of dialysis (either hemodialysis or peritoneal dialysis) met the specified threshold during the reporting period.

- The Committee was unable to discuss related and competing measures during the in-person meeting and had the opportunity to do so during the post-comment call. NQF #2703 and NQF #2705 were not recommended by the Committee, so those measures were included in the discussion. The Committee concluded that the remaining measures were related but not competing. The Committee recommended and the developers agreed to work together to harmonize these measures where possible.

Standing Committee Recommendation for Endorsement with Potential for Reserve Status: 21-Y; 0-N

6. Public and Member Comment

- Four commenters were generally in support of this measure for reserve status.

1454 Proportion of patients with hypercalcemia

Submission | Specifications

Description: Percentage of adult dialysis patients with a 3-month rolling average of total uncorrected calcium (serum or plasma) greater than 10.2 mg/dL (hypercalcemia)

Numerator Statement: Number of patient-months in the denominator with 3-month rolling average of total uncorrected serum (or plasma) calcium greater than 10.2 mg/dL

Denominator Statement: Number of patient-months among adult (greater than or equal to 18 years old) in-center hemodialysis, home hemodialysis, or peritoneal dialysis patients under the care of the dialysis facility for the entire reporting month who have had ESRD for greater

Exclusions: Exclusions that are implicit in the denominator definition include all patients who have not been in the facility the entire reporting month (transient patients), and patients who have had ESRD for <91 days. There are no additional exclusions for this measure.

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: Electronic Clinical Data

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

STANDING COMMITTEE MEETING [05/06/2015-05/07/2015]

1454 Proportion of patients with hypercalcemia

1. Importance to Measure and Report: **The measure does not meet the Importance criteria**

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

1a. Evidence: 0-H; 1-M; 22-L; 0-I; Insufficient Evidence with Exception: 19-Y; 4-N; 1b. Performance Gap: 0-H; 0-M; 21-L; 2-I Reconsideration Performance Gap: 0-H; 7-M; 6-L; 5-I

Rationale:

- For this intermediate outcome measure, evidence provided by the developer included two clinical guidelines and an April 2013 Technical Expert Panel (TEP) review. The Kidney Disease: Improving Global Outcomes (KDIGO) graded the evidence 2D, very low evidence, and the Kidney Disease Outcomes Quality Initiative (KDOQI) was expert opinion only. The TEP did not recommend any revisions to the measure.
- While the Committee acknowledged that this measure was an important safety measure that filled a gap area in bone and mineral disease, members agreed that evidence demonstrating that calcium concentrations less than 10.2 mg/dL place the patient at increased risk of cardiovascular events and all-cause mortality was largely associative. The Committee allowed the measure to move forward on an evidence exception.
- The developer provided January – December 2013 CROWNWeb clinical data on performance scores generated among 5,973 facilities that had at least one eligible patient that indicate the mean gap of performance is two point one percent.
- Disparities data were also provided that imply that there are statistically significant changes in performance scores depending on sex, race, ethnicity, and age; however, the Committee found it was not a clinically meaningful difference.
- The Committee concluded there was very little room for improvement and the current gap did not warrant a national performance measure.
- The Committee considered the measure for endorsement with reserve status due to the fact that there were no other bone and mineral measures; however, determined that losing endorsement would not affect current performance of the measure.
- Some committee members suggested lowering the measure threshold to allow for a greater gap in care, however, the developer stated there was no evidence for a lower threshold and two previous TEPs had supported the current threshold of less than 10.2 mg/dL.
- The Committee encouraged the developer to consider alternative bone and mineral measures. The developer reassured the Committee that they have convened multiple TEPs in order to develop additional measures in this area but have not been successful thus far to create another strong, evidence supported measure in this area.
- At the post-comment call, the Committee decided to reconsider this measure based on the information provided by the developer. While the measure did not pass the gap criterion, the Committee decided they would like to consider this measure for reserve status.

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: 0-H; 15-M; 2-L; 0-I; 2b. Validity: 0-H; 17-M; 0-L; 0-I

Rationale:

- The developer used CROWNWeb and Medicare claims data from January 2013 – December 2013 to calculate the inter-unit reliability (IUR) for the 12 month period to assess the reliability of this measure. The IUR is 0.86 with the confidence interval being 0.78 - 0.84. This suggests that 86% of variation in the measure is attributed to between facility variance. The Committee agreed that the testing results suggest this measure is reliable
- The developer assessed validity using Poisson regression analysis to identify the predictive strength of facility level performance scores for hypercalcemia on mortality, using the 2013 standardized mortality

1454 Proportion of patients with hypercalcemia
ratio. The results of the Poisson regression suggest that facilities with a higher percentage of patient-months with hypercalcemia experience a higher standardized mortality rate relative to facilities with a lower percentage of patients with hypercalcemia. The Committee agreed that the testing results suggest the measure is valid.
3. Feasibility: 12-H; 5-M; 0-L; 0-I (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 elements required are routinely measured as part of patient care and can be derived from CROWNWeb and electronic health records. The Committee agreed that collection of this data is feasible.
4. Use and Usability: 6-H; 12-M; 0-L; 0-I (Meaningful, understandable, and useful to the intended audiences for 4a. Public Reporting/Accountability and 4b. Quality Improvement, 4c. Susceptibility to inaccuracies/unintended consequences identified) Rationale: • The measure is currently in use in the Dialysis Facility Compare program. The Committee did not have any major concerns with the use and usability of this measure.
5. Related and Competing Measures • No related or competing measures noted.
Standing Committee Recommendation for Endorsement with Potential for Reserve Status: 19-Y; 0-N
6. Public and Member Comment • Two commenters agreed with the Committee's initial recommendation to not endorse this measure citing a poor measure would be more harmful than no measure. • Developer Response: During the recent DFC performance period, 1538 facilities had 0% of patients with hypercalcemia, 1494 facilities had 1% of patients with hypercalcemia, 889 facilities had 2%, 594 had 3%, and 1360 facilities had 4% or more of their patients with hypercalcemia. The distribution demonstrates the success of many facilities in their ability to achieve extremely low rates of hypercalcemia, as over 3000 facilities have 1% or less patients with hypercalcemia. However, when one looks at the average national performance of 2%, they may interpret that statistic as demonstrating the absence of a performance gap for this safety measure. That interpretation ignores the highly skewed distribution of facility performance for this safety measure as shown in the figure. For this safety measure, the performance gap is clearly demonstrated by comparing the 1360 US dialysis facilities (23% of the total reported facilities) with 4% or greater patients with hypercalcemia to the majority of dialysis facilities that achieve extremely low hypercalcemia rates. We maintain that the measure is important for safety monitoring, as nearly one-fourth of US dialysis facilities are relatively poor at preventing hypercalcemia, an intermediate outcome consistently associated with poorer patient survival and clearly influenced by providers' bone and mineral disease management practices.