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**NATIONAL VOLUNTARY CONSENSUS STANDARDS FOR
RENAL DISEASE**

Renal Endorsement Maintenance 2011

TECHNICAL REPORT

May 2012

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RENAL ENDORSEMENT MAINTENANCE TECHNICAL REPORT

INTRODUCTION

The [NQF Renal Consensus Standards Endorsement Maintenance Project](#) sought to identify and endorse measures that specifically addressed renal-related diseases for public reporting/accountability and quality improvement applicable to all settings of care. In addition, NQF-endorsed® chronic kidney disease and end stage renal disease consensus standards that were endorsed prior to June 2008 underwent endorsement maintenance review. This project followed the recently completed [End Stage Renal Disease project](#).

The Steering Committee recommended twelve performance measures for endorsement as voluntary consensus standards. The measures address the topics of mortality (1), anemia (2), cardiovascular (1), dialysis adequacy (4), mineral metabolism (1), and vascular access (3).

MEASURE EVALUATION

The Renal Steering Committee evaluated eight new measures and twenty-five measures undergoing endorsement maintenance review against NQF's [measure evaluation criteria](#). To facilitate the evaluation, the committee and candidate standards were divided into groups by topic (anemia/cardiovascular; dialysis adequacy; mineral metabolism/mortality; vascular access/patient education) for evaluation of all the subcriteria prior to final evaluation by the entire Steering Committee.

Table 1. Renal Endorsement Maintenance Measures

	MAINTENANCE	NEW	TOTAL
Submitted	25	8	33
Recommended	9	3	12
Not recommended	16	5	21
Reasons not recommended	9 - Importance to Measure and Report (5 assessment measures with associated intermediate outcome) 7 - Scientific Acceptability of Measure Properties	4- Importance to Measure and Report 1 - Scientific Acceptability of Measure Properties	

Overarching Issues

During the Steering Committee's discussion of the measures, several overarching issues emerged and were discussed. These issues factored into the Committee's ratings and recommendations for multiple measures and are not repeated in detail with each individual measure. This is one of the first projects implementing the 2010 task force recommendations regarding evaluating evidence and measure testing and some of the measure submissions had incomplete responses or did not specifically address the questions asked. NQF will continue to work with developers to increase understanding of what information is needed by Steering Committees to evaluate the measures.

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Evidence

With implementation of the evidence task force guidance, measure developers were asked to submit a summary of the quantity, quality, and consistency of the body of evidence supporting process measures. The goal is greater transparency in regards to the evidence that does or does not exist. Developers are not expected to conduct primary evidence reviews but to use existing systematic reviews and grading of evidence. This project was one of the first to implement the new guidance and the measure submissions indicated some difficulties including:

- not summarizing the quality and consistency of a body of evidence, sometimes just making conclusion statement such as the evidence is strong;
- relying only a guideline recommendation without summarizing the quality and consistency of the body of evidence on which the guideline is based;
- listing a literature search instead of a systematic evidence review;
- not differentiating the difference between the focus of measurement and the topic of the body of evidence;
- indicating that the method of grading the evidence or recommendation was GRADE, when some modification was used without explaining the differences; and
- identifying a different system of grading the evidence or recommendation (which is acceptable), but not providing a description or definitions.

Measure Focus not Proximal to Desired Outcomes

Some measures have a focus that is fairly far removed from desired outcomes (e.g., frequency of assessment). The evidence provided for such measures may not be directly about the specific focus of measurement. In evaluating Importance to Measure and Report, the Steering Committee also noted that it is essential to distinguish between processes that are important to perform in clinical practice from those that should be measured and reported as a national voluntary consensus standard for assessing performance on quality. At the Consensus Standards Approval Committee (CSAC) meeting in July 2011, the CSAC voiced concern over measures focused on frequency or method of assessment. The CSAC emphasized the guidance that process performance measures should focus on processes proximal to desired outcomes supported by evidence.

For the assessment measures reviewed in this project, the Steering Committee considered not only the directness of the evidence for the particular measure, but also the state of the science that exists to support a measure of a more proximal intermediate clinical outcome or process. In this project, the Steering Committee did not recommend process measures about assessment when an associated intermittent clinical outcome measure was recommended. However, in the case of phosphorus, the Committee identified that it was an important parameter but the current state of science did not support setting specific targets or treatment.

Changing Evidence or Guidelines

The NQF guidance on evidence directs that inconsistent evidence of benefit over harm to patients should result in failing the evidence criterion, which would stop further consideration as a national voluntary consensus standard. In an exceptional circumstance, expert opinion might be considered adequate. Prior to and during this project two initiatives on evidence influenced the measure evaluation. On June 24, 2011 the FDA issued another warning and more conservative

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dosing guidelines for erythropoiesis stimulating agents (ESA) in patients with chronic kidney disease (available [here](#)). The warning included:

- “In controlled trials with CKD patients, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered ESAs to target a hemoglobin level of greater than 11 g/dL.
- No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks.
- For patients with CKD, consider starting ESA treatment when the hemoglobin level is less than 10 g/dL. This advice does not define how far below 10 g/dL is appropriate for an individual to initiate. This advice also does not recommend that the goal is to achieve a hemoglobin of 10 g/dL or a hemoglobin above 10 g/dL. Individualize dosing and use the lowest dose of ESA sufficient to reduce the need for red blood cell transfusions. Adjust dosing as appropriate.
- The drug label previously recommended that ESAs should be dosed to achieve and maintain hemoglobin levels within the target range of 10 to 12 g/dL in CKD patients. This target concept has been removed from the label.”

This FDA announcement prompted the Centers for Medicare & Medicaid (CMS) to withdraw its measures of hemoglobin less than 10 for both pediatric and adult patients. Other developers decided to proceed with measures for hemoglobin less than 10 (#1660, #1667). The Steering Committee recommended a pediatric measure for hemoglobin less than 10, but not the adult measure. It determined that there was better evidence of harm in pediatric patients when hemoglobin falls below 10 and the evidence on harms with ESA treatment did not include children.

The second area of changing guidelines is hypertension. The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 8) was updating guidelines, which were due for release in 2012 (information available [here](#)). The draft guidelines were not available for review at the time of the project, but were anticipated to include changes in target blood pressure for CKD patients. In 2011, the NQF Cardiovascular Steering Committee recommended a general measure of hypertension control of less than 140/90 (#0018) after removal of the condition-specific targets and on the condition that if necessary it would be modified further when the JNC 8 guidelines are published. The Renal Steering Committee reviewed and considered the submitted measure (#1633) with a target blood pressure of less than 130/80 several times during the project but did not recommend it for endorsement for several reasons outlined in the evaluation summary. Measure 0018 includes the CKD population so that presents a competing measures issue and the majority of the Committee thought the more general measure adequately includes CKD patients.

Measure Testing (Reliability and Validity)

The NQF guidance on measure testing directs that Scientific Acceptability of Measure Properties is also a threshold criterion and measures must demonstrate adequate reliability and validity to pass the criterion. The validity rating includes validity testing as well as testing related to potential threats to validity such as risk adjustment and exclusions. The items on the measure submission form for testing are essentially unchanged from the prior version. Some issues identified during review of the renal measures included:

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- inappropriate testing method or no rationale for method of testing provided;
- reliance on descriptive statistics and use rather than empirical evidence of reliability and validity as directed in the guidance;
- conducting testing using a different data source or level of analysis from measure specifications;
- reliance on face validity, which although accepted in the criteria is the weakest approach; and then sometime face validity was not systematically assessed or adequately described;
- no analysis to support the use of exclusions/exceptions that are not specified in the evidence (e.g., frequency and distribution).

Lack of Clear Consensus

Several measures had fairly close votes on whether a measure was suitable for endorsement. Both of these reflect the Committee's struggle between the desire to have a performance measure on a topic and the weaknesses of the measures that were submitted.

- [0570](#) Chronic Kidney Disease (CKD): Monitoring Phosphorus (IMS Health) had a split vote of Yes-10 and No-10.
- [0324](#) Patient Education Awareness—Facility Level (KCQA) was not recommended by a vote of Yes-12 and No-10.

A few commenters supported measure 0324 and one supported 0570. After reviewing comments, the Steering Committee affirmed that the identified issues were fundamental to the measures as specified and described in the evaluation summary tables. Neither measure was recommended for endorsement. The Steering Committee emphasized its recommendation for development of patient education measures as indicated in the recommendations for measure development.

Harmonization of Related Measures

Related measures included those for hemodialysis, peritoneal dialysis, and vascular access where there were separate measures for physicians vs. facilities. During the comment period the developers worked on measure harmonization and the final specifications are harmonized to the extent possible. The Steering Committee suggested that facility and physician level measures be combined into one measure and asked the developers to explore that before the next endorsement maintenance review. See side-by-side tables of specifications in [Appendix C](#).

- The peritoneal dialysis measures (#0318, #0321) were harmonized.
- The hemodialysis measures (#0249, #0323) were harmonized on the evidence regarding method of measuring adequacy and threshold values. One remaining difference was thought to not pose any substantial impact: the physician measure denominator is patient months rather than patients as in the facility measure.
- The physician (#0251) and facility (#0256, #0257) vascular access measures are related but have a fundamental difference because the physician measure includes evaluation by a qualified surgeon; whereas, the facility measures simply identify the percentage of patient with fistulas (preferred access) and catheters (most problematic access). There are two differences:
 - The Steering Committee recommended that the evaluation measures specify an exclusion for hospice patients so that they would not be expected to be evaluated for fistula placement. The facility measures do not have a hospice exclusion and it

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was not identified as a problem because it does not include the expectation of evaluation by a surgeon.

- The Steering Committee recommended that the definition of a functioning fistula be expanded from access with two needles to incorporate new single-needle devices. The facility data system currently does not identify single-needle devices so was not able to be changed; however CMS will explore adding to the data system. The physician measure did incorporate the single-needle device.

Competing Measures

The CKD hypertension measure (#1633) was competing with the more general measure (#0018). See side-by-side tables of specifications in [Appendix C](#). The measures differed in the following ways:

- The general measure (0018) includes all patients with a diagnosis of hypertension (including those with CKD) and excludes those with ESRD; the CKD measure (1633) includes all patients with CKD and proteinuria, not on renal replacement therapy (i.e., excludes ESRD).
- The general measure (0018) focuses on the percentage of patients with blood pressure less than 140/90; the CKD measure (1633) has a target blood pressure of less than 130/80 (which may change in JNC 8).
- The CKD measure (1633) also is met for blood pressure greater than the target of 130/80 if there is a documented plan of care; the general measure (0018) is simply the intermediate outcome of blood pressure less than 140/90.

After comment, the Steering Committee reviewed additional information provided by the developer, discussed the two measures at length, and then voted on whether measure 1633 should be recommended in addition to the endorsed measure 0018. The Committee did not recommend measure 1633 for endorsement. See the full discussion in the measure evaluation summary table.

Electronic Health Record Specifications

Several of the physician measures were submitted with additional electronic specifications. Some Steering Committee members identified errors in the code lists provided, so the e-specifications were not considered as the measures were evaluated. NQF is currently clarifying policies related to e-specifications and testing. For the measures that are endorsed, NQF will review the e-specifications according to the final policy.

RECOMMENDATIONS FOR FUTURE MEASURE DEVELOPMENT

Patient Education

The Steering Committee strongly recommended the development of patient education measures. The Steering Committee recognizes the potential for high-quality CKD patient education to positively impact the involvement of these patients in their own care and to inform their decision-making regarding modality of renal replacement therapy and other aspects of their care, as well as understanding of self-management to achieve maximum benefit from dialysis. The Steering Committee strongly recommends the development of patient education measures that are patient-centered and provide for specific aspects of any educational intervention. The

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Committee suggests that measure developers partner with professional societies and patient advocacy groups to develop patient education measures that go beyond merely checking whether educational information was provided to meet regulatory requirements and address the patient's perspective of understanding and comprehension. The Steering Committee noted that education on treatment modalities is most effective prior to beginning dialysis and urged that this be considered in future measure development.

Dialysis Adequacy

The Steering Committee also made some recommendations regarding future measures of dialysis adequacy.

- Use weekly standard Kt/V instead of spKt/V to measure urea kinetics for hemodialysis patients, so that all patients regardless of dialysis frequencies can be included.
- Residual renal function should be considered consistently in measures of dialysis adequacy for both peritoneal dialysis and hemodialysis. Currently, residual renal function is included in urea kinetic measurements of peritoneal dialysis, but not of hemodialysis.
- Developers should consider using other metrics for dialysis adequacy: volume expansion, time, ultrafiltration rate, and quality of life are possible candidates. Urea kinetic modeling is not the only, or perhaps not even the best, measure of dialysis adequacy.
- Dialysis adequacy measures should be harmonized across the facility and the physician level of assessment.

Patient Experience and Function

Two measures due for endorsement maintenance review will be reviewed in upcoming projects:

- The patient experience of care measures based on the CAHPS for dialysis facilities (#0258) will be reviewed in a 2012 project focused on patient experience with care.
- The process measure on administering the KDQoL instrument (#0260) will be reviewed in a 2012 project focused on patient function. The Steering Committee recommended that rather than a process measure, an outcome performance measure be developed and tested.

Other Recommendations

The Steering Committee suggested that facility and physician level measures could be combined into one measure and asked the developers to explore that before the next endorsement maintenance review.

After comment, the Steering Committee agreed that a measure on assessing kidney function in patients at risk of chronic kidney disease should be explored.

Additionally, recommendations for measure development were made by the Steering Committee in the recent [ESRD project](#).

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MEASURE EVALUATION SUMMARIES

The evaluation summary tables include the brief specifications and descriptive measure information, evaluation ratings, rationales, follow-up with developers, and final recommendation. The full measure specifications for the recommended measures are included in [Appendix A](#). The full measure submissions for all measures are available on the [Renal Project web page](#). Hyperlinks are provided in the header row for each measure.

The Steering Committee did not evaluate all measures at the in-person meeting. The remaining measures were evaluated first by the workgroup followed by Steering Committee discussion and vote on the major criteria.

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Measures Recommended

Mortality

0369 Dialysis Facility Risk-adjusted Standardized Mortality Ratio Specifications Submission
<p>Description: Risk-adjusted standardized mortality ratio for dialysis facility patients.</p> <p>Numerator Statement: Number of deaths among eligible patients at the facility during the 4-year time period.</p> <p>Denominator Statement: Target Population: All dialysis patients that have had ESRD for at least 90 days. Number of deaths that would be expected among eligible dialysis patients at the facility during the 4-year time period, given the mortality rate is at the national average and the patient mix at the facility.</p> <p>Exclusions: N/A</p> <p>Adjustment/Stratification: Statistical risk model Cox Model (Proportional Hazards Regression Model): The SMR calculation adjusts for patient age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, nursing home status, duration of ESRD, BMI at incidence, and comorbidities at incidence, as well as N/A</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>Importance to Measure and Report (<i>based on decision logic</i>): Yes</p> <p>1a. Impact: H-21; M-0; L-0; I-0 1b. Performance Gap: H-18; M-3; L-0; I-0</p> <p>Rationale: Mortality is high impact and there is variability.</p> <p>1c. Evidence (<i>based on decision logic</i>): Yes IF a Health Outcome, rationale supports: Y-21; N-0</p> <p>Rationale: Although structure-process-outcome relationships not identified in submission form, the Committee recognized that intermediate outcomes (e.g., dialysis adequacy, anemia) are linked to mortality and healthcare interventions affect those intermediate outcomes and ultimately mortality.</p>
<p>2. Scientific Acceptability of Measure Properties (<i>based on decision logic</i>): Yes</p> <p>2a. Reliability: H-7; M-14; L-0; I-0 2b. Validity: H-5; M-16; L-0; I-0</p> <p>Rationale: Correlation of scores across years was questioned as demonstrating reliability (reproducibility, repeatability) of data because it's a different population and different time period. However, the data elements to identify dialysis patients and those that died are not considered to be subject to much error. For validity testing, the developer correlated scores on SMR with compliance to KDOQI guidelines related to URR and hematocrit, which demonstrated that facilities in the lowest quintile of performance on the KDOQI recommended targets had greater mortality. The risk-adjustment model includes race and ethnicity, which the NQF criteria suggest not be included in risk models because it tends to obscure disparities in care. Therefore, the developer was asked for justification of including race/ethnicity in the risk model. In the case of dialysis patients, black patients have a lower death rate than whites, which is not consistent with disparities in access and quality and lower survival of black CKD patients. A committee member asked if the difference by race was primarily due to age differences in dialysis patients by race. The developer noted that race interacts with age, but that a model including age but not race/ethnicity was not sufficient. The developer reported that the identification of patients who died had been validated in prior studies. The Committee agreed that race/ethnicity should be in the model.</p> <p>The measure takes into account race/ethnicity as discussed regarding the risk model. However, mortality rates are not reported separately by race.</p>
<p>3. Usability: H-15; M-6; L-0; I-0 (<i>Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement</i>)</p> <p>Rationale: CMS reports on Dialysis Facility Compare</p>
<p>4. Feasibility: H-20; M-1; L-0; I-0 (<i>4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented</i>)</p> <p>Rationale: Requires no additional data collection.</p>
<p>5. Related and Competing Measures (<i>5a. Harmonization; 5b. Superior to competing measures</i>)</p> <p>Comments: None</p>

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0369 Dialysis Facility Risk-adjusted Standardized Mortality Ratio [Specifications](#) [Submission](#)

Steering Committee Recommendation for Endorsement: Y-21; N-0

Rationale: Mortality is an important measure of interest to all stakeholders and the measure was evaluated to meet the criteria for reliability, validity usability, and feasibility.

Public and Member Comment

Comments include:

- Need greater transparency;
- Request refinement of the model, but without specific questions or issues.

Developer Response: The comorbidities that are used for the SMR measure are derived from the CMS form, FORM CMS-2728-U3. At this time, the instructions on this form do not include ICD codes. In addition, the linked document, Technical Notes on the Standardized Mortality Ratio, provides clarification regarding the coefficients and programming for the risk model as well as measure scoring (<http://www.dialysisreports.org/pdf/esrd/public/SMRdocumentation.pdf>).

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Anemia

<p>1666 Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL Specifications Submission</p> <p>Description: Percentage of calendar months within a 12-month period during which a Hemoglobin is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy and have a Hemoglobin Level > 12.0 g/dL</p> <p>Numerator Statement: Calendar months during which patients have a Hemoglobin level > 12.0 g/dL*</p> <p>*The hemoglobin values used for this measure should be a most recent (last) hemoglobin value recorded for each calendar month</p> <p>Denominator Statement: All calendar months during which a Hemoglobin is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy</p> <p>Definitions: RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification. This measure is not risk adjusted. We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association - Physician Consortium for Performance Improvement</p>
<p>Importance to Measure and Report (<i>based on decision logic</i>): Yes</p> <p>1a. Impact: <u>H-16; M-5; L-1; I-0</u> 1b. Performance Gap: <u>H-7; M-12; L-0; I-3</u></p> <p>Rationale: 1b. The data on performance gap was only for ESRD patients, not CKD patients who also are included in the measure and the prior ESRD measure also include plan of care. The developer stated that 63.5 of patients did not receive "optimal care" per USRDS. However, "optimal care" was not defined - does this refer to number of patients meeting guideline target (Hgb 10-12) or number of patients with Hgb > 12 per measure specification? THE PQRI performance data indicated variability on the ESRD measure with a median performance of 66.23%; 25th percentile of 38.17%; and 75th percentile of 84.04%.</p> <p>1c. Evidence (<i>based on decision logic</i>): Yes</p> <p>Quantity: <u>H-4; M-17; L-0; I-0</u> Quality: <u>H-1; M-18; L-1; I-0</u> Consistency: <u>H-2; M-16; L-2; I-0</u></p> <p>Rationale: The evidence is clear about harm with higher Hgb values when on ESAs. This should be considered a safety measure. There is a difference between lack of evidence at low end vs. a safety signal.</p>
<p>2. Scientific Acceptability of Measure Properties (<i>based on decision logic</i>): Yes</p> <p>2a. Reliability: <u>H-4; M-9; L-5; I-3</u> 2b. Validity: <u>H-0; M-15; L-4; I-2</u></p> <p>Rationale: 2a1. Specifications - developer states could be implemented in one of 3 ways - medical record, CPTII codes on physician claims, or electronic health record. The Committee noted several problems with eSpecs and they were removed from consideration with the measure. 2a2. Although measure has been implemented in CMS PQRS program using CPTII codes, reliability of data elements was tested on a small sample of 4 group practices. 2b2. Submitted systematic assessment of face validity using the expert group who developed the measure. A committee member suggested that a measure of persistent high levels vs. single measurement would be a more valid indicator of poor care; however, the Committee did not recommend that change. The developer indicated that constructing the measure based on months rather than patients takes into account if a patient's Hgb is elevated for 1 out of 12 months vs. elevated for multiple months. That raised the question of whether the measure will obscure the signal for patients with chronic high levels.</p>
<p>3. Usability: <u>H-2; M-13; L-3; I-2</u> (<i>Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement</i>)</p> <p>Rationale: Used in CMS physician reporting initiatives, however performance data for physicians are not publicly available. Developer indicates will be used in 2011 but only information about participation in reporting not performance results are planned.</p>
<p>4. Feasibility: <u>H-1; M-10; L-8; I-2</u> (<i>4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented</i>)</p>

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1666 Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL [Specifications](#) [Submission](#)

Rationale: CPTII codes seem to be currently feasible.

If applicable, Conditions/Questions for Developer: eSpecs not considered because some codes were not correct - would need crosswalk to specifications before further consideration. Does the construction using months instead of patients obscure the signal for patients with chronic high levels?

Developer Response: PCPI appreciates the opportunity to review and provide an update of our eSpecifications. PCPI specifications staff is in the process of reviewing and updating the hemoglobin lab codes to ensure the appropriate laboratory codes for the hemoglobin level test are included for this measure. Additionally, we will review the dialysis procedure codes for accuracy. We have included procedure codes using SNOMED based on the guidance provided by the ONC Health Information Technology Standards Committee, but have also included CPT during this time of transition to EHRs. Because of the fact that SNOMED concepts are intended to capture clinical information within health IT systems, whereas CPT is designed for billing purposes, there will be differing levels of granularity in each terminology. The codes and concepts identified in each terminology should not be compared to each other but rather the allowable values in each terminology should be assessed as to whether they capture the concept in the performance measure.

We have provided a sample performance calculation to demonstrate how the performance calculation for a given physician would be calculated. The unit of measure for this performance measure is "months." The use of "months" in the measure construction does not obscure the signal for patients with high levels, but rather allows for a more accurate assessment of a patient's hemoglobin levels over the course of a year.

Dr. Smith's Patients (Lower performance - better quality)			
	Patient A	Patient B	Patient C
Jan	12.3	11.6	12.1
Feb	12.0	11.8	12.2
March	11.9	12.1	12.0
Apr	11.0	12.0	11.8
May	11.5	12.0	11.7
June	12.0	11.2	11.9
July	12.4	11.5	11.8
Aug	11.9	10.9	11.5
Sept	11.8	11.3	11.9
Oct	11.8	11.5	12.0
Nov	11.5	12.3	12.1
Dec	12.1	12.0	12.2
Patient Calendar Months > 12.0	3	2	4
Summary Calculation for Dr. Smith			
Total # of levels >12.0 (for all patients)			
Total # of patient calendar months (for all patients)			
Dr. Smith's Performance	$\frac{3+2+4}{12+12+12}$	9/36=25%	

Steering Committee Follow-up: Reviewed on the 10/28 call - no further action suggested.

5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)

Comments: Related to #1667 – no harmonization issues.

Steering Committee Recommendation for Endorsement: Y-15; N-6; A-0

Rationale: Hemoglobin values >12 in patients receiving ESAs is a safety issue and can be reliably measured.

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1667 (Pediatric) ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL Specifications Submission
<p>Description: Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of ESRD receiving hemodialysis or peritoneal dialysis have a Hemoglobin level <10 g/dL</p> <p>Numerator Statement: Calendar months during which patients have a Hemoglobin level <10 g/dL*</p> <p>*The hemoglobin values used for this measure should be the most recent (last) hemoglobin value recorded for each calendar month</p> <p>Denominator Statement: All calendar months during which patients aged 17 years and younger with a diagnosis of ESRD are receiving hemodialysis or peritoneal dialysis</p> <p>Exclusions: Documentation of medical reason(s) for patient having a Hemoglobin level <10g/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 chemo])</p> <p>Adjustment/Stratification: Other We account for risk adjustment by inclusion of the exceptions for this measure. Exceptions for this measure are listed above, in section 2a1.8. We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association - Physician Consortium for Performance Improvement</p>
<p>1. Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: <u>H-8; M-10; L-0; I-0</u> 1b. Performance Gap: <u>H-0; M-9; L-0; I-11</u></p> <p>Rationale: 1b. Data presented was for adult measure; no data identified for pediatric patients. A Committee member noted that a prospective longitudinal cohort study identified that 40% of stage 2-4 CKD children are anemic. There should be some data in the literature that indicates performance gap and PCPI should submit.</p> <p>1c. Evidence (based on decision logic): <u>Yes</u></p> <p>Quantity: <u>H-1; M-17; L-1; I-1</u> Quality: <u>H-0; M-11; L-7; I-0</u> Consistency: <u>H-2; M-16; L-0; I-2</u></p> <p>Rationale: The developer submitted the same evidence for the pediatric measure as the adult measure and highlighted the pediatric studies. The developer noted that the adult targets are considered only opinion-based for children. The pediatric studies included a single RCT with 11 children; 2 observational studies with size not reported; and a nonrandomized interventional study of 18 children. The pediatric members of the Committee advocated for the greater importance of adequate Hgb on growing children and discussed two studies. A newer observational study of 700 children (Ameral, 2006) showed a 70% difference in mortality with HB <10 and >10 and differences in rates of hospitalizations. A prospective cohort study of 105 adolescents (Gerson, 2004) showed that anemia negatively impacts health-related QoL, physical development, cognitive development, and school. Smaller studies showed improvement in measures of cardiac health as Hgb increases. A Committee member noted the problems with the conclusions made about Hgb in adults from the retrospective observational studies and asked if that could be an issue with the pediatric studies. Don't think there is the same issue with high Hgb levels in children as in adult studies. The evidence demonstrated a substantial benefit of Hgb = >10 and there was no evidence of harm with ESAs in children as in the studies of adults that prompted the newest FDA safety announcement. The pediatric experts advocated that the benefits of treating anemia in children to Hgb =>10 greatly outweigh the potential harms of ESAs that may be used to treat anemia and the Steering Committee agreed.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u></p> <p>2a. Reliability: <u>H-1; M-13; L-4; I-2</u> 2b. Validity: <u>H-0; M-16; L-1; I-2</u></p> <p>Rationale: 2a1. Specifications - developer states could be implemented in one of 3 ways - medical record, CPT-II codes on physician claims, or electronic health record. The Committee noted several problems with eSpecs and they were removed from consideration with the measure. 2a2. Appears to be testing for the adult measure not the pediatric measure; however there is no reason to expect a difference in reliability. Although the adult measure has been implemented in CMS PQRS program using CPT-II codes, reliability of data elements was tested for chart abstraction on a sample of 4 group practices. 2b2. Submitted systematic assessment of face validity using the expert group who developed the measure. Exclusions give good examples, but have open statement of "other medical reasons", which can be interpreted with wide variety</p>
<p>3. Usability: <u>H-6; M-14; L-0; I-0</u></p> <p><i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale: Used in physician reporting PQRS but not publicly reported.</p>
<p>4. Feasibility: <u>H-12; M-8; L-0; I-0</u></p>

NATIONAL QUALITY FORUM

1667 (Pediatric) ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL Specifications Submission
<i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i>
If applicable, Conditions/Questions for Developer: Please provide some data in the literature that indicates performance gap. eSpecs not considered because incorrect - would need crosswalk to specifications before further consideration.
Developer Response: PCPI appreciates the opportunity to review and provide an update of our eSpecifications. PCPI specifications staff is in the process of reviewing and updating the hemoglobin lab codes to ensure the appropriate laboratory codes for the hemoglobin level test are included for this measure. Additionally, we will review the dialysis procedure codes for accuracy. We have included procedure codes using SNOMED based on the guidance provided by the ONC Health Information Technology Standards Committee, but have also included CPT during this time of transition to EHRs. Because of the fact that SNOMED concepts are intended to capture clinical information within health IT systems, whereas CPT is designed for billing purposes, there will be differing levels of granularity in each terminology. The codes and concepts identified in each terminology should not be compared to each other but rather the allowable values within each terminology should be assessed as to whether they capture the concept in the performance measure.
<u>Pediatric Anemia Performance Gap Data:</u> The KDOQI Clinical Practice Recommendation for anemia management in pediatric patients (2007 revision) recommends that the target hemoglobin for patients on ESA therapy should be 11-12.0 gm/dL, and that hemoglobin concentration greater than 13 gm/dL should be avoided (CPM 2.1.2 and 2.1.3). For Q4 2010, 32.4% of pediatric patients had hemoglobin 11-12.0 gm/dL which is about the same as Q4 2009 and compares to 48.7% in the adult hemodialysis patient population. Pediatric patients that were diabetic, on hemodialysis, and were adequately dialyzed had the highest percent in the 11-12.0 gm/dL range (35.8% and 36.7% respectively). The lower tail (< 10 gm/dL) of the Hemoglobin distribution in pediatric dialysis patients by patient characteristics, according to the Elab Project Q4 2010, shows opportunities for improvement with 20% of patients with hemoglobin < 10 gm/dL (increased over 2009 when 18.6% were < 10 gm/dL.). 24.5% of patients had hemoglobin ≥ 12 gm/dL. The normal distribution curve shows a slight improvement over the past 4 years with mean hemoglobin of 11.10 ± SD 1.36. Elab 2010 and Trends Report, Renal Network of the Upper Midwest, St. Paul, MN.
5. Related and Competing Measures <i>(5a. Harmonization; 5b. Superior to competing measures)</i> Comments: Related to #1660 – no harmonization issues.
Steering Committee Recommendation for Endorsement: <u>Y-17; N-2</u>
Rationale: The rationale for approving this measure and not the adult measure was discussed. The evidence shows that values less than 10 are detrimental to children whereas with adults the detrimental effects are at values lower than 10. With adults there is evidence and concern about harm with use of ESAs but data on harm does not include pediatric patients with higher hemoglobin values. The Committee agreed that the benefits outweighed potential harm to pediatric patients.
Public and Member Comment Commenters were in support of this measure.

NATIONAL QUALITY FORUM

Cardiovascular

<p>1668 Laboratory Testing (Lipid Profile) Specifications Submission</p> <p>Description: Percentage of patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) who had a fasting lipid profile performed at least once within a 12-month period</p> <p>Numerator Statement: Patients who had a fasting lipid profile performed at least once within a 12-month period</p> <p>Denominator Statement: All patients aged 18 years and older with a diagnosis of CKD (stage 3, stage 4 or 5, not receiving RRT)</p> <p>Definition: RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation</p> <p>Exclusions: Documentation of patient reason(s) for not performing a fasting lipid profile (eg, patient declined, other patient reasons)</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification. As a process measure, no risk adjustment is necessary. We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association</p>
<p>1. Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: <u>H-6; M-14; L-1; I-0</u> 1b. Performance Gap: <u>H-5; M-13; L-0; I-1</u></p> <p>Rationale: Performance gap data for PQRI program median performance 46.7% and 56.6% of patients did not receive lipid profile.</p> <p>1c. Evidence (based on decision logic): <u>Yes</u> IF a Health Outcome, rationale supports: <u>NA</u></p> <p>Quantity: <u>H-13; M-6; L-; I-1</u> Quality: <u>H-1; M-19; L-1; I-0</u> Consistency: <u>H-0; M-16; L-4; I-1</u></p> <p>Rationale: Evidence from clinical practice guidelines. No data on final quantity of studies but started with 100s. Assessing lipid levels is not proximal to desired outcome. Does lipid monitoring affect outcomes? Primary reason is to reduce ACVD, which is unproven; affect on progression of CKD was speculative until SHARP trial which demonstrated no affect on renal outcomes. Inferring what's good for general pop may be good for CKD population. The SHARP trial directly addresses the question of benefit - 9000 patient study nondialysis avg GFR at baseline was 27 among 6,000 nondialysis patients - includes CKD3 - treating improves CV outcomes, which strengthens evidence that screening is worthwhile. SHARP only one so far that treatment improves CV mortality in dialysis patients; 4D and Aurora show improvement with CKD patients.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u></p> <p>2a. Reliability: <u>H-2; M-14; L-4; I-0</u> 2b. Validity: <u>H-1; M-13; L6-; I-1</u></p> <p>Rationale: Reliability testing in 4 nephrology practices only for chart abstraction. eSpecs include CPT-II or actual lab data for numerator but eSpecs need to be checked and cross walked. Face validity systematically assessed by expert group that developed measure. CD coding may miss large numbers of CKD patients cared for by non-nephrologists. Is that a function of the measure or the process? Developer considering adding 2 GFR results <60. Two papers have demonstrated that ICD-9 not sensitive to identify CKD therefore will under-report CKD. No upper age limit - is it necessary to do lipid testing in 85-90 year olds? NHANES arbitray cut-off of 85. No evidence either way. In the very old this as risk factor fades away because will die of something.</p>
<p>3. Usability: <u>H-2; M-16; L-2; I-0</u></p> <p><i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale: The measure using CPT-II codes is reported but physician performance data not publicly available. Stated will be used in 2011 physician reporting; no information on when publicly available.</p>
<p>4. Feasibility: <u>H-0; M-12; L-8; I-1</u></p> <p><i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale: If using medical record what if no note about review of result? The measure is not about review just that result is in the chart. Referring to "documentation" may be confusing.</p> <p>If applicable, Conditions/Questions for Developer: Developer considering adding 2 GFR results <60. eSpecs include CPT-II or actual lab data but eSpecs need to be checked and crosswalked. No upper age limit - is it necessary to do lipid testing in 85-90 year olds? Referring to</p>

NATIONAL QUALITY FORUM

1668 Laboratory Testing (Lipid Profile) Specifications Submission
<p>"documentation" may be confusing.</p> <p>Developer Response: PCPI appreciates the opportunity to review and provide an update of our eSpecifications. PCPI specifications staff is in the process of reviewing and updating the eSpecifications for accuracy. For this measure, we identify patients with Chronic Kidney Disease using a diagnosis code that would be expected to be present in the problem list in an EHR. One of the requirements of the CMS EHR Incentive Program (Meaningful Use) is that the problem list in the EHR is maintained and current. For this reason, and given that these measures are intended for use for patients with known Chronic Kidney Disease, we use the diagnosis to identify eligible patients for this measure. Per the Steering Committee request, we have removed the language of "results documented" from the measure.</p> <p>In regards to an upper age limit for this measure, the Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel IV) is expected to be released for public comment sometime in the Fall of 2011, while the expected release date is not until 2012. The Adult Treatment Panel III (ATP III) does not indicate an upper age limit for lipid testing. On the contrary, ATP III states: "Risk for coronary disease increases steeply with advancing age in men and women. At any given level of LDL cholesterol, risk for CHD is higher in older than in younger people. The principal reason that risk rises with age is that age is a reflection of the progressive accumulation of coronary atherosclerosis, which in turn reflects the cumulative exposure to atherogenic risk factors, both known and unknown. On average, older persons have more coronary atherosclerosis than do younger persons. Once atherosclerosis develops, the coronary plaque itself becomes a 'risk factor' for development of clinical CHD. This is because plaque ruptures produce acute coronary events (unstable angina or myocardial infarction), or when plaques grow large, coronary obstructive symptoms (angina pectoris) occur. Recent clinical trials indicate that older persons benefit from LDL-lowering therapy similarly to middle-aged individuals.</p> <p>Evidence statement: Advancing age is a major, independent risk factor for CHD (C1).</p> <p>Recommendation: Age should count as a risk factor to modify LDL-cholesterol goals in primary prevention.</p> <p>Approximately two-thirds of first major coronary events occur in persons ≥ 65 years. Many asymptomatic older persons have advanced coronary atherosclerosis. Recent clinical trials have revealed that aggressive LDL-lowering therapy is effective in reducing risk for CHD. Therefore, the prospects for reducing clinical CHD in the United States by intensive LDL lowering are good. To maximize this benefit, LDL-lowering drugs will be needed for many persons at higher risk." (National Heart, Lung, and Blood Institute, National Institutes of Health. Third Report of the National Cholesterol Education Program [NCEP] Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults [Adult Treatment Panel III]. September 2002.)</p> <p>In addition, no upper age limit for lipid testing is indicated in the KDOQI Clinical Practice Guidelines for Managing Dyslipidemias in Chronic Kidney Disease (<i>American Journal of Kidney Diseases</i>, Vol 41, No 4, Suppl 3 (April), 2003: pp S1-S2).</p> <p>Steering Committee Follow-up: Reviewed on the 10/28 call – the developer will revise specifications removing language about documentation and two GFR results < 60. No further action suggested.</p>
5. Related and Competing Measures (<i>5a. Harmonization; 5b. Superior to competing measures</i>)
<p>Comments: None</p>
Steering Committee Recommendation for Endorsement: <u>Y-18; N-3</u>
<p>Rationale: Although assessment is not proximal to desired outcomes, the performance gap was substantial and a satisfactory measure of more proximal intermediate outcome or intervention was not submitted.</p>
Public and Member Comment
<p>Two comments included:</p> <ul style="list-style-type: none"> • support of the measure; • question endorsing an assessment measure.

NATIONAL QUALITY FORUM

Dialysis Adequacy

0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose Specifications Submission
<p>Description: Percentage of all adult (>=18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months 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.</p> <p>Numerator Statement: Number of patients in denominator whose 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.</p> <p>Denominator Statement: All adult (>= 18 years old) patients in the sample for analysis who have been on hemodialysis for 6 months or more and dialyzing thrice weekly.</p> <p>Exclusions: Patients on HD less than 6 months; HD patients dialyzing <3 times per week or >3 times per week.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. No stratification for this measure.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Outcome</p> <p>Data Source: Electronic Clinical Data</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>1. Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: <u>H-19; M-1; L-0; I-0</u> 1b. Performance Gap: <u>H-1; M-19; L-1; I-0</u></p> <p>Rationale: CROWNWeb data 2010 shows better adherence to adequacy "standard" than before, but still shows an important performance gap. No disparities in performance were observed.</p> <p>1c. Evidence (based on decision logic): <u>Yes</u> IF a Health Outcome, rationale supports: <u>NA</u></p> <p>Quantity: <u>H-17; M-4; L-0; I-0</u> Quality: <u>H-6; M-15; L-0; I-0</u> Consistency: <u>H-10; M-11; L-0; I-0</u></p> <p>Rationale: Evidence still supports better mortality in highest Kt/V group. There is a consistent correlation with mortality in observational retrospective studies. No RCTs other than HEMO which studied the target specified in this measure and a 16% higher dose, which did not demonstrate a survival advantage. DOPPS data not from an RCT but is prospective and provides evidence for 1.2 in spKt/V. Some DOPPS data on duration of dialysis indicates an independent affect on outcome. No substantial additional studies to address whether Kt/V is the best measure.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>Yes</u></p> <p>2a. Reliability: <u>H-12; M-9; L-0; I-0</u> 2b. Validity: <u>H-2; M-19; L-0; I-0</u></p> <p>Rationale: The developer submitted additional testing information. Precision of the measure score was analyzed and for this measure the interunit reliability was 0.97.</p> <p>When using spKt/V rather than standard Kt/V can only compare if same frequency but there is an increasing # of patients on different frequencies who will not be included in the measure, so the Committee urges the developer to explore changing to standard Kt/V. A question was raised as to whether this measure should address persistent values vs. every month. The developer stated the numerator and denominator are in months but the specifications do not appear that way. Concern was expressed about the exclusion time of 6 mo and asked if the developer could provide some analysis about reducing to 3 mo. It was noted that there is facility variation on proportion of referred patients on a catheter which could differentially affect performance on this measure for a shorter time. Others suggested that would increase the incentive to not use catheters. Validity testing demonstrated that lower performance scores on dialysis adequacy were associated with higher standardized mortality ratio (especially for the 2 lowest quintiles of performance, not strictly linear). One way to potentially game this measure is to encourage patients to stay maximum time for last dialysis session of the month, which is used to calculate the spKt/V.</p>
<p>3. Usability: <u>H-17; M-4; L-0; I-0</u></p> <p><i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale:</p>
<p>4. Feasibility: <u>H-21; M-0; L-0; I-0</u></p> <p><i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale: One way to potentially game this measure is to encourage patients to stay maximum time for last dialysis session of the month, which is used to calculate the spKt/V.</p>
<p>If applicable, Questions for Committee: The developer stated the numerator and denominator are in months but the specifications do not</p>

NATIONAL QUALITY FORUM

0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose [Specifications](#) [Submission](#)

appear that way. Concern was expressed about the exclusion time of 6 mo and asked if the developer could provide some analysis about reducing to 3 mo.

If applicable, Conditions/Questions for Developer: The developer stated the numerator and denominator are in months but the specifications do not appear that way. Concern was expressed about the exclusion time of 6 mo and asked if the developer could provide some analysis about reducing to 3 mo.

Developer Response:

The current measure specifications for measure #0249: *Hemodialysis Adequacy ESRD- HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose for ESRD* require patients to be on hemodialysis for at least 6 months. The NQF Steering Committee has requested analyses in order to determine if this requirement can be reduced from 6 months to 3 months. Attached are descriptive statistics, reliability and validity analyses, and graphical displays of both measures.

Facility-level performance by measure specification

Pearson correlation coefficient showed facility-level performance on these two measures was highly correlated in all measurement months, with coefficients ranging from 0.956 to 0.999. All correlation coefficients were highly significant at $p < 0.0001$.

Table 1 (below) presents the distribution of facility level performance by percentile using CROWNWeb data from January 2010. Using the 6 month measure, 66% of facilities had at least 70% of patients meeting the $\text{spKt/V} \geq 1.2$ dose requirement, compared to 67% if the measure is change to 3 months on dialysis. However, approximately 27% of facilities had at least 90% of patients meeting the 6 month measure requirements, compared to only 10% of facilities with 90% or more patients meeting the 3 month measure requirements.

Reliability Testing

For both measures, reliability was assessed by calculating facility-level month-to-month correlations. Pearson correlation coefficients were calculated between the current performance month and previous month for reporting months July 2009 through October 2010. Results are displayed in Table 2. Correlation coefficients ranged from 0.89 to 0.98 for the 6 month measure, and 0.88-0.98 for the 3 month measure, indicating very high month-to-month correlations and reliable data elements for both measures.

Additionally, the NQF document "Guidance for Measure Testing and Evaluating Scientific Acceptability of Measure Properties" from January 2011 suggests using ANOVA to perform a signal-to-noise analysis. ANOVA was performed on patient level data from October 2010 using each measure as the independent variable and facility as the dependent variable. The intraclass correlation coefficients for the HD adequacy measures were the same ($\text{ICC} = 0.34$) regardless of whether a patient has been on hemodialysis for at least 6 months or 3 months. The interunit reliability was also the same for both measures ($\text{IUR} = 0.97$).

Validity testing

Validity was assessed using Poisson regression models to measure the association between facility level quintiles of performance scores and the 2009 standardized mortality ratio (SMR). Facility-level performance scores were divided into quintiles and the relative risk (RR) of mortality was calculated for each quintile. The highest quintile was used as the reference group. Thus, a $\text{RR} > 1.0$ for the lower performance score quintiles would indicate a higher relative risk of mortality. Results are presented in Tables 4 and 5. Results are nearly the same for both measures, and indicate indicated lower performance scores were significantly associated with a higher SMR ($p < 0.01$).

Disparities by population group

For each facility, the percent of patients by demographic group including sex, race, ethnicity, and age category, was calculated. Facilities were then divided into quintiles based on their percentage within each demographic category. Within each facility-level quintile, the average of each facility's performance measure was calculated. The means were examined for trend across quintile. No disparities in performance were observed by race, sex, ethnicity, or age. The range in percent of patients with $\text{spKt/V} \geq 1.2$ across quintiles is presented in Table 6 below. The national performance for both measures, using CROWNWeb data from 7/2009 through 10/2010, was plotted by month (Figure 1) to determine if trends between measures were similar over time. Although the overall performance decreased slightly over time, the monthly performance rates were nearly the same for both measures.

National performance by measure specification

CROWNWeb data from January 2010 were used to assess the differences in measure performance by measure specification. In 2010, a total of 178,883 patients were eligible for the 6 month measure, and 190,101 were eligible for the 3 month measure. Thus, 11,218 patients would be included in the 3 month measure, but not the 6 month measure. Table 7 presents the measure performance for the 3 month measure, 6 month measure, and the subset of patients in the 3 month measure, but not the 6 month measure.

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0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose [Specifications](#) [Submission](#)

National performance by month since start of dialysis

In Figure 2, Box plots of Kt/V are displayed by time (in months) since the start of dialysis for patients in their first year of hemodialysis. As shown below, patients in the first 3 to 4 months of hemodialysis had lower mean Kt/V compared to patients on dialysis longer.

Steering Committee Follow-up: Review response and data presented below. After reviewing the submitted analyses, on the 10/28 call the Steering Committee recommended the exclusion be 3 months instead of 6 months. CMS agreed and will revise the specifications. Measure harmonization issues with 0323 persist. See comparison table at the end of this document.

5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)

Comments: physician level measure #0323 - see [Appendix C](#) for comparison

Steering Committee Recommendation for Endorsement: Y-21; N-0

Rationale: Intermediate clinical outcome that reflects the objective of dialysis treatment.

Public and Member Comment

Comments included:

- support of the measure;
- use std Kt/V and include residual kidney function;
- concern about the effect of patient non-adherence;
- measure harmonization, combine facility and physician measures.

The Steering Committee has recommended using stdKt/V and residual kidney function in future iterations of all dialysis adequacy measures. Non-adherence by patients is a potential factor in many performance measures. Some reasons non-adherence is not typically used as an exclusion or adjustment in performance measures - a) adherence is influenced by provider practices, b) those patients are randomly distributed across all providers. The Committee reviewed the developers' responses on harmonization and was satisfied, but suggested exploring combining facility and physician level measurement in one measure for the future.

NATIONAL QUALITY FORUM

0323 Hemodialysis Adequacy: Solute Specifications Submission
<p>Description: Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis three times a week for ≥ 90 days have a spKt/V > or = 1.2</p> <p>Numerator Statement: Calendar months during which patients have a spKt/V > or = 1.2</p> <p>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.</p> <p>Exclusions: None</p> <p>Adjustment/Stratification: Other We would account for risk adjustment by inclusion of exceptions for this measure. However, this measure has no exceptions. We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association - Physician Consortium for Performance Improvement</p>
<p>1. Importance to Measure and Report (<i>based on decision logic</i>): Yes</p> <p>1a. Impact: H-20; M-0; L-0; I-0 1b. Performance Gap: H-4; M-17; L-0; I-0</p> <p>Rationale: 2008 PQRI data indicate 41% of patients did not achieve Kt/V of 1.2; physician performance at 25th percentile 29.77%, median at 60%, and 75th percentile at 79.29%. Disparities old data from the 90's.</p> <p>1c. Evidence (<i>based on decision logic</i>): Yes IF a Health Outcome, rationale supports: NA Quantity: H-17; M-4; L-0; I-0 Quality: H-5; M-16; L-0; I-0 Consistency: H-4; M-16; L-1; I-0</p> <p>Rationale: Observational studies show better outcomes with higher dialysis dose. Relatively few RCTs, and one major (HEMO) does not show evidence of improved outcomes with higher Kt/V urea. HEMO dose separation between test and control groups was only about 15% different.</p>
<p>2. Scientific Acceptability of Measure Properties (<i>based on decision logic</i>): Yes</p> <p>2a. Reliability: H-0; M-17; L-2; I-2 2b. Validity: H-0; M-18; L-1; I-2</p> <p>Rationale: Electronic specs removed from consideration due to inaccuracies until developer checks and crosswalks to specifications. Measure has been implemented using CPT-II codes but reliability testing conducted with inter-rate reliability for chart abstraction in 4 physician practices. Chart abstraction demonstrated good reliability. Prior measure included a plan of care component, which has been eliminated; but added a non-specific exclusion of "medical reason" that is determined by each physician being measured. No data was provided on this new exclusion. Face validity systematically assessed by group who developed the measure.</p>
<p>3. Usability: H-14; M-7; L-0; I-0 <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale: Used in PQRI but not publicly reported.</p>
<p>4. Feasibility: H-13; M-8; L-0; I-0 <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale: Implemented with codes entered on claim forms.</p>
<p>If applicable, Conditions/Questions for Developer: eSpecs need to be checked and crosswalked to specifications. Please provide more up-to-date data on disparities.</p> <p>Developer Response: PCPI appreciates the opportunity to review and provide an update of our eSpecifications. PCPI specifications staff is in the process of reviewing and updating the dialysis procedure codes for accuracy. We have included procedure codes using SNOMED based on the guidance provided by the ONC Health Information Technology Standards Committee, but have also included CPT during this time of transition to EHRs. Because of the fact that SNOMED concepts are intended to capture clinical information within health IT systems, whereas CPT is designed for billing purposes, there will be differing levels of granularity in each terminology. The codes and concepts identified in each terminology should not be compared to each other but rather the allowable values within each terminology should be assessed as to whether they capture the concept in the performance measure.</p> <p>HD Adequacy: Solute Disparities Data: The proportion of all patients with an adequate hemodialysis dose increased 2-fold from 43% in 1993 to 86% in 2000. In 1993, 46% of white patients and 36% of black patients received an adequate dose. Corresponding figures for 2000 were 87% and 84%, respectively. Thus, the</p>

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0323 Hemodialysis Adequacy: Solute Specifications Submission
gap between white and black patients decreased from 10% to 3%. In 1993, 54% of female patients and 31% of male patients received an adequate hemodialysis dose. Corresponding figures for 2000 were 91% and 82%, respectively. Thus, the gap between female and male patients decreased from 23% to 9%. In addition, the magnitude of gaps between whites and blacks and between women and men varied by region. Eleven regions had race gaps of 4% or less. However, no region had similarly small sex gaps. Sehgal AR. Impact of Quality Improvement Efforts on Race and Sex Disparities in Hemodialysis. JAMA, February 26, 2003-Vol 289, No. 8. Steering Committee Follow-up: Reviewed on the 10/28 call. No further action related to disparities indicated. Measure harmonization issues with 0323 persist. See comparison table at the end of this document.
5. Related and Competing Measures (<i>5a. Harmonization; 5b. Superior to competing measures</i>)
Comments: facility level measure #0249 - see Appendix C for comparison
Steering Committee Recommendation for Endorsement: <u>Y-20; N-1</u>
Rationale: Intermediate clinical outcome that reflects the objective of dialysis treatment.
Public and Member Comment Comments included: <ul style="list-style-type: none">• support of the measure;• use std Kt/V and include residual kidney function;• concern about the effect of patient non-adherence;• concern about exclusions for medical reason or patient reason;• measure harmonization, facility and physician measures should be identical. The Steering Committee has recommended using stdKt/V and residual kidney function in future iterations of all dialysis adequacy measures. Non-adherence by patients is a potential factor in many performance measures. Some reasons non-adherence is not typically used as an exclusion or adjustment in performance measures - a) adherence is influenced by provider practices, b) those patients are randomly distributed across all providers. The Committee reviewed the developers' responses on harmonization and was satisfied, but suggested exploring combining facility and physician level measurement in one measure for the future. Developer response: The exclusion for the first 90 days in the CMS measure is the way they address residual kidney function. The PCPI has preliminarily decided to eliminate 0323's measure exception for medical reasons (i.e., residual kidney function, other medical reasons) in favor of harmonizing the denominator language with 0249 (including only patients who have been on hemodialysis for 90 days or more in the measure), pending RPA/ASP/PCPI Kidney Disease Work Group approval. Because the CMS measure lists the 90 days as an exclusion, our approach would be to limit the denominator criteria and not have an exclusion at all.

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0318 Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum Specifications Submission
<p>Description: Percentage of all adult (>= 18 years old) peritoneal dialysis patients whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of at least 1.7 (dialytic + residual) during the four month study period.</p> <p>Numerator Statement: Patients are included in the numerator if delivered peritoneal dialysis was a weekly Kt/Vurea of at least 1.7 (dialytic + residual) during the four month study period.</p> <p>Denominator Statement: All adult (>= 18 years old) peritoneal dialysis patients who have been on peritoneal dialysis for at least 90 days.</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification. None. No stratification is required for this measure.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Outcome</p> <p>Data Source: Electronic Clinical Data, Electronic Clinical Data : Laboratory</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>1.Importance to Measure and Report (based on decision logic): Workgroup: <u>Yes</u> Steering Committee: <u>Y-22; N-0</u></p> <p>1a. Impact: Workgroup: <u>H-6; M-0; L0-; I-0</u> 1b. Performance Gap: Workgroup: <u>H-4; M-2; L-0; I-0</u></p> <p>Rationale: 1a. Impact – Preliminary ratings indicated agreement that high impact was met. 1b. Performance Gap – The quartiles of performance scores demonstrate a performance gap (1st quartile-0%; median-27%; 3rd quartile-50%). The developer clarified that description of the data was for all patients, not just peritoneal dialysis patients, which comprise about 9% of dialysis patients.</p> <p>1c. Evidence (based on decision logic): Workgroup: <u>Yes</u></p> <p>Quantity: Workgroup: <u>H-0; M-6; L-0; I-0</u> Quality: Workgroup: <u>H-0; M-6; L-0; I-0</u> Consistency: Workgroup: <u>H-1; M-5; L-0; I-0</u></p> <p>Rationale: The evidence indicates association between dialysis dose and mortality. A committee member noted that the PD measure includes endogenous renal function in the calculation, but not in the HD adequacy measure. Although it was thought that HD patients lose renal function quickly, there can be wide variation. The developer responded that there is no direct evidence that there is more renal function in peritoneal dialysis patients, but recent studies that show mortality differences between dialysis modalities may be an artifact of study design. Endogenous renal function is probably a large part of survival advantage, whatever the dialysis modality.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>Yes</u> Steering Committee: <u>Y-21; N-1</u></p> <p>2a. Reliability: Workgroup: <u>H-2; M-2; L-2; I-0</u> 2b. Validity: Workgroup: <u>H-2; M-2; L-2; I-0</u></p> <p>Rationale: 2a. Reliability – The concern in the preliminary evaluations was related to using correlation of scores across time is not an appropriate test of reliability for data elements or measure score as described in testing task force report. The developer responded they saw it as similar but not identical circumstances. However, the developer also provided additional analysis on interunit reliability. It indicated the IUR was only 0.57, a little above chance. The Committee discussed that it was likely due to small case volume and wide confidence intervals. 2b. Validity – The testing results indicated that performance on this measure is not associated with performance on standardized mortality ratio (all the confidence intervals for the relative risk included 1.0). The developer commented this also was probably due to small case volume and wide confidence intervals, but facilities with persistently low performance should be identified.</p>
<p>3. Usability: Workgroup: <u>H-4; M-2; L-0; I-0</u> Steering Committee: <u>H-12; M-10; L-0; I-0</u></p> <p>Rationale: The preliminary evaluations prior to the meeting indicated no issues with usability.</p>
<p>4. Feasibility: Workgroup: <u>H-5; M-1; L-0; I-0</u> Steering Committee: <u>H-14; M-8; L-0; I-0</u></p> <p>Rationale: The preliminary evaluations prior to the meeting indicated no issues with feasibility.</p>
<p>5. Suitable for endorsement: Workgroup: <u>Y-5; N-1</u></p> <p>Rationale: The preliminary evaluations prior to the meeting were divided primarily due to the issues discussed under scientific acceptability and the Workgroup will re-vote on this measure.</p>
<p>If applicable, Conditions/Questions for Developer: Have one measure (0318) that addresses assessment frequency, method, and</p>

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0318 Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum Specifications Submission
<p>minimum dose. In other words, the numerator would be number of patients who had total solute clearance for urea (endogenous residual and dialytic) measured using Kt/Vurea AND achieved dose of ≥ 1.7 every 4 months If a patient did not have a measure of Kt/Vurea in the time period, they are NOT excluded from the denominator and a facility would not get credit as meeting the measure if not assessed.</p> <p>Developer Response: The other CMS HD adequacy, CMS PD adequacy, and calcium measures can be combined into measures 0249, 0318, and 1454. These 3 measures capture the elements that are critical to the assessment of these clinical areas...for HD/PD adequacy (0249 and 0318) the 2 measures define the frequency, methodology and outcome which provides a comprehensive assessment of the care that is provided by a facility. As for the calcium measure (1454) having the value is critical to the assessment of how well a facility is performing with regards to managing their patient population. Bottom-line it is logical to combine these measures as suggested.</p>
5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)
<p><u>Comments:</u> physician level measure #0321 - see Appendix C for comparison</p>
Steering Committee Recommendation for Endorsement: <u>Y-20; N-2</u>
<p>Rationale: Intermediate clinical outcome that reflects the objective of dialysis treatment.</p>
<p>Public and Member Comment Comments included:</p> <ul style="list-style-type: none"> • support of the measure; • use std Kt/V and include residual kidney function; • concern about the effect of patient non-adherence; • measure harmonization, combine facility and physician measures; <p>The Steering Committee has recommended using stdKt/V and residual kidney function in future iterations of all dialysis adequacy measures. Non-adherence by patients is a potential factor in many performance measures. Some reasons non-adherence is not typically used as an exclusion or adjustment in performance measures - a) adherence is influenced by provider practices, b) those patients are randomly distributed across all providers. The Committee reviewed the developers' responses on harmonization and was satisfied, but suggested exploring combining facility and physician level measurement in one measure for the future.</p>

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0321 Peritoneal Dialysis Adequacy: Solute Specifications Submission
<p>Description: Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a total Kt/V > or = 1.7 per week measured once every 4 months</p> <p>Numerator Statement: Patients who have a total Kt/V > or = 1.7 per week measured once every 4 months</p> <p>Definition: Total Kt/V includes residual kidney function and equals peritoneal dialysate Kt/V plus renal Kt/V</p> <p>Denominator Statement: All patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis</p> <p>Exclusions: None</p> <p>Adjustment/Stratification: We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected. This measure is not risk adjusted.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association - Physician Consortium for Performance Improvement</p>
<p>1.Importance to Measure and Report (based on decision logic): Workgroup: <u>Y-6; N-1</u> Steering Committee: <u>Y-20; N-0</u></p> <p>1a. Impact: Workgroup: <u>H-5; M-2; L-0; I-0</u> 1b. Performance Gap: Workgroup: <u>H-2; M-5; L-0; I-0</u></p> <p>Rationale: 1a. Impact – Preliminary ratings indicated agreement that high impact was met. 1b. Performance Gap – Performance data for this previously endorsed measure was not provided – quoted some statistics from 2008 CMS Clinical Performance Measures but unclear how to interpret for this measure.</p> <p>1c. Evidence (based on decision logic): Workgroup: <u>Y-6; N-1</u> IF a Health Outcome, rationale supports: Workgroup: <u>Y-1; N-0; NA-6</u> Quantity: Workgroup: <u>H-2; M-4; L-1; I-0</u> Quality: Workgroup: <u>H-2; M-4; L-1; I-0</u> Consistency: Workgroup: <u>H-2; M-5; L-0; I-0</u></p> <p>Rationale: The Committee members thought it was difficult to evaluate this measure without knowing if it incorporates residual kidney function in the value of => 1.7 or how the exception of residual kidney function is defined. After this was resolved, the workgroup evaluated the evidence criterion. Evidence linking a clear "cutoff" benefit for weekly Kt/Vurea demonstrating best outcomes is only modest. Only 2 RCTs; observational trials do seem to support findings of RCTs. There is less data on 1.7 as cut off as some studies compare less than 1.5 to 1.7</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>Y-7; N-0</u> Steering Committee: <u>Y-19; N-1</u></p> <p>2a. Reliability: Workgroup: <u>H-4; M-3; L-0; I-0</u> 2b. Validity: Workgroup: <u>H-3; M-4; L-0; I-0</u></p> <p>Rationale: 2a. Reliability – In response to a question, the developer confirmed that the specifications should be >= 1.7. It was noted that the prior specifications included a plan of care component in the numerator, which has been removed and replaced with the denominator exclusions. The testing was based on the prior specifications. The committee asked for an analysis of the exclusion, which was subsequently removed.</p>
<p>3. Usability: Workgroup: <u>H-5; M-2; L-0; I-0</u> Steering Committee: <u>H-10; M-10; L-0; I-0</u></p> <p>4. Feasibility: Workgroup: <u>H-6; M-1; L-0; I-0</u> Steering Committee: <u>H-13; M-7; L-0; I-0</u></p> <p>5. Suitable for endorsement: Workgroup: <u>Y-6; N-1</u></p> <p>Rationale: After clarification from the developer that the measure incorporates endogenous kidney function.</p>
<p>If applicable, Conditions/Questions for Developer:</p> <p>Regarding the Specifications:</p> <ul style="list-style-type: none"> · Please define total Kt/V, specifically accounting for endogenous kidney function. · Please clarify in the <u>Numerator Statement</u> and <u>Numerator Details</u> Kt/V greater than or equal to 1.7, listing specific details for endogenous kidney function. <p>Regarding the Exclusions:</p> <ul style="list-style-type: none"> · Please clarify your definition of residual kidney function. · Please list and define "other medical reasons" as currently named in the Exclusions. · Please provide an analysis of the defined "other medical reasons" from the testing for this measure. <u>If testing data is not available, what additional information can be provided to support the exclusions?</u>

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0321 Peritoneal Dialysis Adequacy: Solute Specifications Submission
Developer Response: (See also revised measure submission form) With regards to the Peritoneal Dialysis Adequacy: Solute measure, we have added a definition to account for endogenous kidney function and have completely removed the exception (exclusion) language from the measure. The numerator statement and measure description have also been updated within the form. The online form has been resubmitted, along with the updated e-specifications for this measure.
Steering Committee Follow-up: Conference call on 10/28/11 and re-evaluate.
5. Related and Competing Measures (<i>5a. Harmonization; 5b. Superior to competing measures</i>)
Comments: facility level measure #0318 - see Appendix C for comparison
Steering Committee Recommendation for Endorsement: <u>Y-19; N-1</u>
Rationale:
Public and Member Comment Comments included: <ul style="list-style-type: none">• support of the measure;• use std Kt/V and include residual kidney function;• concern about the effect of patient non-adherence;• measure harmonization, combine facility and physician measures; The Steering Committee has recommended using stdKt/V and residual kidney function in future iterations of all dialysis adequacy measures. Non-adherence by patients is a potential factor in many performance measures. Some reasons non-adherence is not typically used as an exclusion or adjustment in performance measures - a) adherence is influenced by provider practices, b) those patients are randomly distributed across all providers. The Committee reviewed the developers' responses on harmonization and was satisfied, but suggested exploring combining facility and physician level measurement in one measure for the future.

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Mineral Metabolism

0255 Measurement of Serum Phosphorus Concentration Specifications Submission
<p>Description: Percentage of all adult (>= 18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum phosphorus measured at least once within month.</p> <p>Numerator Statement: Number of adult (>= 18 years of age) dialysis patients included in denominator with serum phosphorus measured at least once within month</p> <p>Denominator Statement: All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis.</p> <p>Exclusions: Transient dialysis patients (in unit < 30 days), pediatric patients and kidney transplant recipients with a functioning graft</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>1.Importance to Measure and Report (based on decision logic): Workgroup: <u>Yes</u> Steering Committee: <u>Y-20; N-2</u></p> <p>1a. Impact: Workgroup: <u>H-7; M-1; L-1; I-0</u> 1b. Performance Gap: Workgroup: <u>H-0; M-4; L-4; I-1</u></p> <p>Rationale: 1a. Impact - Serum phosphorus level has substantial associated clinical consequences. 1b. Performance Gap- The preliminary ratings were spread across all the rating categories. One member questioned whether the performance gap data indicating an average performance of 77% was accurate because most if not all inpatient dialysis facilities are already capturing phosphorus levels of those patients who are treated in the facility. After further discussion, the workgroup agreed that there is a performance gap for this measure.</p> <p>1c. Evidence (based on decision logic): Workgroup: <u>Yes</u> Quantity: Workgroup: <u>H-3; M-6; L-0; I-0</u> Quality: Workgroup: <u>H-0; M-6; L-3; I-0</u> Consistency: Workgroup: <u>H-3; M-4; L-2; I-0</u></p> <p>Rationale: The evidence is indirect, i.e., it is about the association between phosphorus and mortality rather than the frequency of assessment and there was no information submitted about any studies that show a decrease in phosphorus levels will lead to better mortality outcomes. A Committee member noted the inferiority of a measure simply of the frequency of assessment, given the recent NQF guidance on the evaluation criteria. However, the evidence does not support a measure of a specific phosphorus value (also noted by KDIGO). One member noted that the evidence of the association between phosphorus levels and mortality (18% increase in mortality for every 1 mg/dL increase in serum phosphorus) is much stronger than for the association with calcium or PTH. Additionally, the information presented in validity testing demonstrated an association between facility performance on this measure and the facility standardized mortality ratio. While there is excellent evidence correlating phosphorus levels with mortality, there is no evidence that intervention to lower phosphorus levels affects clinical outcomes. Furthermore, there is no evidence that monthly monitoring of phosphorus leads to improved outcomes. Nonetheless, given the absence of such evidence, the preponderance of evidence suggests that very high phosphorus levels should be followed and treated.</p> <p>Several committee members commented that even if one concedes that it should be monitored, there probably is no need to do so on a monthly basis. Another committee member noted that there is no data one way or the other for frequency. Monthly measurement is primarily a function of usual practice because it is paid for on a monthly basis with other lab tests.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>Yes</u> Steering Committee: <u>Y-19; N-3</u></p> <p>2a. Reliability: Workgroup: <u>H-5; M-3; L-1; I-0</u> 2b. Validity: Workgroup: <u>H-3; M-5; L-1; I-0</u></p> <p>Rationale: 2a. Reliability The preliminary reliability ratings were mixed, but CMS did submit additional reliability testing that indicated the interunit reliability was 0.94. 2b. Validity – Validity testing demonstrated association between facility performance on this measure and the facility standardized mortality ratio. The lowest quintile of performance on this assessment measure had a 17% greater risk of mortality than the highest performing quintile; and the risk of mortality decreased as the quintile of performance increased.</p>
<p>3. Usability: Workgroup: <u>H-6; M-1; L-2; I-0</u> Steering Committee: <u>H-8; M-11; L-3; I-0</u></p> <p>Rationale: Because of the limitations already noted under evidence, some Committee members did not think this measure would be that useful for evaluating quality.</p>

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0255 Measurement of Serum Phosphorus Concentration Specifications Submission
4. Feasibility: Workgroup: <u>H-7; M-2; L-0; I-0</u> Steering Committee: <u>H-16; M-5; L-1; I-0</u>
Rationale: Phosphorus is measurable and should be relatively easy to get.
Assessment of Criteria Met/Suitable for Endorsement: Workgroup: <u>Y-6; N-2</u>
Rationale: One member noted that while it is an important issue, it is going to be measured as a part of a patient's general care plan and should not necessarily be a performance measure. Some Committee members were concerned about misinterpretation of the importance if no measure related to serum phosphorus was recommended. For phosphorus, the correlative data to survival is so remarkably strong that it is important enough to be a performance measure.
Steering Committee Recommendation for Endorsement: <u>Y-19; N-3</u>
Rationale: Phosphorus has the greatest implications for mortality. However, the current state of science does not suggest a measure of intermediate outcome or intervention, so a measure of assessment frequency is the best that could be implemented.
Public and Member Comment Comments included: <ul style="list-style-type: none">• endorse only for 2-3 years until replaced with intermediate outcome;• put in reserve status All NQF endorsed measures must undergo evaluation for continued endorsement every 3 years. Whether an intermediate outcome or intervention measure can be developed is dependent on the state of the science to support identifying specific levels that determine optimal care or effective interventions. The measure does not qualify for reserve status because it is not proximal to desired outcomes.

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Vascular Access

0251 Vascular Access—Functional AVF or AV Graft or Evaluation for Placement	Specifications	Submission
<p>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:</p> <p>(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);</p> <p>(2) have a functional AV graft (computed and reported separately); or</p> <p>(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).</p> <p>The total numerator and each of the numerator subgroups (the outcomes subgroups and the process subgroup) will be reported separately. Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.</p> <p>Numerator Statement: Number of patients from the denominator who:</p> <p>(1) have a functional autogenous AVF (defined as two needles used or a single-needle device) (computed and reported separately); or</p> <p>(2) have a functional AV graft (computed and reported separately); or</p> <p>(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 (defined as two needles used or a single needle device) or AV graft at least once during the 12-month reporting period (computed and reported separately).</p> <p>The total numerator and each of the numerator subgroups (the outcomes subgroups and the process subgroup) will be reported separately. Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.</p> <p>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.</p> <p>This measure includes both in-center and home hemodialysis patients.</p> <p>Exclusions: Patients enrolled in hospice.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.</p> <p>Level of Analysis: Clinician : Individual</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data : Electronic Health Record, Paper Records</p> <p>Measure Steward: Kidney Care Quality Alliance</p>		
<p>1. Importance to Measure and Report (based on decision logic): Workgroup: <u>Y-7; N-2</u> Steering Committee: <u>Y-20; N-0</u></p> <p>1a. Impact: Workgroup: <u>H-8; M-2; L-0; I-0</u> 1b. Performance Gap: Workgroup: <u>H-5; M-3; L-1; I-0</u></p> <p>1a. most of country has not achieved the fistula first goal of 66% AVF in prevalent dialysis patients or 50% in incident dialysis patients.</p> <p>1b. Data on performance gap is from data collected in testing (from facility and physician records) that indicated a mean physician performance rate of 72%; no distribution reported. The reported performance gap from facility data was lower than that from MD office sources, but the latter did not include pts with AVG. In response to a question about improvement, the developer stated that the measure was originally endorsed under time-limited status and this is the testing information completed in 2010.</p> <p>1c. Evidence (based on decision logic): Workgroup: <u>Y-9; N-1</u> IF a Health Outcome, rationale supports: Workgroup: <u>Y-2; N-0; NA-8</u> Quantity: Workgroup: <u>H-5; M-3; L-2; I-0</u> Quality: Workgroup: <u>H-2; M-5; L-2; I-0</u> Consistency: Workgroup: <u>H-4; M-4; L-2; I-0</u></p> <p>No RCTs. Evidence supports that fistula have lower rates of complications. Evidence not directly about evaluation by surgeon. Not a strong case that the surgical evaluation required in the measure will affect outcomes. This is actually a process measure somewhat distal to the desired outcome. There is clearly documented evidence of the high impact of fistula placement vs. all other types of access, but no evidence was presented to clearly associate surgical referral per se with this better outcome. This is an implied association only, and it would have enhanced the evidence for both 1a and 1b to include the intermediate outcome of actual fistula placement after the surgical referral.</p>		
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>Y-8; N-2</u> Steering Committee: <u>Y-20; N-0</u></p> <p>2a. Reliability: Workgroup: <u>H-1; M-6; L-2; I-1</u> 2b. Validity: Workgroup: <u>H-2; M-5; L-3; I-0</u></p> <p>Rationale: The data elements for surgical evaluation do not appear to yet be developed for CrownWeb as specified, so at present there is a need for written confirmation of the surgical referral actually happening, which could introduce at least the possibility of unreliability (eg, event happening and not being documented or referral made but clinic visit not carried out, etc).</p> <p>Documentation includes a note by the nephrologist, surgeon, or staff and if AVF not placed, the reason must be documented.</p> <p>Reliability was tested using facility records and physician records. Interrater reliability of data abstraction was high for the resulting score.</p>		

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0251 Vascular Access—Functional AVF or AV Graft or Evaluation for Placement [Specifications](#) [Submission](#)

Representativeness of study sample isn't demonstration of validity of the data or the measure. Face validity seems to be based on the 2008 NQF endorsement and this is not strong validity. Rather, an expert panel should be named as having independently reviewed the measure and its specifications and vouched for its validity in achieving its ends. The developer stated the expert group who developed the measure is in the additional information section.

In response to the question of how "other qualified surgeon" is defined, the developer noted that in some rural areas may not have vascular surgeon and some other surgeon places AVF. The term "qualified" infers a judgment call that is hard to capture in measure. Not just surgeons - interventional nephrologist could be qualified. Also there are different skill levels so a fistula from one surgeon may fail that another surgeon is able to place. Practices vary, so may be better to just say "evaluated by vascular surgeon or other physician for an AVF." Definition of functioning fistula requires only one occurrence of 2 needles.

What about patients who have been evaluated as not being a candidate for AVF? Face validity was assumed because of prior endorsement, but no systematic assessment. The NQF measure testing TF did not consider that in its guidance. Is evaluation every year warranted if patient has functioning graft? Developer stated it was amenable to redirecting to functional permanent access. What about when catheter is only option, e.g., congenital heart disease, behavior/cognitive problems don't tolerate 2 needles. An unintended consequence of fistula first was to ignore patient choice and stratification by need. In the FHN study, home patients use catheters and complications have not been as big a problem. Evaluation may indicate AVF not appropriate. For example vein mapping might be done before would refer to surgeon and could change whether even refer to surgeon. A Committee member suggested that all the potential exceptions identified will be minimal and may not need to be in the measure. Performance on the measure does not have to be 100% and if potential exclusions don't vary substantially across physicians then should not be an issue for comparing performance. Regarding patient choice/readiness, don't want to institutionalize a system to just let it go - need to bring up again.

It was clarified there is no exclusion for hospice patients and then added at request of the committee. Likewise, the measure initially did not recognize that patients with a functionin graft as not needing an annual evaluation for fistula and could lead to overuse of yearly evaluation for approximately 15% of patients with functioning graft. This also was modified at the committee request.

3. Usability: Workgroup: H-3; M-4; L-2; I-1 Steering Committee: H-5; M-13; L-2; I-0

(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)

Rationale: The rationale is an imputed logical leap from surgical referral to actual increase in AVF placements. And the measure is physician level, such that the referring MD will be graded not on the outcomes of the surgical procedures but simply the referral and the surgical visit actually happening then being documented. Still, this could be used as the starting point for quality comparisons and quality improvement within a practice setting.

4. Feasibility: Workgroup: H-0; M-7; L-2; I-1 Steering Committee: H-2; M-17; L-1; I-0

(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)

Rationale: The data elements for this measure do not appear to yet be developed for CrownWeb. Ability to capture evidence for a surgeon or interventional radiologist evaluation in a consistent and meaningful way is not clear. The data needed are not part of the routing care within the dialysis facility. The pilot testing demonstrated that the information can be extracted from charts, but with considerable effort. Yet, presumably, this effort will be worth it and over time, electronic capture of at least part of the necessary data should become feasible as CrownWeb is implemented.

If applicable, Conditions/Questions for Developer: Ask the developer to consider: functioning grafts, potential exclusions: hospice, elderly, patient choice, patient doesn't follow through. Definition of functioning fistula only requires one occurrence of 2 needles - is that sufficient? Consider including interventional nephrologist qualified to place an AVF, use of single needle device, whether new vs. chronic vpatients could be distinguished, and whether measure #0262 is needed with this one also including AV grafts.

Developer Response:

KCQA appreciates the opportunity to respond to the suggestions of the NQF Steering Committee in regards to Measure 0251: Vascular Access—Functional AVF or Evaluation for Placement. Our responses are as follows:

- **Functioning Grafts:** The KCQA Steering Committee agrees to incorporate functional arteriovenous grafts in the numerator statement to allow physicians to receive credit for patients with this safe and effective permanent access type. We note, however, that the measure was originally specified so as to align with *NQF 0257 Maximizing Placement of AVF (CMS)* and so have concern about harmonization issues if that measure is not similarly changed and seek NQF's guidance on how best to address this matter.

NATIONAL QUALITY FORUM

0251 Vascular Access—Functional AVF or AV Graft or Evaluation for Placement Specifications Submission
<ul style="list-style-type: none"> • Hospice Exclusion: The KCQA Steering Committee agrees that this modification is reasonable and would bring the specifications into alignment with the other KCQA vascular access measure (<i>NQF 0262</i>), which <u>does</u> exclude hospice patients. However, KCQA agrees to adopt the exclusion only if the CMS AVF (<i>NQF 0257</i>) and catheter (<i>NQF 0256</i>) measures related to vascular access also incorporate this exclusion, so that all relevant NQF-endorsed measures are harmonized. If the CMS measures do not incorporate this exclusion, KCQA seeks NQF's guidance on how best to address the issue of measure harmonization. We note that only 2 of 1,057 patients were in hospice status during KCQA's testing. • Elderly Patient Exclusion: KCQA does not agree to incorporate an exclusion for elderly patients on the grounds that there is ample evidence indicating that AVFs and AV grafts are safe and effective vascular access options for the majority of patients of advanced age. KCQA believes that this exclusion would be a disincentive to ensuring that all eligible patients are appropriately evaluated for permanent access placement and thus compromise the quality of care provided to elderly ESRD patients. • Patient Choice and Patient Failure to Follow Up Exclusions: KCQA does not agree to incorporate an exclusion for patient choice or patient failure to follow up on the grounds that such exclusions would compromise the measure's intent to incentivize evaluation for permanent access (and concomitant education on the significant benefits of AVFs and AV grafts over catheters during that evaluation), and would make the measure susceptible to gaming. • Functional AVF Definition: The KCQA Steering Committee has concern that revising the definition of "functioning AVF" would compromise harmonization with the NQF-endorsed CMS AVF measure, which also defines functional AVFs in this manner. Moreover, we note that as currently specified, the KCQA measure does <u>not</u> require only one occurrence of two needles. Rather, the measure requires that all hemodialysis patients receive a vascular access status assessment on a yearly basis if they do not have a functioning AVF (and now AV graft). Thus if a previously functioning AVF is no longer functioning (i.e., two needles used), that patient must be evaluated by a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional radiologist at least once during the 12-month reporting period for permanent access placement. • Physicians Eligible to Conduct Vascular Access Evaluation: Though not noted above, the NQF Steering Committee suggested during the meeting that KCQA refine the definition of what types of physicians are eligible to conduct the evaluation for permanent access placement. The current specifications read "vascular surgeon or other qualified surgeon." The NQF Committee noted that interventional radiologists or nephrologists would be excluded under the current construct. The purpose of the measure is for <u>primary</u> placement – something the KCQA Steering Committee thought was not in the purview of interventional nephrologists or interventional radiologists, but rather vascular/other qualified surgeons; HOWEVER, if that's the Steering Committee thinks that is the only issue standing between a recommendation to advance and not, KCQA is willing to modify. The developer eventually agreed to language "interventional nephrologist trained in the primary placement of vascular access." • The developer agreed with the Steering Committee that measure 0262 was no longer needed. • The developer also specified this measure to stratify by incident and prevalent patients.
<p>Assessment of Criteria Met/Suitable for Endorsement: <u>Workgroup: Y-6; N-4</u></p> <p><u>Rationale:</u> The objections included having a physician measure focused on evaluation by surgeon rather than one that was consistent with the facility measures of percentage of patients with fistulas (0257) or catheters (0256); and that the changes requested by the committee resulted in less harmonization with the facility measures. One member also thought the addition of interventional nephrologist was unnecessary.</p>
<p>5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures) Facility measures fistula (0257) and catheters (0256). See Appendix C.</p>
<p>Steering Committee Recommendation for Endorsement: <u>Y-18; N-2</u></p> <p>Rationale: Fistulas are the preferred access and if the patient has a catheter should be evaluated for placement.</p>
<p>Public and Member Comment Comments included:</p> <ul style="list-style-type: none"> • support for the measure; • no evidence to support focus on surgical referral. <p>Developer Response: The measure is reported in three parts: 1) an outcome measure (functioning AV fistula); 2) and outcome measure (AV graft), and 3) a process measure (evaluation by a surgeon). The specifications require documentation that the patient was seen by a surgeon for an evaluation. We do not have data that support that patients with catheters who are seen by a surgeon result in increased AV fistulas. Given such a visit is a pre-requisite for fistula placement, however, it is highly improbable that patients who are evaluated will have fewer AVFs than patients who are not evaluated.</p>

NATIONAL QUALITY FORUM

0256 Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access Specifications Submission
<p>Description: Percentage of patients on maintenance hemodialysis during the last HD treatment of study period with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.</p> <p>Numerator Statement: Patients who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the study period.</p> <p>Denominator Statement: Patients on maintenance hemodialysis during the last HD treatment of study period.</p> <p>Exclusions: Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification No risk adjustment necessary. No stratification is required for this measure.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims, Electronic Clinical Data</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>1. Importance to Measure and Report (<i>based on decision logic</i>): Workgroup: Y-4; N-0 Steering Committee: Y-22; N-0</p> <p>1a. Impact: Workgroup: H-4; M-0; L-0; I-0 1b. Performance Gap: Workgroup: H-3; M-1; L-0; I-0</p> <p>Rationale: 1a Catheters have a high impact on morbidity and mortality 1b. A Committee member questioned the data provided indicating average performance of 5% using catheters, which seemed to be lower than the actual experience but may be lower because of short data collection period. The developer responded that some facilities have as high as 47% chronic catheter use and cited data from Fistula first of 8% chronic catheters.</p> <p>1c. Evidence (<i>based on decision logic</i>): Workgroup: Y-4; N-0</p> <p>Quantity: Workgroup: H-3; M-0; L-1; I-0 Quality: Workgroup: H-3; M-1; L-0; I-0 Consistency: Workgroup: H-3; M-1; L-0; I-0</p> <p>Rationale: Although a large number of articles were referenced, only 5 were included in the discussion. It is not clear if there was a systematic review of the studies for design flaws, biases, etc. Although not presented according to new guidance, sufficient evidence does exist.</p>
<p>2. Scientific Acceptability of Measure Properties (<i>based on decision logic</i>): Workgroup: Y-3; N-1 Steering Committee: Y-22; N-0</p> <p>2a. Reliability: Workgroup: H-3; M-0; L-1; I-0 2b. Validity: Workgroup: H-3; M-0; L-1; I-0</p> <p>Rationale: 2a. Testing for month-to-month consistency of scores may not be an appropriate test of reliability. The developer submitted additional testing information for the reliability (precision) of the measure score: the inter-unit reliability was 0.84 indicating the measure distinguishes among facilities. The committee was satisfied with the developer's measure of reliability and was in agreement that the reliability was met.</p> <p>2b. Validity was demonstrated by the association of performance on chronic catheter measure with performance on the mortality measure. SMR is affected by multiple factors, not only catheters so other associations could have been demonstrated with blood stream infections, dialysis adequacy, or hospitalization rate. A committee member questioned whether home hemodialysis patients should be excluded because infection does not seem to be as big a problem and some patients prefer catheter over needles when on daily schedule. The evidence is not specific to home HD patients but overall catheters are still considered less desirable. Ultimately the Committee members concluded that since there is little evidence available and so few home hemodialysis patients, the measure would not be greatly affected by the inclusion of home hemodialysis patients.</p>
<p>3. Usability: Workgroup: H-3; M-0; L-0; I-0 Steering Committee: H-12; M-10; L-0; I-0</p> <p>(<i>Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement</i>)</p> <p>Rationale: This measure, if accurately assessed, is very useful for for both public reporting and QI.</p>
<p>4. Feasibility: Workgroup: H-4; M-0; L-0; I-0 Steering Committee: H-12; M-10; L-0; I-0</p> <p>(<i>4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented</i>)</p> <p>Rationale: The measure is clearly specified and should be feasible to carry out.</p>
<p>Assessment of Criteria Met/Suitable for Endorsement: Workgroup: Y-3; N-1</p> <p>Comments:</p>
<p>5. Related and Competing Measures (<i>5a. Harmonization; 5b. Superior to competing measures</i>)</p> <p>Physician measure 0251 that includes evaluation by surgeon. See Appendix C.</p>
<p>Steering Committee Recommendation for Endorsement: Y-22; N-0</p>

NATIONAL QUALITY FORUM

0256 Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access Specifications Submission
Rationale: Use of catheters for vascular access is associated with many problems and facilities should work to decrease.
Public and Member Comment Comments included: <ul style="list-style-type: none">• measure harmonization. The measures are harmonized to the extent possible given that 0251 includes evaluation by surgeon. The SC suggests exploring use of same measures for facility and physician.

NATIONAL QUALITY FORUM

0257 Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF) Specifications Submission
<p>Description: Percentage of patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles</p> <p>Numerator Statement: Patients who were on maintenance hemodialysis (HD) using an autogenous AV fistula with two needles at the last HD treatment of month</p> <p>Denominator Statement: Patients on maintenance hemodialysis during the last HD treatment of month including patients on home hemodialysis</p> <p>Exclusions: Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification No risk adjustment necessary. No stratification is required for this measure.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims, Electronic Clinical Data</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>1. Importance to Measure and Report <i>(based on decision logic)</i>: Workgroup: Y-4; N-0 Steering Committee: Y-22; N-0</p> <p>1a. Impact: Workgroup: H-4; M-0; L-0; I-0 1b. Performance Gap: Workgroup: H-3; M-1; L-0; I-0</p> <p><u>Rationale:</u> 1b U.S.fistula rates continue to be low **1a. The assessment of high impact is made based on information in articles referenced rather than specific language in the application. 1b. The gap between the average fistula prevalence and the target established by Fistula First is closing, yet there remain significant variances between facilities **Improvement in AVF use must continue...</p> <p>1c. Evidence <i>(based on decision logic)</i>: Workgroup: Y-4; N-0</p> <p>Quantity: Workgroup: H-3; M-0; L-1; I-0 Quality: Workgroup: H-3; M-1; L-0; I-0 Consistency: Workgroup: H-3; M-1; L-0; I-0</p> <p><u>Rationale:</u> Fistulas provide greater benefit to patients, less infections, clotting **Although a large number of studies are referenced, those cited in the discussion are small (2) with one of those being the kDOQI guideline. RCT type studies are lacking. The evidence linking higher prevalence of AVFs with good health outcomes is consistent--again, based on number of article referenced rather than on a systematic review of all studies by the developer.</p>
<p>2. Scientific Acceptability of Measure Properties <i>(based on decision logic)</i>: Workgroup: Y-4; N-0 Steering Committee: Y-22; N-0</p> <p>2a. Reliability: Workgroup: H-3; M-1; L-0; I-0 2b. Validity: Workgroup: H-3; M-1; L-0; I-0</p> <p><u>Rationale:</u> Facility level month-to-month comparison seems a weak statistic for reliability testing. Use of multiple data sources would be helpful, and having random surveys by outside experts would be another. The developer submitted additional testing information for the reliability (precision) of the measure score: the inter-unit reliability was 0.84 indicating the measure distinguishes among facilities. The committee was satisfied with the developer's measure of reliability and was in agreement that the reliability was met.</p> <p>2b. Validity was demonstrated by the association of performance on the AVF measure with performance on the mortality measure. SMR is affected by multiple factors, not only catheters so other associations could have been demonstrated with blood stream infections, dialysis adequacy, or hospitalization rate.</p> <p>One committee member questioned whether the measure should be focused on permanent access including working grafts. The measure developer noted that measures of catheter rate and fistula rate are linked and the remainder of patients would have an AVG. A question was raised whether the measure should include functioning grafts as discussed regarding measures 0262 and 0251; however those measures require evaluation by a surgeon and the discussion was about not referring patients with a functioning graft. The AV fistula is still the preferred access and should be measured alone. The workgroup had recommended that "single-needle device" to the definition of functioning fistula. CMS responded that it was not currently possible because that was not captured in CROWNWeb. Some committee members suggested removing "with two needles" from the measure description so that it could accommodate single-needle devices in the future and that "using the fistula" implies it is functioning. Another member noted that sometimes a needle and catheter are used and it's when two needles can be used that it's considered functioning; it may be as high as 7% with two access sites. CMS asked if the measure could remain as specified with recommendation to change by the time of next review and some committee members expressed agreement.</p>
<p>3. Usability: Workgroup: H-4; M-0; L-0; I-0 Steering Committee: H-10; M-12; L-0; I-0</p> <p><i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p><u>Rationale:</u></p>
<p>4. Feasibility: Workgroup: H-3; M-1; L-0; I-0 Steering Committee: H-11; M-11; L-0; I-0</p>

NATIONAL QUALITY FORUM

0257 Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF) Specifications Submission
<p><i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale: Someone at the facility has to make an observation and judge if the access is an AVF or AVG. This is not always straightforward and could require reference to the surgical report. The information is added to the EHR (or eventually CROWNWeb) and then submitted. The human element is this assessment can lead to error.</p>
<p>If applicable, Conditions/Questions for Developer: The recommendation from the group is that the measure is suitable for endorsement but the preference would be to add "single-needle device" to the definition of functioning fistula</p>
<p>Developer Response: Because data specific to AVF with a single needle are not currently available from CROWNWeb, Fistula First or Medicare Claims, calculation and testing of this measure with the addition of AV fistula using a single needle dialysis system cannot be performed at this time. CMS is currently considering changes to data collection that would allow these data to be captured in the future. As such, we believe that the measure should remain as it is currently specified at this time. As noted above, the availability of additional specific AV access data should allow evaluation of AV fistula with single needle system inclusion in the AV fistula Measure calculation during the next Measure Maintenance Cycle.</p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Workgroup: <u>Y-4; N-0; A-0</u></p>
<p>Comments: See previous comments. This is a needed, high impact measure. The application does not fully meet the enhanced standards set by the NOF as applies to linking evidence to the measure focus and on reliability and validity testing. I am willing to pass this measure despite this, based on information extraneous to this application which largely fills in these gaps.</p>
<p>5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures)</p>
<p>Physician measure 0251 that includes evaluation by surgeon. See Appendix C.</p>
<p>Steering Committee Recommendation for Endorsement: <u>Y-22; N-0</u></p>
<p>Rationale:</p>
<p>Public and Member Comment</p> <p>Comments included:</p> <ul style="list-style-type: none"> • measure harmonization; • does not capture appropriate use of AV grafts. <p>The measures are harmonized to the extent possible given that 0251 includes evaluation by surgeon. The SC suggests exploring use of same measures for facility and physician. The measure is consistent with the evidence and goals of using AVF. The measure does not require or imply that 100% is the appropriate rate. Constructing a measure so that one could reliably measure when AVF vs. AVG is appropriate may be difficult.</p>

NATIONAL QUALITY FORUM

Measures Not Recommended

0252 Assessment of Iron Stores Submission
<p>Description: Percentage of all adult (>=18 years old) hemodialysis or peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb <11.0 g/dL in at least one month of the study period for whom serum ferritin concentration AND either percent transferrin saturation or reticulocyte Hb content (CHR) are measured at least once in a three-month period for in-center hemodialysis patients, peritoneal dialysis patients, and home hemodialysis patients.</p> <p>Numerator Statement: Number of dialysis patients in the denominator for whom serum ferritin concentration AND either percent transferrin saturation or reticulocyte Hb content (CHR) are measured at least once in a three-month period for in-center hemodialysis patients, peritoneal dialysis patients, and home hemodialysis patients.</p> <p>Denominator Statement: All adult (>=18 years old) hemodialysis or peritoneal dialysis patients prescribed an ESA at any time during the study period or who have a Hb <11.0 g/dL in at least one month of the study period. The study period consists of 3 consecutive months for in-center hemodialysis patients, peritoneal dialysis patients and home hemodialysis. The hemoglobin value reported for the end of each study month (end-of-month Hb) is used for this calculation.</p> <p>Exclusions: Acute HD, transient dialysis patients (seen at the specific center for less than 30 days), and kidney transplant patients are excluded from the calculation this CPM.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification. No risk adjustment necessary. No stratification is required for this measure.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>1. Importance to Measure and Report (<i>based on decision logic</i>): No</p> <p>1a. Impact: H-5; M-14; L-2; I-0 1b. Performance Gap: H-0; M-5; L-16; I-0</p> <p>Rationale: 1b. Mean percentage of patients with assessment of iron stores is 97%, 1st quartile 97% and median 100%. The data by population group show essentially the same range by race/ethnicity *Black 94.0-94.9%; White 94.1-94.9%; Hispanic 93.6-94.8%). Although there was overall high performance with little variability, it was noted that validity testing showed that the two lowest quintiles of performance on this assessment of iron stores measure (94% and 98%) were associated with an 8% higher standardized mortality ratio.</p> <p>1c. Evidence (<i>based on decision logic</i>): Evidence Exception Y-16; N-5</p> <p>Quantity: H-0; M-13; L-6; I-2 Quality: H-0; M-4; L-8; I-9 Consistency: H-0; M-7; L-4; I-10</p> <p>Rationale: The focus of the measure - assessing iron stores in patients receiving ESAs at least every 3 months - is not proximal to the desired outcome and is indirectly supported by the evidence. The evidence presented supports the relationship between Hgb levels and mortality/morbidity and describe the impact of ESAs on Hgb levels and mortality/morbidity. The studies do not describe the impact of iron supplementation on mortality/morbidity or Hgb levels. Because the empirical evidence does not directly address the measure focus, the SC voted on whether to consider an exception to empirical evidence if the benefits greatly outweighed any potential harm to patients.</p> <p>Consider Reserve Status: Y-10; N-11</p> <p>The Committee was asked if this measure should be evaluated further for potential reserve status, which would allow it to be further evaluated. It was not a good candidate for reserve status because the focus of measurement was assessment without strong direct evidence to desired outcomes.</p>
<p>Steering Committee Recommendation for Endorsement: No</p> <p>Rationale: Did not pass the criterion of Importance to Measure and Report</p>

NATIONAL QUALITY FORUM

1660 ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL Submission
<p>Description: 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</p> <p>Numerator Statement: Calendar months during which patients have a Hemoglobin level <10g/dL*</p> <p>*The hemoglobin values used for this measure should be a most recent (last) hemoglobin value recorded for each calendar month</p> <p>Denominator Statement: All calendar months during which patients aged 18 years and older with a diagnosis of ESRD are receiving hemodialysis or peritoneal dialysis</p> <p>Exclusions: Documentation of medical reason(s) for patient having a Hemoglobin level <10g/dL (eg, patients who have non-renal etiologies of anemia [eg, sickle cell anemia or other hemoglobinopathies, multiple myeloma, primary bone marrow disease, anemia related to chemotherapy for diagnosis of malignancy], other medical reasons)</p> <p>Adjustment/Stratification: Other We account for risk adjustment by inclusion of the exceptions for this measure. Exceptions for this measure are listed above, in section 2a1.8. We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association - Physician Consortium for Performance Improvement</p>
<p>1. Importance to Measure and Report (based on decision logic): No</p> <p>1a. Impact: H-12; M-9; L-; I-1 1b. Performance Gap: H-6; M-8; L-; I-8</p> <p>Rationale: The submitter stated that in the PQRI 2008 data 36.51% of patients did not achieve "optimal care", but was not defined - does it mean that patients did not achieve the lower end of the target range or they exceeded the target range? The developer clarified that it meant did not achieve a Hgb of 10. Physician performance on the measure was variable with a median of 66.23%, 25th percentile of 38.17% and 75 percentile of 84.04%.</p> <p>1c. Evidence (based on decision logic): No IF a Health Outcome, rationale supports: NA</p> <p>Quantity: H-1; M-2; L-4; I-15 Quality: H-; M-3; L-3; I-15 Consistency: H-; M-3; L-1; I-17</p> <p>Rationale: The Steering Committee discussed that the current understanding of the accumulation of evidence is that there is insufficient evidence to set a definitive target. Additionally, there are significant and substantial risks of complications and mortality associated with use of ESAs in treating anemia. The recent 6/24/11 FDA announcement (http://www.fda.gov/cder/drug/infopage/RHE/default.htm) is not based on new evidence but the FDA is focused on minimizing harm. Given the current state of the science, a Hgb <10 is not always an indication of poor care. The data support that treatment with ESAs to higher Hgb levels has adverse consequences, but do not provide a clear indication about lower levels at which harm occurs. The focus of anemia management in dialysis patients is individualization, which is nearly impossible to capture in a standardized performance measure. For example, individual factors such as trends of decline, responsiveness to ESAs, cardiovascular risk, and avoidance of allogeneic transfusions should be considered. Individualization of treatment also should include how the patient feels/functions at different levels of Hgb.</p>
<p>Developer requested reconsideration with the following rationale.</p> <p>This measure is designed to be a <i>patient safety measure</i>. It is a surrogate for blood transfusions and is meant to encourage clinicians and patients to pay attention to the lower limit of hemoglobin and its negative consequences, and consequently to address anemia in an individualized way to improve patient care. The SC provided feedback that the requirement for evidence was not met. However, we know from various studies^{1,2,3,4} that red-cell transfusion rates increase when patient hemoglobin levels fall below 10g/dL. Based on all available evidence, our Kidney Disease Expert Work Group agrees that a measure capturing hemoglobin < 10 is of value, as is demonstrated by the SC's support of the identical pediatric measure. A review of performance gap data has allowed our Work Group to identify the need for this measure, and highlighting the low Hgb value is meant to trigger a conversation between the physician and patient, reviewing appropriate treatment options. The threshold of <10 is based on KDOQI's 2007 Clinical Practice Recommendation and is consistent with the recent FDA announcement which says "Consider starting ESA treatment only when the hemoglobin level is less than 10 g/dL and when certain other considerations apply." This measure does not recommend any specific treatment and is irrespective of ESA use.</p> <p>Red-cell transfusions are transiently effective at raising hemoglobin concentrations, but they are associated with a number of serious risks, including allosensitization, transmission of blood-borne viral diseases, transfusion reactions, acute volume and potassium overload, and more chronically, iron overload.^{5,6,7,8,9} Data from the TREAT trial demonstrates an increase in red-cell transfusions in the lower hemoglobin arm given placebo (496 transfusions, or 24.5% of patients) versus the higher hemoglobin group given darbepoetin alfa (297 transfusions, or 14.8% of patients) (P<0.001).¹ Post-hoc analyses provide further context regarding the occurrence of transfusions.</p>

NATIONAL QUALITY FORUM

1660 ESRD Patients Receiving Dialysis: Hemoglobin Level <10g/dL [Submission](#)

These analyses indicate that an increased risk of transfusion is associated with low hemoglobin concentration (< 10 g/dL) and that receiving a transfusion is associated with an increased risk of a subsequent transfusion.³ *Ultimately, by not recommending measure 1660, there will be no NQF-endorsed measure for adult patients on dialysis that addresses the lower limit of hemoglobin.* We hope that these explanatory comments better clarify the design of our measure and we request that the SC reconsider recommending this measure to further emphasize the importance of tracking the outcomes of care *and* the care provided to patients on dialysis.

Steering Committee Follow-up: 10/13 conference call

The Steering Committee discussed the developer's rationale that this was considered a safety measure and a surrogate for blood transfusions because transfusions increase with decreasing hemoglobin values. One committee member stated that there is no definitive evidence of harm in adults with Hgb 8-10. A Steering Committee member asked the developer if there was evidence about the relative risk of transfusion versus use of ESAs, to which the response was no. The patient representatives talked of the impact on quality of life when Hgb falls below 10 and the negative impact of transfusions on eligibility of kidney transplant. The committee agreed that the current evidence and direction of guidelines emphasizes individualized management of anemia, which makes creating a standard performance measure that applies to the entire population very difficult. A performance measure with a threshold of 10 implies that 10 is the goal and could result in transfusions or escalated ESA doses to achieve that threshold value. A committee member stated that patients with malnutrition-inflammation complex syndrome typically receive maximum doses of ESAs and fail to achieve Hgb of 10; upwards of 10-15% of the ESRD population may have refractory anemia.

The Steering Committee voted on whether to reconsider this measure: Y-8; Unsure-1; N- 13

Steering Committee Recommendation for Endorsement: No

Rationale: Did not pass the criterion of Importance to Measure and Report due to issues related to evidence for a specific target in adults.

Public and Member Comment

Comments included:

- request for reconsideration.

The Steering Committee considered and reconsidered the adult measure but in light of the evidence of harm with ESA treatment did not recommend endorsement of the adult measure.

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0626 Chronic Kidney Disease - Lipid Profile Monitoring Submission
<p>Description: The percentage of patients with chronic kidney disease that have been screened for dyslipidemia with a lipid profile.</p> <p>Numerator Statement: Patients who had a lipid profile.</p> <p>Denominator Statement: All patients, males > 10 and females > 13 years of age, diagnosed with chronic kidney disease.</p> <p>Exclusions: DENOMINATOR EXCLUSIONS</p> <p>Specific Exclusions: None</p> <p>General exclusion: Patients with active cancer or metastatic diseases. Patients who were in a skilled nursing facility recently.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification No risk model applied to this measure. The results are not stratified.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Facility, Health Plan, Integrated Delivery System, Population : Community, Population : County or City, Population : National, Population : Regional, Population : State</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy, Electronic Clinical Data : Registry, Patient Reported Data/Survey</p> <p>Measure Steward: ActiveHealth Management</p>
<p>1. Importance to Measure and Report (based on decision logic): No</p> <p>1a. Impact: <u>H-3; M-12; L-4; I-2</u> 1b. Performance Gap: <u>H-0; M-8; L-5; I-7</u></p> <p>Rationale: Lipids are a national health priority. No performance data on this previously endorsed measure even though indicated measure is in use. Performance gap data is for all adults but measure also includes children. A lot of heterogeneity in the measure - kids and adults, on/off dialysis, pre-existing CV disease - includes primary and secondary prevention - evidence varies. Performance gap depends on evidence of whether should be doing it.</p> <p>1c. Evidence (based on decision logic): Quantity: <u>H-1; M-9; L-8; I-3</u> Quality: <u>H-0; M-7; L-6; I-7</u> Consistency: <u>H-0; M-4; L-5; I-12</u></p> <p>Rationale: Assessing lipid levels is not proximal to desired outcome. Does lipid monitoring affect outcomes? Evidence from clinical practice guidelines. Observational study links CKD to hyperlipidemia, some small-volume studies that statins reduce microinflammation and may have beneficial effects in CKD. CKid study 690 children enrolled showing that over half have lipid abnormalities, now studying affect on outcomes. Two bodies of evidence with RCTs not mentioned: 1) 4D trial German diabetic dialysis patients and Aurora counterpart both statin/placebo trials - negative trials with no specific difference in ESRD population; 2) newest SHARP trial of 6000 CKD patients 3000 on dialysis PD and HD patients on lipid lowering therapy showed less CV events but no difference in renal outcomes. Would strengthen the evidence for a measure, not necessarily this one - perhaps a measure for use of lipid-lowering agents.</p>
<p>The Measure Developer asked to Submit Additional Information</p> <p>The Steering Committee had voted that this measure did not pass the criterion on Importance to Measure and Report. The measure developer identified that it had more evidence to support this measure and was asked to revise the submission form. The measure was subsequently re-evaluated by the workgroup and Steering Committee.</p>
<p>1. Importance to Measure and Report (based on decision logic): Workgroup: No Steering Committee: Y-15; N-7</p> <p>1a. Impact: <u>Workgroup:H-4; M-1; L-0; I-1</u> 1b. Performance Gap: <u>Workgroup: H-1; M-1; L-1; I-3</u></p> <p>Rationale: 1a. Impact of prevention of CVD for CKD is high and prevents morbidity and mortality. This measure as written applies to all stages of CKD and for males at least 10 years old and females at least 13 years old. The impact data for pediatric patients is confined to children with ESRD -- there is no data for children with other CKD stages given. The bigger issue is statin treatment. 1b. The revised submission did not provide a distribution of physician level scores – overall 84% across all data. If one excludes those for whom testing is not indicated, (e.g. very elderly)there is not that much of a performance gap. There is also no specific performance gap data for children. Insufficient data on incidence of lipid profiling for CKD 3- 5.</p> <p>1c. Evidence (based on decision logic): Workgroup: Yes/No? (split on quality of evidence) Quantity: <u>Workgroup: H-1; M-4; L-1; I-0</u> Quality: <u>Workgroup: H-0; M-3; L-3; I-0</u> Consistency: <u>Workgroup: H-0; M-5; L1-; I-0</u></p> <p>Rationale: Data is appropriate based on lack of RCT in this area of CKD. Adults with CKD do appear to benefit from statins. For subgroup CKD 3-5 of general population, benefits/harms have not been determined. Insufficient data on pediatric population with CKD and ESRD. The</p>

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measure designers apply this measure to boys who are at least 10 yr. and girls who are at least 13 yr. Many of the guidelines quoted in support of this measure that address the pediatric population are focused on adolescents who have reached the onset of puberty. Clearly, most boys at the age of 10 are pre-pubertal as are a segment of girls at age 13.

2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: Yes/No? (split on validity) Steering Committee: Y-8; N-14

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

Rationale: A description of processes to check data and programming was provided but no empirical analysis or quantification and no actual reliability and validity testing.

Nephrotic syndrome is one of the diagnoses for the denominator and children with Nephrotic syndrome really aren't the same as adults with Nephrotic syndrome in terms of chronic kidney disease. Because the measure applies to children who are pre-adolescent, the types of nephrotic syndrome seen vs. the older aged population will vary (younger children tend to have more therapy-responsive disease that leads to no long-term renal impairment) and these children are unlikely to be similar to the CKD population otherwise stipulated. The developer explained rationale for including diagnosis of hyperlipidemia in numerator details (their data system only codes diagnosis of hyperlipidemia if the patient had a lipid value drawn).

3. Usability: Workgroup: H-2; M-2; L-2; I-0 Steering Committee: Workgroup: H-1; M-13; L-8; I-0

Rationale: Currently report results to clients who may publish results, but indicate they are working on processes for public reporting and QI. It is unclear how meaningful or useful this would be as a quality measure for the pre-pubertal children, especially in the context of the measure designers including what can be a non-chronic condition (nephrotic syndrome) in some of these younger children -- for instance an 11 yr. boy who has been in remission of his nephrotic syndrome for 2 years but who is seen in follow-up of his nephrotic syndrome would qualify for this measure but few clinicians would be checking labs other than urine on him unless specifically indicated.

4. Feasibility: Workgroup: H-2; M-3; L-1; I-0 Steering Committee: Workgroup: H-2; M-15; L-5; I-0

Rationale: Measure is feasible based on current reporting strategy.

Preliminary Assessment of Criteria Met/Suitable for Endorsement: Workgroup: Y-2; N-4

Rationale: Important area for prevention in CKD. Questions about the evidence for children and the specifications for including children. Failed to meet several criteria as discussed above – performance gap, evidence, reliability, and validity.

Steering Committee Recommendation for Endorsement: Y-7; N-15

Rationale: The measure failed to meet the criterion of Scientific Acceptability of Measure Properties.

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0627 Chronic Kidney Disease with LDL Greater than or equal to 130 – Use of Lipid Lowering Agent Submission
<p>Description: The percentage of patients with chronic kidney disease [stage 5] to and an LDL greater than or equal to 130 mg/dl that have a current refill for a lipid lowering agent.</p> <p>Numerator Statement: Patients with a current refill for a lipid lowering agent.</p> <p>Denominator Statement: All patients, ages 18 and older, diagnosed with chronic kidney disease [including] CKD stage 5, dialysis, or kidney transplant, and an LDL level above 130 mg/dL.</p> <p>Exclusions: Specific Exclusions: None</p> <p>General Exclusions:</p> <ul style="list-style-type: none"> • Evidence of metastatic disease or active treatment of malignancy (chemotherapy or radiation therapy) in the last 6 months • Patients who have been in a skilled nursing facility in the last 3 months • Patient or provider feedback indicating allergy or intolerance to the drug in the past • Patient or provider feedback indicating that there is a contraindication to adding the drug <p>Adjustment/Stratification: No risk adjustment or risk stratification No risk model applied to this measure. The results are not stratified.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Facility, Health Plan, Integrated Delivery System, Population : Community, Population : County or City, Population : National, Population : Regional, Population : State</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy, Patient Reported Data/Survey</p> <p>Measure Steward: ActiveHealth Management</p>
<p>1. Importance to Measure and Report (based on decision logic): Steering Committee: <u>No</u></p> <p>1a. Impact: <u>H-3; M-14; L-3; I-0</u> 1b. Performance Gap: <u>H-0; M-3; L-1; I-16</u></p> <p>Rationale: In response to a question about whether the target population is CKD 5 (dialysis and transplant), the developer clarified that the NOS codes are in conjunction with creatinine clearance so not intended to limit to CKD stage 5. 1b. Performance gap data is for CKD stage 3-4 - less than half had LDL levels less than 100. No information on performance on this previously endorsed measure as specified, though developer stated it is in use. Developer stated that the performance gap is based on KDOQI guidelines. Developer stated it could supply data on performance if given the opportunity.</p>
<p>1c. Evidence (based on decision logic): <u>No</u></p> <p>Quantity: <u>H-0; M-6; L-9; I-5</u> Quality: <u>H-0; M-4; L-11; I-5</u> Consistency: <u>H-0; M-3; L-10; I-7</u></p> <p>Rationale: Small number of dated studies cited with no RCT information as discussed under 0626. A SC member asked what was the achieved LDL in the SHARP study and another responded cholesterol 5.3 international units (about 230 with LDL about 120). NKF and KDOQI strongly supported measurement.</p>
<p>If applicable, Conditions/Questions for Developer: What is the data on the performance gap for this measure as specified? Is there specific evidence supporting the effectiveness of lipid lowering drugs in CKD5?</p> <p>Developer Response:</p> <p>Performance Gap for this Measure: Based on data collected from a population of 13 million, we found 185 people who fulfilled the denominator. Out of these, the compliance for use of a lipid-lowering agent in people with chronic kidney disease and an LDL greater than or equal to 130 was found to be 54%.</p> <p>Evidence: Several studies have evaluated the use of HMG Co-A reductase inhibitors (statins) in patients with stage 5 CKD/ ESRD/ on renal replacement therapy. A Cochrane meta-analysis published in 2009 evaluated the role of statins in patients getting dialysis and included 14 studies that recruited 2086 patients in the final analysis (1). The analysis found a lower incidence of non-fatal cardiovascular events in ESRD patients on statins (RR 0.86, 95% CI 0.74 to 0.99), but no difference in overall mortality. Also, there were significant reductions in total cholesterol, LDL cholesterol and triglycerides. Moreover the incidence of rhabdomyolysis and elevated liver enzymes was similar in the statin and placebo groups. The authors concluded that statins reduced cholesterol levels in dialysis patients similar to the general population. As the studies included were of short duration, the effect of statins on decreasing mortality in ESRD patients remained unclear, but they appeared to be safe to use in this high risk population, and that larger studies of longer duration could provide greater insight on the efficacy of mortality reduction in dialysis patients.</p> <p>A randomized, controlled study of simvastatin plus ezetimibe versus placebo in 9270 patients with CKD was published in 2011 (2). This study included 3023 patients on dialysis. After 4.9 years of follow up, patients on simvastatin plus ezetimibe had a 17% proportional reduction in the primary outcome, major atherosclerotic events (RR 0.83; 95% CI 0.74 to 0.94). Non-significantly fewer patients allocated to simvastatin plus</p>

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ezetimibe had a non-fatal myocardial infarction or died from coronary heart disease and there were significant reductions in non-haemorrhagic stroke (2.8% vs. 3.8%; RR 0.75, 95% CI 0.60-0.94) and arterial revascularization procedures (6.1% vs. 7.6%; RR 0.79, 95% CI 0.68-0.93). After weighting for subgroup-specific reductions in LDL cholesterol, there was no good evidence that the proportional effects on major atherosclerotic events differed from the summary rate ratio in any subgroup examined, and, in particular, they were similar in patients on dialysis and those who were not. The excess risk of myopathy was only two per 10,000 patients per year of treatment with this combination (9 [0-2%] vs. 5 [0-1%]). There was no evidence of excess risks of hepatitis, gallstones, or cancer and there was no significant excess of death from any non-vascular cause.

Another multicenter, randomized, double-blind prospective study done in 2005 on over 1200 patients who had type 2 diabetes and were on hemodialysis, showed that while the composite number of deaths from cardiac causes showed no significant difference, the number of all cardiac and cerebrovascular events combined was statistically lower in those people taking atorvastatin as compared with the placebo group (3).

Also worth noting is the statement made by an international, multicenter, randomized, double-blind, prospective trial involving 2776 patients, between the ages of 50 and 80, who were undergoing maintenance hemodialysis(4). Although the study did not show added benefit with the addition of a statin, it is important to note that the authors pointed out that a selection bias may have occurred in the study because they excluded patients already on a statin and because their baseline LDL level was relatively low (100), the study population did not represent the denominator population for our proposed measure. In addition, there existed a high withdrawal rate in this study due to either adverse drug effects or transplantation, which could potentially mask the effects of statins.

Our measure focuses on the use of lipid lowering therapy in patients with CKD/ ESRD who specifically have an elevated LDL cholesterol levels above 130, putting them at even greater risk of cardiovascular morbidity, and making them even more likely to benefit from lipid lowering therapy.

- (1) [Navaneethan SD](#), [Perkovic V](#), [Johnson DW](#), et al. HMG CoA reductase inhibitors (statins) for kidney transplant recipients. [Cochrane Database Syst Rev](#). 2009 Apr 15;(2):CD005019.
- (2) [Baigent C](#), [Landray MJ](#), [Reith C](#), et al. The effects of lowering LDL cholesterol with simvastatin plus ezetimibe in patients with chronic kidney disease (Study of Heart and Renal Protection): a randomised placebo-controlled trial. [Lancet](#). 2011 Jun 25;377(9784):2181-92. Epub 2011 Jun 12.
- (3) [Wanner C](#), [Krane V](#), [März W](#), et al. Atorvastatin in patients with type 2 diabetes mellitus undergoing hemodialysis. [N Engl J Med](#). 2005 Jul 21;353(3):238-48.
- (4) [Fellström BC](#), [Jardine AG](#), [Schmieder RE](#), et al. Rosuvastatin and cardiovascular events in patients undergoing hemodialysis. [N Engl J Med](#). 2009 Apr 2;360(14):1395-407. Epub 2009 Mar 30.

Steering Committee Follow-up: Conference call 10/28 and re-evaluation

Importance to Measure and Report (based on decision logic): Workgroup: Y-2; N-6 Steering Committee: Y-6; N-14
1a. Impact: Workgroup: H-2; M-4; L-2; I-0 **1b. Performance Gap:** Workgroup: H-0; M-4; L-3; I-1

Rationale:

1b. No distribution of performance by physician reported. The developer reported performance of 54% but only identified 185 patients in the denominator. The developer stated the reason for the low denominator was lack of lab value data in the database. A committee member noted that the performance issue could be lack of monitoring; however, that cannot be determined from just the lack of lab value data in the database.

1c. Evidence (based on decision logic): Workgroup: Y-3; N-5 **IF a Health Outcome,** rationale supports: Workgroup: Y-0; N-2; NA-5
Quantity: Workgroup: H-2; M-4; L-2; I-0 **Quality:** Workgroup: H-0; M-4; L-4; I-0 **Consistency:** Workgroup: H-0; M-3; L-4; I-1

Rationale: The primary evidence provided is the ATP III guidelines, which do not support CKD as a risk factor for CVD; and the NKF guidelines, which are opinion-based. The SHARP TRIAL findings are key. Report 32 studies, but not all of these directly applicable to measure Insufficient discussion of consistency across studies. Limited data on early stages of CKD and use of statins. Also, controversy about the positive impact of statins in CKD VI

2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: Y-4; N-4 Steering Committee: Y-7; N-13
2a. Reliability: Workgroup: H-1; M-3; L-4; I-0 **2b. Validity:** Workgroup: H-0; M-4; L-3; I-1

Rationale: Originally, no reliability testing was provided and the developer referred to the NQF testing report that indicated electronic data and methods will result in repeatable data elements. However, in that case, the testing guidance indicates that data element validity should be demonstrated and that testing also was not conducted. On resubmission, the developer described process for checking data and

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<p>programming, but provided no empirical analysis for reliability or validity of the data elements or the performance measure score.</p> <p>The title, denominator statement, and information on performance gap were inconsistent with the detailed specifications. The original denominator indicated “CKD, including Stage 5, dialysis, or kidney transplant”; however, the denominator details only include ESRD patients and stage 5, non-dialysis. While they do include codes that would capture patients in earlier stages of CKD, those patients would have to have a creatinine clearance between 0.1 and 14 - so most they would have to be in stage 5. The initial performance gap data focused on CKD stage 3-4. <i>Just prior to the final vote, the developer clarified that the measure is restricted to CKD 5.</i></p>
<p>3. Usability: Workgroup: <u>H-0; M-4; L-4; I-0</u> Steering Committee: <u>H-0; M-11; L-8; I-1</u> <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p><u>Rationale:</u> The usability is in question due to the very low numbers of patients who meet the denominator specifications for this measure. Measure previously endorsed and not currently publicly reported or used in any accountability application with no specific plan to do so.</p>
<p>4. Feasibility: Workgroup: <u>H-0; M-5; L-2; I-1</u> Steering Committee: <u>H-0; M-15; L-5; I-0</u> <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p><u>Rationale:</u> Data elements are available in electronic records in limited fashion. Not all data is available, hence small numbers of patients meeting denominator specifications. Integration of pharmacy data with lab data not certain.</p>
<p>Assessment of Criteria Met/Suitable for Endorsement: Workgroup: <u>Y-1; N-7</u></p> <p><u>Rationale:</u> Measure does not seem to be able to capture meaningful numbers of patients who would meet the denominator specifications. The measure specifications and information is inconsistent regarding which population is included.</p>
<p>Steering Committee Recommendation for Endorsement: <u>Y-3; N-17</u></p> <p>Rationale: The measure failed on Importance to Measure and Report as well as Scientific Acceptability of Measure Properties.</p>

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1662 Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy [Submission](#)

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

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 no

Adjustment/Stratification: No risk adjustment or risk stratification. As a process measure, no risk adjustment is necessary. We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected.

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

Type of Measure: Process

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

Measure Steward: American Medical Association

1. Importance to Measure and Report (based on decision logic): Steering Committee: Yes

1a. Impact: H-13; M-7; L-0; I-0 1b. Performance Gap: H-2; M-14; L-2; I-2

Rationale: Hypertension is a high impact topic. 1b State that among patients with CKD, use of ACEi/ARBs is 56-57% - but what about use among those with albuminuria/proteinuria (focus of measure)? Performance data on this measure from PQRS: median performance 62.5%; 25th percentile 33.3% and 75th percentile 100%. Disparity in care demonstrated for prevalence of hypertension, but not for use of ACEi/ARB.

1c. Evidence (based on decision logic): Yes

Quantity: H-1; M-19; L-0; I-1 Quality: H-1; M-18; L-1; I-1 Consistency: H-1; M-17; L-1; I-1

Rationale: Although numerous studies have been completed there are still considerable discrepancies in the final outcomes of treatment in various cohorts with high blood pressure and albuminuria, with and without diabetes. Does not clarify quantity of studies examining ACEi/ARB use for CKD with albuminuria independent of blood pressure (measure does not require patients to be hypertensive). However, hard to find patients with no hypertension. Most studies in diabetes with hypertensive patients demonstrate benefit. One-quarter of diabetic patients did not have hypertension and had same benefit. Evidence strong for normotensive diabetics with >300 proteinuria. Most trials include hypertensive patients. What are data to support 300? Most benefit shown at 500. Overt albuminuria is a critical definition in this measure, but few patients may have a 24-hour urine for albuminuria - developer stated working on better definition for proteinuria (>300 in urine over 24 hr, albumin/creatinine ratio >300, protein/creatinine ratio >0.3).

2. Scientific Acceptability of Measure Properties (based on decision logic): Steering Committee: No

2a. Reliability: H-0; M-7; L-11; I-3 2b. Validity: H-0; M-7; L-12; I-1

Rationale: eSpecs have problems, so removed from consideration for now. Reliability testing in 4 practices for chart abstraction only. What was reliability and validity of exclusion data? Face validity systematically assessed by expert group who developed the measure. There was an 18% exception rate and it may be an issue when using electronic record. Some reasons identified for exceptions are actually reasons

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<p>patient should be on ACE/ARB (e.g., renal insufficiency) - demonstrates problem with lack of standardized defined exclusions that are then defined by each individual physician.</p> <p>The developer requested reconsideration based on the following rationale.</p> <p>With regards to our proposed ACE/ARB measure, this measure is highly reliable as shown by the inter-rater reliability testing performed in the CKD/ESRD testing project. In addition, we have performed extensive research and analysis on ACE/ARB measure exception reliability in our Cardio-HIT project. Measure 1662 is identical to the measure tested in Cardio-HIT, differing only in populations. <i>In the Cardio-HIT project, over 90% of exceptions automatically reported were validated upon manual review of the medical record.</i>¹⁴ Some SC members expressed concern about difficulty in documenting the "high" exception rate (18%) in the medical record. We are unaware of any specific evidence that speaks to difficulty in documenting exceptions. On the contrary, we request the opportunity to present the PCPI methodology regarding including exceptions in our measures, as well as data from our Cardio- HIT published study¹⁴ to refute concerns regarding the reliability and validity of the exceptions (Appendix A). We hope that our explanatory comments will better clarify the PCPI exception methodology and lessons learned from the Cardio-HIT and other projects, and we respectfully request that the SC reconsider recommending this ACE/ARB measure to further emphasize the importance of tracking the outcomes of care <i>and</i> the care provided to patients with CKD. Our proposed ACE/ARB measure was tested in the same measure testing project as our other CKD/ESRD performance measures. Four nephrology practice sites representing various types, locations and sizes were identified to participate in testing the measures: <input type="checkbox"/>The number of physicians per site ranged from 5-62 physicians <input type="checkbox"/>The sites were located in four different regions: Midwestern, Western, Eastern, and Southern <input type="checkbox"/>Patient visit volume ranged from 60-2,250 CKD patients and 240-2,800 ESRD patients seen per month <input type="checkbox"/>Sample size per physician organization ranged from 24-30 for a total of 112 patients with Chronic Kidney Disease (CKD) <input type="checkbox"/>Sample selection: Data were collected from the medical records of the first 35 patients seen at each site after July 1, 2007 Data abstracted from patient records were used to calculate inter-rater reliability for the measure. Patients were randomly selected from visits for chronic kidney disease. Data analysis included: • Percent agreement • Kappa statistic to adjust for chance agreement Results from this testing project showed the measure to be highly reliable, and were as follows: Measure (N, % Agreement, Kappa, 95% Confidence Interval) ACE Inhibitor or ARB Therapy Measure (73, 93.15%, 0.8047 (0.6395- 0.9699)) Exceptions included medical reasons and patient reasons—they were analyzed for frequency and variability across providers. The exception rate for this measure was 18%. <i>There is no reason to think that this rate reduces the reliability of the measure (Appendix A). Out of 112 cases, the chart abstractors agreed on 107 of them, for a 95.5% reliability percentage. These numbers include the 13 cases that were coded as exceptions.</i> In a test of exceptions for CAD measures, on average, exceptions in 92.6% (CI, 90.3% to 94.9%) of patients were appropriate.¹⁴ We found no difference between the percentage of valid reported exceptions for the 2 sites that reported exceptions only when the drug was not prescribed versus the percentage for the 3 sites that reported all exceptions ($P = 0.38$; chi-square test).¹⁴ Agreement between automatically reported and manually reported exceptions ranged from 88.6% (CI, 81.3% to 95.4%) for antiplatelet therapy to 93.9% (CI, 90.8% to 97.0%) for therapy to lower LDL cholesterol level, although that pairwise difference was not statistically significant ($P = 0.128$; chi-square test).¹⁴ In summary, our ACE/ARB measure was designed to highlight specific therapy that has been shown to slow the progression of CKD in patients with CKD and proteinuria. In addition, based on the Steering Committee's recommendation, we have updated the definition of proteinuria in the measure. <i>We believe that our ACE/ARB measure exception reliability is the same as that tested in our Cardio-HIT project (Appendix A), differing only in populations.</i> We hope that these explanatory comments better clarify the PCPI exception methodology and lessons learned from the Cardio-HIT and other projects, and we request that the SC reconsider recommending this ACE/ARB measure to further emphasize the importance of tracking the outcomes of care <i>and</i> the care provided to patients with CKD.</p> <p>Steering Committee Follow-up: The Steering Committee voted on whether to reconsider this measure: <u>Y-10; Unsure-3; N-9</u> Conference call 10/28 and re-evaluation</p>
<p>Importance to Measure and Report (based on decision logic): Workgroup: <u>Y-6; N-2</u> Steering Committee: <u>Y-19; N-1</u> 1a. Impact: Workgroup: <u>H-4; M-4; L-0; I-0</u> 1b. Performance Gap: Workgroup: <u>H-2; M-6; L-0; I-0</u></p> <p><u>Rationale:</u> High impact area of care and performance gap demonstrated.</p> <p>1c. Evidence (based on decision logic): Workgroup: <u>Y-6; N-2</u> Quantity: Workgroup: <u>H-2; M-5; L-1; I-0</u> Quality: Workgroup: <u>H-3; M-4; L-1; I-0</u> Consistency: Workgroup: <u>H-2; M-4; L-2; I-0</u></p> <p><u>Rationale:</u> ACE/ARB rx in proteinuric CKD is about the best evidence we have in the field. However, data may not be entirely supportive of ACE/ARB use in this wide range of CKD at a very low level of proteinuria. One committee member stated that the evidence to support therapy for proteinuria >300 was weak compared to higher level of proteinuria. Another noted that it does not take into account other considerations such as comorbidities, history of progression or stability, whether hypertensive.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>Y-3; N-5</u> Steering Committee: <u>Y-10; N-10</u> 2a. Reliability: <u>H-1; M-2; L-5; I-0</u> 2b. Validity: <u>H-0; M-3; L-5; I-0</u></p>

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1662 Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy Submission
<p>Rationale: The developer revised the denominator definition of proteinuria as noted above 2a. A committee member asked about reliability of the CPT-II codes. The developer conducted reliability testing on interabstractor agreement using medical records (measure was implemented using CPT-II codes on claim forms). The reported reliability statistic for medical record abstraction was sufficient (0.80). The reliability statistic was for the measure score so information on the individual data elements such as the exceptions discussed below was not provided. 2b. Only face validity was addressed, and the issue regarding broad exception categories and individual physicians potentially identifying incorrect reasons for an exception is about validity and potential impact on comparability across physicians. There was an 18% exception rate for this measure and the committee identified that some of the exceptions that were reported by physicians were not appropriate. There was an 18% exception rate for this measure and the committee identified that some of the exceptions that were reported by physicians may not be appropriate.</p>
<p>3. Usability: Workgroup: H-0; M-6; L-2; I-0 Steering Committee: H-2; M-15; L-3; I-0 <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale: used in PQRS but not publicly reported.</p>
<p>4. Feasibility: Workgroup: H-0; M-4; L-4; I-0 Steering Committee: H-1; M-12; L-7; I-0 <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale: Feasibility not reasonably demonstrated for documentation of specific data elements. Currently medications are not unique data elements in many EMRs. Until widespread implementation of EMRs will need to implement with record abstraction or CPT-II codes.</p>
<p>Assessment of Criteria Met/Suitable for Endorsement: Workgroup: Y-2; N-6 Measure developer rationale for reconsideration did not change original evaluation of this specific measure.</p>
<p>Steering Committee Recommendation for Endorsement: Y-8; N-12</p>
<p>Rationale: The primary concerns were about reliability and validity and impact of measure specifications for exclusion categories.</p>
<p>Public and Member Comment Comments included:</p> <ul style="list-style-type: none"> • request for reconsideration because ACE/ARB is recommended treatment. <p>Although the Steering Committee already evaluated this measure 3 times, it agreed with the treatment objective and was interested in recommending such a measure if the identified reliability and validity issues could be addressed. The questions sent to the developer were:</p> <ol style="list-style-type: none"> 1. <i>Can you specify this measure with a discrete set of evidence-based exclusions/exceptions rather than the broad medical reason and patient reason categories? Please provide how the exclusions/exceptions would be specified (statement and details).</i> 2. <i>Do you have any data on reliability of the CPT-II codes for which the measure is specified and has been implemented?</i>
<p>Developer Response: 1) Our ACEI/ARB measure was designed to highlight specific therapy that has been shown to slow the progression of CKD in patients with CKD and proteinuria. In the desire to review measure 1662 again, some members of the Renal Steering Committee have verified that this measure reinforces standard of care and good practice for patients with CKD.</p> <p>ACE inhibitors and ARBs are recommended as preferred agents for diabetic kidney disease and nondiabetic kidney diseases with proteinuria, even in the absence of hypertension. In these diseases, they lower blood pressure, reduce proteinuria, slow the progression of kidney disease, and likely reduce CVD risk by mechanisms in addition to lowering blood pressure. (National Kidney Foundation. (2004) K/DOQI clinical practice guidelines on hypertension and antihypertensive agents in chronic kidney disease. Am J Kidney Dis. May;43(5 Suppl 1):S1-S290.)</p> <p>The use of ACE inhibitors and ARBs may result in adverse effects, which are more common in CKD. The most common side-effects—early decrease in GFR, hypotension and hyperkalemia—can usually be managed without discontinuation of the agent. With careful monitoring of therapy, most patients can be treated with ACE inhibitors and ARBs, even at low levels of GFR. (K/DOQI 2004)</p> <p>The effectiveness of ACEIs and ARBs is due to the capacity of these agents to lower blood pressure, glomerular hyperfiltration, and proteinuria. However, the agents remain underutilized, in part because of concerns that they may actually worsen kidney function. An acute reduction in renal function (ARF) can occur when therapy is initiated or continued in four situations:</p> <ul style="list-style-type: none"> • Blood pressure falls to low levels

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1662 Angiotensin Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy [Submission](#)

- Volume depletion from overaggressive diuretic therapy or non-renal losses is present
- There is high-grade narrowing of the artery to both kidneys
- Kidney blood flow is compromised by certain agents, particularly nonsteroidal anti-inflammatory agents (NSAIDs) or cyclosporine.

(National Kidney Foundation. (2004) CKD Update: Cautions with Angiotensin Converting Enzyme Inhibitor (ACEI) and Angiotensin Receptor Blocker (ARB) Therapy by Anton Schoolwerth, MD. http://www.imakenews.com/ckdupdate/e_article000327587.cfm?x=b11,0,w)

The above situations must be anticipated before instituting therapy. Even in the absence of these situations, an initial fall in GFR with ACEI/ARB therapy may occur and is an indication that the drugs are exerting their desired actions to help preserve kidney function. A 10-20% increase in serum creatinine can be anticipated and is not an indication to discontinue the agents. However, unless one of the above situations exists, the decrease in GFR is usually less than 20%, is transient (occurring in the first two weeks of therapy), followed by stabilization or improvement. Thus, there is no serum creatinine level or GFR *per se* for which ACEI/ARB therapy is contraindicated. (National Kidney Foundation. (2004) CKD Update: Cautions with Angiotensin Converting Enzyme Inhibitor (ACEI) and Angiotensin Receptor Blocker (ARB) Therapy by Anton Schoolwerth, MD. http://www.imakenews.com/ckdupdate/e_article000327587.cfm?x=b11,0,w)

Vote Following Consideration of Public and Member Comments

2. Scientific Acceptability of Measure Properties

2a. Reliability: H-0; M-3; L-15; I-1 2b. Validity: H-0; M-2; L-15; I-2

Steering Committee Recommendation for Endorsement: Y-3; N-16

Rationale: The measure did not meet criteria for Scientific Acceptability of Measure Properties primarily related to the broad exclusions categories and lack of reliability data for the CPT-II codes used specifically in this measure.

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1633 Blood Pressure Management Submission
<p>Description: Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) and proteinuria with a blood pressure <130/80 mmHg OR >= 130/80 mmHg with a documented plan of care</p> <p>Numerator Statement: Patient visits with blood pressure < 130/80 mmHg OR >= 130/80 mmHg with a documented plan of care*</p> <p>Definitions: Plan of Care: *A documented plan of care should include one or more of the following: recheck blood pressure within 90 days; initiate or alter pharmacologic therapy for blood pressure control; initiate or alter non-pharmacologic therapy (lifestyle changes) for blood pressure control; documented review of patient's home blood pressure log which indicates that patient's blood pressure is or is not well controlled</p> <p>Numerator Instructions: If multiple blood pressure measurements are taken at a single visit, use the most recent measurement taken at that visit.</p> <p>The PCPI recommends that this measure be reported as follows: % of patient visits meeting blood pressure < 130/80 mmHg (component 1) % of patient visits meeting blood pressure >= 130/80 mmHg with plan of care (component 2) % of patient visits meeting blood pressure < 130/80 mmHg AND patient visits meeting blood pressure >= 130/80 mmHg with plan of care (total measure score)</p> <p>Denominator Statement: All patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) and proteinuria</p> <p>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</p> <p>RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT (Renal Replacement Therapy) includes hemodialysis, peritoneal dialysis, and kidney transplantation</p> <p>Exclusions: None</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification This measure is not risk adjusted. We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected.</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team</p> <p>Type of Measure: Outcome</p> <p>Data Source: Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records</p> <p>Measure Steward: American Medical Association</p>
Steering Committee Evaluation at the In-person Meeting
<p>1. Importance to Measure and Report (based on decision logic): <u>No</u></p> <p>1a. Impact: <u>H-20; M-1; L-0; I-0</u> 1b. Performance Gap: <u>H-14; M-6; L-0; I-0</u></p> <p><u>Rationale:</u> Hypertension is a high impact topic. Performance on this measure from PQRS data demonstrated median performance at 67.53%; 25th percentil 25.76%; and 75th percentile 92.54%. Data on differences in Bp control among races cited.</p> <p>1c. Evidence (based on decision logic): <u>No</u> IF a Health Outcome, rationale supports: <u>NA</u></p> <p>Quantity: <u>H-8; M-4; L-2; I-6</u> Quality: <u>H-0; M-7; L-3; I-10</u> Consistency: <u>H-0; M-7; L-6; I-8</u></p> <p><u>Rationale:</u> No studies for this patient population, extrapolating from other populations. Proteinuria is a worse prognostic indicator, but studies with or without proteinuria not done. KDOQI review is 7-8 yrs old; KDIGO indicates not a high grade for evidence. JNC8 recommendations scheduled for release in November 2011. JNC using a different process and will be strictly evidence-based and it is likely will see different numbers.</p> <p>Encouraged resubmission based on latest evidence reviews and recommendations after they are published.</p>
Steering Committee Assessment of Suitability for Endorsement: <u>No</u> . The Importance to Measure and Report criterion was not met.
<p>The developer requested reconsideration of this measure.</p> <p>This measure is designed to address the critical need of BP Management in CKD and is consistent with the recent NephSAP review which found: "Presently, it appears that a target BP of 130/80 mm/Hg in patients with CKD is better for renoprotection than a higher level in the presence of proteinuria."10 It is for this reason that our measure denominator includes patients with CKD and proteinuria. In addition, based on the Steering Committee's recommendation, we have updated the definition of proteinuria in the measure. The SC provided feedback that</p>

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1633 Blood Pressure Management	Submission
<p>the requirement for evidence was not met. However, this measure is based on KDOQI's 2004 clinical practice guidelines on hypertension and antihypertensive agents in chronic kidney disease (CKD), which is based on JNC 7 and other evidence that is currently available. Despite the <i>current</i> guidelines and reviews supporting the measure, the SC hesitated to move forward with a measure based on guidelines that are in the process of being updated and for which a publication date is imminent. While we can appreciate the concern, we would like to call attention to the NOF Cardiovascular Steering Committee's recent decisions regarding measures related to blood pressure and cholesterol targets that will be similarly affected by upcoming guideline updates, including JNC 8. <i>The Cardiovascular SC recommended several of these measures for endorsement, provided that the measure developers agree to modify the measures as appropriate upon the release of the updated guidelines.</i> The PCPI has a process in place to update our measures once new evidence becomes available. We therefore respectfully request that the SC reconsider recommending this BP Management measure. . Several recent studies (Chronic Renal Insufficiency Cohort [CRIC], Third National Health and Nutrition Examination Survey [NHANES III], Kidney Early Evaluation Program) have confirmed that in many patients with chronic kidney disease (CKD), blood pressure (BP) is not controlled to the target of < 130/80 mm Hg as recommended in most clinical practice guidelines.¹¹ To help support greater efforts to control hypertension in patients with CKD, we submitted a BP management measure aimed at improving the number of patients with blood pressure controlled at < 130/80 mmHg. The plan of care component of the measure allows for patients to have blood pressure ≥ 130/80 mmHg with a plan of care (i.e., recheck blood pressure within 90 days; initiate or alter pharmacologic therapy for blood pressure control) in place. Accurate measurement in CKD is especially important, because hypertension is more common in CKD, and because JNC 7 identifies CKD as a "compelling indication" for more aggressive antihypertensive therapy because of the higher risk of CVD in CKD than in the general population.¹² Hypertension is both a cause and a complication of CKD; more than 50% to 75% of patients with CKD have blood pressure > 140/90 mm Hg. In addition, hypertension is a risk factor for progression of kidney disease and for CVD.¹³ <i>Ultimately, by not recommending measure 1633, there will be no NQF-endorsed measure for blood pressure control in patients with CKD.</i> We hope that these explanatory comments better clarify the evidence upon which our proposed measure is based and further explain that we have a process in place for updating measures. We therefore request that the SC reconsider recommending this BP Management measure to further emphasize the importance of tracking the outcomes of care <i>and</i> the care provided to patients with CKD.</p>	
Steering Committee Discussion on Conference Call Regarding Reconsideration	
1.Importance to Measure and Report	
<p>1c. Evidence A committee member reported that JNC8 is taking a very rigorous review of the evidence and the recommended value of <130/80 for CKD patients is likely to change.). Other committee members noted that the guideline cited was significantly opinion based and that the data at that time supported a BP in the 130s rather than < 130. Some committee members do not want to recommend a measure that will not be supported by the evidence; others were concerned about waiting for the evidence review from JNC8 and not having a blood pressure measure (however, 0018 does include CKD patients with hypertension</p> <p>Some committee members asked if they could vote on this measure with the condition that it be modified when JNC8 guidelines are published. NQF responded:</p> <ol style="list-style-type: none"> 1. The Steering Committee should first review #0018 (See Appendix C) to determine if another measure is needed. Measure 0018 will be modified when JNC8 guidelines are published (including different values for different diagnoses if indicated). NQF prefers to have one measure that applies to all relevant patient populations and settings as supported by the evidence. Measure 0018 would include all CKD patients (except ESRD) with a diagnosis of hypertension. 2. The key question is whether 0018 includes CKD patients. One consideration is whether CKD patients with proteinuria but without a diagnosis of hypertension are left out and what is the impact. If necessary and if the CKD measure meets NQF criteria, it could be recommended on the condition of modification based on JNC8. 	
Steering Committee Subsequent Re-Vote Following Conference Call	
<p>Importance to Measure and Report (based on decision logic): Workgroup: <u>Y-7; N-2</u> Steering Committee: <u>Y-19; N-1</u> 1a. Impact: Workgroup: <u>H-7; M-2; L-0; I-0</u> 1b. Performance Gap: Workgroup: <u>H-5; M-4; L-0; I-0</u></p> <p><u>Rationale:</u> A BP target in CKD is a crucial measure. The measure should reflect recent JNC 8 recommendations.</p> <p>1c. Evidence (based on decision logic): Workgroup: <u>Y-7; N-2</u> Quantity: Workgroup: <u>H-5; M-2; L-2; I-0</u> Quality: Workgroup: <u>H-2; M-4; L-3; I-0</u> Consistency: Workgroup: <u>H-2; M-5; L-2; I-0</u></p> <p><u>Rationale:</u> Quality of evidence not described - only supports measure specifications, but does not describe quality of studies, methodologies, etc. Consistency of data across studies not described. Major citation is KDOQI guideline (2004). Most recent draft guideline (KDIGO) recommends same goal of 130/80 but grades it 2C. It is clear from the application that there are few if any studies that directly address this proposed metric. However, based on our understandings about CKD and CVD and the strong data for BP control in the general population, that this metric should have an exemption on body of evidence.</p>	
2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>Y-7; N-2</u> Steering Committee: <u>Y-14; N-6</u>	
<p>2a. Reliability: Workgroup: <u>H-1; M-6; L-2; I-0</u> 2b. Validity: Workgroup: <u>H-3; M-3; L-3; I-0</u></p>	

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<p>1633 Blood Pressure Management Submission</p> <p>Rationale: No data on reliability of CPT II codes included; reliability testing primarily applies to chart review, which does not appear to be the primary method of measure implementation. Relies on face validity. The measure specification also allows for BP>130/80 with a documented plan of care. The developer indicates the numerator is reported separately for ccontrol and careplan; however, the performance data provided from the PQRI program is only one score not the 3 numerators as specified.</p>
<p>3. Usability: Workgroup: <u>H-4; M-4; L-1; I-0</u> Steering Committee: <u>H-3; M-16; L-1; I-0</u> <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale: Measure currently in use for PQRS program. It is a very reasonable metric to use for quality improvement, I believe.</p>
<p>4. Feasibility: Workgroup: <u>H-3; M-4; L-2; I-0</u> Steering Committee: <u>H-5; M-13; L-2; I-0</u> <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale: Data is readily available. May be problems with EHR if the plan of care or the BP itself are in text fields requiring human review to locate.</p>
<p>Workgroup Assessment of Criteria Met/Suitable for Endorsement: <u>Y-4; N-5</u></p> <p>Rationale: The split vote reflected differences on how the impending changes with JNC 8 should factor into a recommendation for endorsement at this time.</p>
<p>5. Related and Competing Measures (5a. Harmonization; 5b. Superior to competing measures) Measure #0018 See Appendix C</p>
<p>Steering Committee Assessment of Suitability for Endorsement: <u>Y-14; N-6</u> (on condition it is modified to be consistent with JNC 8)</p> <p>However, the majority of the committee also indicated that #0018 adequately captures CKD patients: <u>Y-13; N-6</u></p>
<p>Public and Member Comment and Evaluation of Competing Measures Comments included:</p> <ul style="list-style-type: none"> • support of the measure. <p>The Steering Committee reviewed the additional information from the developer and discussed the competing measures of 1633 and 0018. There was consensus that measure 0018 is appropriate for CKD patients based on the KEEP study and the expectation that JNC 8 will publish guidelines consistent with that. So the issue (for voting) was whether or not to also recommend measure 1633 for endorsement.</p> <ul style="list-style-type: none"> • While 1633 is labeled Blood Pressure Management it may be viewed as a kidney protection measure, targeting only proteinuric CKD patients. • The evidence supports a BP target of <140/90 as in 0018 (see KEEP study); the evidence for <130/80 is less clear even in proteinuric patients. • 0018 includes all patients with a diagnosis of hypertension. Although not all patients with CKD have hypertension, the key issue is how many CKD patients with hypertension will not have a diagnosis of hypertension and would be missed in measure 0018 – this is thought to be quite small. • The marginal benefit of BP <130/90 vs. <140/90 is small and driving everyone to a lower BP carries increased risk. Whereas, achieving BP <140/90 would benefit all patients and does not restrict individualized management to lower values for patients as clinically indicated. • 1633 gives "credit" when the BP target is not met if there is a plan of care. Therefore, it will produce confusing data and the score cannot distinguish performance on achieving blood pressure control even if the target is consistent with JNC8. (i.e., you can consistently have a plan of care without impacting a blood pressure of 160/90.) • 1633 targets a subset of the CKD population – those with proteinuria. Although proteinuric patients are at higher risk of progression of renal disease, they represent a minority of CKD patients and all CKD patients with hypertension should have blood pressure under control.
<p>Vote Following Consideration of Public and Member Comments and Evaluation of Competing Measures</p> <p>Steering Committee Recommend for Endorsement: <u>Y-4; N-15</u></p> <p>Rationale: Measure 0018 includes CKD patients; the evidence is not sufficient to support a lower target for the subset of proteinuric patients; and the plan of care component creates confusion in terms of measuring performance on blood pressure management.</p>

NATIONAL QUALITY FORUM

0250 ESRD- HD Adequacy CPM III: Minimum Delivered Hemodialysis Dose for ESRD hemodialysis patients undergoing dialytic treatment for a period of 90 days or greater. [Submission](#)

Description: 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, and have a residual renal function (if measured in the last three months) less than 2 ml/min/1.73m^2 , whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a $\text{spKt/V} \geq 1.2$ during the reporting period.

Numerator Statement: Number of patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a $\text{spKt/V} \geq 1.2$.

Denominator Statement: 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 and whose RRF is unmeasured or whose $\text{RRF} < 2 \text{ ml/min/1.73m}^2$ (if measured in the last three months).

Exclusions: Patients on HD less than 90 days. Patients with $\text{RRF} > 2 \text{ ml/min/1.73m}^2$ (measured in the last three months). Patients not in thrice weekly dialysis.

Adjustment/Stratification: No risk adjustment or risk stratification

Level of Analysis: Facility

Type of Measure: Outcome

Data Source: Administrative claims

Measure Steward: Centers for Medicare & Medicaid Services

Steering Committee Recommendation for Endorsement: No

Rationale: The measure is untested and because another measure of dialysis adequacy (0249) is available, the Committee suggested that this measure not be considered. It recommended that CMS test the dialysis adequacy measure with the inclusion of residual renal function and submit a modified measure at the next opportunity for endorsement maintenance.

NATIONAL QUALITY FORUM

0247 Hemodialysis Adequacy Clinical Performance Measure I: Hemodialysis Adequacy- Monthly measurement of delivered dose Submission
<p>Description: Percentage of all adult (>= 18 years old) HD patients in the sample for analyses with documented monthly adequacy measurements (spKt/V) or its components in the calendar month</p> <p>Numerator Statement: Number of patients in the denominator with documented monthly adequacy measurements (spKt/V) or its components in the calendar month.</p> <p>Denominator Statement: Number of adult patients (>=18 years) receiving in-center hemodialysis or home hemodialysis (irrespective of frequency of dialysis).</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification No risk adjustment necessary. No stratification is required for this measure.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>1. Importance to Measure and Report (based on decision logic): Workgroup: <u>Yes</u></p> <p>1a. Impact: Workgroup: <u>H-5; M-1; L-0; I-0</u> 1b. Performance Gap: Workgroup: <u>H-2; M-4; L-0; I-0</u></p> <p><u>Rationale:</u></p> <p>1a. The topic area of dialysis adequacy is high impact.</p> <p>1b. Performance gap on this measure: 1st quartile-67%; median-79%; 3rd quartile-88%</p> <p>1c. Evidence (based on decision logic): Workgroup: <u>Yes</u></p> <p>Quantity: Workgroup:<u>H-1; M-5; L-0; I-0</u> Quality: Workgroup: <u>H-1; M-4; L-1; I-0</u> Consistency: Workgroup: <u>H-1; M-5; L-0; I-0</u></p> <p><u>Rationale:</u> The evidence is indirect – it's about dialysis adequacy, not frequency of measurement. Assessment is necessary but not sufficient to achieving adequate dialysis. The validity testing presented demonstrates a relationship to SMR. Measurement of spKt/V assumes everyone is on same frequency and increasingly, patients are on different schedules. The Steering Committee strongly recommends that CMS refine measures to use standard Kt/V; CMS should have all the data elements required to do that. The developer responded that CMS has the data, but may need to validate the height and weight data. The Committee agreed that the three measures about dialysis adequacy should be combined into one measure that addresses method, frequency, and adequacy.</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>Yes</u></p> <p>2a. Reliability: Workgroup: <u>H-4; M-2; L-0; I-0</u> 2b. Validity: Workgroup: <u>H-3; M-3; L-0; I-0</u></p> <p><u>Rationale:</u> Good reliability and validity reported.</p> <p>2a. Reliability – The concern in the preliminary evaluations was related to using correlation of scores across time is not an appropriate test of reliability for data elements or measure score as described in testing task force report. The developer responded they saw it as similar but not identical circumstances. However, the developer also provided additional analysis that demonstrated adequate interunit reliability (0.94) to distinguish among facilities.</p> <p>2b. Validity – The testing results indicated that performance on this measure is associated with performance on standardized mortality ratio but primarily between the highest quintile and all others (8-13% higher risk of mortality).</p> <p>3. Usability: Workgroup: <u>H-5; M-1; L-0; I-0</u></p> <p><u>Rationale:</u> This measure is probably not needed - should be incorporated into adequacy measure.</p> <p>4. Feasibility: Workgroup: <u>H-6; M-0; L-0; I-0</u></p> <p><u>Rationale:</u> No issues with feasibility</p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Workgroup: <u>Y-6; N-0</u></p> <p><u>Rationale:</u> Although could be suitable, the workgroup recommended consolidation into a single metric with 0249.</p> <p>If applicable, Conditions/Questions for Developer: Consolidate 0247 into one measure (0249) that addresses assessment frequency,</p>

NATIONAL QUALITY FORUM

0247 Hemodialysis Adequacy Clinical Performance Measure I: Hemodialysis Adequacy- Monthly measurement of delivered dose [Submission](#)

method, and minimum dose. In other words, the numerator would be number of patients who had spKt/V measured using UKM or Daugirdas II method AND achieved dose of ≥ 1.2 monthly. If a patient did not have a measure of spKt/V in a month, they are NOT excluded from the denominator and a facility would not get credit as meeting the measure if not assessed.

Developer Response: The CMS HD adequacy, CMS PD adequacy measures can be combined into measures 0249 and 0318. These 2 measures capture the elements that are critical to the assessment of these clinical areas...for HD/PD adequacy (0249 and 0318) the 2 measures define the frequency, methodology and outcome which provides a comprehensive assessment of the care that is provided by a facility. It is logical to combine these measures as suggested. CMS decided that 0249 did not need to be modified to ensure that spKt/V is assessed monthly because the regulatory and payment policies provide adequate safeguards. CMS agreed that if the measure of dialysis adequacy (0249) is endorsed, this measure is not needed.

Steering Committee Follow-up: The Steering Committee will vote on whether it agrees that this measure is not needed.

Steering Committee Recommendation for Endorsement: No

Rationale: This measure is not needed when dialysis adequacy is measured: Measure Not Needed-19; Measure Needed-3

NATIONAL QUALITY FORUM

0248 Hemodialysis Adequacy Clinical Performance Measure II: Method of Measurement of Delivered Hemodialysis Dose [Submission](#)

Description: Percentage of all adult (>= 18 years old) hemodialysis patients in the sample for analyses for whom delivered HD dose was calculated using UKM or Daugirdas II during the study period and for whom the frequency of HD per week is specified.

Numerator Statement: Number of patients in the denominator for whom delivered HD dose for a single dialysis session was calculated using UKM or Daugirdas II during the reporting period and for whom the frequency of HD per week is specified.

Denominator Statement: Number of adult patients (>=18 years) receiving in-center hemodialysis or home hemodialysis.

Exclusions: None.

Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. This measure is not stratified.

Level of Analysis: Facility

Type of Measure: Process

Data Source: Electronic Clinical Data

Measure Steward: Centers for Medicare & Medicaid Services

1. Importance to Measure and Report (based on decision logic): Workgroup: Yes

1a. Impact: Workgroup: H-6; M-0; L-0; I-0 **1b. Performance Gap:** Workgroup: H-1; M-3; L-1; I-1

Rationale: 1a. The topic of dialysis adequacy is high impact.

1b. The performance on this measure (1st quintile-44%; 2nd quintile-63%; 3rd quintile-69%; 4th quintile-76%; 5th quintile-100%) is probably related to whether it's measured not the method – that is, if not measured at all will not be counted in the numerator. No exclusions are specified.

1c. Evidence (based on decision logic): Workgroup: Yes

Quantity: Workgroup: H-0; M-5; L-1; I-0 **Quality:** Workgroup: H-1; M-4; L-1; I-0 **Consistency:** Workgroup: H-0; M-5; L-0; I-1

Rationale: Assessment is necessary but not sufficient to achieving adequate dialysis. Indirect evidence provided for measure (evidence of kinetic modeling to health outcomes, but not the specific method of measurement). No evidence supporting one method over another. Daugirdas II also can be used with standard Kt/V and different frequencies as long as the pre-dialysis interval is known.

2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: Yes

2a. Reliability: Workgroup: H-4; M-1; L-1; I-0 **2b. Validity:** Workgroup: H-3; M-3; L-0; I-0

Rationale: 2a. Reliability – The concern in the preliminary evaluations was related to using correlation of scores across time is not an appropriate test of reliability for data elements or measure score as described in testing task force report. The developer responded they saw it as similar but not identical circumstances. However, the developer also provided additional analysis that demonstrated adequate interunit reliability (0.96) to distinguish among facilities.

2b. Validity – The testing results indicate that performance on this measure is associated with performance on standardized mortality ratio but primarily difference between the highest quintile and all others (5-12% higher risk of mortality).

The measure is incorrectly specified - it does not do what the title implies. The denominator should be the number of patients who had a Kt/V so that the metric actually measures the percentage using the favored method. Instead the basically metric measures those who had kt/V measured, same as the prior metric.

3. Usability: Workgroup: H-5; M-0; L-0; I-1

Rationale: This measure is probably not needed - should be incorporated into adequacy measure. The Committee agreed that the three measures about dialysis adequacy should be combined into one measure that addresses method, frequency, and adequacy.

4. Feasibility: Workgroup: H-6; M-0; L-0; I-0

Rationale: No issues with feasibility

Preliminary Assessment of Criteria Met/Suitable for Endorsement: Workgroup: Y-5; N-1

Rationale: Would recommend moving toward weekly standardized Kt/V measurements for measures to account for different frequencies dialysis sessions. The Workgroup recommended this measure be incorporated into the intermediate outcome measure for dialysis adequacy (0249).

NATIONAL QUALITY FORUM

0248 Hemodialysis Adequacy Clinical Performance Measure II: Method of Measurement of Delivered Hemodialysis Dose [Submission](#)

If applicable, Conditions/Questions for Developer: Consolidate 0248 into one measure (0249) that addresses assessment frequency, method, and minimum dose. In other words, the numerator would be number of patients who had spKt/V measured using UKM or Daugirdas II method AND achieved dose of ≥ 1.2 monthly. If a patient did not have a measure of spKt/V in a month, they are NOT excluded from the denominator and a facility would not get credit as meeting the measure if not assessed.

Developer Response: The CMS HD adequacy and CMS PD adequacy, measures can be combined into measures 0249 and 0318. These 2 measures capture the elements that are critical to the assessment of these clinical areas for HD/PD adequacy (0249 and 0318). The 2 measures define the frequency, methodology and outcome which provides a comprehensive assessment of the care that is provided by a facility. It is logical to combine these measures as suggested. CMS decided that 0249 did not need to be modified to ensure that spKt/V is assessed using the specific method because the regulatory and payment policies provide adequate safeguards. CMS agreed that if the measure of dialysis adequacy (0249) is endorsed, this measure is not needed. **Steering Committee Follow-up:** The Steering Committee will vote on whether it agrees that this measure is not needed.

Steering Committee Recommendation for Endorsement: No

Rationale: This measure is not needed when dialysis adequacy is measured. Not Needed-19; Measure Needed-3

NATIONAL QUALITY FORUM

0253 Peritoneal Dialysis Adequacy Clinical Performance Measure I - Measurement of Total Solute Clearance at Regular Intervals Submission
<p>Description: Percentage of all adult (>= 18 years old) peritoneal dialysis patients with total solute clearance for urea (endogenous residual renal urea clearance & dialytic) measured at least once in a four month time period.</p> <p>Numerator Statement: Patients with total solute clearance for urea (endogenous residual renal urea clearance & dialytic) measured at least once in a four month time period.</p> <p>Denominator Statement: All adult (>= 18 years old) peritoneal dialysis patients.</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification None. No stratification is required for this measure.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data</p> <p>Measure Steward: Centers for Medicare & Medicaid Services</p>
<p>1. Importance to Measure and Report (based on decision logic): Workgroup: Yes</p> <p>1a. Impact: Workgroup: <u>H-6; M-0; L-0; I-0</u> 1b. Performance Gap: Workgroup: <u>H-6; M-0; L-0; I-0</u></p> <p><u>Rationale:</u> 1a. The topic of dialysis adequacy is high impact. 1b. Performance gap: (1st quartile-0%; median-50%; 3rd quartile-80%).</p> <p>1c. Evidence (based on decision logic): Workgroup: Yes</p> <p>Quantity: Workgroup: <u>H-1; M-5; L-0; I-0</u> Quality: Workgroup: <u>H-0; M-5; L-1; I-0</u> Consistency: Workgroup: <u>H-0; M-6; L-0; I-0</u></p> <p><u>Rationale:</u> Indirect evidence provided (addresses association of adequacy with mortality, but does not address frequency of measurement with outcomes). Assessment is necessary but not sufficient to achieving adequate dialysis. The Committee agreed that the three measures about dialysis adequacy should be combined into one measure that addresses method, frequency, and adequacy.</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: No</p> <p>2a. Reliability: Workgroup: <u>H-1; M-4; L-1; I-0</u> 2b. Validity: Workgroup: <u>H-2; M-2; L-1; I-0</u></p> <p><u>Rationale:</u></p> <p>2a. Reliability – The concern in the preliminary evaluations was related to using correlation of scores across time is not an appropriate test of reliability for data elements or measure score as described in testing task force report. The developer responded they saw it as similar but not identical circumstances. However, the developer also provided additional analysis that demonstrated adequate interunit reliability (0.78) to distinguish among facilities.</p> <p>2b. Validity – The testing results did not demonstrate an association between performance on this measure with performance on standardized mortality ratio (confidence intervals for relative risk included 1.0). The committee discussed that the results may be reflective of low numbers of patients.</p> <p>3. Usability: Workgroup: <u>H-5; M-1; L-0; I-0</u></p> <p><u>Rationale:</u> This measure is probably not needed - should be incorporated into adequacy measure.</p> <p>4. Feasibility: Workgroup: <u>H-5; M-1; L-0; I-0</u></p> <p><u>Rationale:</u> no issues with feasibility.</p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Workgroup: <u>Y-5; N-1</u></p> <p><u>Rationale:</u> The Workgroup recommended this measure be incorporated into the intermediate outcome measure for dialysis adequacy (0318).</p>
<p>If applicable, Conditions/Questions for Developer: Consolidate into one measure (0318) that addresses assessment frequency, method, and minimum dose. In other words, the numerator would be number of patients who had total solute clearance for urea (endogenous residual and dialytic) measured using Ki/Vurea AND achieved dose of >=1.7 every 4 months. If a patient did not have a measure of Ki/Vurea in the time period, they are NOT excluded from the denominator and a facility would not get credit as meeting the</p>

NATIONAL QUALITY FORUM

0253 Peritoneal Dialysis Adequacy Clinical Performance Measure I - Measurement of Total Solute Clearance at Regular Intervals Submission
measure if not assessed.
Developer Response: The other CMS HD adequacy and CMS PD adequacy measures can be combined into measure 0249 and 0318. These 2 measures capture the elements that are critical to the assessment of these clinical areas for HD/PD adequacy (0249 and 0318). The 2 measures define the frequency, methodology and outcome which provides a comprehensive assessment of the care that is provided by a facility. It is logical to combine these measures as suggested. CMS decided that 0318 did not need to be modified to ensure that spKt/V is assessed every 4 months because the regulatory and payment policies provide adequate safeguards. CMS agrees that if the measure of dialysis adequacy (0318) is endorsed, this measure is not needed.
Steering Committee Follow-up: The Steering Committee will vote on whether it agrees that this measure is not needed.
Steering Committee Recommendation for Endorsement: <u>No</u>
Rationale: This measure is not needed when dialysis adequacy is measured. Not Needed-18; Measure Needed-4

NATIONAL QUALITY FORUM

0254 Peritoneal Dialysis Adequacy Clinical Performance Measure II - Calculate Weekly Kt/Vurea in the Standard Way
Submission
Description: Percentage of all adult (>= 18 years old) peritoneal dialysis patients with weekly Kt/V urea (endogenous residual renal urea clearance & dialytic) calculated in a standard way.
Numerator Statement: Patients with: (1) Weekly Kt/Vurea used to measure delivered peritoneal dialysis dose and endogenous renal urea clearance; (2) Residual renal function (unless negligible [$< 100\text{mL}$ urine in 24 hours]) assessed by measuring the renal component of Kt/Vurea and estimating the patient's glomerular filtration rate (GFR) by calculating the mean of urea and creatinine clearance; (3) Total body water (V) estimated by either the Watson or Hume method using actual body weight, and BSA estimated by either the Dubois and Dubois method, the Gehan and George method, or the Haycock method of using actual body weight; during the four month study period.
Denominator Statement: All adult (>= 18 years old) peritoneal dialysis patients.
Exclusions: None.
Adjustment/Stratification: No risk adjustment or risk stratification. None. No stratification is required for this measure.
Level of Analysis: Facility
Type of Measure: Process
Data Source: Electronic Clinical Data
Measure Steward: Centers for Medicare & Medicaid Services
1. Importance to Measure and Report (based on decision logic): Workgroup: <u>No</u>
1a. Impact: Workgroup: <u>H-5; M-1; L-0; I-0</u> 1b. Performance Gap: Workgroup: <u>H-2; M-2; L1-; I-1</u>
Rationale: 1a. Impact – Preliminary ratings indicated agreement that high impact was met. 1b. Performance Gap – The performance gap (1 st quartile-0%; median-33%; 3 rd quartile-57%) is probably related to whether it's measured not the method – that is, if not measured at all will not be counted in the numerator. It is unclear whether the performance gap represents non-collection of the clearance, or using a method other than the measure-recommended method.
1c. Evidence (based on decision logic): Workgroup: <u>Yes</u>
Quantity: Workgroup: <u>H-0; M-5; L-1; I-0</u> Quality: Workgroup: <u>H-0; M-5; L-1; I-0</u> Consistency: Workgroup: <u>H-0; M-6; L-0; I-0</u>
Rationale: Indirect evidence provided for outcomes of measuring dialysis adequacy, but does not address the method of measurement. The evidence does not address which method of measurement is best. The Committee agreed that the three measures about dialysis adequacy should be combined into one measure that addresses method, frequency, and adequacy.
2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>Yes</u>
2a. Reliability: Workgroup: <u>H-0; M-4; L-2; I-0</u> 2b. Validity: Workgroup: <u>H-0; M-4; L-2; I-0</u>
Rationale: 2a. Reliability – The concern in the preliminary evaluations was related to using correlation of scores across time is not an appropriate test of reliability for data elements or measure score as described in testing task force report. The developer responded they saw it as similar but not identical circumstances. However, the developer also provided additional analysis that demonstrated adequate interunit reliability (0.64) to distinguish among facilities. 2b. Validity – The testing results did not demonstrate an association between performance on this measure with performance on standardized mortality ratio (confidence intervals for relative risk included 1.0). Wide confidence intervals probably related to small numbers of patients.
Not specified properly so does not measure what the title of the metric implies. The numerator is a composite of 2 processes: if a measurement was made, and the method of calculating that measurement. To determine the percentage using the proper method, the denominator would need to be those with a measurement.
3. Usability: Workgroup: <u>H-3; M-2; L-1; I-0</u>
Rationale: This measure is probably not needed - should be incorporated into adequacy measure.
4. Feasibility: Workgroup: <u>H-5; M-1; L-0; I-0</u>

NATIONAL QUALITY FORUM

0254 Peritoneal Dialysis Adequacy Clinical Performance Measure II - Calculate Weekly KT/Vurea in the Standard Way Submission
Rationale: no issues with feasibility.
Preliminary Assessment of Criteria Met/Suitable for Endorsement: Workgroup: <u>Y-3; N-3</u>
Rationale: The Workgroup recommended this measure be incorporated into the intermediate outcome measure for dialysis adequacy (0318).
If applicable, Conditions/Questions for Developer: Consolidate into one measure (0318) that addresses assessment frequency, method, and minimum dose. In other words, the numerator would be number of patients who had total solute clearance for urea (endogenous residual and dialytic) measured using Kt/Vurea AND achieved dose of ≥ 1.7 every 4 months. If a patient did not have a measure of Kt/Vurea in the time period, they are NOT excluded from the denominator and a facility would not get credit as meeting the measure if not assessed.
Developer Response: The other CMS HD adequacy and CMS PD adequacy measures can be combined into measures 0249 and 0318. These 2 measures capture the elements that are critical to the assessment of these clinical areas...for HD/PD adequacy (0249 and 0318) the 2 measures define the frequency, methodology and outcome which provides a comprehensive assessment of the care that is provided by a facility It is logical to combine these measures as suggested. CMS decided that 0318 did not need to be modified to ensure that spKt/V is assessed using the specific method because the regulatory and payment policies provide adequate safeguards. CMS agreed that if the measure of dialysis adequacy (0318) is endorsed, this measure is not needed.
Steering Committee Follow-up: The Steering Committee will vote on whether it agrees that this measure is not needed.
Steering Committee Recommendation for Endorsement: <u>No</u>
Rationale: This measure is not needed when dialysis adequacy is measured. Not Needed-16; Measure Needed-6

NATIONAL QUALITY FORUM

0261 Measurement of Serum Calcium Concentration [Submission](#)

Description: Percentage of all adult peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum calcium measured at least once within month

Numerator Statement: Number of adult (>= 18 years of age) dialysis patients included in denominator with serum calcium measured at least once within month

Denominator Statement: All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis.

Exclusions: Transient dialysis patients (in unit < 30 days), pediatric patients and kidney transplant recipients with a functioning graft.

Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A

Level of Analysis: Facility

Type of Measure: Process

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

Measure Steward: Centers for Medicare & Medicaid Services

1. Importance to Measure and Report (based on decision logic): Workgroup: No

1a. Impact: Workgroup: H-2; M-4; L-3; I-0 **1b. Performance Gap:** Workgroup: H-0; M-4; L-4; I-1

Rationale:

1a. The topic of mineral metabolism is a high impact aspect of healthcare for dialysis patients.

1b. The mean performance rate was also 77% on this measure (as with the phosphorus assessment measure).

1c. Evidence (based on decision logic): Workgroup: No

Quantity: Workgroup: H-2; M-5; L-2; I-0 **Quality:** Workgroup: H-0; M-5; L-4; I-0 **Consistency:** Workgroup: H-0; M-5; L-4; I-0

Rationale: The evidence is indirect, i.e., it is about the association between calcium and mortality rather than the frequency of assessment. Most of what the measure developer cites is tangential to the specific question about the benefit of measuring monthly calcium. Little data (and no RCTs) on intervention and actual outcome. In general lots of studies which in the end point to association mostly with phosphorus and CVD outcomes, much less if any such association independently with PTH/calcium.

A Committee member suggested that although this may not be the most important measure – it is a start and it is something that is measurable. One committee member noted that the big difference between this measure and the phosphorus measure has to do with a safety signal. Monitoring calcium is an opportunity to identify patients with potential hypercalcemia related to treatment. However, it was noted that a measure of hypercalcemia (# 1454) was endorsed in the Phase I project. It was recommended that this measure of assessing calcium be combined with the recently endorsed measure of hypercalcemia.

2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: Yes

2a. Reliability: Workgroup: H-5; M-2; L-2; I-0 **2b. Validity:** Workgroup: H-3; M-4; L-1; I-1

Rationale: 2a. Concerns expressed about correlations over time as a test of reliability. CMS submitted additional reliability testing that indicates the interunit reliability was 0.94.

2b. Validity – Validity testing demonstrated association between facility performance on this measure and the facility standardized mortality ratio. The lowest quintile of performance on this assessment measure had a 16% greater risk of mortality than the highest performing quintile; and the risk of mortality decreased as the quintile of performance increased.

3. Usability: Workgroup: H-4; M-3; L-2; I-0

Rationale: Concerns regarding how meaningful or understandable 261 would be as a quality measure. The measure of hypercalcemia is more useful.

4. Feasibility: Workgroup: H-6; M-2; L-1; I-0

Rationale: No issues with feasibility.

Preliminary Assessment of Criteria Met/Suitable for Endorsement: Workgroup: Y-5; N-3

Rationale: My main issue with 0261 relates to the 1 month time interval and the fact that these are process measures with less linkage to

NATIONAL QUALITY FORUM

0261 Measurement of Serum Calcium Concentration [Submission](#)

hard outcomes. **I find it difficult to endorse 261 for all ESRD patients without regard to their treatment status (on vitamin D, cinacalcet, etc. or not) and am concerned about a CPM with monthly testing in the absence of data to support this specific testing interval. With some revision I would support a phosphorus measure. **Measurement of serum calcium is important to identify patients at risk for hypercalcemia. This measure complements and should be harmonized with 1454 (proportion of patients with hypercalcemia). Together, the two measures can provide sound clinical care to identify patients at risk before they develop hypercalcemia.

**There is insufficient evidence that serum calcium levels correlate with outcomes. There is no evidence that treating calcium levels lead to improved outcomes. However, ESRD patients are often treated with drugs that may raise serum calcium levels to dangerous levels. For this reason, calcium levels should be monitored at intervals (unclear that monthly is the best interval) in patients with ESRD receiving these medications. I would therefore approve this measure, but ask it be harmonized with the physician-level measure for hypercalcemia recently recommended for approval.

The preliminary ratings were spread across all the rating categories.

One member expressed that this measure should be harmonized with the hypercalcemia measure. Another member agreed that in order to detect a safety issue, it infers that it has to be measured. The Workgroup will revote on this measure.

The Workgroup recommended this measure be incorporated into the intermediate outcome endorsed measure for hypercalcemia (1454).

If applicable, Conditions/Questions for Developer: Have one measure (1454) that addresses assessment frequency and level
In other words, the numerator would be number of patients who either did not have serum calcium measured at least once OR had calcium >10 as a rolling average for 3months
If a patient did not have a measure of calcium in the time period, they are NOT excluded from the denominator and a facility score would indicate less than optimal care if either not assessed OR too high.

Developer Response: The CMS calcium measures can be combined into measure 1454. As for the calcium measure (1454) having the value is critical to the assessment of how well a facility is performing with regards to managing their patient population. It is logical to combine these measures as suggested. CMS decided that 1454 did not need to be modified to ensure that calcium is assessed monthly because the regulatory and payment policies provide adequate safeguards. CMS agreed that with the endorsed measure of hypercalcemia (1454), this measure is not needed.

Steering Committee Follow-up: The Steering Committee will vote on whether it agrees that this measure this not needed.

Steering Committee Recommendation for Endorsement: No

Rationale: This measure is not needed when dialysis adequacy is measured. **Not Needed-19; Measure Needed-3**

NATIONAL QUALITY FORUM

0570 Chronic Kidney Disease (CKD): Monitoring Phosphorus Submission
<p>Description: To ensure that members with chronic kidney disease (CKD) who are not on dialysis are monitored for blood phosphorus levels at least once annually.</p> <p>Numerator Statement: Members with phosphorus level blood tests during the measurement year.</p> <p>Denominator Statement: Members with at least 1 inpatient diagnosis of chronic kidney disease during the year prior to the measurement year or members with at least 2 diagnoses of chronic kidney disease in an outpatient setting during the measurement year or year prior (at least 1 of which must be during the year prior to the measurement year).</p> <p>Exclusions: Members who are on dialysis or in hospice during the measurement year. Members who were hospitalized during the numerator time frame and did not fulfill numerator criteria.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Health Plan</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims</p> <p>Measure Steward: IMS Health</p>
<p>1. Importance to Measure and Report (based on decision logic): Workgroup: <u>Y-5; N-5</u></p> <p>1a. Impact: Workgroup: <u>H-4; M-4; L-2; I-0</u> 1b. Performance Gap: Workgroup: <u>H-3; M-6; L-1; I-0</u></p> <p><u>Rationale:</u> 1a. Impact Because the focus is to detect early bone disease, it is an area of high impact. 1b. Performance Gap- The developer did not initially provide performance data on this previously endorsed measure as specified for clinician level performance. The Committee agreed that there is an opportunity for improvement because there are many people who have different degrees of CKD and suspect that fairly low numbers of them actually have serum phosphorus measured annually. Subsequent performance data provided by the developer indicated a performance gap on this measure.</p> <p>1c. Evidence (based on decision logic): Workgroup: <u>Y-5; N-5</u></p> <p>Quantity: Workgroup: <u>H-1; M-4; L-5; I-0</u> Quality: Workgroup: <u>H-1; M-4; L-5; I-0</u> Consistency: Workgroup: <u>H-1; M-4; L-3; I-1</u></p> <p><u>Rationale:</u> As with 0255, the evidence is indirect for this assessment measure, (i.e., it is about the association between phosphorus and mortality rather than the frequency of assessment); however, the evidence currently does not support a more proximal measure of intermediate outcome or intervention. There were few studies and most were epidemiological studies. Evidence for phosphorus management in CKD and impact on outcomes is limited. Even in CKD (non-dialysis) there is an association between mortality and the phosphorus level but that was not cited as a rationale, just early detection of bone disease. There was no information submitted about any studies that show a decrease in phosphorus levels will lead to better outcomes. There is a question of whether the evidence supports an annual phosphorus lab test in all CKD patients including those who are aging into CKD.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>Y-9; N-1</u></p> <p>2a. Reliability: Workgroup: <u>H-3; M-5; L-1; I-1</u> 2b. Validity: Workgroup: <u>H-1; M-7; L-2; I-0</u></p> <p><u>Rationale:</u> 2a. Reliability – The Committee members questioned whether reliability was demonstrated merely by correlating scores for two plans across two years. The measure developer responded that the reason for their correlation approach was because they do not have access to electronic medical records or charts to perform any other reliability tests. However, NQF criteria allow for a variety of approaches to testing. Subsequently the developer submitted signal-to-noise analysis for reliability of the clinician level score. 2b. Validity – Committee members questioned the accuracy of claims data in identifying individuals with CKD. The measure developer responded that the way they defined the CKD denominator population was in line with the literature but the specific sensitivity and specificity of claims data was not provided. A committee member noted that validity is likely compromised because of reliance on ICD-9 codes for CKD, which has been shown in two prior papers to be suboptimal overall and likely worse to identify specific stages of CKD (e.g., stage III-V). Validity testing was not conducted.</p>
<p>3. Usability: Workgroup: <u>H-2; M-7; L-1; I-0</u></p> <p><u>Rationale:</u> The measure is currently used for a QI program by one of the sponsor's customers. No specific plans for public reporting were identified. A member questioned whether this measure would be usable beyond a closed system that has access to all the claims data. Another said that usability depends on whether it is reliable and valid.</p>
<p>4. Feasibility: Workgroup: <u>H-2; M-6; L-1; I-0</u></p> <p><u>Rationale:</u> One member expressed that it may not be very feasible to implement because the majority of patients in America with CKD are not</p>

NATIONAL QUALITY FORUM

0570 Chronic Kidney Disease (CKD): Monitoring Phosphorus [Submission](#)

identified in large health systems data. It was clarified that any entity could use the measure as specified if endorsed by NQF.

Assessment of Criteria Met/Suitable for Endorsement: Workgroup: Y-4; N-5

Rationale: Some committee members think the performance gap and relation to morbidity and mortality justify the measure. Other committee members think it fails on a consistent body of evidence related to interventions that will impact outcomes and the validity issue of identifying CKD in claims data.

If applicable, Conditions/Questions for Developer: Please provide additional information to demonstrate a performance gap for this measure. Do you have any data at the provider level to support this measure? Also, what is the rationale for comparing plan level scores to a range found in the literature as a demonstration of validity (accuracy) of the data elements? NQF is asking for evidence of the validity of either: 1) the data used in the measure (e.g., accuracy of the lab date, lab method, dialysis dose); or 2) the measure score (correctness of conclusion about quality). Can you provide evidence of accuracy of patient-level data? How are patients identified with particular physicians for physician performance scores? Is the 12-month prior for purposes of looking for CKD dx?

Developer Response: (See revised measure submission form.)

1b. Performance on this measure

The developer provided performance on this measure in 2b5 (but did not enter in 1b2) demonstrating performance gap.

Plan A

n = 644 (number of providers scored)

Mean score = 55%, median = 50%, SD = 24%, Min = 0, Max = 100% 25th percentile = 36%, 75th percentile = 69%

Plan B

n = 835 (number of providers scored)

Mean = 52%, Median = 53%, SD = 18%, Min = 0%, Max = 100% 25th percentile = 41%, 75th percentile = 63%

2a. Reliability The developer submitted additional reliability testing using method for signal to noise analysis as identified in the NQF measure testing report.

See 2a2

Plan A: 2,222 physicians, treating 31,935 CKD patients

Plan B: 6,645 physicians, treating 35,543 patients

We cannot provide descriptive information on the stage of CKD. Our algorithm determines whether or not the patient suffers from CKD stage ≥ 3 , however, we cannot discriminate between stages 3, 4, and 5 using administrative data.

We applied a denominator threshold 10. The distribution of physician reliability scores is as follows:

Plan A: n=835, mean = 0.72, standard deviation=0.12, minimum=0.49, maximum=1.00,
25th percentile=0.62, 75th percentile=0.80, 90th percentile=0.89

Plan B: n=664, mean = 0.81, standard deviation=0.10, minimum=0.67, maximum=1.00,
25th percentile=0.73, 75th percentile=0.88, 90th percentile=0.97

2b. Validity

Accuracy of Denominator

The IMS denominator algorithm to identify patient with chronic renal disease (stage III or greater, GFR < 60ml/min/1.73 m²) is consistent with algorithms in the literature which were able to identify patients with CKD with > 97% specificity when compared to data obtained by other sources (i.e., creatinine values). Note: the provided study by Kern indicated low sensitivity-only 20.2 to 42.4 percent of individuals with CKD received a renal-related diagnosis code.

The results provided for validity (rates by plan) does not represent actual validity testing of the measure as specified, but could support face validity. See description in 2b2.3.

Q: 2a1.4-7 Denominator

How are patients identified with particular physicians for physician performance scores?

All physicians who saw the patient during the measurement year are scored on this measure.

Q: 2a1.6 – Time window for the denominator. Is the 12-month prior for purposes of looking for CKD dx?

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<p>0570 Chronic Kidney Disease (CKD): Monitoring Phosphorus Submission</p>
<p>We apologize if this was not clearly stated; the continuous enrollment requirement for this measure is the 12 month period of the measurement year. Diagnoses in the year prior to the measurement year are necessary to qualify for the denominator, but there is no continuous enrolment requirement during the year prior to the measurement year.</p>
<p>Steering Committee Vote after Response from Developer</p>
<p>1. Importance to Measure and Report (<i>based on decision logic</i>): Steering Committee: <u>Y-15; N-5</u> 2. Scientific Acceptability of Measure Properties (<i>based on decision logic</i>): Steering Committee: <u>Y-11; N-9</u> 3. Usability: Steering Committee: <u>H-2; M-15; L-3; I-0</u> 4. Feasibility: Steering Committee: <u>H-4; M-13; L-3; I-0</u></p>
<p>Steering Committee Recommendation for Endorsement: <u>Y-10; N-10</u></p>
<p>Rationale: The rationale for recommending the measure is the association between phosphorus and morbidity and mortality in CKD. The rationale against recommending the measure stems from the weakness of the evidence for entire CKD population (not just ESRD); lack of evidence that treatment influences outcomes; and validity issues with identifying CKD patients in claims data, particularly stage 3.</p>
<p>Member and Public Comment</p> <p>One commenter asked for reconsideration.</p> <p>Two issues support not recommending it for endorsement as a national performance measure:</p> <ol style="list-style-type: none"> 1) Insufficient evidence that annual assessment of phosphorus in all CKD patients (=>stage3) was linked to improved outcomes. The evidence is weak (nonexistent?) in this really large group of CKD 3 patients (many who have aged into CKD 3) that having a phosphorus level drawn, actually improves anything. The developers cite K/DIGO clinical practice guideline (evidence 1C). 2) Reservations about the ability to identify CKD patients in claims data. Although the method used to identify CKD patients in claims has good specificity (patients with CKD dx do have CKD), it has very low sensitivity (the cited study indicated that only 20.2 to 42.4 percent of individuals with CKD received a renal-related diagnosis code).

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0571 CHRONIC KIDNEY DISEASE (CKD): MONITORING PARATHYROID HORMONE (PTH) Submission
<p>Description: To ensure that members with chronic kidney disease are monitored for PTH levels at least once annually.</p> <p>Numerator Statement: Members who received a PTH level test during the measurement year.</p> <p>Denominator Statement: Members with chronic kidney disease during the year prior to the measurement year or members with at least 2 diagnoses of chronic kidney disease in an outpatient setting during the measurement year or the year prior (at least 1 of which must be during the year prior to the measurement year), or members on dialysis or who utilized dialysis during the year prior to the measurement year.</p> <p>Exclusions: Members who are in hospice during the measurement year.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Health Plan</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims</p> <p>Measure Steward: IMS Health</p>
<p>1. Importance to Measure and Report (based on decision logic): Workgroup: <u>No</u> Steering Committee: <u>Y-8; N-14</u></p> <p>1a. Impact: Workgroup: <u>H-1; M-1; L-7; I-0</u> 1b. Performance Gap: Workgroup: <u>H-2; M-4; L-3; I-0</u></p> <p>Rationale: 1a. Risks associated with PTH not as relevant to early stages of CKD and routine monitoring may result in unnecessary test. 1b. The developer did not provide performance data on this previously endorsed measure as specified for clinician level performance. One member noted that it is not considered an improvement to increase the frequency of measurement of PTH for CKD.</p> <p>1c. Evidence (based on decision logic): Workgroup: <u>No</u></p> <p>Quantity: Workgroup: <u>H-1; M-3; L-5; I-0</u> Quality: Workgroup: <u>H-0; M-2; L-6; I-1</u> Consistency: Workgroup: <u>H-0; M-3; L-5; I-1</u></p> <p>Rationale: Indirect evidence, not about frequency of assessment. The measurement of these elements in patients with CKD stages 3, 4 and 5 has not been studied in a rigorous fashion such that the quality and consistency of the evidence is low. Many studies point to association mostly with phosphorus and CVD outcomes, much less if any such association independently with PTH/calcium. In CKD, need to account for stage but also stability of prior values. Most CKD Stage 3 patients are stable and do not really require this.</p> <p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>No</u> Steering Committee: <u>Y-5; N-17</u></p> <p>2a. Reliability: Workgroup: <u>H-0; M-1; L-5; I-2</u> 2b. Validity: Workgroup: <u>H-0; M-0; L-6; I-2</u></p> <p>Rationale: 2a. For reliability testing, rates were given for two plans for two years, which does not demonstrate reliability, much less for a physician level measure.</p> <p>2b. For validity testing, rates for 5 plans and the literature were provided. This does not address validity of the data elements or measure score for clinicians. Other concerns were expressed about the codes used to define CKD and that errors here could result in misclassification.</p> <p>3. Usability: Workgroup: <u>H-0; M-3; L-5; I-1</u> Steering Committee: <u>H-0; M-8; L-13; I-1</u></p> <p>Rationale: Not publicly reported and no plan provided. May not be usable beyond closed systems.</p> <p>4. Feasibility: Workgroup: <u>H-1; M-1; L-5; I-2</u> Steering Committee: <u>H-0; M-12; L-10; I-0</u></p> <p>Rationale: CKD patients get care in various settings so labs may be available in some records but not others; a big issue for non-closed health plans. With patients spread out in multiple health care systems, it is difficult to believe this will be widely feasible (beyond the VA or Kaiser Permanente) in the next 3 years.</p> <p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: Workgroup: <u>Y-0; N-8</u></p> <p>Rationale: Measuring PTH in millions of patients with CKD stage III is unlikely to have any significant outcome benefit. Measure does not improve quality of care for patients with CKD and may negatively impact patients with unnecessary blood draws. The workgroup was positive about trying to develop measures for earlier stages of CKD and encourages them to continue to explore other, more concrete measures as suggested in the workgroup meeting (SCr and proteinuria).</p>
Steering Committee Recommendation for Endorsement: <u>Y-4; N-18</u>

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0571 CHRONIC KIDNEY DISEASE (CKD): MONITORING PARATHYROID HORMONE (PTH) [Submission](#)

Rationale:

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0574 CHRONIC KIDNEY DISEASE (CKD): MONITORING CALCIUM Submission
<p>Description: To ensure that members with chronic kidney disease (CKD), but who are not on dialysis, are monitored for blood calcium levels at least annually.</p> <p>Numerator Statement: Members who received a calcium level blood test during the measurement year.</p> <p>Denominator Statement: Members with at least 1 inpatient diagnosis of chronic kidney disease during the year prior to the measurement year or members with at least 2 diagnoses of chronic kidney disease in an outpatient setting during the measurement year or year prior (at least 1 of which must be during the year prior to the measurement year).</p> <p>Time Window: The year prior to the measurement year.</p> <p>Exclusions: Members who are on dialysis or in hospice during the measurement year. Members who were hospitalized during the numerator time frame and did not fulfill numerator criteria.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification N/A N/A</p> <p>Level of Analysis: Clinician : Group/Practice, Clinician : Individual, Clinician : Team, Health Plan</p> <p>Type of Measure: Process</p> <p>Data Source: Administrative claims</p> <p>Measure Steward: IMS Health</p>
<p>1. Importance to Measure and Report (based on decision logic): Workgroup: <u>No</u> Steering Committee: <u>Y-8; N-14</u></p> <p>1a. Impact: Workgroup: <u>H-1; M-1; L-7; I-0</u> 1b. Performance Gap: Workgroup: <u>H-1; M-3; L-5; I-0</u></p> <p>Rationale: 1a. Risks associated with serum calcium not as relevant to early stages of CKD. Concern regarding rationale for impact and data provided for performance gap as suboptimal. ** In CKD, need to account for stage but also stability of prior values. ** Rated as Low Impact because ** Impact is low as there is</p> <p>1b. The developer did not provide performance data on this previously endorsed measure as specified for clinician level performance. The studies cited indicate fairly high performance (82% to 97.6%, depending on the patient population).</p> <p>1c. Evidence (based on decision logic): Workgroup: <u>No</u> Quantity: Workgroup: <u>H-0; M-2; L-7; I-0</u> Quality: Workgroup: <u>H-0; M-0; L-9; I-0</u> Consistency: Workgroup: <u>H-0; M-3; L-5; I-0</u></p> <p>Rationale: The evidence is indirect, not about assessment frequency. The measurement of these elements in patients with CKD stages 3, 4 and 5 has not been studied in a rigorous fashion such that the quality and consistency of the evidence is low. Studies point to association mostly with phosphorus and CVD outcomes, much less if any such association independently with PTH/calcium. It is much less convincing for a yearly measurement of calcium in the wide population base of people with CKD stage 3. Another member agreed that it's important to do as part of good medical care, but not necessarily a valuable performance measure. Many if not most CKD Stage 3 patients are stable and do not require this. Also, there is no rationale to measure as a safety monitor.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>No</u> Steering Committee: <u>Y-5; N-17</u></p> <p>2a. Reliability: Workgroup: <u>H-1; M-1; L-4; I-2</u> 2b. Validity: Workgroup: <u>H-0; M-1; L-5; I-2</u></p> <p>Rationale: 2a. For reliability testing, rates were given for two plans for two years, which does not demonstrate reliability, much less for a physician level measure.</p> <p>2b. For validity testing, rates for 6 plans and the literature were provided. This does not address validity of the data elements or measure score for clinicians. The appropriate inpatient and outpatient codes were questioned- whether they appropriately identify individuals with CKD. The developer confirmed that the measure includes CKD stage 3 and above.</p>
<p>3. Usability: Workgroup: <u>H-0; M-5; L-4; I-0</u> Steering Committee: <u>H-2; M-9; L-11; I-0</u></p> <p>Rationale: Not publicly reported and no plan provided. May not be usable beyond closed systems.</p>
<p>4. Feasibility: Workgroup: <u>H-1; M-1; L-6; I-1</u> Steering Committee: <u>H-4; M-9; L-9; I-0</u></p> <p>Rationale: CKD patients get care in various settings so labs may be available in some records but not others; a big issue for non-closed health plans. With patients spread out in multiple health care systems, it is difficult to believe this will be widely feasible (beyond the VA or Kaiser Permanente) in the next 3 years.</p>

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0574 CHRONIC KIDNEY DISEASE (CKD): MONITORING CALCIUM [Submission](#)

Preliminary Assessment of Criteria Met/Suitable for Endorsement: Workgroup: Y-0; N-8

Rationale: Measure does not improve quality of care for patients with CKD. Inadequate evidence that monitoring patients with stages 3, 4 and 5 CKD calcium levels have any relationship to outcomes. Also, no effective testing for validity, reliability done by developer. The workgroup was positive about trying to develop measures for earlier stages of CKD and encourages them to continue to explore other, more concrete measures as suggested in the workgroup meeting (SCr and proteinuria).

Steering Committee Recommendation for Endorsement: Y-4; N-18

Rationale:

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<p>1655 ESRD patients with PTH >400pg/mL and not treated with a calcimimetic or vitamin D analog. Submission</p>
<p>Description: Percentage of end stage renal disease (ESRD) patients aged 18 years and older with serum intact PTH levels >400pg/mL who are NOT treated with a calcimimetic agent or vitamin D analog to lower the PTH during the 3-month reporting period.</p> <p>Numerator Statement: Number of patients from the denominator with serum intact PTH >400pg/mL who are NOT being treated with a calcimimetic agent or vitamin D analog to lower the PTH.</p> <p>Denominator Statement: All hemodialysis and peritoneal dialysis patients aged 18 years and older at the dialysis facility for at least 30 days who have been on dialysis for greater than 90 days and who have not been discharged from the facility prior to the last day of the most recent month of the 3-month reporting period.</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory</p> <p>Measure Steward: Amgen Inc.</p>
<p>1. Importance to Measure and Report (based on decision logic): <u>No</u></p> <p>1a. Impact: <u>H-8; M-12; L-1; I-0</u> 1b. Performance Gap: <u>H-8; M-13; L-0; I-0</u></p> <p>Rationale: While CKDbone disease is a high impact problem, the focus of this measure may not be. Provided some evidence that patients with PTH>400 were not being treated with the two drugs (16% in LDO and 25% in DOPPS). A study by De Boer identified that race is a determinant of secondary hyperparathyroidism.</p> <p>1c. Evidence (based on decision logic): <u>No</u> IF a Health Outcome, rationale supports: <u>NA</u></p> <p>Quantity: <u>H-4; M-11; L-2; I-4</u> Quality: <u>H-1; M-7; L-8; I-5</u> Consistency: <u>H-0; M-9; L-6; I-6</u></p> <p>Rationale: There is some evidence of association between high PTH and poor outcomes but no evidence that altering the level affects outcomes. A systematic review and meta-analysis (Palmer) failed to demonstrate a strong or consistent relationship between high PTH and mortality; however, the submitters questioned the validity of the study. The measure implies that two drugs are the right intervention. There is evidence they will lower PTH but no evidence of improved outcomes. No RCTs to demonstrate that reducing PTH improves outcomes. In response to a question about whether a trial could be done, other Committee members said yes. KDIGO concluded that the guideline did not meet standard for performance measure. The measure also raises the question of whether a lab value from one point in time is valid when you need to check PTH multiple times to get stable value. Questions also were raised about what is appropriate threshold and why this should be considered a safety signal. The developer replied it's a safety issue because it's a progressive disease. The Committee noted that different assays provide different results. The developer said all assays are FDA approved and reliability is greater than discussed. In response to a question about evidence from bone biopsy to confirm bone disease, the developer stated that in a study, PTH above 500-600 had confirmed bone disease about half were treated w/VitD and some with calcimimetic. The submitter identified that the harm of treating high PTH with the specified drugs is adynamic bone disease, which is not the most predominant renal osteodystrophy.</p>
<p>Steering Committee Recommendation for Endorsement: <u>No</u></p> <p>Rationale: The measure did not pass the criterion of Importance to Measure and Report,</p>

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<p>1658 ESRD patients with PTH <130pg/mL and continued treatment with a calcimimetic or vitamin D analog. Submission</p>
<p>Description: Percentage of end stage renal disease (ESRD) patients aged 18 years and older with serum intact PTH levels <130pg/mL who continue to be treated with a calcimimetic agent or vitamin D analog during the 3-month reporting period.</p> <p>Numerator Statement: Number of patients from the denominator with serum intact PTH <130pg/mL who continue to be treated with a calcimimetic agent or vitamin D analog.</p> <p>Denominator Statement: All hemodialysis and peritoneal dialysis patients aged 18 years and older at the dialysis facility for at least 30 days who have been on dialysis for greater than 90 days and who have not been discharged from the facility prior to the last day of the most recent month of the 3-month reporting period.</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory</p> <p>Measure Steward: Amgen Inc.</p>
<p>1. Importance to Measure and Report (based on decision logic): <u>Yes</u></p> <p>1a. Impact: <u>H-1; M-20; L-0; I-0</u> 1b. Performance Gap: <u>H-4; M-15; L-1; I-0</u></p> <p>Rationale: Performance gap indicated many patients with PTH<130 continue to be treated with drugs. In response to a question about reduction vs. stopping, the developer stated these levels are very low so should be off the drugs. Disparity is more in the racial differences in PTH levels rather than testing and treatment</p> <p>1c. Evidence (based on decision logic): <u>Yes</u> IF a Health Outcome, rationale supports: <u>NA</u></p> <p>Quantity: <u>H-11; M-8; L-1; I-1</u> Quality: <u>H-1; M-3; L-14; I-3</u> Consistency: <u>H-2; M-10; L-4; I-0</u></p> <p>Rationale: Studies show association between low PTH and adynamic bone disease. No studies looked at outcomes when calcitriol or cinacalcet was stopped. Is it appropriate to use one value vs. trends? There is very little if any direct evidence related to any specific PTH level. especially given variability of different assays. KDIGO rating to stop vitamin D or calcimimetics is 'low'. Even though concerns about evidence, seen more as a safety monitoring issue when someone with very suppressed PTH is on VitD/calcimimetic.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): <u>No</u></p> <p>2a. Reliability: <u>H-1; M-3; L-16; I-1</u> 2b. Validity: <u>H-0; M-3; L-6; I-12</u></p> <p>Rationale: The submission indicated the data would come from CROWNWeb and developer had initial conversation with CMS about modifying CROWNWeb to capture both VitD and calcimimetics. No reliability testing was performed. The developer stated that it was not necessary because it was electronic data. The Measure Testing guidance indicates that measures based on electronic record data identified and computed using computer programs will be repeatable/reproducible and that if validity testing of data elements is conducted, reliability of data elements does not need to be done. However, the developer did not conduct validity testing of the data elements. Although the developer referred to validity of data elements, it only compared population level estimates between the LDOs and DOPPS data so there is no information about the accuracy of the data elements used in the measure (PTH value, VitD/calcimimetic prescription). Other types of validity are acceptable, but then reliability testing would need to be conducted.</p> <p>Timing is a problem - looking at low PTH and meds in same time period. Could perhaps use low PTH level as index event and then look at prescriptions after that. Because of variability in assays, could consider cutoff of 2x upper limit of normal for that lab assay. Because of need for multiple test to have a stable value, could consider 2 suppressed values. Possible exclusion needed for parathyroidectomy or low VitD3.</p>
<p>Steering Committee Recommendation for Endorsement: <u>No</u></p>
<p>Rationale: The measure did not pass the criterion of Scientific Acceptability of Measure properties.</p>

NATIONAL QUALITY FORUM

0259 Hemodialysis Vascular Access - Decision-making by Surgeon to Maximize Placement of Autogenous Arterial Venous Fistula Submission
<p>Description: Percentage of patients with advanced chronic disease (CKD4 or 5) or end-stage renal disease (ESRD) undergoing open surgical implantation of permanent hemodialysis access who receive an autogenous arteriovenous fistula (AVF).</p> <p>Numerator Statement: CKD4, CKD5 or End-stage renal disease patient requiring hemodialysis vascular access documented by surgeon to have received autogenous AV fistula OR Fistula not Performed for Medical Reasons OR Fistula not Performed for Patient Reasons.</p> <p>Denominator Statement: Patients with CKD4, CKD5 or End-stage renal disease who undergo open surgical placement of permanent hemodialysis access ICD-9 585.3, 585.4, 585.5, 585.6 or 996.73 AND CPT 36818, 36819, 36820, 36821, 36825, or 36830</p> <p>Exclusions: Adjustment/Stratification: No risk adjustment or risk stratification Level of Analysis: Clinician : Group/Practice, Clinician : Individual Type of Measure: Process Data Source: Administrative claims Measure Steward: Society for Vascular Surgery</p>
<p>1. Importance to Measure and Report (based on decision logic): Steering Committee: <u>No</u> 1a. Impact: <u>H-17; M-3; L-1; I-0</u> 1b. Performance Gap: <u>H-0; M-0; L-2; I-18</u></p> <p>Rationale: Without data to review on this measure as specified it is not possible to know if there is a performance gap. The SC agrees there is room for improvement in placing fistulas, but the concern is whether this metric will identify that gap.</p>
<p>If applicable, Conditions/Questions for Developer: What is the performance on this measure <u>as specified</u>?</p> <p>Developer Response: See PQRI (now PQRS) data that addresses the question the committee had about the performance gap for our measure. There is only data for 2009, 2010 is not yet available. We're happy to provide any other additional information the committee needs if requested. 133 physicians participated and had a mean performance rate of 91.18%.</p>
<p>Evaluation after Measure Developer Response</p>
<p>Importance to Measure and Report (based on decision logic): Workgroup: <u>Y-2; N-7</u> Steering Committee: <u>Y-5; N-15</u> 1a. Impact: Workgroup: <u>H-7; M-1; L-1; I-0</u> 1b. Performance Gap: Workgroup: <u>H-2; M-1; L-4; I-2</u></p> <p>Rationale: 1a. Fistula first goal of 66% for ESRD prevalent patients and 50% for incident patients has not been met, high impact and large performance gap in most areas of the country but it isn't relevant to this measure which is a measure of surgical performance on new placement.</p> <p>1b. Performance on this measure as specified is at 91% which indicates there is not a large performance gap (in part because of the way the measure is written which allows a positive score for placing a graft if the surgeon thinks it is a better choice or if the patient refuses a fistula.) Developer said the PQRI data probably shows high performance but because that doesn't include all surgeons, it won't be definitive answer on performance gap.</p> <p>1c. Evidence (based on decision logic): Workgroup: <u>Y-4; N-5</u> Quantity: Workgroup: <u>H-0; M-2; L-4; I-3</u> Quality: Workgroup: <u>H-0; M-3; L-2; I-4</u> Consistency: Workgroup: <u>H-0; M-3; L-1; I-5</u></p> <p>Rationale: No summary of evidence provided – quoted guideline recommendation indicating AV fistule in wrist in first preference. The committee agreed the evidence supports placement of AV fistula, but the measure construction is not consistent with the evidence because it will not provide a clear indication of percentage of AV fistulas placed.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>Y-3; N-6</u> Steering Committee: <u>Y-6; N-14</u> 2a. Reliability: Workgroup: <u>H-1; M-2; L-2; I-4</u> 2b. Validity: Workgroup: <u>H-1; M-0; L-4; I-4</u></p>

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0259 Hemodialysis Vascular Access - Decision-making by Surgeon to Maximize Placement of Autogenous Arterial Venous Fistula Submission
<p>Rationale: Basically no reliability or validity testing was done to support this submission – they provided rates for 3 practices using ICD and CPT codes.</p> <p>If the surgeon excludes patients who aren't candidates for AVF as specified in the measure, then generally the result will be 100% unless the measure focuses on success rate of a functioning fistula (so it won't distinguish performance). Large prospective randomized study (JAMA 2008) shows 60% failure rate - fistulas were in but not usable. The developer thinks the exclusions are necessary to prevent a perverse incentive to place a fistula even if not an appropriate candidate.</p>
<p>3. Usability: Workgroup: <u>H-0; M-3; L-5; I-1</u> Steering Committee: <u>H-1; M-4; L-15; I-0</u> <i>(Meaningful, understandable, and useful to the intended audiences for 3a. Public Reporting and 3b. Quality Improvement)</i></p> <p>Rationale: While the outcome of this measure for an individual surgeon could be used for credentialing and certification, any agency using the metric would need to understand the subjectivity introduced by allowing that surgeon to independently declare any patient for whom a fistula was not constructed to be a non-candidate.</p>
<p>4. Feasibility: Workgroup: <u>H-0; M-2; L-6; I-1</u> Steering Committee: <u>H-0; M-5; L-15; I-0</u> <i>(4a. Clinical data generated during care process; 4b. Electronic data; 4c. Susceptibility to inaccuracies/ unintended consequences identified 4d. Data collection strategy can be implemented)</i></p> <p>Rationale: While the result of the metric can be arrived at through a combination of CPT codes and the surgeon's statement of exclusions, it does not seem feasible to capture the intent of this measure in a way that allows for non-biased comparison of one surgeon to another.</p>
<p>Assessment of Criteria Met/Suitable for Endorsement: Workgroup: <u>Y-1; N-8</u></p> <p>Rationale: Failed on demonstrating a performance gap, body of evidence, reliability, validity and feasibility. Besides the low quantity and the non-specific nature of the evidence presented, the main problem lies in the subjectivity of how the surgeon can exclude cases from the denominator.</p>
<p>Steering Committee Recommendation for Endorsement: <u>Y-2; N-18</u></p> <p>Rationale: The measure failed on Scientific Acceptability of Measure Properties as well as the alignment of the evidence with the measure as specified.</p>

NATIONAL QUALITY FORUM

0262 Vascular Access—Catheter Vascular Access and Evaluation by Vascular Surgeon for Permanent Access [Submission](#)

Description: Percentage of patients aged 18 years and older with a diagnosis of end stage renal disease (ESRD) with a catheter after 90 days on hemodialysis who are seen/evaluated by a vascular surgeon or other surgeon qualified in the area of vascular access for permanent vascular access at least once during the 12-month reporting period.

Numerator Statement: Number of patients from the denominator who are seen/evaluated by a vascular surgeon or other surgeon qualified in the area of vascular access for permanent vascular access at least once during the 12-month reporting period.

Denominator Statement: All patients aged 18 years and older with a diagnosis of ESRD with a catheter after 90 days on hemodialysis.

Exclusions: Patients enrolled in hospice.

Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.

Level of Analysis: Clinician : Individual

Type of Measure: Process

Data Source: Electronic Clinical Data : Electronic Health Record, Paper Records

Measure Steward: Kidney Care Quality Alliance

Steering Committee Recommendation for Endorsement: No

Rationale: The Steering Committee questioned whether this measure was needed any longer because it is a subset of 0251. With 0251 now including functioning AV graft, the “failures” on both measures would be patients with catheters who are not evaluated. Several committee members commented that it would be useful to stratify by new vs. chronic patients. The developer agreed this measure was not needed in addition to 0251 and withdrew it. It specified 0251 to stratify by incident and prevalent patients.

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0324 Patient Education Awareness—Facility Level Submission
<p>Description: Percentage of a physician’s end stage renal disease (ESRD) patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.</p> <p>Numerator Statement: Number of patients from the denominator with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.</p> <p>Denominator Statement: All ESRD patients aged 18 years and older.</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.</p> <p>Level of Analysis: Facility</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data : Electronic Health Record, Paper Records</p> <p>Measure Steward: Kidney Care Quality Alliance</p>
<p>The Steering Committee discussed 0324 and 0320 together. They have the same specifications except the level of analysis (0324-facility; 0320-clinicain). If measures were recommended they could be combined into one measure with two levels of analysis.</p>
<p>1. Importance to Measure and Report (based on decision logic): Steering Committee 1st Vote: <u>Yes</u> (based on exception to evidence)</p> <p>1a. Impact: <u>H-11; M-9; L-1; I-0</u> 1b. Performance Gap: <u>H-4; M-10; L-1; I-6</u></p> <p>1. Importance to Measure and Report (based on decision logic): Workgroup: <u>No</u> Steering Committee: <u>Y-18; N-4</u></p> <p>1a. Impact: Workgroup:<u>H-2; M-4; L-1; I-0</u> 1b. Performance Gap: Workgroup:<u>H-2; M-3; L-1; I-1</u></p> <p><u>Rationale:</u> Although there are tremendous educational deficiencies among CKD and ESRD patients, it is not clear that this measure can address them. Data on impact is about pre-dialysis vs. this measure focused on dialysis patients. It was noted that it is good to repeat the education even after begin dialysis because patients forget or may be too overwhelmed when first given information. Limited data on performance from testing indicates no patients received teaching on ALL modalities. Does the performance gap indicate lack of documentation vs. lack of education. In response to a question, the developer clarified that education must be given every year and documented. Assessment of performance gap was before patient education on modalities became a condition of coverage. Big leap from giving information to understanding and effective decisionmaking.</p> <p>1c. Evidence (based on decision logic): Steering Committee 1st Vote: <u>No</u> Exception to evidence: <u>Y-18; N-3</u> Quantity: <u>H-; M-2; L-6; I-13</u> Quality: <u>H-1; M-3; L-4; I-13</u> Consistency: <u>H-; M-1; L-4; I-16</u></p> <p>1c. Evidence (based on decision logic): Workgroup: <u>No</u> Quantity: Workgroup: <u>H-0; M-1; L-6; I-0</u> Quality: Workgroup: <u>H-0; M-1; L-6; I-0</u> Consistency: Workgroup: <u>H-0; M-1; L-4; I-2</u></p> <p><u>Rationale:</u> Although the Committee agreed there is evidence of effectiveness of various teaching interventions, it is not specific to the focus of these measures – documentation of a discussion with patients currently on dialysis of all renal replacement modalities. Some of the evidence referred to by the developer was obtained in pre-dialysis CKD patients and not in the ESRD population. The Right Start and Impact programs occur in first 90 days on dialysis so they are applicable to the population in this measure. The RightStart program involves multiple levels of intervention with education only one of several components. Thus, positive outcomes associated with the RightStart program cannot be attributed purely to the educational component. The developer also noted a new study on patient education on modality options (June 2011 AM J Kidney Disease). The Steering Committee decided to consider the measure further as an exception to evidence criterion.</p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>No</u> Steering Committee: <u>Y-10; N-12</u></p> <p>2a. Reliability: Steering Committee 1st Vote: <u>H-0; M-11; L-8; I-2</u></p> <p>2a. Reliability: Workgroup: <u>H-0; M-2; L-3; I-3</u> 2b. Validity: Workgroup: <u>H-0; M-1; L-4; I-2</u></p> <p><u>Rationale:</u> 2a. Although the developer specified that the data will be obtained through CROWNWeb, CROWNWeb currently does not include fields for patient education. Therefore, currently it is a medical record measure (as tested).The developer stated that has had a</p>

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<p>conversation with CMS who expressed interest in including in CROWNWeb. Reliability testing was conducted in facilities - interabstractor reliability of data between facility abstractor and study abstractor. The kappa for the measure score was reported as (-0.0026). The developer explained that more errors were missed information resulting in under-reporting. The kappa for the same measure in physician office testing with interabstractor reliability between two study abstractors was high (0.8474) indicating that the measure can be reliable and that the conditions of coverage will increase attention to documentation. Measure requires checkbox not quality or effectiveness of education. It's good that the measure stipulates that regardless of whether the facility offers the various modalities.</p> <p>2b. The measure submission relies on face validity and the committee noted various issues that affect validity as a quality indicator. The committee discussed that the limiting issue is that this measure is essentially just checking off that the required education on modalities was provided; it does not address the content or quality of the education or patient comprehension. So, will it facilitate improvement or demonstrate quality? Caregiver and patient perceptions of what was taught and what education was received differ so it would be preferable to measure the patient's understanding or the patient's perception of whether received information. Another committee member stated that neither of those types of measures is available and may be an impossible bar. The In-Center Dialysis CAHPS measures do include a composite titled Providing Information to Patients (web page). The questions include some modalities (Q36, Q38, Q39, Q40), but not home hemodialysis, or no treatment). The CAHPS measures were endorsed in 2007 and will be reviewed in 2012 in a project on patient experience with care.</p> <p>Some reservations were expressed because the measure cannot distinguish between the physician and facility roles that contribute to a patient's education. However, from a patient perspective, it's better not to parse that out because the issue is whether the patient received the appropriate education, regardless of who provides it.</p> <p>One committee member questioned why no more evidence of validity for a previously endorsed measure (e.g., whether adherence to the measure in ESRD patients is connected to improvement in quality such as increased fistulas, home dialysis, or transplants). The original endorsement was time-limited because the measure was not tested at that time and original testing was reviewed by NQF about a year ago – no new testing or implementation data since that time.</p> <p>Some committee members thought this measure was better than nothing and that not endorsing the measure might indicate it was not an important area for improvement. Other committee members disagreed because even though the topic was important, a measure still needs to meet criteria and that endorsing a measure that did not meet criteria would be more problematic. It could impede development of a better measure.</p>
<p>3. Usability: Workgroup: H-2; M-3; L-2; I-0 Steering Committee: H-3; M-9; L-7; I-3</p> <p><u>Rationale:</u> The committee discussed that education on all modalities is addressed in the regulations and surveyor guidance and questioned the usefulness of a performance measure. The developer commented that surveys are only required every 3 years, and some states are very far behind. A committee member reported that some facilities have not been surveyed for 10 years. It also is unclear if surveyors review all patients or just a sample; and performance measures could be used to inform the survey process. Additionally, survey data often not publicly available so a performance measure could be useful if reported.</p>
<p>4. Feasibility: Workgroup: H-2; M-2; L-2; I-1 Steering Committee: H-1; M-15; L-5; I-1</p> <p><u>Rationale:</u> Currently, there is no data field in CROWNWeb to capture the patient education information. So if endorsed, it would be as a medical record abstraction measure. However, unless facilities have electronic records, much of the data for CROWNWeb require abstraction from the medical record. As a "checkbox" measure, easy and feasible.</p>
<p>Assessment of Criteria Met/Suitable for Endorsement: Workgroup: Y-3; N-4</p> <p><u>Rationale:</u> Topic is important, but there were issues with evidence and validity and a question if needed when the conditions of coverage already require modality education.</p>
<p>Steering Committee Recommendation for Endorsement: Y-10; N-12</p> <p><u>Rationale:</u> The Steering Committee emphasized the importance of the topic area, but did not think the measure met NQF criteria for endorsement. Even with an exception for evidence, it failed to meet the criteria for Scientific Acceptability of Measure Properties. Because education on modalities is mandated in Conditions for Coverage, a "checkbox" measure may not add substantially to improved care.</p>
<p>Member and Public Comment: Comments included:</p>

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- agreement measure should not be recommended; and
- request for reconsideration.

The Steering Committee discussed again. Although there is great interest in measures of patient education, this measure does not meet NQF criteria. The Committee strongly recommended the development of patient education measures that are measured from the patient perspective. The Steering Committee emphasized the role of patient education in facilitating informed choice regarding modality of renal replacement therapy, as well as understanding of self-management to achieve maximum benefit from dialysis. The committee suggested that measure developers partner with patient advocates to develop patient education measures that go beyond checking whether information was given and meeting regulatory requirements. The Steering Committee noted that education on treatment modalities is most effective prior to beginning dialysis as implemented in the studies.

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<p>0320 Patient Education Awareness—Physician Level Submission</p> <p>Description: Percentage of end stage renal disease (ESRD) patients aged 18 years and older with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.</p> <p>Numerator Statement: Number of patients from the denominator with medical record documentation of a discussion of renal replacement therapy modalities (including hemodialysis, peritoneal dialysis, home hemodialysis, transplants and identification of potential living donors, and no/cessation of renal replacement therapy) at least once during the 12-month reporting period.</p> <p>Denominator Statement: All ESRD patients aged 18 years and older receiving renal replacement therapy.</p> <p>Exclusions: None.</p> <p>Adjustment/Stratification: No risk adjustment or risk stratification Not applicable. Not applicable.</p> <p>Level of Analysis: Clinician : Individual</p> <p>Type of Measure: Process</p> <p>Data Source: Electronic Clinical Data : Electronic Health Record, Paper Records</p> <p>Measure Steward: Kidney Care Quality Alliance</p>
<p>The workgroup thought all their comments on 0324 apply to this measure because it's essentially the same except for being applied to the individual clinician (please see 0324 on the previous page).</p> <p>The only additional discussion was a question of the need for a physician-level measure because Medicare has placed responsibility on the facility. The developer responded that it sees patient education as a primary responsibility of the physician. The committee agreed that physicians have responsibility, but questioned the use of this measure.</p>
<p>1. Importance to Measure and Report (based on decision logic): Workgroup: <u>Yes</u> Steering Committee: <u>Y-15; N-7</u></p> <p>1a. Impact: Workgroup: <u>H-2; M-4; L-1; I-0</u> 1b. Performance Gap: Workgroup: <u>H-1; M-4; L-0; I-2</u></p> <p>1c. Evidence (based on decision logic): Workgroup: <u>No</u></p> <p>Quantity: Workgroup: <u>H-0; M-2; L-5; I-0</u> Quality: Workgroup: <u>H-0; M-1; L-6; I-0</u> Consistency: Workgroup: <u>H-0; M-1; L-4; I-2</u></p>
<p>2. Scientific Acceptability of Measure Properties (based on decision logic): Workgroup: <u>No</u> Steering Committee: <u>Y-7; N-15</u></p> <p>2a. Reliability: Workgroup: <u>H-0; M-2; L-3; I-2</u> 2b. Validity: Workgroup: <u>H-0; M-1; L-4; I-2</u></p>
<p>3. Usability: Workgroup: <u>H-1; M-1; L-3; I-2</u> Steering Committee: <u>H-2; M-9; L-9; I-2</u></p>
<p>4. Feasibility: Workgroup: <u>H-2; M-0; L-2; I-3</u> Steering Committee: <u>H-1; M-12; L-9; I-0</u></p>
<p>Preliminary Assessment of Criteria Met/Suitable for Endorsement: <u>Y-0; N-7</u></p>
<p>Steering Committee Recommendation for Endorsement: <u>Y-5; N-17</u></p> <p>Rationale: The Steering Committee emphasized the importance of the topic area, but did not think the measure met NQF criteria for endorsement. Even with an exception for evidence, it failed to meet the criteria for Scientific Acceptability of Measure Properties.</p>

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0369 Dialysis Facility Risk-adjusted Standardized Mortality Ratio	
Steward	Centers for Medicare & Medicaid Services
Description	Risk-adjusted standardized mortality ratio for dialysis facility patients.
Type	Outcome
Data Source	Administrative claims Data for the SMR is derived from Program Medical Management and Information System (PMMIS/REMIS), Medicare claims, the Standard Information Management System (SIMS) database maintained by the 18 ESRD Networks, the CMS Annual Facility Survey (CMS Form 2744), the CMS Medical Evidence Form (CMS Form 2728), the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. URL http://www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS018912 URL http://www.cms.gov/Manuals/IOM/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=1&sortOrder=ascending&itemID=CMS018912&intNumPerPage=10
Level	Facility
Setting	Dialysis Facility
Numerator Statement	Number of deaths among eligible patients at the facility during the 4-year time period.
Numerator Details	Time Window: Four years. Information on death is obtained from several sources which include the CMS ESRD Program Medical Management Information System, the Death Notification Form (CMS Form 2746), and the Social Security Death Master File. The number of deaths that occurred among eligible dialysis patients during the four year period is calculated. This count does not include deaths from street drugs or accidents unrelated to treatment: Deaths from these causes varied by facility, with certain facilities (in particular, urban facilities that treated large numbers of male and young patients) reporting large numbers of deaths from these causes and others reporting extremely low numbers (Turenne, 1996). Since these deaths are unlikely to have been due to treatment facility characteristics, they are excluded them from the calculations.
Denominator Statement	Target Population: All dialysis patients that have had ESRD for at least 90 days Number of deaths that would be expected among eligible dialysis patients at the facility during the 4-year time period, given the mortality rate is at the national average and the patient mix at the facility.
Denominator Details	Time Window: Four years. Denominator Data Collection: For each patient, the dialysis provider was identified using a combination of the Medicare paid dialysis claims, the Medical Evidence Form, and data from the Standard Information Management System (SIMS) maintained by the ESRD Networks. Treatment facility histories were determined for each patient starting at day 91 of ESRD. Patients are assigned to a facility only once they have been treated there for 60 days. Similarly, patients remain assigned to a facility for 60 days after transfer out of the facility. The continued tabulation of the time at risk for 60 days after transfer out of the facility ensures that the sequelae of treatment at a facility are attributed to that facility, even if the patient is transferred to another facility, such as a hospital-based facility, after the patient's condition worsens. In particular, patients are placed in their initial facility on day 91 of ESRD if they have been treated for at least 60 days at the facility. If on day 91, the patient has been treated at the facility for less than 60 days, the patient is not placed in any facility until they reach day 60 of treatment at a facility. Paid dialysis claims and SIMS data are used to determine that a patient has transferred to another facility. Patient outcomes are attributed to the original facility for 60 days after transfer out. On day 61 after transfer out of a facility, the patient will be placed in the new facility if they have been treated there for 60 days. If the patient has not been treated for 60 days at the new facility (for instance, if there were 2 switches within 60 days of each other), the patient is not placed in any facility until they reach day 60 of treatment at a facility. Patients who receive a transplant are removed from the facility on the day of transplant. Patients who withdraw from dialysis or recover renal function remain assigned to the facility of treatment for 60 days after withdrawal or recovery. Patients are considered lost to follow-up and are removed from the analyses for a facility 1 year after the last evidence of dialysis treatment. In other words, if there is a 1 year period where there are no paid dialysis claims and no SIMS information indicating that a patient is receiving dialysis treatment, the patient is considered lost to follow-up and is not used in the analysis unless dialysis claims or other evidence of dialysis reappears. Time at Risk For all patients, time at risk began at the start of the facility treatment period (as described above) and continued until the earliest occurrence of the following: transplant; date of death; end of facility treatment period; or December 31 of the year. A

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0369 Dialysis Facility Risk-adjusted Standardized Mortality Ratio	
	<p>patient may have been treated at one facility for multiple periods during the same year; patient years at risk include time at risk for all periods of treatment at a facility.</p> <p>Expected Deaths The number of expected deaths for each patient is calculated as $-\ln(S_i(t_i))$, where $S_i(t)$ was the survival curve from a Cox model adjusted to the characteristics of patient i, and t_i was the amount of follow-up time (patient years at risk) for that patient during the year (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994). The Cox model is adjusted for age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, nursing home status, duration of ESRD, BMI at incidence, and comorbidities at incidence. In cases where the comorbidities and BMI were missing for a patient, we used the average values of the group of patients with similar characteristics (age, race sex, diabetes). We also control for age-adjusted population death rates by state and race, based on the U.S. population in 2001-2003 (National Center for Health Statistics, 2005). The number of expected deaths for the facility during the 4-year time period is the total expected for all eligible patients at the facility.</p>
Exclusions	N/A
Exclusion Details	N/A
Risk Adjustment	<p>Statistical risk model Cox Model (Proportional Hazards Regression Model): The SMR calculation adjusts for patient age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, nursing home status, duration of ESRD, BMI at incidence, and comorbidities at incidence, as well as state population death rates by comparing actual to expected deaths at the facility (indirect method of standardization). The number of expected deaths for patients at the facility is based on a Cox model accounting for these patient characteristics.</p> <p>The Standardized Mortality Ratio measure appears in the Dialysis Facility Report. Sections III and IV of the Guide to the Dialysis Facility Reports (1) and the document Technical Notes (2) on the Standardized Mortality Ratio contain information about the calculation of the SMR (including the risk adjustment methodology). These are available at the Dialysis Facility Reports website: http://www.dialysisreports.org/Methodology.aspx URL http://www.dialysisreports.org/Methodology.aspx</p>
Stratification	N/A
Type Score	Ratio better quality = lower score
Algorithm	<p>Time at Risk For all patients, time at risk began at the start of the facility treatment period and continued until the earliest occurrence of the following: transplant; date of death; end of facility treatment period; or December 31 of the year. A patient may have been treated at one facility for multiple periods during the same year; patient years at risk include time at risk for all periods of treatment at a facility. Deaths Information on death is obtained from several sources which include the CMS ESRD Program Medical Management Information System, the Death Notification Form (CMS Form 2746), and the Social Security Death Master File.</p> <p>Deaths The number of deaths that occurred among eligible dialysis patients during the four year period is calculated. This count does not include deaths from street drugs or accidents unrelated to treatment. Since these deaths are unlikely to have been due to treatment facility characteristics, they are excluded them from the calculation.</p> <p>Expected Deaths The number of expected deaths for each patient is calculated as $-\ln(S_i(t_i))$, where $S_i(t)$ was the survival curve from a Cox model adjusted to the characteristics of patient i, and t_i was the amount of follow-up time (patient years at risk) for that patient during the year (SAS Institute Inc., 2000; Andersen, 1993; Collett, 1994). The Cox model is adjusted for age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, nursing home status, duration of ESRD, BMI at incidence, and comorbidities at incidence (as included on table 7 of DFR). In cases where the comorbidities and BMI were missing for a patient, we used the average values of the group of patients with similar characteristics (age, race sex, diabetes). We also control for age-adjusted population death rates by state and race, based on the most current and relevant U.S. population (National Center for Health Statistics). The number of expected deaths for the facility during the 4-year time period is the total expected for all eligible patients at the facility.</p> <p>The SMR calculation adjusts for patient age, sex, race, Hispanic ethnicity, diabetes as a cause of ESRD, nursing home status, duration of ESRD, BMI at incidence, and comorbidities at incidence, as well as state population death rates by comparing actual to expected deaths at the facility (indirect method of standardization). The number of expected deaths for patients at the facility is based on a Cox model accounting for these patient characteristics.</p> <p>The SMR for a facility is the ratio of the total number of observed to the total number of expected deaths during the four year</p>

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	0369 Dialysis Facility Risk-adjusted Standardized Mortality Ratio
	period at the facility. URL http://www.dialysisreports.org/Methodology.aspx
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	1666 Patients on Erythropoiesis Stimulating Agent (ESA)--Hemoglobin Level > 12.0 g/dL
Steward	American Medical Association - Physician Consortium for Performance Improvement
Description	Percentage of calendar months within a 12-month period during which a Hemoglobin is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy and have a Hemoglobin Level > 12.0 g/dL
Type	Outcome
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records N/A Attachment AMA-PCPI_AKID-7_ESA Therapy Hgb greater than 12.0.pdf
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office, Dialysis Facility, Home Health, Other, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility
Numerator Statement	Calendar months during which patients have a Hemoglobin level > 12.0 g/dL* *The hemoglobin values used for this measure should be a most recent (last) hemoglobin value recorded for each calendar month
Numerator Details	Time Window: Once during the measurement period. See attached for EHR specifications. For Claims/Administrative: Report CPT Category II 3XXXf: Hemoglobin level > 12.0 g/dL
Denominator Statement	All calendar months during which a Hemoglobin is measured for patients aged 18 years and older with a diagnosis of advanced CKD (stage 4 or 5, not receiving RRT) or ESRD (who are on hemodialysis or peritoneal dialysis) who are also receiving ESA therapy Definitions: RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation
Denominator Details	Time Window: 12 Consecutive months See attached for EHR specifications. For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT) AND CPT® Category II Code: 4171F - Patient receiving erythropoiesis-stimulating agent (ESA) therapy OR HCPCS codes to identify erythropoietin therapy: J0881, J0885
Exclusions	None.
Exclusion Details	N/A
Risk Adjustment	No risk adjustment or risk stratification This measure is not risk adjusted.
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = lower score
Algorithm	Calculation algorithm is included in data dictionary/code table attachment (2a1.30).
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	1667 (Pediatric) ESRD Patients Receiving Dialysis: Hemoglobin Level < 10g/dL
Steward	American Medical Association - Physician Consortium for Performance Improvement
Description	Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of ESRD receiving hemodialysis or peritoneal dialysis have a Hemoglobin level <10 g/dL
Type	Outcome
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records N/A Attachment AMA-PCPI_PKID-3_Hgblessthan10.pdf
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office, Dialysis Facility, Home Health, Other, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility Domiciliary, Rest Home, or Custodial Care Services
Numerator Statement	Calendar months during which patients have a Hemoglobin level <10 g/dL* *The hemoglobin values used for this measure should be the most recent (last) hemoglobin value recorded for each calendar month
Numerator Details	Time Window: Once during the measurement period. See attached for EHR specifications. For Claims/Administrative: Report CPT Category II 3XXXf: Hemoglobin level < 10g/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
Denominator Details	Time Window: 12 consecutive months See attached for EHR specifications. For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT)
Exclusions	Documentation of medical reason(s) for patient having a Hemoglobin level <10g/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)
Exclusion Details	Append modifier to CPT II code 3XXXf-1P
Risk Adjustment	Other We account for risk adjustment by inclusion of the exceptions for this measure. Exceptions for this measure are listed above, in section 2a1.8.
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = lower score
Algorithm	Calculation algorithm is included in data dictionary/code table attachment (2a1.30).
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1668 Laboratory Testing (Lipid Profile)	
Steward	American Medical Association
Description	Percentage of patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) who had a fasting lipid profile performed at least once within a 12-month period
Type	Process
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Registry, Paper Records N/A Attachment AMA-PCPI_AKID-3_LipidProfile.pdf
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office, Dialysis Facility, Home Health, Laboratory, Other, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility Domicillary, Rest Home or Custodial Care Services
Numerator Statement	Patients who had a fasting lipid profile performed at least once within a 12-month period
Numerator Details	Time Window: Once during the measurement period See attached for EHR specifications. For Claims/Administrative: Report CPT II code 4XXXXF: Fasting Lipid Profile performed, results documented
Denominator Statement	All patients aged 18 years and older with a diagnosis of CKD (stage 3, stage 4 or 5, not receiving RRT) Defintion: RRT (Renal Replacement Therapy)-For the purposes of this measure, RRT includes hemodialysis, peritoneal dialysis, and kidney transplantation
Denominator Details	Time Window: 12 consecutive months See attached for EHR specifications. For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT)
Exclusions	Documentation of patient reason(s) for not performing a fasting lipid profile (eg, patient declined, other patient reasons)
Exclusion Details	Append modifier to CPT II code 4XXXXF- 2p
Risk Adjustment	No risk adjustment or risk stratification As a process measure, no risk adjustment is necessary.
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score
Algorithm	Calculation algorithm is included in data dictionary/code table attachment (2a1.30).
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	0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose
Steward	Centers for Medicare & Medicaid Services
Description	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 $\text{spKt/V} \geq 1.2$ during the study period.
Type	Outcome
Data Source	Electronic Clinical Data CROWNWeb URL http://www.projectcrownweb.org URL http://projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility
Setting	Dialysis Facility
Numerator Statement	Number of patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a $\text{spKt/V} \geq 1.2$.
Numerator Details	Time Window: The entire calendar month. The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2.
Denominator Statement	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.
Denominator Details	Time Window: The entire calendar month. The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients ≥ 18 years old who have been on dialysis for 90 days or longer and "Sessions per Week" is equal to 3. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "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 AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.
Exclusions	Patients on HD less than 90 days; HD patients dialyzing < 3 times per week or > 3 times per week.
Exclusion Details	Exclusions to this measure include patients who are not receiving dialysis thrice weekly ("Sessions per Week" not equal to 3) and have not been on dialysis at least 90 days. The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began".
Risk Adjustment	No risk adjustment or risk stratification Not applicable.
Stratification	No stratification for this measure.
Type Score	Rate/proportion better quality = higher score
Algorithm	The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients ≥ 18 years old who have been on dialysis for 90 days or longer and "Sessions per Week" is equal to 3. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "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 AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2. Attachment Appendix C CPM Calculation Flow charts_a 5.pdf
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	0323 Hemodialysis Adequacy: Solute
Steward	American Medical Association - Physician Consortium for Performance Improvement
Description	Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis three times a week for ≥ 90 days have a $spKt/V > \text{ or } = 1.2$
Type	Outcome
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records N/A Attachment AMA-PCPI_AKID-10_HDAdequacy_11.8.2011.pdf
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office, Dialysis Facility, Home Health, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility
Numerator Statement	Calendar months during which patients have a $spKt/V > \text{ or } = 1.2$ Note: Urea kinetic modeling (UKM) or the second generation Daugirdas formula (simplified multivariable equation) are the most appropriate ways to calculate $spKt/V$, and the two accepted methods for calculating $spKt/V$ per the KDOQI guidelines. For more information on these methods, please refer to National Kidney Foundation's KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. Am J Kidney Dis 48:S1-S322, 2006 (suppl 1).
Numerator Details	Time Window: Each calendar month within measurement period See attached for EHR specifications. For Claims/Administrative: Report CPT II code 3XXXF: $spKt/V$ greater than or equal to 1.2 (single-pool clearance of urea [Kt]/volume[V])
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.
Denominator Details	Time Window: 12 consecutive calendar months See attached for EHR specifications. For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT)
Exclusions	None
Exclusion Details	Not applicable
Risk Adjustment	Other We would account for risk adjustment by inclusion of exceptions for this measure. However, this measure has no exceptions.
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score
Algorithm	Calculation algorithm is included in data dictionary/code table attachment (2a1.30).
Copyright	Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) convened Physician Consortium for Performance Improvement® (PCPI™).

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	0318 Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum
Steward	Centers for Medicare & Medicaid Services
Description	Percentage of all adult (≥ 18 years old) peritoneal dialysis patients whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of at least 1.7 (dalytic + residual) during the four month study period.
Type	Outcome
Data Source	Electronic Clinical Data, Electronic Clinical Data : Laboratory CROWNWeb. URL http://www.projectcrownweb.org URL http://projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility
Setting	Dialysis Facility
Numerator Statement	Patients are included in the numerator if delivered peritoneal dialysis was a weekly Kt/Vurea of at least 1.7 (dalytic + residual) during the four month study period.
Numerator Details	Time Window: A four month time period. The numerator will be determined by counting the patients in the denominator who had a delivered peritoneal dialysis weekly Kt/Vurea of at least 1.7 (dalytic + residual) during the four month study period. Specifically, the algorithm first counts the number of non-missing values for the "Weekly Kt/V value: Peritoneal Dialysis, reporting month" (pd_weekly_ktv) variable. If the number of non-missing values is ≥ 1 and the patient is counted in the denominator, then the patient is counted in the numerator if the most recent month with data meets these conditions: (1) "Kt/V method" either "Watson" OR "Hume" AND (2) "BSA method" either "Dubois & Dubois" OR "Gehan & George" OR "Haycock" AND (3) ("Urine Volume" < 100) OR ("Urine Volume" ≥ 100 AND "PD Residual Renal Function" = "Yes") AND (4) "Weekly Kt/V" ≥ 1.7
Denominator Statement	All adult (≥ 18 years old) peritoneal dialysis patients who have been on peritoneal dialysis for at least 90 days.
Denominator Details	Time Window: A four month time period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. Peritoneal dialysis patients are defined as follows: (1) "Admit Date" to the specified facility is prior or equal to the first day of the study period; (2) the patient has not been discharged (i.e., the discharge date is null or blank or the discharge date is greater than or equal to the last day of the study period); (3) the treatment start date is less than or equal to the date of the study period; (4) the type of dialysis treatment = "PD"; (5) the primary dialysis setting is "Home" or "Dialysis Facility/Center"; (6) the "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients ≥ 18 years old who are PD patients assigned to a single facility for a four month period.
Exclusions	None.
Exclusion Details	None.
Risk Adjustment	No risk adjustment or risk stratification None
Stratification	No stratification is required for this measure.
Type Score	Rate/proportion better quality = higher score
Algorithm	This measure is calculated by dividing the number of patients in the numerator by the number of patients in the denominator. Attachment PD_CPM3_Flowchart.pdf
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	0321 Peritoneal Dialysis Adequacy: Solute
Steward	American Medical Association - Physician Consortium for Performance Improvement
Description	Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a total Kt/V > or = 1.7 per week measured once every 4 months
Type	Outcome
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records N/A Attachment AMA-PCPI_AKID-11_PeritonealAdequacy_eSPEC.pdf
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Ambulatory Care : Clinician Office, Dialysis Facility, Home Health, Other, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility Domiciliary, Rest Home, or Custodial Care Services
Numerator Statement	Patients who have a total Kt/V > or = 1.7 per week measured once every 4 months Definition: Total Kt/V includes residual kidney function and equals peritoneal dialysate Kt/V plus renal Kt/V
Numerator Details	Time Window: Three times (at least 4 months apart) during the measurement period. Definition: Total Kt/V includes residual kidney function and equals peritoneal dialysate Kt/V plus renal Kt/V See attached for EHR specifications. For Claims/Administrative: Report CPT Category II 3XXXF: Total Kt/V greater than or equal to 1.7 (total clearance of urea [Kt]/volume [V])
Denominator Statement	All patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis
Denominator Details	Time Window: 12 consecutive months. See attached for EHR specifications. For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT)
Exclusions	None
Exclusion Details	Not applicable
Risk Adjustment	Other No risk adjustment or risk stratification. This measure is not risk adjusted.
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score
Algorithm	Calculation algorithm is included in data dictionary/code table attachment (2a1.30).
Copyright	Physician Performance Measures (Measures) and related data specifications have been developed by the American Medical Association (AMA) convened Physician Consortium for Performance Improvement® (PCPI™). These performance Measures are not clinical guid

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0255 Measurement of Serum Phosphorus Concentration	
Steward	Centers for Medicare & Medicaid Services
Description	Percentage of all adult (≥ 18 years of age) peritoneal dialysis and hemodialysis patients included in the sample for analysis with serum phosphorus measured at least once within month.
Type	Process
Data Source	Electronic Clinical Data CROWNWeb URL www.projectcrownweb.org URL http://projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility
Setting	Dialysis Facility
Numerator Statement	Number of adult (≥ 18 years of age) dialysis patients included in denominator with serum phosphorus measured at least once within month
Numerator Details	Time Window: One month The numerator comprises all eligible patients who, during the 1-month study period, have a non-missing value in for the variable "Serum Phosphorus"
Denominator Statement	All adult peritoneal dialysis and hemodialysis patients included in the sample for analysis.
Denominator Details	Time Window: One month The denominator comprises all patients who, during the 1 month study period, have an "Admit Date" prior or equal to the first day of the month; whose "Discharge Date" is blank or greater than or equal to the last day of the month; whose "Primary Type of Treatment" = 'Hemodialysis,' 'CAPD' or 'CCPD' on the last day of the study period; and whose "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the Study Period
Exclusions	Transient dialysis patients (in unit < 30 days), pediatric patients and kidney transplant recipients with a functioning graft
Exclusion Details	We exclude records with an "Admit Date" later than the first day of the study month or with a "Discharge Date" less than the last day of the study month. We also exclude patients whose age is less than 18 years. For all CROWNWeb-collected measures, we make a global exclusion for patients not on either HD or PD, which includes kidney transplant recipients with a functioning graft.
Risk Adjustment	No risk adjustment or risk stratification N/A
Stratification	N/A
Type Score	Rate/proportion better quality = higher score
Algorithm	<ol style="list-style-type: none"> 1. Using CROWNWeb-reported data (data stored as SAS files), identify the number of adult HD and PD patients under the care of a facility. 2. From this group, remove patients who were not in the facility for the entirety of the month (i.e., transient patients). 3. To form the denominator, remove from this group any kidney transplant recipients with a functioning graft. 4. To form the numerator, remove all denominator-eligible patients who do not have a serum phosphorus (variable name, "phosphorus") measurement for the study month. 5. Calculate the facility's rate of serum phosphorus measurement by dividing the number calculated in Step 3 (the denominator) by the number calculated in Step 4 (the numerator). Attachment Phos_Calculation_Flowchart.pdf
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0251 Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	
Steward	Kidney Care Quality Alliance
Description	<p>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:</p> <p>(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);</p> <p>(2) have a functional AV graft (computed and reported separately); or</p> <p>(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).</p> <p>Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.</p> <p>The total numerator and each of the numerator subgroups (the outcomes subgroups and the process subgroup) will be reported separately.</p>
Type	Outcome
Data Source	Electronic Clinical Data : Electronic Health Record, Paper Records All data elements for the measure can be collected using the KCQA Vascular Access Data Collection Form (attached), which reflect the data elements to be included in CROWNWeb. Attachment fmKCQADataFormVascAccess11-07-11NQFrecs.pdf Attachment txKCQADataDictionaryAVF11-07-11NQFrecs.pdf
Level	Clinician : Individual
Setting	Ambulatory Care : Clinician Office, Dialysis Facility
Numerator Statement	<p>Number of patients from the denominator who:</p> <p>(1) have a functional autogenous AVF (defined as two needles used or a single-needle device) (computed and reported separately); or</p> <p>(2) have a functional AV graft (computed and reported separately); or</p> <p>(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 (defined as two needles used or a single needle device) or AV graft at least once during the 12-month reporting period (computed and reported separately).</p> <p>The total numerator and each of the numerator subgroups (the outcomes subgroups and the process subgroup) will be reported separately.</p> <p>Reporting should be stratified by incident versus prevalent patients, as defined by USRDS.</p>
Numerator Details	<p>Time Window: 12-month reporting period.</p> <p>The necessary data elements are to be collected via the Centers for Medicare and Medicaid (CMS) CROWNWeb data repository when functional, as indicated by the measure's inclusion in CMS's list of Phase III ESRD Clinical Performance Measures in effect April 1, 2008.</p> <p>1. Access type (select one):</p> <ul style="list-style-type: none"> • AVF with 2 needles used or single needle device --> END. • AV graft with 2 needles used --> END. • AVF with AV graft --> END. • AVF with catheter --> GO TO 2. • AV graft with catheter --> GO TO 2. • Catheter --> GO TO 2. • Other/unknown --> GO TO 2. <p>2. Vascular access referral status (select one):</p> <ul style="list-style-type: none"> • Patient referred to a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period --> GO TO 3. • Patient NOT referred to a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period --> END. <p>3. Vascular access evaluation status (select one):</p>

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	<ul style="list-style-type: none"> • Patient 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 an AVF or AV graft during the 12-month reporting period -> GO TO 4. • Patient NOT 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 an AVF or AV graft during the 12-month reporting period -> END. <p>4. Type of documentation of the surgical evaluation in facility's medical records/CROWNWeb (select one):</p> <ul style="list-style-type: none"> • No documentation --> END. • A note or letter prepared by the primary nephrologist --> GO TO 5. • A note or letter prepared by the vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access --> GO TO 5. • A note prepared by facility personnel --> GO TO 5. <p>5. Date of the surgical evaluation: (MM/YYYY) --> GO TO 6.</p> <p>6. If permanent access was not placed, the reason for this decision --> END.</p>
Denominator Statement	<p>All ESRD patients aged 18 years and older receiving hemodialysis during the 12-month reporting period and on dialysis for greater than 90 days.</p> <p>This measure includes both in-center and home hemodialysis patients.</p>
Denominator Details	<p>Time Window: 12-month reporting period.</p> <p>The necessary data elements are to be collected via the CMS CROWNWeb data repository when functional, as indicated by the measure's inclusion in CMS's list of Phase III ESRD Clinical Performance Measures in effect April 1, 2008.</p> <p>The denominator population consists of all ESRD patients receiving hemodialysis for a given nephrologist. Data elements required to identify the denominator population:</p> <ul style="list-style-type: none"> • Patient diagnosis = ESRD AND • Patient primary type of dialysis = hemodialysis AND • Patient's date of birth AND • Date regular chronic dialysis began AND • Nephrologist's name
Exclusions	Patients enrolled in hospice.
Exclusion Details	Identify all patients in the denominator enrolled in hospice.
Risk Adjustment	<p>No risk adjustment or risk stratification</p> <p>Not applicable.</p>
Stratification	Not applicable.
Type Score	Rate/proportion better quality = higher score
Algorithm	<p>DENOMINATOR</p> <p>Include in the denominator all patients for a given nephrologist who meet the following criteria in the most recent month of the 12-month study period and who are not enrolled in hospice:</p> <ol style="list-style-type: none"> 1. Diagnosis = ESRD AND 2. Primary type of dialysis = hemodialysis or home hemodialysis AND 3. Age = >18 years or older as of the first day of the most recent month of the reporting period. (Patient's age is or shall be determined by subtracting the patient's date of birth from the first day of the most recent month of the reporting period.) AND 4. Time on dialysis = >90 days as of the first day of the most recent month of the reporting period. (Patient's time on dialysis is or shall be determined by subtracting the patient's Date Regular Chronic Dialysis Began from the first day of the most recent month of the reporting period. Patients on dialysis <90 days are excluded so that emergent patients and patients requiring only transient dialysis are not encompassed, as permanent access would not be appropriate in these populations.)

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0251 Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement	
	<p>NUMERATOR</p> <p>Include in the numerator all patients from the denominator who meet the following criteria:</p> <p>1. Access Type = Functional autogenous AVF (defined as 2 needles used or single-needle device)</p> <p>OR</p> <p>2. Access type = Functional AV graft</p> <p>OR</p> <p>3. Access type = AVF combined with AV graft</p> <p>OR</p> <p>4. Access type (select one):</p> <ul style="list-style-type: none"> • AVF with a catheter • AV graft with a catheter • Catheter • Other/unknown <p>AND</p> <p>2. Patient referred to a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period</p> <p>AND</p> <p>3. Patient 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 an AVF or AV graft during the 12-month reporting period</p> <p>AND</p> <p>4. Facility medical records contain the following types of documentation of the surgical evaluation:</p> <ul style="list-style-type: none"> • A note or letter prepared by the primary nephrologist OR • A note or letter prepared by the vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access OR • A note prepared by facility personnel <p>AND</p> <ul style="list-style-type: none"> • Date of the surgical evaluation: (MM/YYYY) <p>AND</p> <ul style="list-style-type: none"> • If permanent access was not placed, the reason for this decision Attachment txKCOACalcAlgorithmAVF11-07-11NQFrecs.pdf
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	0256 Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access
Steward	Centers for Medicare & Medicaid Services
Description	Percentage of patients on maintenance hemodialysis during the last HD treatment of study period with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.
Type	Process
Data Source	Administrative claims, Electronic Clinical Data CROWNWeb is the primary data source. However, this measure can be collected through Medicare claims data (since July 2010) and Fistula First Breakthrough Initiative data (though the definition of the measure is slightly different). URL http://www.projectcrownweb.org URL http://projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility
Setting	Dialysis Facility
Numerator Statement	Patients who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the study period.
Numerator Details	Time Window: For the ESRD CPM, we propose a one month time period. However, if the measure is adapted by other organizations for other purposes, there is no technical problem with using longer evaluation periods. The numerator will be determined by counting the patients in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month ("Access Type for Dialysis" = "Catheter" AND "Date Access Type for Dialysis Changed" is blank or, if populated, is more than 90 days prior to the last hemodialysis session of the month).
Denominator Statement	Patients on maintenance hemodialysis during the last HD treatment of study period.
Denominator Details	Time Window: For the ESRD CPM, we propose a one month time period. However, if the measure is adapted by other organizations for other purposes, there is no technical problem with using longer evaluation periods. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. Hemodialysis patients are defined as follows: "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 AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients at least 18 years old who are determined to be in-center hemodialysis or home hemodialysis patients.
Exclusions	Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age.
Exclusion Details	See above denominator details.
Risk Adjustment	No risk adjustment or risk stratification No risk adjustment necessary.
Stratification	No stratification is required for this measure.
Type Score	Rate/proportion better quality = lower score
Algorithm	For this measure calculation, the numerator will be divided by the denominator. Calculation of the numerator and denominator is described below. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. Hemodialysis patients are defined as follows: "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 AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients at least 18 years old who are determined to be in-center hemodialysis or home

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	0256 Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access
	hemodialysis patients. The numerator will be determined by counting the patients in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month ("Access Type for Dialysis" = "Catheter" AND "Date Access Type for Dialysis Changed" is blank or, if populated, is more than 90 days prior to the last hemodialysis session of the month). Attachment Appendix C CPM Calculation Flow charts_Catheter.pdf
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0257 Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)	
Steward	Centers for Medicare & Medicaid Services
Description	Percentage of patients on maintenance hemodialysis during the last HD treatment of month using an autogenous AV fistula with two needles
Type	Process
Data Source	Administrative claims, Electronic Clinical Data This measure is primarily designed for collection in CROWNWeb but can also be calculated from Fistula First and Medicare claims data. URL http://www.projectcrownweb.org/crown/index.php URL http://projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents
Level	Facility
Setting	Dialysis Facility
Numerator Statement	Patients who were on maintenance hemodialysis (HD) using an autogenous AV fistula with two needles at the last HD treatment of month
Numerator Details	Time Window: For the ESRD CPM, we propose a one month time period. However, if the measure is adapted by other organizations for other purposes, there is no technical problem with using longer evaluation periods. The numerator will be determined by counting the patients in the denominator for whom "Access Type for Dialysis" = "autogenous AV fistula with two needles" at the last treatment of the month.
Denominator Statement	Patients on maintenance hemodialysis during the last HD treatment of month including patients on home hemodialysis
Denominator Details	Time Window: One Month. However, facilities implementing this measure may choose any time period. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. Hemodialysis patients are defined as follows: "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 AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients at least 18 years old who are determined to be in-center hemodialysis or home hemodialysis patients. The denominator will include all patients greater than or equal to 18 years old who are determined to be in-center hemodialysis, or home hemodialysis patients.
Exclusions	Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age
Exclusion Details	See above denominator details.
Risk Adjustment	No risk adjustment or risk stratification No risk adjustment necessary.
Stratification	No stratification is required for this measure.
Type Score	Rate/proportion better quality = higher score
Algorithm	For this measure calculation, the numerator will be divided by the denominator. Calculation of the numerator and denominator is described below. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. Hemodialysis patients are defined as follows: "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 AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The denominator will include all patients at least 18 years old who are determined to be in-center hemodialysis or home hemodialysis patients. The denominator will include all patients greater than or equal to 18 years old who are determined to be in-center hemodialysis, or home hemodialysis patients. The numerator will be determined by counting the patients in the denominator for whom "Access Type for Dialysis" = "autogenous AV fistula with two needles" at the last treatment of the month. Attachment Appendix C CPM Calculation Flow

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	0257 Hemodialysis Vascular Access- Maximizing Placement of Arterial Venous Fistula (AVF)
	charts_AVF.pdf
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APPENDIX C—RELATED AND COMPETING MEASURE COMPARISON TABLES

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Blood Pressure Management

	1633 Blood Pressure Management	0018 Controlling High Blood Pressure
Steward	American Medical Association	National Committee for Quality Assurance 1100 13th Street NW, Suite 1000 Washington District Of Columbia 20005
Description	Percentage of patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 5, not receiving RRT) and proteinuria with a blood pressure <130/80 mmHg OR >= 130/80 mmHg with a documented plan of care	The percentage of patients 18–85 years of age who had a diagnosis of hypertension (HTN) and whose blood pressure (BP) was adequately controlled (<140/90) during the measurement year.
Type	Outcome	Outcome
Data Source	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records N/A Attachment AMA-PCPI_AKID-1_BPManagement.pdf	Electronic administrative data/claims, Electronic Clinical Data, Electronic Health/Medical Record, Paper medical record/flow-sheet
Level	Clinician : Group/Practice, Clinician : Individual, Clinician : Team	Clinicians : Group, Clinicians : Individual
Setting	Ambulatory Care : Clinician Office, Dialysis Facility, Home Health, Other, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility Domicillary, Rest Home or Custodial Care Services	All settings, Ambulatory Care : Amb Surgery Center, Ambulatory Care : Clinic, Ambulatory Care : Emergency Dept, Ambulatory Care : Hospital Outpatient, Ambulatory Care : Office
Numerator Statement	<p>Patient visits with blood pressure < 130/80 mmHg OR >= 130/80 mmHg with a documented plan of care*</p> <p>Definitions: Plan of Care: *A documented plan of care should include one or more of the following: recheck blood pressure within 90 days; initiate or alter pharmacologic therapy for blood pressure control; initiate or alter non-pharmacologic therapy (lifestyle changes) for blood pressure control; documented review of patient's home blood pressure log which indicates that patient's blood pressure is or is not well controlled</p> <p>Numerator Instructions: If multiple blood pressure measurements are taken at a single visit, use the most recent measurement taken at that visit.</p> <p>The PCPI recommends that this measure be reported as follows: % of patient visits meeting blood pressure < 130/80 mmHg (component 1) % of patient visits meeting blood pressure >= 130/80 mmHg with plan of care (component 2) % of patient visits meeting blood pressure < 130/80 mmHg AND patient visits meeting blood pressure >= 130/80 mmHg with plan of care (total measure score)</p>	The number of patients in the denominator whose most recent, representative BP is adequately controlled during the measurement year. For a member's BP to be controlled, both the systolic and diastolic BP must be <140/90mm Hg.
Numerator Details	<p>Time Window: Once during the measurement period</p> <p>See attached for EHR specifications. For Claims/Administrative: Report one CPT Category II codes for systolic blood pressure: 3074F – Most recent systolic blood pressure <130 mmHg</p>	<p>Time Window: The measurement year.</p> <p>The number of patients in the denominator whose most recent, representative BP is adequately controlled during the measurement year. For a member's BP to be controlled, both the systolic and diastolic BP must be <140/90mm Hg. Follow these steps to identify the representative BP:</p>

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	1633 Blood Pressure Management	0018 Controlling High Blood Pressure
	<p>3075F – Most recent systolic blood pressure 130 mmHg to 139 mmHg 3077F – Most recent systolic blood pressure \geq140 mmHg AND Report one CPT Category II codes for diastolic blood pressure 3078F – Most recent diastolic blood pressure $<$80 mmHg 3079F – Most recent diastolic blood pressure 80 mmHg to 89 mmHg 3080F – Most recent diastolic blood pressure \geq90 mmHg AND (if systolic blood pressure \geq 130 mmHg OR diastolic blood pressure is \geq 80 mmHg) Report CPT Category II code 0513F – Elevated blood pressure plan of care documented</p>	<p>-Identify the most recent blood pressure reading noted during the measurement year. The reading must occur after the date when the diagnosis of hypertension was made or confirmed. Do not include readings that meet the following criteria: taken during an acute inpatient stay or an ED visit, taken during an outpatient visit that was for the sole purpose of having a diagnostic test or surgical procedure performed (e.g., sigmoidoscopy, removal of a mole), taken the same day as a major diagnostic procedure (e.g., stress test, administration of IV contrast for a radiology procedure, endoscopy), reported by or taken by the patient, documentation of "VS within normal limits" or "vital signs normal". -Identify the lowest systolic and lowest diastolic reading from the most recent blood pressure notation in the medical record. If multiple readings were recorded for a single date, use the lowest systolic and the lowest diastolic reading on that date as the representative blood pressure. Results do not need to come from the same reading.</p>
Denominator Statement	<p>All patient visits for those patients aged 18 years and older with a diagnosis of CKD (stage 3, 4 or 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 (Renal Replacement Therapy) includes hemodialysis, peritoneal dialysis, and kidney transplantation</p>	<p>Patients 18-85 with hypertension. A patient is considered hypertensive if there is at least one outpatient encounter with a diagnosis of HTN during the first six months of the measurement year.</p>
Denominator Details	<p>Time Window: 12 consecutive months See attached for EHR specifications. For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT)</p>	<p>Time Window: Age range verified as of December 31st of the measurement year, while the hypertensive diagnosis is verified in the first 6months of the measurement year. Patients 18-85 as of December 31st of the measurement year who meet the following inclusion criteria: Continuous enrollment using health plan data: Patients continuously enrolled during the measurement year with no more than one gap in enrollment of up to 45 days during the measurement year. Continuous enrollment using non-health plan data: any enrollment, claim or encounter transaction any time during the measurement year. Event/Diagnosis: Hypertensive: At least one outpatient encounter (Table CBP-B) with a diagnosis of hypertension (Table CBP-A) during the first six months of the measurement year. Table CBP-A: Codes to Identify Hypertension Description ICD-9-CM Diagnosis</p>

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	1633 Blood Pressure Management	0018 Controlling High Blood Pressure								
		<p>Hypertension 401 Table CBP-B: Codes to Identify Outpatient Visits Description CPT Outpatient visits: 99201-99205, 99211-99215, 99241-99245, 99384-99387, 99394-99397 The diagnosis of hypertension must be confirmed by chart review on or before June 30 of the measurement year finding notation of one of the following: HTN, High BP, Elevated BP, Borderline HTN, Intermittent HTN, History of HTN, Hypertensive vascular disease, Hyperpiesia, Hyperpiesis.</p>								
Exclusions	None	<p>Exclude from the eligible population all patients with evidence of end-stage renal disease (ESRD) (including dialysis or renal transplant), all patients who are pregnant, and all patients who had an admission to a nonacute inpatient setting on or prior to December 31 of the measurement year.</p>								
Exclusion Details	None	<p>Exclude from the eligible population all patients with evidence of end-stage renal disease (ESRD) on or prior to December 31 of the measurement year. Documentation in the medical record must include a dated note indicating evidence of ESRD. Documentation of dialysis or renal transplant also meets the criteria for evidence of ESRD.</p> <ul style="list-style-type: none"> •Exclude from the eligible population all members with a diagnosis of pregnancy during the measurement year. •Exclude from the eligible population all members who had an admission to a nonacute inpatient setting any time during the measurement year. <p>Table CBP-C: Codes to Identify ESRD and Pregnancy Exclusions Description: CPT HCPCS ICD-9-CM ICD-9-CM UB UB POS Diagnosis Procedure Revenue type of Bill</p> <table border="0"> <tr> <td>Evidence of ESRD</td> <td>36145, 36800, 36818, 36819, 36820, 36821, 36831-36833, 50300, 50320, 50340, 50360, 50365, 50370, 50380, 90921, 90925, 90935, 90937, 90939,</td> <td>G0257, G0314-G0319, G0322, G0323, G0326, G0327, G0392, G0393, S9339,</td> <td>585.5, V42.0, V45.1, V56, 39.93-39.95, 54.98, 55.6,</td> <td>38.95, 39.42, 39.43, 39.53,</td> <td>0367, 082x, 085x, 088x,</td> <td>72X, 080x,</td> <td>65,</td> </tr> </table>	Evidence of ESRD	36145, 36800, 36818, 36819, 36820, 36821, 36831-36833, 50300, 50320, 50340, 50360, 50365, 50370, 50380, 90921, 90925, 90935, 90937, 90939,	G0257, G0314-G0319, G0322, G0323, G0326, G0327, G0392, G0393, S9339,	585.5, V42.0, V45.1, V56, 39.93-39.95, 54.98, 55.6,	38.95, 39.42, 39.43, 39.53,	0367, 082x, 085x, 088x,	72X, 080x,	65,
Evidence of ESRD	36145, 36800, 36818, 36819, 36820, 36821, 36831-36833, 50300, 50320, 50340, 50360, 50365, 50370, 50380, 90921, 90925, 90935, 90937, 90939,	G0257, G0314-G0319, G0322, G0323, G0326, G0327, G0392, G0393, S9339,	585.5, V42.0, V45.1, V56, 39.93-39.95, 54.98, 55.6,	38.95, 39.42, 39.43, 39.53,	0367, 082x, 085x, 088x,	72X, 080x,	65,			

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	1633 Blood Pressure Management	0018 Controlling High Blood Pressure
		90940, 90945, 90947, 90989, 90993, 90997, 90999, 99512 Evidence of Pregnancy: ICD-9-CM Diagnosis: 630-679, V22, V23, V28 Table FUH-B codes to identify non-acute inpatient exclusions: Hospice: UB Rev (0115, 0125, 0135, 0145, 0155, 0650, 0656, 0658, 0659), UB Type Bill (81x, 82x), POS (34) SNF: UB Rev (019x), UB Type Bill (21x, 22x, 28x), POS (31, 32) Hospital Transitional Care: UB Type Bill (18x) Rehabilitation: UB Rev (0118, 0128, 0138, 0148, 0158) Respite: UB Rev (0655) Intermediate Care Facility: POS (54) Residential Substance Abuse Treatment Facility: UB Rev (1002), POS (55) Psychiatric Residential Treatment Facility Center: HCPCS (T2048, H0017-19), UB Rev (1001), POS (56) Comprehensive Inpatient Rehabilitation Facility: POS (61)
Risk Adjustment	No risk adjustment or risk stratification This measure is not risk adjusted.	no risk adjustment necessary None.
Stratification	We encourage the results of this measure to be stratified by race, ethnicity, primary language, and gender, and have included these variables as recommended data elements to be collected.	N/A
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score
Algorithm	Calculation algorithm is included in data dictionary/code table attachment (2a1.30).	

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Hemodialysis

	0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose	0323 Hemodialysis Adequacy: Solute
Steward	Centers for Medicare & Medicaid Services	American Medical Association - Physician Consortium for Performance Improvement
Description	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.	Percentage of calendar months within a 12-month period during which patients aged 18 years and older with a diagnosis of ESRD receiving hemodialysis three times a week for ≥ 90 days have a spKt/V > or = 1.2
Developer comments on harmonization	<p>As for the AMA measures we feel that there are too many methodological issues that would make it difficult to harmonize at this time; however, we certainly be open to working towards harmonizing these measures in the future. Our rationale for harmonization not being practical at this time are:</p> <ol style="list-style-type: none"> 1. The number of exclusions and methodology for the AMA measure would defeat our goal for achieving better patient outcomes through the delivery of adequate. For example: <ol style="list-style-type: none"> a. The AMA exclusion criteria "Documentation of medical reason(s) for patient not having a spKt/V > or = 1.2 (eg, patient has residual kidney function, other medical reasons)" would likely result in many patients being dropped from the calculation of the measure based on what one could describe as "subjective" criteria. A Kt/V value of 1.2 is the accepted "minimum" value throughout the renal community and excluding a patient with a Kt/V of <1.2 because of residual function or "other medical reasons" should not excuse the clinician from making appropriate prescription adjustments to attain the minimum outcome level. Residual renal function for the HD population drops off to an insignificant level within 6 months of the initiation of dialysis making the rationale for dropping patients based on this unreasonable. b. The AMA measure does not specify the formula that is used to calculate the Kt/V which could result in "gaming" to achieve the desired value. However, this is something that should easily be worked out between CMS and AMA since Daguardis 2 and UMK are accepted formulas throughout the renal community and CMS already requires providers to use these formulas. c. CMS and AMA would need to arrive at some agreement on the time period used for calculating the Kt/V outcome. <p>The facility level measure is being used in the QIP program and the specifications are outlined in the rule in place through payment year 2014 and any change would</p>	<p>We have reviewed the request by the NQF Renal Endorsement Maintenance Steering Committee, for harmonization of measures 0249 and 0323. Our RPA/ASPN/PCPI Kidney Disease expert Work Group panel provided the following feedback, explaining their belief that the measures are already effectively harmonized.</p> <p>Regarding the calculation method for Kt/V, we are happy to add the calculation method to the measure, consistent with the CMS measure. UKM or the second generation Daugirdas formula are the most appropriate ways to calculate spKt/V, and the only two accepted methods for calculating Kt/V per the KDOQI guidelines.</p> <p>The CMS measure, 0249, is appropriate for monthly reporting, which is required for the CPM project that relied on data from the last three months of the calendar year. Reporting this as percentage of calendar months, as our measure does, increases the denominator and therefore makes this measure more interpretable at the individual physician level, where the number of patients may be smaller. In reality, the results using reporting method for the CMS measure and for our measure should converge as the denominator increases.</p> <p>Finally, the exclusion for the first 6 months in the CMS measure is the way they try to deal with residual kidney function; our measure, on the other hand, makes residual kidney function a denominator exception (exclusion). Our Work Group highlighted that there is no reason to think that in the first months of dialysis that a Kt/V <1.2 would be appropriate in the absence of residual kidney function; therefore, the approach taken in measure 0323 is actually a bit more rigorous.</p>

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	0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose	0323 Hemodialysis Adequacy: Solute
	require going through rulemaking.	
Type	Outcome	Outcome
Data Source	Electronic Clinical Data CROWNWeb URL http://www.projectcrownweb.org URL http://projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records N/A Attachment AMA-PCPI_AKID-10_HDAdequacy_11.8.2011.pdf
Level	Facility	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Dialysis Facility	Ambulatory Care : Clinician Office, Dialysis Facility, Home Health, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility
Numerator Statement	Number of patients in denominator whose delivered dose of hemodialysis (calculated from the last measurements of the month using the UKM or Daugirdas II formula) was a $spKt/V \geq 1.2$.	Calendar months during which patients have a $spKt/V > \text{or} = 1.2$ Note: Urea kinetic modeling (UKM) or the second generation Daugirdas formula (simplified multivariable equation) are the most appropriate ways to calculate $spKt/V$, and the two accepted methods for calculating $spKt/V$ per the KDOQI guidelines. For more information on these methods, please refer to National Kidney Foundation's KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access. Am J Kidney Dis 48:S1-S322, 2006 (suppl 1).
Numerator Details	Time Window: The entire calendar month. The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2.	Time Window: Each calendar month within measurement period See attached for EHR specifications. For Claims/Administrative: Report CPT II code 3XXXf: $spKt/V$ greater than or equal to 1.2 (single-pool clearance of urea [Kt]/volume[V])
Denominator Statement	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.	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
Denominator Details	Time Window: The entire calendar month. The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients ≥ 18 years old who have been on dialysis for 90 days or longer and "Sessions per Week" is equal to 3. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "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	Time Window: 12 consecutive calendar months See attached for EHR specifications. For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT)

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	0249 Hemodialysis Adequacy Clinical Performance Measure III: Hemodialysis Adequacy--HD Adequacy-- Minimum Delivered Hemodialysis Dose	0323 Hemodialysis Adequacy: Solute
	period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.	
Exclusions	Patients on HD less than 90 days; HD patients dialyzing <3 times per week or >3 times per week.	None
Exclusion Details	Exclusions to this measure include patients who are not receiving dialysis thrice weekly ("Sessions per Week" not equal to 3) and have not been on dialysis at least 90 days. The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began".	Not applicable
Risk Adjustment	No risk adjustment or risk stratification Not applicable.	Other We would account for risk adjustment by inclusion of exceptions for this measure.
Stratification	No stratification for this measure.	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score
Algorithm	The duration of hemodialysis treatment will be calculated as the difference between the first "Kt/V Collection Date" and "Date Regular Chronic Dialysis Began". The denominator will include all in-center hemodialysis patients >=18 years old who have been on dialysis for 90 days or longer and "Sessions per Week" is equal to 3. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. In-center hemodialysis patients are defined as follows: "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 AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period. The numerator will be determined by counting the patients in the denominator for whom "Kt/V Hemodialysis Method" is 'Daugirdas II' OR 'UKM' AND "Kt/V" is greater than or equal to 1.2. Attachment Appendix C CPM Calculation Flow charts_a 5.pdf	Calculation algorithm is included in data dictionary/code table attachment (2a1.30).

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Peritoneal Dialysis

	0318 Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum	0321 Peritoneal Dialysis Adequacy: Solute
Steward	Centers for Medicare & Medicaid Services	American Medical Association - Physician Consortium for Performance Improvement
Description	Percentage of all adult (≥ 18 years old) peritoneal dialysis patients whose delivered peritoneal dialysis dose was a weekly Kt/Vurea of at least 1.7 (dialytic + residual) during the four month study period.	Percentage of patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis who have a total Kt/V $> \text{ or } = 1.7$ per week measured once every 4 months
Type	Outcome	Outcome
Data Source	Electronic Clinical Data, Electronic Clinical Data : Laboratory CROWNWeb. URL http://www.projectcrownweb.org URL http://projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents	Administrative claims, Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Registry, Paper Records N/A Attachment AMA-PCPI_AKID-11_PeritonealAdequacy_eSPEC.pdf
Level	Facility	Clinician : Group/Practice, Clinician : Individual, Clinician : Team
Setting	Dialysis Facility	Ambulatory Care : Clinician Office, Dialysis Facility, Home Health, Other, Post Acute/Long Term Care Facility : Nursing Home/Skilled Nursing Facility Domiciliary, Rest Home, or Custodial Care Services
Numerator Statement	Patients are included in the numerator if delivered peritoneal dialysis was a weekly Kt/Vurea of at least 1.7 (dialytic + residual) during the four month study period.	Patients who have a total Kt/V $> \text{ or } = 1.7$ per week measured once every 4 months Definition: Total Kt/V includes residual kidney function and equals peritoneal dialysate Kt/V plus renal Kt/V
Numerator Details	<p>Time Window: A four month time period.</p> <p>The numerator will be determined by counting the patients in the denominator who had a delivered peritoneal dialysis weekly Kt/Vurea of at least 1.7 (dialytic + residual) during the four month study period.</p> <p>Specifically, the algorithm first counts the number of non-missing values for the "Weekly Kt/V value: Peritoneal Dialysis, reporting month" (pd_weekly_ktv) variable. If the number of non-missing values is ≥ 1 and the patient is counted in the denominator, then the patient is counted in the numerator if the most recent month with data meets these conditions:</p> <p>(1) "Kt/V method" either "Watson" OR "Hume" AND (2) "BSA method" either "Dubois & Dubois" OR "Gehan & George" OR "Haycock" AND (3) ("Urine Volume" < 100) OR ("Urine Volume" ≥ 100 AND "PD Residual Renal Function" = "Yes") AND (4) "Weekly Kt/V" ≥ 1.7</p>	<p>Time Window: Three times (at least 4 months apart) during the measurement period.</p> <p>Definition: Total Kt/V includes residual kidney function and equals peritoneal dialysate Kt/V plus renal Kt/V See attached for EHR specifications. For Claims/Administrative: Report CPT Category II 3XXXF: Total Kt/V greater than or equal to 1.7 (total clearance of urea [Kt]/volume [V])</p>

NATIONAL QUALITY FORUM

	0318 Peritoneal Dialysis Adequacy Clinical Performance Measure III - Delivered Dose of Peritoneal Dialysis Above Minimum	0321 Peritoneal Dialysis Adequacy: Solute
Denominator Statement	All adult (>= 18 years old) peritoneal dialysis patients who have been on peritoneal dialysis for at least 90 days.	All patients aged 18 years and older with a diagnosis of ESRD receiving peritoneal dialysis
Denominator Details	<p>Time Window: A four month time period.</p> <p>The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month.</p> <p>Peritoneal dialysis patients are defined as follows: (1) "Admit Date" to the specified facility is prior or equal to the first day of the study period; (2) the patient has not been discharged (i.e., the discharge date is null or blank or the discharge date is greater than or equal to the last day of the study period); (3) the treatment start date is less than or equal to the date of the study period; (4) the type of dialysis treatment = 'PD'; (5) the primary dialysis setting is "Home" or "Dialysis Facility/Center"; (6) the "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.</p> <p>The denominator will include all patients >= 18 years old who are PD patients assigned to a single facility for a four month period.</p>	<p>Time Window: 12 consecutive months.</p> <p>See attached for EHR specifications.</p> <p>For Claims/Administrative: See coding tables attached for coding (ICD-9-CM, ICD-10-CM, CPT)</p>
Exclusions	None.	None
Exclusion Details	None.	Not applicable
Risk Adjustment	No risk adjustment or risk stratification None	Other No risk adjustment or risk stratification. This measure is not risk adjusted.
Stratification	No stratification is required for this measure.	We encourage the results of this measure to be stratified by race, ethnicity, gender, and primary language, and have included these variables as recommended data elements to be collected.
Type Score	Rate/proportion better quality = higher score	Rate/proportion better quality = higher score
Algorithm	This measure is calculated by dividing the number of patients in the numerator by the number of patients in the denominator. Attachment PD_CPM3_Flowchart.pdf	Calculation algorithm is included in data dictionary/code table attachment (2a1.30).

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Vascular Access

	0256 Hemodialysis Vascular Access- Minimizing use of catheters as Chronic Dialysis Access	0251 Vascular Access—Functional Arteriovenous Fistula (AVF) or AV Graft or Evaluation for Placement
Steward	Centers for Medicare & Medicaid Services	Kidney Care Quality Alliance
Description	Percentage of patients on maintenance hemodialysis during the last HD treatment of study period with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session.	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. The total numerator and each of the numerator subgroups (the outcomes subgroups and the process subgroup) will be reported separately.
Type	Process	Outcome
Data Source	Administrative claims, Electronic Clinical Data CROWNWeb is the primary data source. However, this measure can be collected through Medicare claims data (since July 2010) and Fistula First Breakthrough Initiative data (though the definition of the measure is slightly different). URL http://www.projectcrownweb.org URL http://projectcrownweb.org/crown/index.php?page=Public_Documents&subPage=Release_Documents	Electronic Clinical Data : Electronic Health Record, Paper Records All data elements for the measure can be collected using the KCQA Vascular Access Data Collection Form (attached), which reflect the data elements to be included in CROWNWeb. Attachment fmKCQADataFormVascAccess11-07-11NQFreqs.pdf Attachment txKCQADataDictionaryAVF11-07-11NQFreqs.pdf
Level	Facility	Clinician : Individual
Setting	Dialysis Facility	Ambulatory Care : Clinician Office, Dialysis Facility
Numerator Statement	Patients who were continuously using a chronic catheter as hemodialysis access for 90 days or longer prior to the last hemodialysis session during the study period.	Number of patients from the denominator who: (1) have a functional autogenous AVF (defined as two needles used or a single-needle device) (computed and reported separately); or (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 (defined as two needles used or a single needle device) 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. The total numerator and each of the numerator subgroups (the outcomes subgroups and the

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		process subgroup) will be reported separately.
Numerator Details	<p>Time Window: For the ESRD CPM, we propose a one month time period. However, if the measure is adapted by other organizations for other purposes, there is no technical problem with using longer evaluation periods.</p> <p>The numerator will be determined by counting the patients in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month (“Access Type for Dialysis” = “Catheter” AND “Date Access Type for Dialysis Changed” is blank or, if populated, is more than 90 days prior to the last hemodialysis session of the month).</p>	<p>Time Window: 12-month reporting period.</p> <p>The necessary data elements are to be collected via the Centers for Medicare and Medicaid (CMS) CROWNWeb data repository when functional, as indicated by the measure’s inclusion in CMS’s list of Phase III ESRD Clinical Performance Measures in effect April 1, 2008.</p> <ol style="list-style-type: none"> 1. Access type (select one): <ul style="list-style-type: none"> • AVF with 2 needles used or single needle device --> END. • AV graft with 2 needles used --> END. • AVF with AV graft --> END. • AVF with catheter --> GO TO 2. • AV graft with catheter --> GO TO 2. • Catheter --> GO TO 2. • Other/unknown --> GO TO 2. 2. Vascular access referral status (select one): <ul style="list-style-type: none"> • Patient referred to a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period --> GO TO 3. • Patient NOT referred to a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period --> END. 3. Vascular access evaluation status (select one): <ul style="list-style-type: none"> • Patient 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 an AVF or AV graft during the 12-month reporting period --> GO TO 4. • Patient NOT 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 an AVF or AV graft during the 12-month reporting period --> END. 4. Type of documentation of the surgical evaluation in facility’s medical records/CROWNWeb (select one): <ul style="list-style-type: none"> • No documentation --> END. • A note or letter prepared by the primary nephrologist --> GO TO 5. • A note or letter prepared by the vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access --> GO TO 5.

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		<ul style="list-style-type: none"> • A note prepared by facility personnel --> GO TO 5. 5. Date of the surgical evaluation: (MM/YYYY) --> GO TO 6. 6. If permanent access was not placed, the reason for this decision --> END.
Denominator Statement	Patients on maintenance hemodialysis during the last HD treatment of study period.	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.
Denominator Details	<p>Time Window: For the ESRD CPM, we propose a one month time period. However, if the measure is adapted by other organizations for other purposes, there is no technical problem with using longer evaluation periods.</p> <p>The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month.</p> <p>Hemodialysis patients are defined as follows: "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 AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.</p> <p>The denominator will include all patients at least 18 years old who are determined to be in-center hemodialysis or home hemodialysis patients.</p>	<p>Time Window: 12-month reporting period.</p> <p>The necessary data elements are to be collected via the CMS CROWNWeb data repository when functional, as indicated by the measure's inclusion in CMS's list of Phase III ESRD Clinical Performance Measures in effect April 1, 2008.</p> <p>The denominator population consists of all ESRD patients receiving hemodialysis for a given nephrologist. Data elements required to identify the denominator population:</p> <ul style="list-style-type: none"> • Patient diagnosis = ESRD AND • Patient primary type of dialysis = hemodialysis AND • Patient's date of birth AND • Date regular chronic dialysis began AND • Nephrologist's name
Exclusions	Patients on acute hemodialysis, peritoneal dialysis, or patients <18 years of age.	Patients enrolled in hospice.
Exclusion Details	See above denominator details.	Identify all patients in the denominator enrolled in hospice.
Risk Adjustment	No risk adjustment or risk stratification No risk adjustment necessary.	No risk adjustment or risk stratification Not applicable.
Stratification	No stratification is required for this measure.	Not applicable.
Type Score	Rate/proportion better quality = lower score	Rate/proportion better quality = higher score
Algorithm	For this measure calculation, the numerator will be divided by the denominator. Calculation of the numerator and denominator is described below. The patient's age will be determined by subtracting the patient's date of birth from the first day of the reporting month. Hemodialysis patients are defined as follows: "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	<p>DENOMINATOR</p> <p>Include in the denominator all patients for a given nephrologist who meet the following criteria in the most recent month of the 12-month study period and who are not enrolled in hospice:</p> <ol style="list-style-type: none"> 1. Diagnosis = ESRD AND 2. Primary type of dialysis = hemodialysis or home hemodialysis

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	<p>facility is greater than or equal to the last day of the study period AND "Treatment Dialysis Broad Start Date" is prior or equal to the first day of the study period, AND "Dialysis Broad Type of Treatment" = 'HD', AND "Primary Dialysis Setting" = 'Dialysis Facility/Center' or 'Home' on the last day of the study period, AND "Date Regular Chronic Dialysis Began" is prior to the first day of the study period.</p> <p>The denominator will include all patients at least 18 years old who are determined to be in-center hemodialysis or home hemodialysis patients.</p> <p>The numerator will be determined by counting the patients in the denominator who were on maintenance hemodialysis with a chronic catheter continuously for 90 days or longer prior to the last hemodialysis session of the month ("Access Type for Dialysis" = "Catheter" AND "Date Access Type for Dialysis Changed" is blank or, if populated, is more than 90 days prior to the last hemodialysis session of the month). Attachment Appendix C CPM Calculation Flow charts_Catheter.pdf</p>	<p>AND</p> <p>3. Age = >18 years or older as of the first day of the most recent month of the reporting period. (Patient's age is or shall be determined by subtracting the patient's date of birth from the first day of the most recent month of the reporting period.)</p> <p>AND</p> <p>4. Time on dialysis = >90 days as of the first day of the most recent month of the reporting period. (Patient's time on dialysis is or shall be determined by subtracting the patient's Date Regular Chronic Dialysis Began from the first day of the most recent month of the reporting period. Patients on dialysis <90 days are excluded so that emergent patients and patients requiring only transient dialysis are not encompassed, as permanent access would not be appropriate in these populations.)</p> <p>NUMERATOR</p> <p>Include in the numerator all patients from the denominator who meet the following criteria:</p> <ol style="list-style-type: none"> 1. Access Type = Functional autogenous AVF (defined as 2 needles used or single-needle device) OR 2. Access type = Functional AV graft OR 3. Access type = AVF combined with AV graft OR 4. Access type (select one): <ul style="list-style-type: none"> • AVF with a catheter • AV graft with a catheter • Catheter • Other/unknown <p>AND</p> <p>2. Patient referred to a vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access for an AVF or AV graft during the 12-month reporting period</p> <p>AND</p> <p>3. Patient 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 an AVF or AV graft during the 12-month reporting period</p> <p>AND</p> <p>4. Facility medical records contain the following types of documentation of the surgical evaluation: <ul style="list-style-type: none"> • A note or letter prepared by the primary nephrologist OR </p>

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		<ul style="list-style-type: none"> • A note or letter prepared by the vascular surgeon, other surgeon qualified in the area of vascular access, or interventional nephrologist trained in the primary placement of vascular access OR • A note prepared by facility personnel AND • Date of the surgical evaluation: (MM/YYYY) AND • If permanent access was not placed, the reason for this decision Attachment txKCQACalcAlgorithmAVF11-07-11NQFrecs.pdf