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Renal, Spring 2019 Cycle: CDP Report

TECHNICAL REPORT
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Contents

Executive Summary

Kidney disease has long been a leading cause of morbidity and mortality in the U.S. More than 36 million adults—representing more than 14 percent of the adult population—have chronic kidney disease (CKD).[1] Untreated, CKD can progress to an advanced state of kidney disfunction known as end-stage renal disease (ESRD) and a host of other health complications such as cardiovascular disease, hyperlipidemia, anemia and metabolic bone disease. Currently, over half a million people in the U.S. have received a diagnosis of ESRD.[1] 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.

Quality measurement plays a central role in facilitating improvement in the quality of care received by CKD patients, especially those on hemodialysis. NQF-endorsed kidney care measures are used in several quality and performance improvement programs administered by the Centers for Medicare and Medicaid Programs (CMS), such as the ESRD Quality Improvement Program (ESRD QIP).

For this project, the Standing Committee evaluated five measures undergoing maintenance review against NQF's standard evaluation criteria evaluation criteria. After careful review and deliberation, the Committee recommended all five measures for continued endorsement. The NQF Consensus Standards Approval Committee (CSAC) upheld the Committee's recommendations. The endorsed measures are:

- 0318 Delivered Dose of Peritoneal Dialysis Above Minimum
- 1423 Minimum spKt/V for Pediatric Hemodialysis Patients
- 2706 Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V
- 1424 Monthly Hemoglobin Measurement for Pediatric Patients
- 1425 Measurement of nPCR for Pediatric Hemodialysis Patients

Brief summaries of the measures reviewed are included in the body of the report; detailed summaries of the Committee's discussion and ratings of the criteria for each measure are in Appendix A.

Introduction

Kidney disease has long been a leading cause of morbidity and mortality in the U.S. More than 36 million adults—representing more than 14 percent of the adult population—have chronic kidney disease (CKD).[1] Untreated, CKD can progress to an advanced state of kidney disfunction known as end-stage renal disease (ESRD) and a host of other health complications such as cardiovascular disease, hyperlipidemia, anemia and metabolic bone disease. Currently, over half a million people in the U.S. have received a diagnosis of ESRD.[1] 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.

In 1972, President Richard Nixon signed section 2991 of Public Law 92-603, which established ESRD as the only healthcare condition that Medicare covers for people under the age of 65.[1] Under this provision, people are eligible for Medicare regardless of their age if their kidneys are no longer functioning, if they need regular dialysis, or if they have had a kidney transplant. Considering the high mortality rates and high healthcare costs associated with ESRD, the need to focus on quality measures for patients with renal disease is particularly important. The United States continues to spend significant resources on care and treatment of CKD and ESRD. In 2010, total Medicare spending rose 6.5 percent, to $522.8 billion, and expenditures for ESRD rose 8 percent, to $32.9 billion.[2]

This project sought to identify and endorse performance measures for accountability and quality improvement that address conditions, treatments, interventions, or procedures relating to kidney disease. On June 7, 2019, NQF convened the Renal Standing Committee, a multistakeholder group composed of 24 individuals to evaluate five measures undergoing maintenance review and make recommendations for endorsement.

NQF Portfolio of Performance Measures for Renal Conditions

The Renal Standing Committee (Appendix C) oversees NQF's portfolio of Renal measures (Appendix B). This portfolio contains 20 measures: six process measures, 10 intermediate outcome measures, and four outcome measures (see table below).

Table 1. NQF Renal Portfolio of Measures

	Process	Intermediate Outcome	Outcome
Hemodialysis	1	2	-
Hemodialysis - Pediatric	-	1	-
Hemodialysis Vascular Access	1	4	-
Dialysis Monitoring	1	1	-
Dialysis Monitoring - Pediatric	2	1	-
Peritoneal Dialysis	-	4	-
Patient Safety	-	-	4
Treatment Initiation	1	-	-
Total	6	10	4

There are additional measures related to renal care, but they are designated as more appropriate for inclusion in other NQF portfolios. These include various diabetes assessment and screening measures, eye care measures, ACEI/ARB medication measures, complications and outcomes measures, and cost and resource use measures.

Renal Measure Evaluation

On June 7, 2019, the Renal Standing Committee evaluated five measures undergoing maintenance review using NQF's standard evaluation criteria.

Table 2. Renal Measure Evaluation Summary

	Maintenance	New	Total
Measures under consideration	5	0	5
Measures endorsed	5	0	5

Comments Received Prior to Committee Evaluation

NQF invites comments on endorsed measures on an ongoing basis through the Quality Positioning System (QPS). In addition, NQF solicits comments for a continuous 16-week period during each evaluation cycle via an online tool located on the project webpage. For this evaluation cycle, the commenting period opened on April 24, 2019 and closed on August 23, 2019; no public comments were submitted.

Overarching Issues

During the Standing Committee's discussion of the measures, one overarching issue emerged that was factored into the Committee's ratings and recommendations for multiple measures and is not necessarily repeated in detail with each individual measure.

Measurement in the Pediatric Dialysis Population

Four out of the five measures evaluated by the Renal Standing Committee during this cycle were focused on the pediatric population. Because there are relatively few pediatric patients requiring dialysis, there is a very small sample size on which to do research, collect evidence, and test measures. As a result, these measures are based largely on evidence from the adult population, with the inference that they are also appropriate for the pediatric population. Committee members noted that pediatric dialysis patients are an extremely vulnerable group, and that quality of treatment has a significant effect on growth and development. The Committee agreed that measurement of care for this population is very important and outweighs the relative paucity of direct evidence focused on pediatric patients, suggesting that predicating pediatric measures on adult data is a reasonable approach to take.

Summary of Measure Evaluation

The following brief summaries of the measure evaluation highlight the major issues that the Committee considered. Details of the Committee's discussion and ratings of the criteria for each measure are included in Appendix A.

0318 Delivered Dose of Peritoneal Dialysis Above Minimum (University of Michigan Kidney Epidemiology and Cost Center): Endorsed

Description: Percentage of all patient months for adult patients (>= 18 years old) whose delivered peritoneal dialysis dose was a weekly Kt/Vurea >= 1.7 (dialytic + residual).; **Measure Type**: Outcome: Intermediate Clinical Outcome; **Level of Analysis**: Facility; **Setting of Care**: Other; **Data Source**: Claims, Registry Data

This is an intermediate outcome measure intended to assess the proportion of adult patients receiving adequate doses of peritoneal dialysis, as indicated by achievement of weekly Kt/V ≥1.7 (dialytic and residual). Because this is a maintenance measure, and the developer attested that there had been no change in the evidence since its last endorsement, a vote on Evidence was not required. The Renal Standing Committee agreed to accept the Evidence rating from the previous review, and indicated that there is a performance gap sufficient to warrant measurement. The measure was reviewed by NQF's Scientific Methods Panel (SMP); the SMP found the measure to have met NQF's standards for reliability and validity. However, upon reviewing the SMP's findings, the Renal Standing Committee determined that additional clinical issues beyond the SMP's methodological review could have significant impact on the Scientific Acceptability criteria. Among the issues discussed by the Committee were the method of reliability testing and the interpretability of results, the measure's treatment of missing data, and whether the measure adequately accounts for residual kidney function. Ultimately, the Committee judged the measure to have met NQF's criteria for reliability and validity. This measure is in use in the Centers for Medicare & Medicaid Services' (CMS) Dialysis Facility Compare Program; in addition, the measure is included as part of a composite measure of dialysis adequacy used in the ESRD Quality Incentive Program (ESRD QIP).

1423 Minimum spKt/V for Pediatric Hemodialysis Patients (University of Michigan Kidney Epidemiology and Cost Center): Endorsed

Description: Percentage of patient months for all pediatric (<18 years old) in-center hemodialysis patients in which the delivered dose of hemodialysis (calculated from the last measurement of the month using the UKM or Daugirdas II formula) was spKt/V >= 1.2.; **Measure Type**: Outcome: Intermediate Clinical Outcome; **Level of Analysis**: Facility; **Setting of Care**: Other; **Data Source**: Claims, Registry Data

This is an intermediate outcome measure intended to assess the proportion of pediatric patients receiving a minimum dose of hemodialysis, as indicated by achievement of spKt/V ≥1.2. The Renal Standing Committee noted that, as with many pediatric measures, there is little evidence specific to the pediatric population, and that this measure is predicated on adult data with the assumption that children should be doing at least as well as adults. The Committee agreed that this is a reasonable approach to take. Because this is a maintenance measure, and the developer attested that there had

been no change in the evidence since its last endorsement, a vote on Evidence was not required. The Renal Standing Committee agreed to accept the Evidence rating from the previous review and indicated that there is a performance gap sufficient to warrant measurement. The Committee discussed whether this measure should be considered "topped out," given that the average performance is high (95.2 percent) with relatively little variation across providers. Committee members noted that the measure addresses an extremely vulnerable population, and that quality of treatment has a significant effect on growth and development, suggesting that measurement in this area is needed and warranted despite relatively high performance. This measure was reviewed by the SMP; the SMP found the measure to have met NQF's standards for reliability and validity, and the Renal Standing Committee accepted the SMP's ratings. This measure is used in Dialysis Facility Compare and ESRD QIP, as well as quality improvement initiatives at the national and community levels.

1424 Monthly Hemoglobin Measurement for Pediatric Patients (University of Michigan Kidney Epidemiology and Cost Center): Endorsed

Description: Percentage of patient months of pediatric (< 18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients who have monthly measures for hemoglobin during the reporting period.; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Other; **Data Source**: Claims, Registry Data

This is a process measure intended to assess whether pediatric dialysis patients are being adequately monitored for anemia, as indicated by monthly measurement of hemoglobin. The Renal Standing Committee agreed that there is evidence showing that pediatric patients who are anemic are at higher risk for morbidity and mortality. Because this is a maintenance measure, and the developer attested that there had been no change in the evidence since its last endorsement, a vote on Evidence was not required. The Committee agreed to accept the Evidence rating from the previous review. The Committee observed that there is a fairly modest performance gap for this measure, but an important one that continues to persist. The Committee was satisfied that testing results demonstrated adequate reliability and validity. The Committee noted that this measure is not currently in use, but that the developer provided a credible plan for implementation and use. Committee members suggested that this measure will encourage facilities to comply with Kidney Disease Outcomes Quality Initiative (KDOQI) practice recommendations.

1425 Measurement of nPCR for Pediatric Hemodialysis Patients (University of Michigan Kidney Epidemiology and Cost Center): Endorsed

Description: Percentage of patient months of pediatric (< 18 years old) in-center hemodialysis patients (irrespective of frequency of dialysis) with documented monthly nPCR measurements.; **Measure Type**: Process; **Level of Analysis**: Facility; **Setting of Care**: Other; **Data Source**: Claims, Registry Data

This is a process measure intended to assess whether the nutritional status of pediatric dialysis patients is being adequately monitored, as indicated by monthly measurement of nPCR (an estimate of dietary protein intake). While the Committee acknowledged that the evidence and performance gap data were based on the adult population, they concluded that the evidence and performance gap could be inferred to support a measure of the pediatric population. Committee members noted that nPCR is often used in concert with other determinants, none of which are perfect; it was suggested that this indicator gives

dieticians something to rely on when managing the nutrition of pediatric patients. The Committee was satisfied that testing results demonstrated adequate reliability and validity. This measure is currently being publicly reported through Dialysis Facility Compare. The developer noted that 2017 was the first year of public reporting and suggested that this may be too short of a time frame to observe meaningful trends, particularly because of the small number of facilities for which the measure is calculated.

2706 Pediatric Peritoneal Dialysis Adequacy: Achievement of Target Kt/V (University of Michigan Kidney Epidemiology and Cost Center): Endorsed

Description: Percentage of pediatric (< 18 years old) peritoneal dialysis patient-months whose delivered peritoneal dialysis dose was a weekly Kt/Vurea >= 1.8 (dialytic + residual); **Measure Type**: Outcome: Intermediate Clinical Outcome; **Level of Analysis**: Facility; **Setting of Care**: Other; **Data Source**: Claims, Registry Data

This is an intermediate outcome measure intended to assess the proportion of pediatric and adult patients receiving adequate doses of peritoneal dialysis, as indicated by achievement of weekly Kt/V values of ≥1.7 for pediatric patients and ≥1.8 for adult patients. This measure is based on studies in adult peritoneal dialysis patients because an equivalent evidence base does not exist for children. Renal Standing Committee members agreed that when no pediatric-specific data exist, performance measures for adults should serve as the minimum standard. Because this is a maintenance measure, and the developer attested that there had been no change in the evidence since its last endorsement, a vote on Evidence was not required. The Committee agreed to accept the Evidence rating from the previous review and indicated that there is a sufficient performance gap to warrant measurement. This measure was reviewed by the SMP; the SMP found the measure to have met NQF's standards for reliability and validity, and the Renal Standing Committee accepted the SMP's ratings. This measure is in use in Dialysis Facility Compare; in addition, the measure is included as part of a composite measure of dialysis adequacy used in the ESRD QIP.

Measures Withdrawn from Consideration

Three measures previously endorsed by NQF have not been re-submitted for maintenance of endorsement or have been withdrawn during the endorsement evaluation process. Endorsement for these measures will be removed.

Table 3. Measures Withdrawn from Consideration

Measure	Reason for withdrawal
0256 Minimizing Use of Catheters as Chronic Dialysis Access	This is a previous version of a vascular access catheter measure; the measure steward replaced it with measure 2977 *Hemodialysis Vascular Access: Long-term Catheter Rate*
0257: Maximizing Placement of Arterial Venous Fistula (AVF)	This is a previous version of an arterial venous fistula measure; the measure steward replaced it with measure 2978 *Hemodialysis Vascular Access: Standardized Fistula Rate*
2704 Minimum Delivered Peritoneal Dialysis Dose	CMS is no longer maintaining the combined adult and pediatric peritoneal dosing measure; the individual adult (0318) and pediatric (2706) measures remain endorsed.

References

[1] U.S. Renal Data System (USRDS). *2018 Annual Data Report: Epidemiology of Kidney Disease in the United States*. Bethesda, MD: National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases; 2018. http://www.usrds.org/atlas.htm. Last accessed January 2020.

[2] CROWNWeb. CROWNWeb: History, Purpose, and Usage [video]. http://mycrownweb.org/help/about-crownweb/. Last accessed December 2015.

Appendix A: Details of Measure Evaluation

Rating Scale: H=High; **M**=Moderate; **L**=Low; **I**=Insufficient; **NA**=Not Applicable

Endorsed Measures

0318 Delivered Dose of Peritoneal Dialysis Above Minimum

Submission | Specifications

Description: Percentage of all patient months for adult patients (>= 18 years old) whose delivered peritoneal dialysis dose was a weekly Kt/Vurea >= 1.7 (dialytic + residual).

Numerator Statement: Number of patient months in the denominator whose delivered peritoneal dialysis was a weekly Kt/Vurea >= 1.7 (dialytic + residual, measured in the last 4 months).

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

Exclusions: Exclusions that are implicit in the denominator definition include

1) Patients not on peritoneal dialysis for the entire month
2) Pediatric patients (<18 years old)
3) Patients who have had ESRD for <91 days
4) Patients 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: Other

Type of Measure: Outcome: Intermediate Clinical Outcome

Data Source: Claims, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/07/2019

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

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

1a. Evidence: **Carried over votes from previous evaluation**; 1b. Performance Gap: **H-2; M-13; L-1; I-0**

Rationale:

- The developer presented evidence from the previous endorsement review (in 2015), which included 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.
- Because this is a maintenance measure, and the developer attested that there had been no change in the evidence since its last endorsement, a vote on Evidence was not required. The Committee agreed to accept the Evidence rating from the previous review.

- The developer indicated that analysis using CROWNWeb and Medicare claims data from January to December 2017 indicate the mean percentage of patients with peritoneal adequacy measurements that achieved the target at least once in four months was 90.8% (SD=10.9%). These results indicate that on average, facilities are meeting the Kt/Vurea guidelines in 91% of peritoneal dialysis patients.
- The sample size included 57,969 peritoneal dialysis patients at 1,924 facilities with at least 11 peritoneal dialysis patients.

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

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

2a. Reliability: **H-1; M-14; L-0; I-0**; 2b. Validity: **H-0; M-12; L-4; I-0**

<u>Rationale</u>:

- This measure was reviewed by the SMP; the SMP found the measure to have met NQF's standards for reliability and validity. However, upon reviewing the SMP's findings, the Renal Standing Committee determined that additional clinical issues beyond the SMP's methodological review could have significant impact on the Scientific Acceptability criteria.
- Reliability testing was conducted at the score level by assessing inter-unit reliability (IUR) across 12 reporting months, using a bootstrap approach to estimate the proportion of measure variability that is attributable to between-facility variance.
- Testing resulted in an IUR of 0.858, which suggests 86% of variation in the measure is attributed to between-facility variation and approximately 14% attributed to within-facility variation.
- The Renal Standing Committee sought clarification from the developer on the method for testing reliability and how the results should be interpreted; the developer noted that the IUR calculation was a conservative estimate of reliability and that the results may underestimate the variation attributable to between-facility differences.
- The Committee discussed the measure's treatment of patients with a kt/V missing for the measurement month; the developer clarified that the measure looks back over the prior three months, using the most recent kt/V value collected within that timeframe.
- Validity was assessed at the score level using Spearman correlations to measure the association between facility-level performance scores and the 2017 standardized mortality ratio (SMR) and standardized hospitalization ratio (SHR). The developer hypothesized that both the SMR and the SHR would have negative correlations with this measure.
- The Spearman correlation between the HD Kt/V measure and SMR is -0.058, and statistically significant ($p<.01$). The Spearman correlation between HD Kt/V measure and SHR is -0.116, and statistically significant ($p<.0001$).
- SMP reviewers found the testing methods appropriate and the results supportive but weak (low correlation values). They suggested the information on face validity helped to bolster confidence in the measure's validity, despite it not meeting NQF's requirements for face validity assessments.
- SMP reviewers expressed some concern about the measure's ability to identify meaningful differences between measured entities and noted that the developer's analysis only identifies "as expected" and "worse" categories, and not "better"/ "good" performance.
- One Renal Standing Committee member questioned whether the measure adequately accounted for patients with residual kidney function, suggesting there could be potential

incentives to over-dialyze these patients to reach a particular kt/V value. However, Committee members agreed that the measure was consistent with current practice guidelines.

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3. Feasibility: H-9; M-6; L-0; I-0

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

Rationale:

- The Committee noted that all data elements are in defined fields in a combination of electronic sources, including the CROWNWeb registry, and that the data are generated, collected and used by healthcare personnel during provision of care.

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4. Usability and Use: The maintenance measure meets the Use subcriterion

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

4a. Use**: Pass-16; No Pass-**0; 4b. Usability: **H-6; M-10; L-0; I-0**

Rationale:

- The measure is in use in the Centers for Medicare & Medicaid Services (CMS)'s Dialysis Facility Compare Program.
- In addition, the measure is one component of a composite measure of dialysis adequacy used in the ESRD Quality Incentive Program (ESRD QIP).
- The developer noted that analysis of their data shows a slight increase in performance across three years for the measure as implemented on Dialysis Facility Compare; mean performance increased from 84% in 2015 to 90.85 in 2017.
- The developer indicated that they had not been notified of documented unintended impacts on patients as a result of measure implementation.

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5. Related and Competing Measures

- No related or competing measures noted.

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6. Standing Committee Recommendation for Endorsement: Yes-15**;** No-0

7. Public and Member Comment

- No NQF member or public comments were received.

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8. Consensus Standards Approval Committee (CSAC) Endorsement Decision: Yes-13; No-0 (October 21-22, 2019: Approved for continued endorsement)

- CSAC upheld the Committee's decision to recommend the measure for endorsement.

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9. Appeals

No appeals were received

1423 Minimum spKt/V for Pediatric Hemodialysis Patients

Submission | Specifications

Description: Percentage of patient months for all pediatric (<18 years old) in-center hemodialysis patients in which the delivered dose of hemodialysis (calculated from the last measurement of the month using the UKM or Daugirdas II formula) was spKt/V >= 1.2.

Numerator Statement: Number of patient months from the denominator in which the delivered dose of hemodialysis (calculated from the last measurement of the month using the UKM or Daugirdas II formula) was spKt/V >= 1.2.

Denominator Statement: To be included in the denominator for particular month, a patient must be on hemodialysis for the entire month, must be <18 years old at the beginning of the month, must have had ESRD for greater than 90 days at the beginning of the month, must be on thrice weekly in-center hemodialysis 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) Patients on home hemodialysis
2) Patients on peritoneal dialysis
3) Adult patients (>=18 years old)
4) Patients on ESRD less than 91 days
5) Patients not on thrice weekly dialysis
6) Patients 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: Other

Type of Measure: Outcome: Intermediate Clinical Outcome

Data Source: Claims, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/07/2019

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

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

1a. Evidence: **Carried over votes from previous evaluation**; 1b. Performance Gap: **H-0; M-12; L-4; I-0**

Rationale:

- This measure is based on 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). The KDOQI guideline was graded as A (strong evidence).
- The Committee noted that, as with many pediatric measures, there is little evidence specific to the pediatric population because of the low number of patients. The measure is predicated on adult data with the assumption that children should be doing at least as well as adults; the Committee suggested that is a reasonable approach to take.

- The Committee accepted the Evidence rating from the previous endorsement review.
- The developer presented performance data based on 2017 CROWNWeb and Medicare claims data.
- Out of about 14 facilities, the mean performance score was 95.2 percent, with a standard deviation of 4.6 percent.
- Given that the small sample of facilities, the developer determined it was not possible to display useful disparities data.
- The developer cited observational pediatric studies showing that older, larger, and African-American children are less likely to receive an spKt/V greater than 1.2 consistently.
- The Committee discussed whether this measure should be considered "topped out," given the high mean score and the relatively low variation.
- Committee members noted that this measure addresses an extremely vulnerable population, and that quality of treatment has a significant effect on growth and development—enough of a gap to warrant measurement despite relatively high performance.
- Committee members agreed there is need for a measure to ensure a minimum level of adequacy for pediatric patients.

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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: **Accepted the Scientific Methods Panel evaluation**; 2b. Validity: **Accepted the Scientific Methods Panel evaluation**

<u>Rationale</u>:

- This measure was reviewed by the SMP.
- Reliability testing was conducted at the score level by assessing inter-unit reliability (IUR) across 12 reporting months, using a bootstrap approach to estimate the proportion of measure variability that is attributable to between-facility variance.
- The IUR was calculated to be 0.750, suggesting about 75% of variation in the measure is due to between-facility variation.
- SMP members requested more detail about the developer's bootstrapping method. The developer explained that the bootstrapping method was done within facilities by resampling individuals.
- The Renal Standing Committee accepted the SMP rating for reliability.
- The developer provided a face validity assessment in support of the measure.
- To justify providing only face validity at the time of maintenance review, the developer stated that it is difficult to interpret results of empiric validity testing with any confidence, given the small sample size.
- The developer noted that an empirical analysis for one measure; results were not statistically significant because of the extremely small sample sizes and relatively small variations in outcomes for many measures.
- The SMP and the Renal Committee were satisfied with this rationale.
- The Committee noted that not only is there a limited number of pediatric patients and facilities, there is high variability within this population.
- The Committee accepted the SMP rating for validity.

3. Feasibility: **H-11; M-4; L-0; I-0**

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

Rationale:

- The Committee noted that all data elements are in defined fields in a combination of electronic sources, including the CROWNWeb registry, and that the data are generated, collected and used by healthcare personnel during provision of care.

4. Usability and Use: The maintenance measure meets the Use subcriterion

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

4a. Use**: Pass-15; No Pass-1**; 4b. Usability: **H-6; M-10; L-1; I-0**

Rationale:

- This measure is used in Dialysis Facility Compare and ESRD QIP.
- Committee members pointed out the measure is also used in quality improvement initiatives at the national and community levels.
- The developer reported that data demonstrates a slight increase in performance across three years for the measure with the mean increasing from 88% in 2015 to 95.2% in 2017.

5. Related and Competing Measures

- No related or competing measures noted.

6. Standing Committee Recommendation for Endorsement: Yes-17; **No-0**

7. Public and Member Comment

- No NQF member or public comments were received.

8. Consensus Standards Approval Committee (CSAC) Endorsement Decision: Yes-13; No-0 (October 21-22, 2019: Approved for continued endorsement)

- CSAC upheld the Committee's decision to recommend the measure for endorsement.

9. Appeals

No appeals were received

1424 Monthly Hemoglobin Measurement for Pediatric Patients

Submission | Specifications

Description: Percentage of patient months of pediatric (< 18 years old) 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 (< 18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients with a measurement of hemoglobin during the reporting period.

Denominator Statement: All patient months for pediatric (< 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: Other

Type of Measure: Process

Data Source: Claims, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/07/2019

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

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

1a. Evidence: **Carried over votes from previous evaluation**; 1b. Performance Gap: **H-0; M-16; L-2; I-0**

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 the literature. The recommendation is defined as “expert opinion” based on TEP consensus, and thus was not graded.
- The Committee agreed that there is evidence showing that pediatric patients who are anemic are at higher risk for morbidity and mortality.
- Because this is a maintenance measure, and the developer attested that there had been no change in the evidence since its last endorsement, a vote on Evidence was not required. The Committee agreed to accept the Evidence rating from the previous review.
- The developer provided 2017 CROWNWeb clinical data (January 2017-December 2017).
- In 62 facilities with at least 11 eligible pediatric patients, the mean and median performance scores were 90% and 92%, respectively. The 25th percentile was 89% and the 75th percentile was 97%.
- The Committee observed that this is a fairly modest performance gap, but an important one that continues to persist.

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

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

2a. Reliability: **H-5; M-12; L-0; I-0**; 2b. Validity: **H-5; M-12; L-0; I-0**

Rationale:

- To test reliability of the measure score, the developer assessed inter-unit reliability (IUR) across 12 reporting months, using a bootstrap approach to estimate the proportion of measure variability that is attributable to between-facility variance.
- IUR=0.82; The developer states that this value is high and suggests 82% of variation in the measure is attributed to between facility variation.
- In addition, the developer calculated facility-level Pearson correlation coefficients between the current performance month and the preceding month for reporting months during January 2017 – December 2017
- The developer reported that "the median of Pearson correlation coefficients of each pair of the current and the preceding months was 0.84, with a range of 0.28 to 0.92. All were statistically significant ($p<0.05$), indicating this measure is reliable over time."
- To demonstrate validity of the measure score, the developer computed the Spearman correlation to assess the association between the annual performance scores and the NQF endorsed (0369) standardized mortality ratio (SMR) using the 2017 SMR.
- The developer hypothesized that this measure would have a negative correlation with the SMR, since facilities with successful processes for monitoring clinically important intermediate outcomes of care would be expected to have better primary outcomes, including lower mortality.
- Testing showed that the spearman correlation coefficient was 0.07, $p=0.55$.
- The developer's interpretation of these results is that they do not suggest a statistically significant association between the measure (calculated as patient months) and mortality.
- The developer also cites approval of the measure by a Clinical Technical Expert Panel (TEP), suggesting that this demonstrates face validity of the measure.

3. Feasibility: H-16; M-1; L-0; I-0

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

Rationale:

- The Committee noted that all data elements are in defined fields in a combination of electronic sources, including the CROWNWeb registry, and that the data are generated, collected and used by healthcare personnel during provision of care.

4. Usability and Use: The maintenance measure meets the Use subcriterion

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

4a. Use**: Pass-17; No Pass-0**; 4b. Usability: **H-6; M-11; L-0; I-0**

Rationale:

- The Committee noted that this measure is not currently in use, but that the developer provided a credible plan for implementation and use.
- Committee members suggested that this measure will encourage facilities to comply with KDOQI practice recommendations.

5. Related and Competing Measures

- No related or competing measures noted.

6. Standing Committee Recommendation for Endorsement: Yes-17; **No-0**

7. Public and Member Comment

- No NQF member or public comments were received.

8. Consensus Standards Approval Committee (CSAC) Endorsement Decision: Yes-13; No-0 (October 21-22, 2019: Approved for continued endorsement)

- CSAC upheld the Committee's decision to recommend the measure for endorsement.

9. Appeals

No appeals were received

1425 Measurement of nPCR for Pediatric Patients

Submission | Specifications

Description: Percentage of patient months of pediatric (< 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 adult patients (greater than or equal to 18 years of age), all patients who have not been in the facility for the entire reporting month, and all home hemodialysis and peritoneal dialysis patients. There are no additional exclusions for this measure.

Adjustment/Stratification No risk adjustment or risk stratification

Level of Analysis: Facility

Setting of Care: Other

Type of Measure: Process

Data Source: Claims, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING 06/07/2019

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

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

1a. Evidence: **H-0; M-12; L-2; I-4**; 1b. Performance Gap: **H-3; M-14; L-0; I-1**;

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.
- Committee members noted that nPCR is often used in concert with other determinants, none of which are perfect; it was suggested that this indicator gives dieticians a "hook to hang their hat on" when managing the nutrition of pediatric patients.
- The developer provided 2017 CROWNWeb clinical data (January 2017-December 2017)
- Mean (SD) = 76.64% (32.5%), min = 0%, max = 99.3%, 25th percentile = 75.8%, 50th percentile = 90.8%, and 75th percentile = 94.1%
- The Committee found there to be a sufficient performance gap to warrant measurement in this area.

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

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

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

Rationale:

- To test reliability of the measure score, the developer assessed inter-unit reliability (IUR) across 12 reporting months, using a bootstrap approach to estimate the proportion of measure variability that is attributable to between-facility variance.
- IUR=0.963; The developer states that this value is high and suggests 96.3% of variation in the measure is attributed to between facility variation.
- To demonstrate measure validity, the developer examined the association between facility percentage of reporting nPCR month and mean nPCR value via the means of two-sample t-test.
- The developer hypothesizes that facilities with at least 85% reporting of nPCR among their pediatric patients are likely paying attention to this parameter in their clinical management (i.e., assessment of protein intake) of pediatric dialysis patients.

- The developer reports that "among facilities with at least 11 eligible pediatric patients and recorded nPCR values, facilities with 85% or higher reporting of recorded nPCR values had a mean nPCR of 0.9974, while facilities with less than 85% reporting of recorded nPCR values had a mean nPCR of 0.6587. According to the t-test (Satterthwaite version), the mean nPCR values of these two groups were not statistically significant (p-value=0.13)."
- The developer also cited approval of the measure by a Clinical Technical Expert Panel (TEP), suggesting that this demonstrates face validity of the measure.

---

3. Feasibility: H-7; M-11; L-0; I-0

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

Rationale:

- The Committee noted that all data elements are in defined fields in a combination of electronic sources, including the CROWNWeb registry, and that the data are generated, collected and used by healthcare personnel during provision of care.

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4. Usability and Use: The maintenance measure meets the Use subcriterion

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

4a. Use**: Pass-18; No Pass-0**; 4b. Usability: **H-3; M-15; L-0; I-0**

Rationale:

- This measure is currently being publicly reported through CMS's Dialysis Facility Compare program.
- The developer states that CY 2017 was the first year of public reporting and suggests that this may be too short of a time frame to observe meaningful trends, particularly because of the small number of facilities for which the measure is calculated.

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5. Related and Competing Measures

- No related or competing measures noted.

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6. Standing Committee Recommendation for Endorsement: **Yes-18**; **No-0**

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7. Public and Member Comment

- No NQF member or public comments were received.

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8. Consensus Standards Approval Committee (CSAC) Endorsement Decision: Yes-13; No-0 (October 21-22, 2019: Approved for continued endorsement)

- CSAC upheld the Committee's decision to recommend the measure for endorsement.

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9. Appeals

No appeals were received

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

Submission | Specifications

Description: Percentage of pediatric (< 18 years old) peritoneal dialysis patient-months whose delivered peritoneal dialysis dose was a weekly Kt/Vurea >= 1.8 (dialytic + residual)

Numerator Statement: Number of patient months in the denominator in which delivered peritoneal dialysis dose was a weekly Kt/Vurea >= 1.8 (dialytic + residual, measured in the last 6 months)

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

Exclusions: Exclusions that are implicit in the denominator definition include

1) Patients not on peritoneal dialysis for the entire month
2) Adult patients (>=18 years old)
3) All patients who have had ESRD for <91 days, and
4) Patients 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: Other

Type of Measure: Outcome: Intermediate Clinical Outcome

Data Source: Claims, Registry Data

Measure Steward: Centers for Medicare & Medicaid Services

STANDING COMMITTEE MEETING [06/07/2019]

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

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

1a. Evidence: **Carried over votes from previous evaluation**; 1b. Performance Gap: **H-2; M-15; L-0; I-0**

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 standard.
- Because this is a maintenance measure, and the developer attested that there had been no change in the evidence since its last endorsement, a vote on Evidence was not required. The Committee agreed to accept the Evidence rating from the previous review.
- The developer presented performance data based on 2017 CROWNWeb and Medicare claims data.

- Out of about 31 facilities, the mean performance score was 71.3 percent, with a standard deviation of 21.2 percent.
- The Committee found there to be a sufficient performance gap to warrant measurement in this area.

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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: **Accepted the Scientific Methods Panel evaluation**; 2b. Validity: **Accepted the Scientific Methods Panel evaluation**

<u>Rationale</u>:

- This measure was reviewed by the SMP.
- Reliability testing was conducted at the score level by assessing inter-unit reliability (IUR) across 12 reporting months, using a bootstrap approach to estimate the proportion of measure variability that is attributable to between-facility variance.
- Testing resulted in an IUR of 0.961 (with a confidence interval of (0.937,0.979)), which suggests 96% of variation in the measure is attributed to between facility variation.
- Validity testing was conducted at the score level using a face validity assessment.
- At maintenance review, empirical validity testing is required. However, face validity is sufficient for maintenance endorsement if adequate justification is provided.
- The developer stated that it is difficult to interpret results of empiric validity testing with any confidence, given the small sample size. The SMP and the Renal Standing Committee were satisfied with this rationale.
- The Committee agreed to accept the Scientific Methods Panel's ratings for reliability and validity.

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3. Feasibility: H-10; M-6; L-0; I-0

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

<u>Rationale</u>:

- The Committee noted that all data elements are in defined fields in a combination of electronic sources, including the CROWNWeb registry, and that the data are generated, collected and used by healthcare personnel during provision of care.

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4. Usability and Use: <u>The maintenance measure meets the Use subcriterion</u>

(Used and useful to the intended audiences for 4a. Accountability and Transparency; 4b. Improvement; and 4c. Benefits outweigh evidence of unintended consequences)

4a. Use**: Pass-17; No Pass-0**; 4b. Usability: **H-5; M-12; L-0; I-0**

<u>Rationale</u>:

- The measure is in use in the Centers for Medicare & Medicaid Services (CMS)'s Dialysis Facility Compare Program.
- In addition, the measure is one component of a composite measure of dialysis adequacy used in the ESRD Quality Incentive Program (ESRD QIP).

- The developer notes that feedback received during Dialysis Facility Compare preview periods has resulted in more detailed and accurate documentation available to the public, primarily via the ESRD Measures Manual and the Guide to the Quarterly Dialysis Facility Reports.

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5. Related and Competing Measures

- No related or competing measures noted.

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6. Standing Committee Recommendation for Endorsement: Yes-17; No-0

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7. Public and Member Comment

- No NQF member or public comments were received.

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8. Consensus Standards Approval Committee (CSAC) Endorsement Decision: Yes-13; No-0 (October 21-22, 2019: Approved for continued endorsement)

- CSAC upheld the Committee's decision to recommend the measure for endorsement.

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9. Appeals

No appeals were received

Appendix B: Renal Portfolio—Use in Federal Programs

Based on information provided in the CMS Measures Inventory Tool as of January 31, 2020.

NQF #	Title	Federal Programs: Finalized as of January 31, 2020
0255	Measurement of Phosphorus Concentration	End-Stage Renal Disease Quality Incentive Program
0256	Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access	End-Stage Renal Disease Quality Incentive Program
0257	Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)	End-Stage Renal Disease Quality Incentive Program
0318	Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum	End-Stage Renal Disease Quality Incentive Program
0369	Dialysis Facility Risk-adjusted Standardized Mortality Ratio	End-Stage Renal Disease Quality Incentive Program
1423	Minimum spKt/V for Pediatric Hemodialysis Patients	End-Stage Renal Disease Quality Incentive Program
1454	Proportion of patients with hypercalcemia	End-Stage Renal Disease Quality Incentive Program
1463	Standardized Hospitalization Ratio for Admissions	End-Stage Renal Disease Quality Incentive Program
1667	Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL	Merit-Based Incentive Payment System (MIPS)
2977	Hemodialysis Vascular Access: Standardized Fistula Rate	End-Stage Renal Disease Quality Incentive Program
2978	Hemodialysis Vascular Access: Long-term Catheter Rate	End-Stage Renal Disease Quality Incentive Program
2979	Standardized Transfusion Ratio for Dialysis Facilities	End-Stage Renal Disease Quality Incentive Program
2988	Medication Reconciliation for Patients Receiving Care at Dialysis Facilities	End-Stage Renal Disease Quality Incentive Program

Appendix C: Renal Standing Committee and NQF Staff

STANDING COMMITTEE

Constance Anderson, BSN, MBA (Co-Chair)
Vice President of Clinical Operations, Northwest Kidney Centers
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Vice President, Epidemiology and Research, Fresenius Medical Care North America
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Senior Vice President, Quality Measurement

Andrew Lyzenga, MPP
Senior Director

Amy Moyer, MS, PMP
Director

Janaki Panchal, MSPH
Project Manager

Appendix D: Measure Specifications

0318 Delivered Dose of Peritoneal Dialysis Above Minimum

STEWARD

Centers for Medicare & Medicaid Services

DESCRIPTION

Percentage of all patient months for adult patients (>= 18 years old) whose delivered peritoneal dialysis dose was a weekly Kt/Vurea >= 1.7 (dialytic + residual).

TYPE

Outcome: Intermediate Clinical Outcome

DATA SOURCE

Claims, Registry Data For the analyses supporting this submission, the measure is calculated using CROWNWeb as the primary data source for the Kt/V values used to determine the numerator. If a patient's Kt/V data are missing in CROWNWeb, Kt/V values from outpatient Medicare dialysis claims are used as an additional source for obtaining that information. Please see the attached data dictionary for a list of specific data elements that are used from each data source.

LEVEL

Facility

SETTING

Other Dialysis Facility

NUMERATOR STATEMENT

Number of patient months in the denominator whose delivered peritoneal dialysis was a weekly Kt/Vurea >= 1.7 (dialytic + residual, measured in the last 4 months).

NUMERATOR DETAILS

Reporting months with weekly Kt/Vurea >=1.7 (dialytic + residual) are counted in the numerator. If no weekly Kt/Vurea value is reported for a given patient in the reporting month, the most recent peritoneal dialysis weekly Kt/Vurea value in the prior 3 months is applied to the calculation for that month.

Missing, expired, and not performed are not counted as achieving the minimum weekly Kt/Vurea threshold.

DENOMINATOR STATEMENT

To be included in the denominator for a particular reporting month, the patient must be on peritoneal dialysis for the entire month, be >= 18 years old at the beginning of the month, must have had ESRD for greater than 90 days at the beginning of the month, and must be assigned to that facility for the entire month.

DENOMINATOR DETAILS

A treatment history file is the data source for the denominator calculation used for the analyses supporting this submission. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. CROWNWeb is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source of information in certain situations. Information regarding first ESRD service date, death, and transplant is obtained from CROWNWeb (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN).

EXCLUSIONS

Exclusions that are implicit in the denominator definition include

1) Patients not on peritoneal dialysis for the entire month
2) Pediatric patients (<18 years old)
3) Patients who have had ESRD for <91 days
4) Patients not assigned to the facility for the entire month

There are no additional exclusions for this measure.

EXCLUSION DETAILS

N/A

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

N/A

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

Denominator: For the reporting month, patients are included in the denominator if:

Patient modality is indicated as PD during the entire month

Patient age as of the beginning of the reporting month is at least 18 years

Patient has had ESRD for greater than 90 days at the beginning of the month

Patient has been assigned to the facility for the entire month

Numerator: For the reporting month, patients from the denominator are also included in the numerator if they have a weekly Kt/Vurea >= 1.7.

If no weekly Kt/Vurea value is reported for a given patient in a month, the most recent peritoneal dialysis weekly Kt/Vurea value in the prior 3 months is applied to the calculation for that month. 109110| 132512| 136622| 141592

1423 Minimum spKt/V for Pediatric Hemodialysis Patients

STEWARD

Centers for Medicare & Medicaid Services

DESCRIPTION

Percentage of patient months for all pediatric (<18 years old) in-center hemodialysis patients in which the delivered dose of hemodialysis (calculated from the last measurement of the month using the UKM or Daugirdas II formula) was spKt/V >= 1.2.

TYPE

Outcome: Intermediate Clinical Outcome

DATA SOURCE

Claims, Registry Data For the analyses supporting this submission, the measure is calculated using CROWNWeb as the primary data source for the Kt/V values used to determine the numerator. If a patient's Kt/V data are missing in CROWNWeb, Kt/V values from outpatient Medicare dialysis claims are used as an additional source for obtaining that information. Please see the attached data dictionary for a list of specific data elements that are used from each data source.

LEVEL

Facility

SETTING

Other Dialysis Facility

NUMERATOR STATEMENT

Number of patient months from the denominator in which the delivered dose of hemodialysis (calculated from the last measurement of the month using the UKM or Daugirdas II formula) was spKt/V >= 1.2.

NUMERATOR DETAILS

Months with spKt/V >=1.2 are counted in the numerator. Eligible spKt/V values are those >=1.2 during the reporting month. The last spKt/V value reported, not including missing, expired, and not performed, is selected when multiple values are reported in the month.

Missing, expired, and not performed are not counted as achieving the minimum spKt/V threshold.

DENOMINATOR STATEMENT

To be included in the denominator for particular month, a patient must be on hemodialysis for the entire month, must be <18 years old at the beginning of the month, must have had ESRD for greater than 90 days at the beginning of the month, must be on thrice weekly in-center hemodialysis during the month, and must be assigned to that facility for the entire month.

DENOMINATOR DETAILS

A treatment history file is the data source for the denominator calculation used for the analyses supporting this submission. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. CROWNWeb is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source of information in certain situations. Information regarding first ESRD service date, death, and transplant is obtained from CROWNWeb (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN).

EXCLUSIONS

Exclusions that are implicit in the denominator definition include:

1) Patients on home hemodialysis
2) Patients on peritoneal dialysis
3) Adult patients (>=18 years old)
4) Patients on ESRD less than 91 days
5) Patients not on thrice weekly dialysis
6) Patients not assigned to the facility for the entire month

There are no additional exclusions for this measure.

EXCLUSION DETAILS

N/A

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

N/A

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

Denominator:

For the reporting month, patients are included in the denominator if:

Patient modality is indicated as Hemodialysis during the entire month (in-center)

Patient is dialyzing thrice weekly during the month

Patient age as of the beginning of the reporting month is less than 18 years

Patient has had ESRD for greater than 90 days at the beginning of the month

Patient is assigned to the facility for the entire month

Numerator:

For the reporting month, patient months from the denominator are also included in the numerator if they have a spKt/V >=1.2. The last spKt/V value reported, not including missing, expired, and not performed, is selected when multiple values are reported in the month.
117737| 136622| 141592

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1424 Monthly Hemoglobin Measurement for Pediatric Patients

STEWARD

Centers for Medicare & Medicaid Services

DESCRIPTION

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

TYPE

Process

DATA SOURCE

Claims, Registry Data CROWNWeb and Medicare claims.

LEVEL

Facility

SETTING

Other Dialysis Facility

NUMERATOR STATEMENT

Number of patient months of pediatric (< 18 years old) in-center hemodialysis, home hemodialysis, and peritoneal dialysis patients with a measurement of hemoglobin during the reporting period.

NUMERATOR DETAILS

The numerator will be determined by counting all patient months in the denominator that include values for 'Hemoglobin' and 'Hemoglobin Collection Date.' A valid hemoglobin value is defined as between 5-20 g/dL. The hemoglobin value reported for the end of each reporting month (end-of-month hemoglobin) is used as evidence of measurement for the calculation.

DENOMINATOR STATEMENT

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

DENOMINATOR DETAILS

Patients are included in the facility calculation if "Admit Date" to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged ("Discharge Date" is null or blank), OR "Discharge Date" from the facility is greater than or equal to the last day of the study period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. All patients under the facility's care for the entire calendar month and are < 18 years of age will be included in the denominator.

A treatment history file is the data source for the denominator calculation used for the analyses supporting this submission. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the

patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. CROWNWeb is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source of information in certain situations. Information regarding first ESRD service date, death, and transplant is obtained from CROWNWeb (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN).

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.

EXCLUSION DETAILS

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.

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

N/A

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

Patients are included in the facility calculation if “Admit Date” to the specified facility is prior or equal to the first day of the study period, AND the patient has not been discharged (“Discharge Date” is null or blank), OR “Discharge Date” from the facility is greater than or equal to the last day of the study period. The patient’s age will be determined by subtracting the patient’s date of birth from the first day of the reporting month. All in-center HD, home HD, and PD patients under the facility’s care for the entire calendar month and are < 18 years of age will be included in the denominator. The numerator will be determined by counting all patients in the denominator who have values for ‘Hemoglobin’ and ‘Hemoglobin Collection Date.’ 117737| 136622| 141592

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N/A

1425 Measurement of nPCR for Pediatric Hemodialysis Patients

STEWARD

Centers for Medicare & Medicaid Services

DESCRIPTION

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

TYPE

Process

DATA SOURCE

Claims, Registry Data CROWNWeb and Medicare claims.

LEVEL

Facility

SETTING

Other Dialysis Facility

NUMERATOR STATEMENT

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

NUMERATOR DETAILS

The number of patients in the study month where (1) nPCR value and the date the nPCR were collected and reported or (2) the following 7 components used to calculate nPCR (BUN pre-dialysis, BUN post-dialysis, pre-dialysis weight, pre-dialysis weight unit of measure, post-dialysis weight, post-dialysis weight unit of measure, and delivered minutes of BUN hemodialysis session), and the date of collection are all reported.

Note: Interdialytic time is also needed to calculate nPCR; however CROWNWeb currently does not allow collection of that data element therefore the measure does not require reporting of this variable.

DENOMINATOR STATEMENT

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

DENOMINATOR DETAILS

A treatment history file is the data source for the denominator calculation used for the analyses supporting this submission. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. CROWNWeb is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source of information in certain situations. Information regarding first ESRD service date, death, and

transplant is obtained from CROWNWeb (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN).

EXCLUSIONS

Exclusions that are implicit in the denominator definition include adult patients (greater than or equal to 18 years of age), all patients who have not been in the facility for the entire reporting month, and all home hemodialysis and peritoneal dialysis patients. There are no additional exclusions for this measure.

EXCLUSION DETAILS

N/A

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

N/A

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

To be included in the denominator for a particular month, the patient must be on in-center hemodialysis for the entire month, must be < 18 years old at the beginning of the month, and must be assigned to that facility for the entire month. An individual patient may contribute up to 12 patient-months per year.

The numerator counts the number of patients in the study month where (1) nPCR value and the date the nPCR were collected and reported or (2) the components that allow calculation of nPCR (BUN pre-dialysis, BUN post-dialysis, pre-dialysis weight, pre-dialysis weight unit of measure, post-dialysis weight, post-dialysis weight unit of measure, and delivered minutes of BUN hemodialysis Session) and the date of collection are all known.

Note: Interdialytic time is also needed to calculate nPCR; however, CROWNWeb currently does not allow collection of that data element, therefore the measure does not require reporting of that variable. 117737| 136622| 141592

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N/A

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

STEWARD

Centers for Medicare & Medicaid Services

DESCRIPTION

Percentage of pediatric (< 18 years old) peritoneal dialysis patient-months whose delivered peritoneal dialysis dose was a weekly Kt/Vurea >= 1.8 (dialytic + residual)

TYPE

Outcome: Intermediate Clinical Outcome

DATA SOURCE

Claims, Registry Data For the analyses supporting this submission, the measure is calculated using CROWNWeb as the primary data source for the Kt/V values used to determine the numerator. If a patient's Kt/V data are missing in CROWNWeb, Kt/V values from outpatient Medicare dialysis claims are used as an additional source for obtaining that information. Please see the attached data dictionary for a list of specific data elements that are used from each data source.

LEVEL

Facility

SETTING

Other Dialysis Facility

NUMERATOR STATEMENT

Number of patient months in the denominator in which delivered peritoneal dialysis dose was a weekly Kt/Vurea >= 1.8 (dialytic + residual, measured in the last 6 months)

NUMERATOR DETAILS

Reporting months with weekly Kt/Vurea >=1.8 (dialytic + residual) are counted in the numerator. If no weekly Kt/Vurea value is reported for a given patient in the reporting month, the most recent peritoneal dialysis weekly Kt/Vurea value in the prior 5 months is applied to the calculation for that month.

Missing, expired, and not performed are not counted as achieving the minimum weekly Kt/Vurea threshold.

If RRF is to be incorporated in the Kt/V calculation, this will be calculated using the urea clearance derived from 24 hour urine collection. Total body water (V) should be estimated by one of the following pediatric specific V approximation methods:

•Prediction equation based upon heavy water dilution

Males: TBW=0.10 (ht x wt)0.68 – 0.37 (wt)

Females: TBW=0.14 (ht x wt) 0.64 – 0.35 (wt)

•Simplified V estimating equations derived from the above prediction equations:

Males: TBW=20.88 x BSA – 4.29

Females: TBW=16.92 x BSA – 1.81

•Sex specific normograms derived from the above prediction equations and published in KDOQI PD guidelines for the pediatric population update from 2006.

DENOMINATOR STATEMENT

To be included in the denominator for a particular reporting month, the patient must be on peritoneal dialysis for the entire month, be < 18 years old at the beginning of the month, must have had ESRD for greater than 90 days at the beginning of the month, and must be assigned to that facility for the entire month.

DENOMINATOR DETAILS

A treatment history file is the data source for the denominator calculation used for the analyses supporting this submission. This file provides a complete history of the status, location, and dialysis treatment modality of an ESRD patient from the date of the first ESRD service until the patient dies or the data collection cutoff date is reached. For each patient, a new record is created each time he/she changes facility or treatment modality. Each record represents a time period associated with a specific modality and dialysis facility. CROWNWeb is the primary basis for placing patients at dialysis facilities and dialysis claims are used as an additional source of information in certain situations. Information regarding first ESRD service date, death, and transplant is obtained from CROWNWeb (including the CMS Medical Evidence Form (Form CMS-2728) and the Death Notification Form (Form CMS-2746)) and Medicare claims, as well as the Organ Procurement and Transplant Network (OPTN).

EXCLUSIONS

Exclusions that are implicit in the denominator definition include

1) Patients not on peritoneal dialysis for the entire month
2) Adult patients (>=18 years old)
3) All patients who have had ESRD for <91 days, and
4) Patients not assigned to the facility for the entire month

There are no additional exclusions for this measure.

EXCLUSION DETAILS

N/A

RISK ADJUSTMENT

No risk adjustment or risk stratification

STRATIFICATION

N/A

TYPE SCORE

Rate/proportion better quality = higher score

ALGORITHM

Denominator: For the reporting month, patients are included in the denominator if:

1. Patient modality is indicated as peritoneal dialysis during the entire month
2. Patient age as of the beginning of the reporting month is less than 18 years

3. Patient has had ESRD for greater than 90 days at the beginning of the month
4. Patient has been assigned to the facility for the entire month

   Numerator:

   For the reporting month, patients from the denominator are also included in the numerator if they have a weekly Kt/Vurea >= 1.8.

   If no weekly Kt/Vurea value is reported for a given patient in a month, the most recent peritoneal dialysis weekly Kt/Vurea value in the prior 5 months is applied to the calculation for that month. 139029| 141592

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